# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# POST-EFFECTIVE AMENDMENT NO. 1 TO FORM F-1 REGISTRATION STATEMENT

UNDER
THE SECURITIES ACT OF 1933

# **ALVOTECH**

(Exact name of Registrant as Specified in Its Charter)

Grand Duchy of Luxembourg (Jurisdiction of Incorporation or Organization) 2836 (Primary Standard Industrial Classification Code Number) 98-1629342 (I.R.S. Employer Identification No.)

Société Anonyme (Public Limited Company) 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg R.C.S. Luxembourg: B258884 +354 422 4500

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Joel Morales Chief Executive Officer Alvotech USA Inc. 1201 Wilson Blvd., Ste. 2130 Arlington, Virginia 22209 Tel: (703) 859-6815

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Michal Berkner, Esq.
Nicolas H.R. Dumont, Esq.
Divakar Gupta, Esq.
Cooley (UK) LLP
22 Bishopsgate
London EC2N 4BQ
United Kingdom
Tel: +44 (0) 20 7583 4055

Fax: +44 (0) 20 7785 9355

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 (as amended, the "Securities Act"), check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.  $\Box$ 

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company ⊠

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act of

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

#### **EXPLANATORY NOTE**

On July 14, 2022, the registrant filed a Registration Statement on Form F-1 (File No. 333-266136), as amended by Amendment No. 1 filed on July 27, 2022 and Amendment No. 2 on September 13, 2022, and subsequently declared effective by the U.S. Securities and Exchange Commission (the "SEC") on September 21, 2022 (as amended and supplemented from time to time, the "Registration Statement").

The Registration Statement initially registered (i) the issuance of 10,916,647 ordinary shares, \$0.01 par value, issuable upon the exercise of the Warrants, (ii) the resale by the selling securityholders named therein of up to 219,616,200 ordinary shares, \$0.01 par value, and (iii) 4,666,667 Private Placement Warrants (as defined below), including any additional securities that may become issuable by reason of share splits, share dividends or other similar transactions. All fees applicable to the registration of these securities were paid at the time of the original filing of the Registration Statement.

This Post-Effective Amendment No. 1 to the Registration Statement on Form F-1 is being filed to (i) include information contained in the registrant's Annual Report on Form 20-F for the fiscal year ended December 31, 2022, filed with the SEC on March 1, 2023, and (ii) update certain other information in the Registration Statement.

The information included in this filing amends the Registration Statement and the prospectus contained therein.

The information in this preliminary prospectus is not complete and may be changed. The selling securityholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated March 13, 2023

#### PRELIMINARY PROSPECTUS



Up to 10,916,647 Ordinary Shares Issuable Upon Exercise of Warrants
Up to 219,616,200 Ordinary Shares Offered by Selling Securityholders
Up to 4,666,667 Warrants to purchase Ordinary Shares offered by the Sponsor

This prospectus relates to the issuance by us of 10,916,647 Ordinary Shares consisting of (i) 6,249,980 of our ordinary shares, \$0.01 nominal value, ("Ordinary Shares") that may be issued upon exercise of warrants to purchase Ordinary Shares at an exercise price of \$11.50 (the "Public Warrants"), which were originally issued in the initial public offering of Oaktree Acquisition Corp. II ("OACB") at a price of \$10.00 per unit, with each unit consisting of one OACB Class A Ordinary Share (as defined below) and one-fourth of a Public Warrant, and (ii) 4,666,667 Ordinary Shares that may be issued upon exercise of warrants issued to Oaktree Acquisition Holdings II, L.P. (the "Sponsor"), and its transferees to purchase Ordinary Shares at an exercise price of \$11.50 (the "Private Placement Warrants"). We refer to the Public Warrants and the Private Placement Warrants together as the "Warrants." The Warrants were originally issued by OACB entitling the holder to purchase one share of the OACB Class A Ordinary Shares (as defined below) at an exercise price of \$11.50 per share ("OACB Warrants") and automatically converted into Warrants on substantially the same terms as the OACB Warrants, entitling the holder to purchase our Ordinary Shares, on the closing of the Business Combination among us, OACB and Alvotech Holdings S.A. ("Alvotech Holdings") The Business Combination is defined and described in greater detail in this prospectus. See "*Prospectus Summary–Recent Developments–Business Combination*."

This prospectus also relates to the offer and sale from time to time by the selling securityholders named in this prospectus (collectively, the "Selling Securityholders"), or their permitted transferees, of up to (i) 17,493,000 Ordinary Shares subscribed for by the Selling Securityholders, for a subscription price of \$10.00 per share, in the context of the PIPE Financing (as defined below), (ii) 6,250,000 Ordinary Shares issued to the Sponsor in exchange for OACB's Class B Ordinary Shares, par value \$0.0001 (the "OACB Class B Ordinary Shares" or the "Founder Shares") (which were purchased by the Sponsor for \$25,000 or approximately \$0.004 per share) in connection with the Business Combination, (iii) 4,666,667 Ordinary Shares issuable upon exercise of Private Placement Warrants, (iv) 186,206,553 Ordinary Shares issued to former shareholders of Alvotech Holdings in exchange for their Alvotech Holdings Ordinary Shares in connection with the Business Combination (subject to vesting and lockups) at an equity consideration value of \$10.00 per share, (v) 5,000,000 Ordinary Shares subscribed for by Alvogen and Aztiq, for a subscription price of \$10.00 per share, in the context of the Alvogen-Aztiq Loan Advance Conversion (as defined below), and (vi) 4,666,667 Private Placement Warrants, which were purchased by the Sponsor at a price of \$1.50 per warrant.

Concurrently with the execution of the Business Combination Agreement, OACB and Alvotech entered into subscription agreements with certain U.S.-based institutional and accredited investors (each a "U.S. Subscription Agreement") and non-U.S. persons (as defined in Regulation S under the Securities Act (each a "Foreign Subscription Agreement" and, together with the U.S. Subscription Agreements, the "Initial Subscription Agreements") with certain investors (the "Initial Subscribers"), pursuant to which the Initial Subscribers have agreed to subscribe for, and Alvotech has agreed to issue to the Initial Subscribers, an aggregate of 15,393,000 Ordinary Shares at a price of \$10.00 per share, for aggregate gross proceeds of \$153,930,000 (the "Initial PIPE Financing"). Subsequent to the Initial PIPE Financing, on January 18, 2022, OACB and Alvotech entered into Subscription Agreements (the "Subscription Agreements") with certain investors (the "Subsequent Subscribers", and together with the Initial Subscribers, the "Subscribers" or the "Selling Securityholders"), pursuant to which the Subsequent Subscribers have agreed to subscribe for, and Alvotech has agreed to issue to the Subsequent Subscribers, an aggregate of 2,100,000 Ordinary Shares at a price of \$10.00 per share, for aggregate gross proceeds of \$21,000,000 (the "Subsequent PIPE Financing", and together with the Initial PIPE Financing, the "PIPE Financing"). The aggregate number of Ordinary Shares to be issued pursuant to the PIPE Financing was 17,493,000 for aggregate gross proceeds of \$174,930,000. The Subscription Agreements contain substantially the same terms, except that the investors that entered into the Foreign Subscription Agreement agreed to subscribe for Ordinary Shares at a price that is net of a 3.5% placement fee. The Business Combination is described in greater detail in this prospectus. See "Prospectus Summary–Recent Developments–Business Combination."

In connection with the Business Combination, holders of 24,023,495 OACB Class A Ordinary Shares, or 96% of the shares with redemption rights, exercised their right to redeem their shares for cash at a redemption price of approximately \$10.00 per share, for an aggregate redemption amount of \$240,234,950. The Ordinary Shares being offered for resale pursuant to this prospectus by the Selling Securityholders represent approximately 80.35% of the outstanding Ordinary Shares as of February 15, 2023 (after giving effect to the issuance of shares upon exercise of outstanding Warrants). Given the substantial number of Ordinary Shares being registered for potential resale by the Selling Securityholders pursuant to this prospectus, the sale of shares by the Selling Securityholders, or the perception in the market that the Selling Securityholders intend to sell shares, could increase the volatility of the market price of the Ordinary Shares or result in a significant decline in the public trading price of the Ordinary Shares. Even if our trading price is significantly below \$10.00, the offering price for the units offered in OACB's initial public offering (the "IPO"), certain of the Selling Securityholders may still have an incentive to sell the Ordinary Shares because they purchased the shares at prices lower than the public investors or the current trading price of the Ordinary Shares. For example, based on the closing price of our Ordinary Shares of \$13.22 as of March 10, 2023, the Sponsor and other holders of the Founder Shares would experience a potential profit of up to approximately \$12.10 per share, or up to approximately \$75.63 million in the aggregate. Public investors may not experience a similar rate of return on the securities they purchase due to differences in the purchase prices and the current trading price of the Ordinary Shares.

We will receive proceeds from the exercise of the Warrants. The exercise price of our Public Warrants and Private Placement Warrants is \$11.50 per warrant. We believe the likelihood that warrant holders will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Ordinary Shares. If the trading price for our Ordinary Shares is less than \$11.50 per share, we believe holders of our Public Warrants and Private Placement Warrants will be unlikely to exercise their Warrants.

We will not receive any proceeds from the sale of the Ordinary Shares by the Selling Securityholders pursuant to this prospectus. However, we will pay the expenses, other than underwriting discounts and commissions and expenses incurred by the Selling Securityholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Securityholders in disposing of the securities, associated with the sale of the Ordinary Shares pursuant to this prospectus.

Our registration of the Ordinary Shares covered by this prospectus does not mean that either we or the Selling Securityholders will issue, offer or sell, as applicable, any of the Ordinary Shares. The Selling Securityholders may offer and sell the Ordinary Shares covered by this prospectus in a number of different ways and at varying prices. We provide more information about how the Selling Securityholders may sell the Ordinary Shares in the section entitled "*Plan of Distribution*."

We are a "foreign private issuer" under applicable Securities and Exchange Commission (the "SEC") rules and an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and are eligible for reduced public company disclosure requirements.

You should read this prospectus and any prospectus supplement or amendment carefully before you invest in our securities. Investing in our securities involves risks. See "*Risk Factors*" beginning on page 25 of this prospectus.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

PROSPECTUS DATED , 2023

# TABLE OF CONTENTS

	Page
ABOUT THIS PROSPECTUS	1
IMPORTANT INFORMATION ABOUT IFRS AND NON-IFRS FINANCIAL MEASURES	3
INDUSTRY AND MARKET DATA	4
FREQUENTLY USED TERMS	5
CONVENTIONS WHICH APPLY TO THIS PROSPECTUS	9
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS	10
PROSPECTUS SUMMARY	13
SUMMARY TERMS OF THE OFFERING	20
SUMMARY HISTORICAL FINANCIAL INFORMATION OF ALVOTECH	23
RISK FACTORS	25
<u>USE OF PROCEEDS</u>	108
<u>DIVIDEND POLICY</u>	109
<u>CAPITALIZATION</u>	110
<u>BUSINESS</u>	111
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	153
BOARD OF DIRECTORS AND EXECUTIVE MANAGEMENT	179
<u>DESCRIPTION OF SECURITIES</u>	190
CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS	216
MAJOR SHAREHOLDERS	230
SELLING SECURITYHOLDERS	232
MATERIAL LUXEMBOURG INCOME TAX CONSIDERATIONS	236
MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS	242
<u>PLAN OF DISTRIBUTION</u>	249
EXPENSES RELATED TO THE OFFERING	254
SERVICE OF PROCESS AND ENFORCEMENT OF CIVIL LIABILITIES UNDER U.S. SECURITIES LAWS	254
LEGAL MATTERS	254
<u>EXPERTS</u>	254
WHERE YOU CAN FIND MORE INFORMATION	254
INDEX TO FINANCIAL STATEMENTS	F-1
PART IL INFORMATION NOT REQUIRED IN PROSPECTUS	II_1

#### ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus, any amendment or supplement to this prospectus or any free writing prospectus prepared by us or on our behalf. Any amendment or supplement may also add, update or change information included in this prospectus. Any statement contained in this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in such amendment or supplement modifies or supersedes such statement. Any statement so modified will be deemed to constitute a part of this prospectus only as so modified, and any statement so superseded will be deemed not to constitute a part of this prospectus. See "Where You Can Find More Information."

Neither we nor the Selling Securityholders have authorized any other person to provide you with different or additional information. Neither we nor the Selling Securityholders take responsibility for, nor can we provide assurance as to the reliability of, any other information that others may provide. The information contained in this prospectus is accurate only as of the date of this prospectus or such other date stated in this prospectus, and our business, financial condition, results of operations and/or prospects may have changed since those dates. This prospectus contains summaries of certain provisions contained in some of the documents described in this prospectus, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to in this prospectus have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described under "Where You Can Find More Information."

Neither we nor the Selling Securityholders are making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. Except as otherwise set forth in this prospectus, neither we nor the Selling Securityholders have taken any action to permit a public offering of these securities outside the United States or to permit the possession or distribution of this prospectus outside the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about and observe any restrictions relating to the offering of these securities and the distribution of this prospectus outside the United States.

On June 15, 2022, Alvotech consummated the transactions contemplated by the Business Combination Agreement by and among OACB, Alvotech Holdings and Alvotech. Capitalized terms used in this section have the meanings given to them in the section "Frequently Used Terms" below. Pursuant to the Business Combination Agreement:

- at the First Merger Effective Time, OACB merged with and into Alvotech, whereby (i) all of the outstanding shares of OACB were exchanged for Ordinary Shares on a one-for-one basis, pursuant to a share capital increase of Alvotech, and (ii) all of the outstanding OACB Warrants automatically ceased to represent a right to acquire shares of OACB and automatically represented a right to be issued one Ordinary Share on substantially the same contractual terms and conditions as were in effect immediately prior to the First Merger Effective Time under the terms of the Warrant Agreement, with Alvotech as the surviving company in the merger;
- immediately after the effectiveness of the First Merger but prior to the Conversion, Alvotech redeemed and cancelled the shares held by the initial sole shareholder of Alvotech pursuant to a share capital reduction of Alvotech;
- immediately after the effectiveness of the First Merger and the Redemption, the legal form of Alvotech changed from a simplified joint stock company (*société par actions simplifiée*) to a public limited liability company (*société anonyme*) under Luxembourg law;

- immediately after the change of the legal form of Alvotech, Alvotech issued 17,493,000 Ordinary Shares at a price of \$10.00 per share pursuant to the PIPE Financing for aggregate gross proceeds of \$174,930,000; and
- immediately following the effectiveness of the Conversion and the PIPE Financing, Alvotech Holdings merged with and into Alvotech, whereby all outstanding Alvotech Holdings Ordinary Shares were exchanged for Ordinary Shares, pursuant to a share capital increase of Alvotech, with Alvotech as the surviving company in the merger.

Concurrently with the execution of the Business Combination Agreement, OACB and Alvotech entered into subscription agreements with certain U.S.-based institutional and accredited investors (each a "U.S. Subscription Agreement") and non-U.S. persons (as defined in Regulation S under the Securities Act (each a "Foreign Subscription Agreement" and, together with the U.S. Subscription Agreements, the "Initial Subscribtion Agreements") with certain investors (the "Initial Subscribers"), pursuant to which the Initial Subscribers have agreed to subscribe for, and Alvotech has agreed to issue to the Initial Subscribers, an aggregate of 15,393,000 Ordinary Shares at a price of \$10.00 per share, for aggregate gross proceeds of \$153,930,000 (the "Initial PIPE Financing"). Subsequent to the Initial PIPE Financing, on January 18, 2022, OACB and Alvotech entered into Subscription Agreements (the "Subsequent Subscription Agreements", and together with the Initial Subscribtion Agreements, the "Subscription Agreements") with certain investors (the "Subsequent Subscribers", and together with the Initial Subscribers, the "Subscribers" or the "Selling Securityholders"), pursuant to which the Subsequent Subscribers have agreed to subscribe for, and Alvotech has agreed to issue to the Subsequent Subscribers, an aggregate of 2,100,000 Ordinary Shares at a price of \$10.00 per share, for aggregate gross proceeds of \$21,000,000 (the "Subsequent PIPE Financing", and together with the Initial PIPE Financing, the "PIPE Financing"). The aggregate number of Ordinary Shares to be issued pursuant to the PIPE Financing was 17,493,000 for aggregate gross proceeds of \$174,930,000. The Subscription Agreements contain substantially the same terms, except that the investors that entered into the Foreign Subscription Agreement agreed to subscribe for Ordinary Shares at a price that is net of a 3.5% placement fee.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays may appear without the <sup>®</sup> or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade name or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Certain amounts that appear in this prospectus may not sum due to rounding.

# IMPORTANT INFORMATION ABOUT IFRS AND NON-IFRS FINANCIAL MEASURES

Alvotech's historical consolidated financial statements are prepared in accordance with IFRS.

Certain of the measures included in this prospectus may be considered non-IFRS financial measures. Non-IFRS financial measures should not be considered in isolation from, or as a substitute for, financial information presented in compliance with IFRS, and non-IFRS financial measures as used by Alvotech may not be comparable to similarly titled amounts used by other companies.

#### INDUSTRY AND MARKET DATA

This prospectus contains estimates, projections, and other information concerning Alvotech's industry and business, as well as data regarding market research, estimates, and forecasts prepared by Alvotech's management. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. The industry in which Alvotech operates is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "*Risk Factors*." Unless otherwise expressly stated, Alvotech obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry and general publications, government data, and similar sources. In some cases, Alvotech does not expressly refer to the sources from which this data is derived. In that regard, when Alvotech refers to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from sources which Alvotech paid for, sponsored, or conducted, unless otherwise expressly stated or the context otherwise requires. While Alvotech has compiled, extracted, and reproduced industry data from these sources, Alvotech has not independently verified the data. Forecasts and other forward-looking information with respect to industry, business, market, and other data are subject to the same qualifications and additional uncertainties regarding the other forward-looking statements in this prospectus. See "Cautionary Note Regarding Forward-Looking Statements."

#### FREQUENTLY USED TERMS

In this prospectus:

- "2022 Plan" means Alvotech's 2022 equity incentive plan, or the Alvotech Management Incentive Plan.
- "Alvogen" means Alvogen Lux Holdings S.à r.l., a limited liability company (*Société à responsabilité limitée*) incorporated and existing under the laws of the Grand Duchy of Luxembourg having its registered office at 5, Rue Heienhaff, L-1736 Senningerberg, Grand Duchy of Luxembourg and registered with the Luxembourg Trade and Company Register (*Registre de Commerce et des Sociétés*, *Luxembourg*) under number B 149045.
- "Alvogen-Aztiq Loan Advance Conversion" means the private placement dated July 12, 2022, pursuant to which Alvogen and Aztiq subscribed to 2,500,000 Ordinary Shares each, for a subscription price of \$10.00 per share.
- "Alvogen Facility" means that subordinated loan agreement dated November 16, 2022 between Alvotech, as borrower, and Alvogen, as lender, for a loan in an aggregate principal amount equal to \$112.5 million.
- "Alvotech" means as the context requires, (a) the registrant, a legal entity named Alvotech, previously known as Alvotech Lux Holdings S.A.S., a public limited liability company (*société anonyme*) incorporated and existing under the laws of the Grand Duchy of Luxembourg having its registered office at 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg, registered with the Luxembourg Trade and Company Register (*Registre de Commerce et des Sociétés*, *Luxembourg*) under number B258884, individually or together with its consolidated subsidiaries; or (b) Alvotech Holdings.
- "Alvotech Holdings" means Alvotech Holdings S.A., a public limited liability company (société anonyme) incorporated under the laws of the Grand Duchy of Luxembourg having its registered office at 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg and registered with the Luxembourg Trade and Company Register (Registre de Commerce et des Sociétés, Luxembourg) under number B 229193, individually or together with its consolidated subsidiaries.
- "Alvotech Holdings Class A Ordinary Shares" means the Class A Ordinary Shares, with a nominal value of \$0.01 per share, of Alvotech Holdings, which converted into Ordinary Shares at the closing of the Business Combination.
- "Alvotech Holdings Class B Shares" means the Class B Shares, with a nominal value of \$0.01 per share, of Alvotech Holdings, which converted into Ordinary Shares at the closing of the Business Combination.
- "Alvotech Holdings Ordinary Shares" means the Alvotech Holdings Class A Ordinary Shares and the Alvotech Holdings Class B Shares, collectively.
  - "Alvotech Holdings Shareholders" means the holders of Alvotech Holdings Ordinary Shares.
- "Aztiq" means Aztiq Pharma Partners S.à r.l., a limited liability company (*Société à responsabilité limitée*) incorporated and existing under the laws of the Grand Duchy of Luxembourg having its registered office at 5, Rue Heienhaff, L-1736 Senningerberg, Grand Duchy of Luxembourg and registered with the Luxembourg Trade and Company Register (*Registre de Commerce et des Sociétés*, *Luxembourg*) under number B 147728.
  - "Aztiq Convertible Bond" means the convertible bond, subordinated to the Senior bonds, issued by Alvotech to Aztiq on November 16, 2022.

- "Business Combination" means the transactions contemplated by the Business Combination Agreement, including the Mergers.
- "Business Combination Agreement" means the Business Combination Agreement, dated as of December 7, 2021 as may be amended, by and among OACB, Alvotech Holdings and Alvotech.
  - "Closing" means the consummation of the Business Combination, which occurred on June 15, 2022.
  - "Closing Date" means June 15, 2022, the date upon which the Closing occurred.
  - "Code" means the Internal Revenue Code of 1986, as amended.
  - "Company" means the legal entity named Alvotech, individually or together with its consolidated subsidiaries.
- "Conversion" means the change of Alvotech's legal form from a simplified joint stock company (*société par actions simplifiée*) to a public limited liability company (*société anonyme*) under Luxembourg law immediately after the effectiveness of the First Merger and the Redemption.
- "December 2022 Convertible Bonds" means the Tranche A and Tranche B convertible bonds issued by Alvotech on December 16, 2022 for an aggregate principal amount of \$59.1 million.
  - "EMA" means the European Medicines Agency.
  - "Exchange Act" means the Securities Exchange Act of 1934, as amended.
  - "FDA" means the U.S. Food and Drug Administration.
  - "First Merger" means when OACB merges with and into Alvotech, with Alvotech as the surviving company.
- "First Merger Effective Time" means the date and time at which the notarial deed of the sole shareholder's resolutions of Alvotech approving the First Merger becomes effective, upon its publication in the Recueil Electronique des Sociétés et Associations (the Luxembourg legal gazette), subject to the execution of a plan of merger between OACB and Alvotech and the filing and registration of such Plan of First Merger and such other documents as required under the Companies Act (as amended) of the Cayman Islands.
  - "IFRS" means the International Financial Reporting Standards as adopted by the International Accounting Standards Board.
  - "IMA" means Icelandic Medicines Agency.
  - "IPO" means OACB's initial public offering of units, consummated on September 21, 2020.
  - "JOBS Act" means the Jumpstart Our Business Startups Act of 2012, as amended.
- "Joint Venture" means Alvotech & CCHN Biopharmaceutical Limited Liability Company in 2019, a joint venture created together with the Joint Venture Partner.
  - "Joint Venture Partner" means Changchun High & New Technology Industries (Group) Inc., a Chinese corporation.

- "Luxembourg Company Law" means the Luxembourg law of August 10, 1915 on commercial companies, as amended.
- "Mergers" means the First Merger and the Second Merger collectively.
- "MHRA" means the UK Medicines and Healthcare products Regulatory Agency.
- "Nasdaq" means The Nasdaq Stock Market LLC.
- "Nasdag First North" means the Nasdag First North Growth Market.
- "Nasdaq Iceland Main Market" means the Nasdaq Main Market in Iceland.
- "OACB" means Oaktree Acquisition Corp. II, a Cayman Islands exempted company.
- "OACB Class A Ordinary Shares" means the Class A ordinary shares, par value 0.0001 per share, of OACB, which converted into Ordinary Shares at the closing of the Business Combination.
- "OACB Class B Ordinary Shares" or "Founder Shares" means the 6,250,000 Class B ordinary shares, par value \$0.0001 per share, of OACB, which were issued to the Sponsor in a private placement prior to OACB's initial public offering for approximately \$0.004 per share and converted into Ordinary Shares at the closing of the Business Combination.
  - "OACB Ordinary Shares" means the OACB Class A Ordinary Shares and the OACB Class B Ordinary Shares, collectively.
- "OACB Private Placement Warrants" means the warrants to purchase OACB Class A Ordinary Shares purchased in a private placement in connection with the IPO, which automatically ceased to represent a right to acquire purchase OACB Class A Ordinary Shares and automatically represented a right to acquire Ordinary Shares at the Closing of the Business Combination.
- "OACB Public Warrants" means each whole warrant of OACB entitling the holder to purchase one OACB Class A Ordinary Share at a price of \$11.50 per share, which automatically ceased to represent a right to acquire purchase OACB Class A Ordinary Shares and automatically represented a right to acquire Ordinary Shares at the closing of the Business Combination. The OACB Public Warrants were originally sold in the initial public offering of OACB as part of the units at a price of \$10.00 per unit, with each unit consisting of one OACB Class A Ordinary Share and one-fourth of one OACB Public Warrant.
  - "OACB Warrants" means the OACB Public Warrants and the OACB Private Placement Warrants.
  - "Ordinary Shares" means the ordinary shares, with a nominal value of \$0.01 per share, of Alvotech.
- "PIPE Financing" means the private placement pursuant to which the Subscribers subscribed to Ordinary Shares, for a subscription price of \$10.00 per share.
- "Private Placement Warrants" means the former OACB Private Placement Warrants converted at the First Merger Effective Time into a right to acquire one Ordinary Share on substantially the same terms as were in effect immediately prior to the First Merger Effective Time under the terms of the Warrant Agreement.
- "Public Shares" means the OACB Class A Ordinary Shares issued as part of the units sold in the IPO, which converted into Ordinary Shares at the closing of the Business Combination.

"Public Shareholders" means the holders of the OACB Class A Ordinary Shares, which converted into Ordinary Shares at the closing of the Business Combination.

"Public Warrants" means the former OACB Public Warrants converted at the First Merger Effective Time into a right to acquire one Ordinary Share on substantially the same terms as were in effect immediately prior to the First Merger Effective Time under the terms of the Warrant Agreement.

"Redemption" means Alvotech's redemption and cancellation of the initial shares held by the initial sole shareholder of Alvotech pursuant to a share capital reduction of Alvotech immediately after the effectiveness of the First Merger but prior to the Conversion.

"SEC" means the U.S. Securities and Exchange Commission.

"Second Merger" means when Alvotech Holdings merges with and into Alvotech, with Alvotech as the surviving company.

"Second Merger Effective Time" means the date and time at which the Second Merger becomes effective, on the Closing Date immediately after giving effect to the First Merger, the Redemption, the Conversion and the PIPE Financing.

"Securities Act" means the Securities Act of 1933, as amended.

"Senior Bonds" means the senior bonds issued by Alvotech Holdings on December 14, 2018, as amended and restated on November 16, 2022.

"SEPA" means the standby equity purchase agreement, dated as of April 18, 2022, by and among Alvotech and Yorkville.

"Sponsor" means Oaktree Acquisition Holdings II, L.P., a Cayman Islands exempted limited partnership.

"Subscribers" means the institutional investors that have committed to subscribe to Ordinary Shares in the PIPE Financing.

"U.S. GAAP" means United States generally accepted accounting principles.

"Warrants" means the former OACB Warrants converted at the First Merger Effective Time into a right to acquire one Ordinary Share on substantially the same terms as were in effect immediately prior to the First Merger Effective Time under the terms of the Warrant Agreement.

"Warrant Agreement" means the warrant agreement, dated September 21, 2020 by and between OACB and Continental Stock Transfer & Trust Company, as warrant agent, governing OACB's outstanding warrants, which was assigned to and assumed by Alvotech pursuant to that certain Assignment, Assumption and Amendment Agreement dated as of June 15, 2022.

"Yorkville" means YA II PN, LTD., a Cayman Islands exempt limited partnership.

# CONVENTIONS WHICH APPLY TO THIS PROSPECTUS

In this prospectus, unless otherwise specified or the context otherwise requires:

"\$," "USD" and "U.S. dollar" each refers to the United States dollar; and

"€," "EUR" and "euro" each refers to the lawful currency of certain participating member states of the European Union.

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus constitute forward-looking statements that do not directly or exclusively relate to historical facts. You should not place undue reliance on such statements because they are subject to numerous uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Forward-looking statements include information concerning our possible or assumed future results of operations, including descriptions of our business strategy. These statements are often, but not always, made through the use of words or phrases such as "may," "might," "will," "could," "would," "should," "expects," "intends," "plans," "believes," "anticipates," "estimates," "potential," "continue," "ongoing," "targets", "possible," "project," and "predict" and similar expressions or variations of such phrases. All such forward-looking statements involve estimates and assumptions that are subject to risks, uncertainties and other factors that could cause actual results to differ materially from the results expressed in the statements. Among the key factors that could cause actual results to differ materially from those projected in the forward-looking statements are the following:

- Development and projections relating to our competitors and industry, including the estimated growth of the industry;
- The timing of, and our ability to obtain and maintain regulatory approval for our product candidates of the FDA, European Commission and comparable national or regional authorities;
- The timing of the announcement of clinical study results, the commencement of patient studies, regulatory applications, approvals and market launches;
- Our expectations regarding regulatory review and interactions, including the timing and results of the facility inspection by the FDA or other foreign regulatory authorities;
- Our financial performance;
- · Changes in our strategy, future operations, financial position, estimated revenues and losses, projected costs, prospects and plans;
- Our strategic advantages and the impact those advantages will have on future financial and operational results;
- Our expansion plans and opportunities,
- Our ability to grow our business in a cost-effective manner;
- The implementation, market acceptance and success of our business model;
- Developments and projections relating to our competitors and industry, including the estimated growth of the industry;
- Our approach and goals with respect to technology;
- Our expectations regarding our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- The impact of public health emergencies, such as the COVID-19 pandemic, on our business;
- Changes in applicable laws or regulations;
- The outcome of any known and unknown litigation and regulatory proceedings;
- Our ability to maintain the listing of Ordinary Shares or Warrants on The Nasdaq Stock Market LLC and Nasdaq Iceland Main Market;
- Our ability to comply with all applicable laws and regulations;

- Our ability to successfully launch our products in certain markets after obtaining regulatory approval for such market;
- Our estimates of expenses and profitability;
- Our ability to raise additional adequate funds through equity or debt financing;
- Our ability to identify and successfully develop new product candidates;
- Our relationship with third party providers for clinical and non-clinical studies, supplies, and manufacturing of our products;
- Our ability to manage our manufacturing risks;
- The impact of worsening or unpredictable macroeconomic conditions, including rising inflation, interest rates and cost of energy, and general market conditions, war in Ukraine and global geopolitical tension, and public health emergencies, such as COVID-19 pandemic, on the business, financial position, strategy and anticipated milestones; and
- Our relationship with partners for the commercialization of our product candidates.

These forward-looking statements are based on information available as of the date of this prospectus, and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

You should not place undue reliance on these forward-looking statements in deciding to invest in our securities. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include:

- The outcome of any legal proceedings that may be instituted against us or others following the Business Combination;
- The outcome of any legal or regulatory proceedings;
- The ability to raise substantial additional funding, which may not be available on acceptable terms or at all;
- · The ability to maintain the listing of Ordinary Shares on The Nasdaq Stock Market LLC and Nasdaq Iceland Main Market;
- Our ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition and our ability to grow and manage growth profitably;
- Changes in applicable laws or regulations;
- The effects of public health emergencies, such as the COVID-19 pandemic, on our business, including the surge in COVID-19 cases in China at the end of 2022 and the beginning of 2023;
- The inherent uncertainty of projected financial information with respect to us, and the possibility that the assumption underlying such projects ultimately prove incorrect;
- The effects of competition on our future business;
- Our position in the market against current and future competitors;
- Our expansion into new products, services, technologies or geographic regions;

- Our ability to implement business plans, forecasts and other expectations, and identify and realize additional opportunities and to continue as a going concern;
- · The risk of downturns and the possibility of rapid change in the highly competitive industry in which we operate;
- The risk that we and our current and future commercial partners are unable to successfully develop, seek regulatory approval for, and commercialize our products or services, or experience significant delays in doing so;
- The risk that we may never achieve or sustain profitability;
- The risk that we may need to raise additional capital to execute our business plan, which may not be available on acceptable terms or at all:
- · The risk that we experience difficulties in managing our growth and expanding operations;
- The risk that we have identified a material weakness in our internal control over financial reporting which, if not corrected, could affect the reliability of our financial statements;
- The risk that we are unable to secure or protect our intellectual property;
- The risk that estimated growth of the industry does not occur, or does not occur at the rates or timing we have assumed based on third-party estimates and on our own internal analyses; and
- The possibility that we may be adversely affected by other economic, business, and/or competitive factors.
- Other risks and uncertainties described in this prospectus, including those under the section entitled "Risk Factors."

#### PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. Before making an investment decision, you should read this entire prospectus carefully, especially "Risk Factors" and the financial statements and related notes thereto, and the other documents to which this prospectus refers. Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements" for more information.

#### Alvotech

We are a vertically integrated biotech company focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Our purpose is to improve the health and quality of life of patients around the world by improving access to proven treatments for various diseases. Since our inception, we have built our company with key characteristics we believe will help us capture the substantial global market opportunity in biosimilars: a leadership team that has brought numerous successful biologics and biosimilars to market around the world; a purpose-built biosimilars R&D and manufacturing platform; commercial partnerships in global markets; and a diverse, expanding portfolio and pipeline addressing many of the biggest disease areas and health challenges globally.

For more information about Alvotech, see the sections entitled "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operation."

#### **Recent Developments**

#### **Business Combination**

On June 15, 2022, Alvotech consummated the transactions contemplated by the Business Combination Agreement by and among OACB, Alvotech Holdings and Alvotech. Pursuant to the Business Combination Agreement:

- at the First Merger Effective Time, OACB merged with and into Alvotech, whereby (i) all of the outstanding shares of OACB were exchanged for Ordinary Shares on a one-for-one basis, pursuant to a share capital increase of Alvotech, and (ii) all of the outstanding OACB Warrants automatically ceased to represent a right to acquire shares of OACB and automatically represented a right to be issued one Ordinary Share on substantially the same contractual terms and conditions as were in effect immediately prior to the First Merger Effective Time under the terms of the Warrant Agreement, with Alvotech as the surviving company in the merger;
- immediately after the effectiveness of the First Merger but prior to the Conversion, Alvotech redeemed and cancelled the shares held by the initial sole shareholder of Alvotech pursuant to a share capital reduction of Alvotech;
- immediately after the effectiveness of the First Merger and the Redemption, the legal form of Alvotech changed from a simplified joint stock company (*société par actions simplifiée*) to a public limited liability company (*société anonyme*) under Luxembourg law;
- immediately after the change of the legal form of Alvotech, Alvotech issued 17,493,000 Ordinary Shares at a price of \$10.00 per share pursuant to the PIPE Financing for aggregate gross proceeds of \$174,930,000; and
- immediately following the effectiveness of the Conversion and the PIPE Financing, Alvotech Holdings merged with and into Alvotech, whereby all outstanding Alvotech Holdings Ordinary Shares were exchanged for Ordinary Shares, pursuant to a share capital increase of Alvotech, with Alvotech as the surviving company in the merger.

Concurrently with the execution of the Business Combination Agreement, OACB and the Alvotech entered into the Initial Subscription Agreements with the Initial Subscribers, pursuant to which the Initial Subscribers have agreed to subscribe for, and Alvotech has agreed to issue to the Initial Subscribers, an aggregate of 15,393,000 Ordinary Shares at a price of \$10.00 per share, for aggregate gross proceeds of \$153,930,000. Subsequent to this Initial PIPE Financing, on January 18, 2022, OACB and Alvotech entered into the Subsequent Subscription Agreements with the Subsequent Subscribers, pursuant to which the Subsequent Subscribers have agreed to subscribe for, and Alvotech has agreed to issue to the Subsequent Subscribers, an aggregate of 2,100,000 Ordinary Shares at a price of \$10.00 per share, for aggregate gross proceeds of \$21,000,000. The aggregate number of Ordinary Shares to be issued pursuant to the PIPE Financing was 17,493,000 for aggregate gross proceeds of \$174,930,000. The Subscription Agreements contain substantially the same terms, except that the investors that entered into the Foreign Subscription Agreement agreed to subscribe for Ordinary Shares at a price that is net of a 3.5% placement fee.

In connection with the Business Combination, holders of 24,023,495 OACB Class A Ordinary Shares, or 96% of the shares with redemption rights, exercised their right to redeem their shares for cash at a redemption price of approximately \$10.00 per share, for an aggregate redemption amount of \$240,234,950.

On the Closing Date, Alvotech, the Sponsor and certain Alvotech Holdings Shareholders entered into an Investor Rights and Lock-Up Agreement which provides customary demand and piggyback registration rights and which restricts the transfer of the Ordinary Shares during the applicable lock-up periods.

On June 16, 2022, our Ordinary Shares and Warrants began trading on the Nasdaq, under the new ticker symbols "ALVO" and "ALVOW", respectively. On June 23, 2022, our Ordinary Shares began trading on the Nasdaq First North under the ticker symbol "ALVO," until their admission on the Nasdaq Iceland Main Market on December 8, 2022. To ensure compliance with applicable Icelandic and European securities rules and regulations, due to the listing of our Ordinary Shares on the Nasdaq Icelandic Main Market, this Registration Statement on Form F-1 will be published on Nasdaq Main Market's website as well.

In June 2022, we also announced that its commercial partner, STADA Arzneimittel AG ("STADA"), launched Alvotech's AVT02 product, a biosimilar to Humira (adalimumab), under the name Hukyndra in selected European countries, including France, Germany, Finland, and Sweden. As of December 31, 2022, AVT02 is available in Canada and sixteen select European markets.

On November 16, 2022, we announced that we had secured gross proceeds of approximately \$136 million through the following sources:

• We amended and restated certain terms and conditions of existing senior bonds and issued new senior bonds in an aggregate principal amount equal to \$70,000,000 (the "Senior Bonds"). Pursuant to the terms of the amended Senior Bonds, we are required to use commercially reasonable endeavors to raise new funding through issuance of additional Ordinary Shares (by way of ordinary shares, structured equity and/or preference shares) and/or unsecured convertible bond(s), for net proceeds of at least \$75.0 million by December 15, 2022, and \$150.0 million by March 31, 2023. If we failed to raise at least \$75.0 million in net proceeds by December 15, 2022, we were required to grant penny warrants representing 1.5% of the ordinary share capital to the bondholders, and if we fail to raise at least \$150.0 million by March 31, 2023, we are required to grant penny warrants representing 1.0% of the ordinary share capital to the bondholders.

Since we had not raised \$75.0 million by December 15, 2022, we issued 4,198,807 warrants to the bondholders on December 31, 2022. Each new warrant entitles the bondholders, upon exercise, to receive from us one Ordinary Share, at the exercise price of one cent (\$0.01) per share. Following the issuance of the December 2022 Convertible Bonds (as described below) and the closing of the private

placement of Ordinary Shares for gross proceeds of \$137.0 million on February 10, 2023 (as described below), we are not obligated to issue the additional 1.0% warrants to the bondholders.

- We entered into the Alvogen Facility agreement and agreed to (i) roll over the \$63.3 million, which includes \$3.3 million of accrued interest, outstanding under the Alvogen loans, into the new subordinated loan agreement, and upsize the loan facility by \$50.0 million; (ii) an increase of the interest rate from 10.0% per annum to 17.5% per annum on the outstanding amounts under the loan facility; and (iii) a repayment date of 91 days after the full redemption or the final maturity date of the Senior Bonds.
  - In connection with the Alvogen Facility, we also entered into a warrant agreement with Alvogen pursuant to which Alvogen will subscribe for warrants, allocated for no consideration. The warrants would have been issued on the earlier of (i) December 15, 2022, if a Successful New Capital Increase (as defined in the Alvogen Warrant Agreement) had not occurred on or before that date, or (ii) December 20, 2022 if any amount remained outstanding pursuant to the Alvogen Facility on that date. Each warrant would have entitled Alvogen, upon exercise, to receive one fully paid and non-assessable Ordinary Share, at the exercise price of one cent (\$0.01) per Ordinary Share. On December 16, 2022, Alvotech completed the private placement of \$59.1 million of December 2022 Convertible Bonds (as described below). The December 2022 Convertible Bonds qualified as a Successful New Capital Increase (as defined in the Alvogen Warrant Agreement) and Alvotech used the majority of the net proceeds to replace the Alvogen Facility. As a result, Alvotech did not issue any warrants to Alvogen under the Alvogen Warrant Agreement.
- We issued a convertible bond (the "Aztiq Convertible Bond") to ATP Holdings ehf. for the acquisition of the Alvotech manufacturing facility. The Aztiq Convertible Bond has a principal amount of \$80.0 million and carries an interest rate of 12.5% per annum. Interest payable in six-month intervals and is capitalized and added to the outstanding principal amount of the bonds. The maturity date of the convertible bond is the later of the (i) November 16, 2025, or (ii) 91 days after the earlier of the full redemption or the final maturity date of the Senior Bonds. Bondholders have the right to convert their outstanding bonds into ordinary shares of Alvotech on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date, for a conversion price of \$10.00 per share.

On December 20, 2022, we issued two tranches of convertible bonds (the "December 2022 Convertible Bonds"). Tranche A is ISK denominated with a principal balance of \$59.1 million, of which \$3.5 million in cash proceeds were received subsequent to December 31, 2022, and carries an annual payment-in-kind interest rate of 15% per year, while tranche B is USD denominated with a principal balance of \$0.6 million and carries an annual payment-in-kind interest rate of 12.5% per year. Holders of both the Tranche A and Tranche B convertible bonds, may elect, at their sole discretion, to convert all or part of the principal amount and accrued interest into Ordinary Shares at a conversion price of \$10.00 per share on December 31, 2023, or June 30, 2024. On January 25, 2023, we issued an additional \$10.0 million in the Tranche B December 2022 Convertible Bonds.

In December 2022, we received a complete response letter ("CRL") from the FDA regarding the interchangeability BLA (the "December 2022 CRL"). Under this December 2022 CRL, correction of the same deficiencies identified in the August 2022 CRL with respect to the manufacturing facility is required for approval of the interchangeability BLA. In January 2023, we received confirmation from the FDA that the reinspection of our facility in Reykjavik, Iceland is scheduled for March 6-17, 2023. We are working collaboratively with FDA to resolve these issues but there can be no guarantee that all deficiencies will be resolved to the satisfaction of the FDA and that the FDA will not find new deficiencies during this inspection.

Effective January 1, 2023, Mark Levick, our former Chief Executive Officer, has decided to step down and Robert Wessman, Executive Chairman and founder became our new Chief Executive Officer, and

Hafrun Fridriksdottir, previously Executive Vice President and Head of Global R&D at Teva, was appointed as our Chief Operating Officer.

On January 6, 2023, we announced that the FDA had accepted for review a BLA for AVT04 and on February 9, 2023, we announced that the EMA had accepted a Marketing Authorization Application for AVT04. We, directly or indirectly through our partners, also submitted marketing applications for AVT04 in, Japan and Canada in the second half of 2022.

On January 11, 2023, we announced the initiation of a pharmacokinetic study for AVT05, a biosimilar candidate to Simponi® and Simponi Aria® (golimumab). The study will assess the pharmacokinetics, safety, and tolerability of AVT05 compared to Simponi in healthy adult subjects.

On February 10, 2023, we closed a private placement of 11,834,061 Ordinary Shares at a purchase price of \$11.57 per Ordinary Share for proceeds of \$137.0 million and transaction costs of \$4.8 million. The offer or sale of Ordinary Shares was made in an overseas directed offering directed solely into Iceland and in accordance with local laws and customary practices and documentation.

### Implications of Being an "Emerging Growth Company" and a "Foreign Private Issuer"

Alvotech qualifies as an "emerging growth company" as defined in the JOBS Act. As an "emerging growth company," Alvotech may take advantage of certain exemptions from specified disclosure and other requirements that are otherwise generally applicable to public companies. These exemptions include:

- not being required to comply with the auditor attestation requirements for the assessment of our internal control over financial reporting provided by Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");
- · reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation or seek shareholder approval of any golden parachute payments not previously approved.

Alvotech may take advantage of these reporting exemptions until it is no longer an "emerging growth company."

Alvotech is also considered a "foreign private issuer" and will report under the Securities Exchange Act of 1934 (as amended, the "Exchange Act") as a non-U.S. company with "foreign private issuer" status. This means that, even after Alvotech no longer qualifies as an "emerging growth company," as long as it qualifies as a "foreign private issuer" under the Exchange Act, it will be exempt from certain provisions of the Exchange Act that are applicable to U.S. public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for
  insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Alvotech may take advantage of these reporting exemptions until such time that it is no longer a "foreign private issuer." Alvotech could lose its status as a "foreign private issuer" under current SEC rules and regulations if more than 50% of Alvotech's outstanding voting securities become directly or indirectly held of

record by U.S. holders and any one of the following is true: (i) the majority of Alvotech's directors or executive officers are U.S. citizens or residents; (ii) more than 50% of Alvotech's assets are located in the United States; or (iii) Alvotech's business is administered principally in the United States.

Alvotech may choose to take advantage of some but not all of these reduced burdens. Alvotech has taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained in this prospectus may be different from the information you receive from Alvotech's competitors that are public companies, or other public companies in which you have made an investment.

As a foreign private issuer, Alvotech is permitted to follow certain Luxembourg corporate governance practices in lieu of certain listing rules of Nasdaq, or Nasdaq Listing Rules. Alvotech plans to follow the corporate governance requirements of the Nasdaq Listing Rules, except that it intends to follow Luxembourg practice with respect to quorum requirements for shareholder meetings in lieu of the requirement under Nasdaq Listing Rules that the quorum be not less than 33 1/3% of the outstanding voting shares. Under Alvotech's articles of association, at an ordinary general meeting, there is no quorum requirement and resolutions are adopted by a simple majority of validly cast votes. In addition, under Alvotech's articles of association, for any resolutions to be considered at an extraordinary general meeting of shareholders, the quorum shall be at least one half of our issued share capital unless otherwise mandatorily required by law. In addition, three of Alvotech's eight directors are independent as defined in Nasdaq listing standards and Alvotech currently has only one director who serves on the compensation committee who meets the heightened independence standards for members of a compensation committee.

#### **Summary Risk Factors**

Investing in our securities entails a high degree of risk as more fully described under "*Risk Factors*." You should carefully consider such risks before deciding to invest in our securities. These risks include, among others:

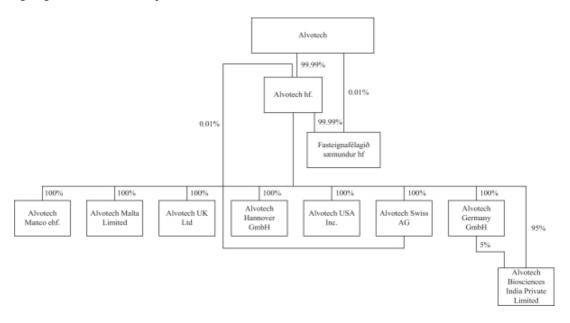
- We have a limited operating history in a highly regulated environment, have incurred significant losses since inception, anticipate that we may continue to incur significant losses for the immediate future and may never be profitable.
- We have substantial indebtedness and expect to continue to use leverage in executing our business strategy, which could have important consequences on our business and adversely affect the return on our assets.
- We may need to raise substantial additional funding from shareholders or third parties. This additional funding may not be available
  on acceptable terms or at all. Failure to obtain such necessary capital when needed may force us to delay, limit or terminate our
  product development efforts or other operations.
- The regulatory approval processes of the FDA, European Commission, IMA and comparable national or regional authorities are lengthy and time consuming and we cannot give any assurance that marketing authorization applications for any of our product candidates will receive regulatory approval.
- Our product candidates may cause unexpected side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if granted.
- Even if we obtain regulatory approval for a product candidate, our products will remain subject to continuous subsequent regulatory obligations and scrutiny.
- We rely on third parties to conduct our nonclinical and clinical studies, to manufacture aspects of clinical and commercial supplies of our product candidates, and to store critical components of our

product candidates. If these third parties do not successfully carry out their contractual duties, or are not compliant with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates.

- We are subject to a multitude of risks related to manufacturing. Any adverse developments affecting the manufacturing operations of our biosimilar products could substantially increase our costs and limit supply for our products, or could affect the approval status of our products.
- Our expected benefits from the Joint Venture may not materialize as expected or at all, either of which could have adverse effects on our business.
- Our biosimilar product candidates, if approved, will face significant competition from the reference products, from other biosimilar
  products that reference the same reference products including those which may have regulatory exclusivities, and from other
  medicinal products approved for the same indication(s) as the reference products. Our failure to effectively compete may prevent us
  from achieving significant market penetration and expansion.
- We currently have no marketing and sales organization. We are dependent on our partners for the commercialization of our biosimilar products candidates in certain major markets, and their failure to commercialize in those markets could have a material adverse effect on our business and operating results.
- If we or one of our partners infringe or are alleged to infringe the intellectual property rights of third parties, our business could be harmed. For example, our Canadian partner, JAMP Pharma, is involved in legal proceedings adverse to AbbVie that may impact our adalimumab product, AVT02.
- Our recurring losses raise substantial doubt as to our ability to continue as a going concern.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise is unable to develop and maintain an effective system of internal controls in the future, we may not be able to produce timely and accurate financial statements or comply with applicable laws and regulations.
- Future issuances of debt securities and equity securities, including by selling shareholders with resales covered by effective shelf
  registration statements, may adversely affect us, including the market price of our Ordinary Shares and may be dilutive to existing
  shareholders.

#### **Corporate Structure**

The following diagram illustrates our corporate structure as of December 31, 2022.



#### **Corporate Information**

The legal entity named Alvotech, previously known as Alvotech Lux Holdings S.A.S., was incorporated under the laws of the Grand Duchy of Luxembourg on August 23, 2021 as a simplified joint stock company (*société par actions simplifiée*) having its registered office at 9, Rue de Bitbourg L-1273 Luxembourg, Grand Duchy of Luxembourg and registered with the Luxembourg Trade and Company Register (*Registre de Commerce et des Sociétés, Luxembourg*) under number B258884. On February 16, 2022, Alvotech Lux Holdings S.A.S. changed its name to "Alvotech". On June 15, 2022, Alvotech consummated the Business Combination and changed its legal form from a simplified joint stock company (*société par actions simplifiée*) to a public limited liability company (*société anonyme*) under Luxembourg law.

Alvotech's principal website address is *www.alvotech.com*. We do not incorporate the information contained on, or accessible through, Alvotech's websites into this prospectus, and you should not consider it a part of this prospectus.

#### SUMMARY TERMS OF THE OFFERING

The summary below describes the principal terms of the offering. The "Description of Securities" section of this prospectus contains a more detailed description of our securities.

We are registering the issuance by us of up to 10,916,647 Ordinary Shares that may be issued upon exercise of Warrants at an exercise price of \$11.50 per share.

We are also registering the resale by the Selling Securityholders or their permitted transferees of up to 219,616,200 Ordinary Shares, and the resale by the Sponsor or their permitted transferees of up to 4,666,667 Private Placement Warrants to purchase Ordinary Shares.

Any investment in the securities offered hereby is speculative and involves a high degree of risk. You should carefully consider the information set forth under "Risk Factors" on page 25 of this prospectus.

Issuer

Alvotech (f/k/a/ Alvotech Lux Holdings S.A.S.)

#### **Issuance of Ordinary Shares**

Ordinary Shares issued by us

10,916,647 Ordinary Shares consisting of

- 6,249,980 ordinary shares issuable upon exercise of Public Warrants, and
- 4,666,667 Ordinary Shares issuable upon exercise of Private Placement Warrants.

Ordinary Shares outstanding prior to exercise of all Warrants

262,500,781 Ordinary Shares (as of February 15, 2023). This does not include the Ordinary Shares held in treasury by Alvotech's subsidiary, Alvotech Manco ehf.

Ordinary Shares outstanding assuming exercise of all Warrants

273,324,464 Ordinary Shares (based on outstanding shares as of February 15, 2023). This does not include the Ordinary Shares held in treasury by Alvotech's subsidiary, Alvotech Manco ehf. or the 2,274,556 Ordinary Shares underlying the penny warrants issued to holders of the Senior Bonds on December 31, 2022 that remain outstanding as of February 15, 2023.

warrants

Exercise price of public warrants and private placement \$11.50 per share, subject to adjustments as described herein. The exercise price of the Warrants is \$11.50 per share and the closing price of our Ordinary Shares on Nasdaq on March 10, 2023 was \$13.22 per ordinary share.

Use of Proceeds

We could potentially receive up to an aggregate of \$125.5 million if all the Warrants are exercised to the extent such Warrants are exercised for cash. We expect to use the net proceeds from the exercise of the Warrants for general corporate purposes. We believe the likelihood that Warrant holders will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Ordinary Shares. If the trading price for our Ordinary Shares is less than \$11.50 per share, we believe holders will be unlikely to exercise their Warrants. See the section entitled "Use of Proceeds."

#### **Resale of Ordinary Shares and Warrants**

Ordinary Shares offered by the Selling Securityholders We are registering the resale by the Selling Securityholders named in this prospectus, or their permitted transferees, an aggregate of up to 219,616,200 Ordinary Shares, consisting

- 17,493,000 Ordinary Shares issued in the PIPE Financing;
- 6,250,000 Ordinary Shares issued to the Sponsor in exchange for the Founder Shares in connection with the Business Combination (subject to vesting and lockups);
- 4,666,667 Ordinary Shares issuable upon exercise of Private Placement Warrants;
- 186,206,553 Ordinary Shares issued to former shareholders of Alvotech Holdings in exchange for their Alvotech Holdings Ordinary Shares in connection with the Business Combination (subject to vesting and lockups); and
- 5,000,000 Ordinary Shares subscribed to by Alvogen and Aztiq in the Alvogen-Aztiq Loan Advance Conversion.

Warrants offered by the Selling Securityholders

Up to 4,666,667 Private Placement Warrants.

Redemption

The Private Placement Warrants are redeemable in certain circumstances. See the section entitled "Description of Securities—Warrants" for further discussion.

Use of Proceeds

We will not receive any proceeds from the sale of the Ordinary Shares or Warrants to be offered by the Selling Securityholders. See the section entitled "Use of Proceeds."

Lock-up agreements

Certain of our securityholders are subject to certain restrictions on transfer until the termination of applicable lock-up periods. See the sections entitled "Certain Relationships and Related Party Transactions-Sponsor Support Agreement" and "Description of Our Securities-Lock-Up Provisions in Bylaws" for further discussion.

Dividend policy

Other than as disclosed elsewhere in this prospectus, we currently expect to retain all future earnings for use in the operation and expansion of our business and do not plan to pay any dividends on our Ordinary Shares in the near future. The declaration and payment of any dividends in the future will be determined by our board of directors in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition, applicable law and contractual restrictions. See "Dividend Policy."

Registration Rights and Lock-Up Agreement

Certain of our shareholders are subject to certain restrictions on transfer until the termination of applicable lock-up periods. See "Certain Relationships and Related Party Transactions—Investor Rights and Lock-Up Agreement."

Market for our securities

Our Ordinary Shares and Warrants are listed on The Nasdaq Stock Market LLC under the symbols "ALVO" and "ALVOW,"

	respectively. Our Ordinary Shares are also listed on the Nasdaq Iceland Main Market under the ticker symbol "ALVO."
Risk factors	Investing in our securities involves substantial risks. See " <i>Risk Factors</i> " for a description of certain of the risks you should consider before investing in Alvotech.

#### SUMMARY HISTORICAL FINANCIAL INFORMATION OF ALVOTECH

The summary historical financial information of Alvotech as of December 31, 2022 and 2021 and for the years ended December 31, 2022, 2021 and 2020, was derived from the historical audited consolidated financial statements of Alvotech included elsewhere in this prospectus.

The following summary historical financial information should be read together with the consolidated financial statements and accompanying notes, "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus. The summary historical financial information in this section is not intended to replace Alvotech's historical consolidated financial statements and the related notes. Alvotech's historical results are not necessarily indicative of Alvotech's future results.

#### **Summary Historical Financial Information:**

## **Consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss:**

USD in thousands, except for per share amounts	Year l	Year Ended December 31,	
	2022	2021	2020
Product revenue	24,836	—	—
License and other revenue	58,193	36,772	66,616
Other income	1,988	2,912	2,833
Cost of product revenue	(64,095)	_	_
Research and development expenses	(180,622)	(191,006)	(148,072)
General and administrative expenses	(186,742)	(84,134)	(58,914)
Operating loss	(346,442)	(235,456)	(137,537)
Share of net loss of joint venture	(2,590)	(2,418)	(1,505)
Finance income	2,549	51,568	5,608
Finance costs	(188,419)	(117,361)	(161,551)
Exchange rate differences	10,566	2,681	3,215
(Loss) / gain on extinguishment of financial liabilities	(27,311)	151,788	
Non-operating (loss) / profit	(205,205)	86,258	(154,233)
Loss before taxes	(551,647)	(149,198)	(291,770)
Income tax benefit	38,067	47,694	121,726
Loss for the year	(513,580)	(101,504)	(170,044)
Other comprehensive income / (loss)			
Item that will be reclassified to profit or loss in subsequent periods:			
Exchange rate differences on translation of foreign operations	(6,111)	(305)	5,954
Total comprehensive loss	(519,691)	(101,809)	(164,090)
Loss per share			
Basic and diluted loss for the year per share	(2.60)	(0.92)	(1.82)

#### **Consolidated Statements of Financial Position Data:**

USD in thousands		As of December 31,	
	2022	2021	
Total assets	828,443	597,977	
Total equity	(564,416)	(135,612)	
Total liabilities	1,392,859	733,589	

# **Consolidated Statements of Cash Flows Data:**

USD in thousands	Year I	Year Ended December 31,		
	2022	2021	2020	
Net cash used in operating activities	(312,389)	(228,170)	(74,295)	
Net cash used in investing activities	(63,537)	(40,633)	(16,903)	
Net cash generated from financing activities	424,910	254,831	55,402	

#### RISK FACTORS

An investment in our securities carries a significant degree of risk. In addition to the other information contained in this prospectus, including the matters addressed under the heading "Forward-Looking Statements," you should carefully consider the following risk factors in deciding whether to invest in our securities. The occurrence of one or more of the events or circumstances described in these risk factors, alone or in combination with other events or circumstances, may have a material adverse effect on our business, reputation, revenue, financial condition, results of operations and future prospects, in which event the market price of our securities could decline, and you could lose part or all of your investment. Additional risks and uncertainties of which we are not presently aware or that we currently deem immaterial could also affect our business operations and financial condition.

#### Risks Related to Our Financial Position and Need for Capital

We have a limited operating history in a highly regulated environment on which to assess our business, have incurred significant losses since inception and anticipate that we may continue to incur significant losses for the immediate future.

We are a biotech company with a limited operating history. We have incurred losses in each year since inception in 2013, including losses of \$513.6 million, \$101.5 million, and \$170.0 million for the years ended December 31, 2022, 2021, and 2020, respectively. We had an accumulated deficit of \$1,654.1 million as of December 31, 2022.

We have devoted substantially all of our financial resources to identify and develop our product candidates, including conducting, among other things, analytical characterization, process development and manufacture, formulation and clinical studies and providing general and administrative support for these operations. To date, we have financed our operations primarily through the sale of equity securities, debt financing by way of shareholder loans (convertible and non-convertible) and the issuance of bond instruments (convertible and non-convertible) to third party investors and related parties, as well as through milestone payments under certain license and development agreements with our partners, for example Teva Pharmaceuticals International GmbH ("Teva") and STADA Arzneimittel AG ("STADA"). The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings or strategic collaborations. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.

• Our biologics license application ("BLA") supporting biosimilarity for AVT02, a biosimilar to Humira (adalimumab), was filed with the FDA in 2020, and our BLA supporting interchangeability was accepted for review in February 2022. In September 2022, we announced that we had received communication from the FDA, which included a complete response letter ("CRL") detailing its assessment of the March 2022 inspection of our manufacturing facility in Reykjavik, Iceland and our subsequent written responses to the FDA (the "August 2022 CRL"). The FDA's August 2022 CRL to the initial biosimilar BLA for AVT02 noted certain deficiencies related to the Reykjavik facility and stated that satisfactory resolution of the deficiencies is required before FDA may approve this first-filed BLA. In December 2022, we received a CRL from the FDA regarding the interchangeability BLA (the "December 2022 CRL"). Under this December 2022 CRL, correction of the same deficiencies identified in the August 2022 CRL with respect to the manufacturing facility is required for approval of the interchangeability BLA. In January 2023, we received confirmation from the FDA that the reinspection of our facility in Reykjavik, Iceland is scheduled for March 6-17, 2023. We are working collaboratively with FDA to resolve these issues but there can be no guarantee that all deficiencies will be resolved to the satisfaction of the FDA and that the FDA will not find new deficiencies during this inspection. Since 2021, we, directly or through our partners, received regulatory approval for AVT02 in the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia, and dossiers are under review in multiple countries.

- For AVT04, a proposed biosimilar to Stelara (ustekinumab), we reported positive topline results from two clinical studies in May 2022. In January 2023, we announced that the FDA had accepted for review a BLA for AVT04. We anticipate that the FDA's review will be completed in the second half of 2023. In February 2023, we announced that the EMA had accepted a Marketing Authorization Application for AVT04. We, directly or indirectly through our partners, also submitted marketing applications for AVT04 in, Japan and Canada in the second half of 2022.
- We are in the earlier stages of development for our other lead product candidates, namely AVT03, a biosimilar candidate to Prolia / Xgeva (denosumab) for which we initiated clinical studies in July 2022, AVT05, a biosimilar candidate to Simponi and Simponi Aria (golimumab) for which we initiated a pharmacokinetic (PK) study in December 2022, AVT06, a biosimilar candidate to Eylea (aflibercept) for which we initiated a clinical study in July 2022, and AVT23, a biosimilar candidate to Xolair (omalizumab) for which a PK study has been completed.

There can be no guarantee that we will receive regulatory approval for our product candidates in any country. If we obtain regulatory approval to market a biosimilar product candidate, our future revenue will depend upon the therapeutic indications for which approval is granted, the size of any markets in which our product candidates may receive approval and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our product candidates in those markets. However, even if one or more of our product candidates gains regulatory approval and is commercialized, we may never become profitable.

We expect to continue to incur significant expenses, which could lead to increasing operating losses for the immediate future. We anticipate that our expenses will increase substantially if and as we:

- continue our analytical, nonclinical and clinical development of our product candidates;
- incur costs associated with being a public company;
- expand the scope of our current clinical studies for our product candidates;
- advance our programs into more expensive clinical studies;
- initiate additional analytical, nonclinical, clinical or other studies for our product candidates;
- change or add contract manufacturers, clinical research service providers, testing laboratories, device suppliers, legal service providers or other vendors or suppliers;
- establish a sales and marketing infrastructure;
- seek to identify, assess, acquire and/or develop other biosimilar product candidates or products that may be complementary to our products;
- make upfront, milestone, royalty or other payments under any license agreements;
- seek to create, maintain, protect, expand and enforce our intellectual property portfolio;
- engage legal counsel and technical experts to help evaluate and avoid infringing any valid and enforceable intellectual property rights of third parties;
- engage in litigation including patent litigation with reference product companies or others that may hold patents allegedly infringed by us;
- seek to attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts; and
- experience any delays or encounters issues with any of the above, including but not limited to failed studies, conflicting results, safety issues, supply chain issues, and other delays, whether or not due to

public health emergencies, such as the COVID-19 pandemic, litigation or regulatory challenges that may require longer follow-up of existing studies, additional major studies or additional supportive studies in order to obtain regulatory approval.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year such that a period-to-period comparison of our results of operations may not be a good indication of our future performance quarter-to-quarter and year-to-year due to factors including the timing of clinical trials, any litigation that we may file or that may be filed against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder.

#### We have never generated any substantial revenue from product sales and may never be profitable.

Although we have received upfront payments, milestone and other contingent payments and/or funding for development from some of our collaboration and license agreements, and some product revenue since we launched AVT02 in Canada and sixteen select European markets in 2022, we have never generated substantial revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, as well as successfully commercialize, one or more of our product candidates. We cannot predict if and when we will begin generating revenue from product sales outside of Canada and Europe, as this depends heavily on our success in many areas, including but not limited to:

- completing analytical, nonclinical and clinical development of our product candidates;
- developing and testing of our product formulations;
- · obtaining and retaining regulatory approvals for product candidates for which we complete clinical studies;
- developing a sustainable and scalable manufacturing process for any approved product candidates that is compliant with regulatory
  manufacturing requirements and establishing and maintaining supply and manufacturing relationships with third parties that can conduct
  the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our product
  candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory approval, either directly or with collaboration partners
  or distributors;
- obtaining adequate third-party payor coverage and reimbursements for our products;
- obtaining market acceptance of biosimilar pharmaceuticals and our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing and developing (or acquiring/in-licensing) new product candidates;
- negotiating favorable or commercially reasonable terms in any collaboration, licensing or other arrangements into which we may enter;
- · maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- · attracting, hiring and retaining qualified personnel; and
- the result of potential litigation including patent litigation with reference product companies or others that may allege infringement by us.

Even if one or more of the product candidates that we develop is approved for commercial sale, we may incur significant costs in order to manufacture and commercialize any such product. Our expenses could increase

beyond our expectations if we are required by the FDA, the European Commission, the EMA, other comparable regulatory authorities, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against us, to change our manufacturing processes or assays or to perform clinical, nonclinical, analytical or other types of studies in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the timing of our entry into a particular market or territory, the number of biosimilar competitors in such markets and whether any have regulatory exclusivity, the national laws governing substitution, the accepted price for the product, the ability to get reimbursement at any price, the nature and degree of competition from the reference product and other biosimilar companies (including competition from large pharmaceutical companies entering the biosimilar market that may be able to gain advantages in the sale of biosimilar products based on brand recognition and/or existing relationships with customers and payors), our ability to manufacture sufficient quantities of the product of sufficient quality and at a reasonable cost and whether we own (or has partnered to own) the commercial rights for that territory. If the market for our product candidates (or its share of that market) is not as significant as we expect, the regulatory approval is narrower in scope than we expect (e.g., for a narrow indication or set of indications) or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are unable to successfully complete development and obtain regulatory approval for our lead products, namely AVT02 (outside of the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia, where we received approval), AVT03, AVT04, AVT05, AVT06 and AVT23, our business may suffer. Additionally, if we are not able to generate substantial revenue from the sale of any approved products or the costs necessary to generate revenues increase significantly, we may never become profitable.

#### Our operating and financial results are subject to concentration risk.

Our operational and financial results are subject to concentration risk. Our success will depend significantly on the development of a limited number of product candidates, their regulatory approval in a limited number of jurisdictions and their commercialization by a limited number of commercial partners. Even if we are successful in developing and commercializing all of these products, our revenue will be dependent on a limited number of products that would account for a significant majority of our revenues. This concentration risk would increase to the extent we are successful in developing and commercializing fewer products as we would be dependent on a lower number of products for the significant majority of our revenues. Unfavorable changes or the non-occurrence of certain anticipated events with respect to any of these limited number of products, jurisdictions or commercial partners may disproportionally affect our global results. As of December 31, 2022, we have only generated product revenue through sales of AVT02 in Canada and sixteen select European markets in 2022 through certain commercialization partners. See also "—We are dependent on our partners, such as Teva and STADA for the commercialization of our biosimilar products candidates in certain major markets, and their failure to commercialize in those markets could have a material adverse effect on our revenue, business and operating results."

# We may be unable to generate sufficient cash flow to satisfy our significant debt service obligations, which would adversely affect our financial condition and results of operations.

Our ability to make principal and interest payments on and to refinance our indebtedness will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that may be beyond our control. If our business does not generate sufficient cash flow, if currently anticipated costs and revenues are not realized on schedule, in the amounts projected or at all, or if future borrowings are not available to us in amounts sufficient to enable us to pay our indebtedness or to fund our other liquidity needs, our financial condition and results of operations may be adversely affected. Furthermore, our debt obligations are secured by substantially all of our intellectual property. If we cannot service our debt payments under the Senior Bonds, the bondholders may take possession, sell, exchange, license or otherwise dispose of our intellectual property, which we have pledged as collateral for

the Senior Bonds. If we cannot generate sufficient cash flow to make scheduled principal and interest payments on our debt obligations in the future, we may need to refinance all or a portion of our indebtedness on or before maturity, sell assets, delay capital expenditures or seek additional equity. If we are unable to refinance any of our indebtedness on commercially reasonable terms or at all or to effect any other action relating to our indebtedness on satisfactory terms or at all, we may be forced to reduce or discontinue operations or seek protection of the bankruptcy laws, our business may be harmed and our securityholders may lose some or all of their investment.

We may need to raise substantial additional funding from shareholders or third parties. This additional funding may not be available on acceptable terms or at all. Failure to obtain such necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing our product candidates is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates through clinical studies.

As of December 31, 2022, we had cash and cash equivalents, excluding restricted cash, of \$66.4 million. In February and March 2022, we received interest free loan advances of \$25.0 million from each of Alvogen and Aztiq, who agreed to settle these outstanding amounts in Ordinary Shares rather than cash in July 2022. Additionally, during the year 2022, the Company received \$60.0 million in loans from Alvogen. As a result of the consummation of the Business Combination, we received \$131.9 million in net proceeds, after deduction of costs related to the Business Combination, including the liabilities assumed from OACB. In November and December 2022, we amended and upsized our outstanding Senior Bonds and the Alvogen Facility, resulting in net cash proceeds of \$57.9 million and \$50.0 million, respectively. Additionally, we received net cash proceeds of \$73.4 million from the issuance of the December 2022 Convertible Bonds and loans related to the Alvotech's manufacturing facility, of which \$50.0 million was used to repay amounts drawn from the Alvogen Facility. During the year ended December 31, 2022, we received \$81.2 million in payments pursuant to its out-license contracts with commercial partners.

On April 18, 2022, we entered into a standby equity purchase agreement (the "SEPA") with YA II PN, LTD. ("Yorkville") pursuant to which we have the option, but not the obligation, to issue, and Yorkville shall subscribe for, an aggregate amount of up to \$150.0 million of Ordinary Shares at the time of our choosing during the term of the agreement, subject to certain limitations. The SEPA will continue for a term of three years commencing from the date of execution of the definitive agreement. As of the date of this prospectus, we have not used this facility and have recently announced that we do not intend to use the facility for the foreseeable future.

On February 10, 2023, we closed a private placement of 11,834,061 of Ordinary Shares at a purchase price of \$11.57 per Ordinary Share for proceeds of \$137.0 million and transaction costs of \$4.8 million. The offer or sale of Ordinary Shares was made in an overseas directed offering directed solely into Iceland and in accordance with local laws and customary practices and documentation.

However, even with the aforementioned cash received during 2022 and 2023 and expected to be received in the future, management has determined that there is a material uncertainty that may cast significant doubt about our ability to continue as a going concern. The audited consolidated financial statements appearing at the end of this prospectus have been prepared on a going concern basis without adjustments that might result from the outcome of this uncertainty and the report of our independent registered public accounting firm thereon includes an explanatory paragraph to that effect.

We may require significant additional funding to obtain regulatory approval for, and to successfully commercialize, our product candidates. In addition, our operating plans may change as a result of many factors

that are currently unknown to us, and we may need to seek additional funding sooner than planned. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our analytical studies, clinical studies, nonclinical testing and other related activities;
- the cost of manufacturing clinical supplies and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any milestone and royalty payments thereunder;
- the cost, timing and outcomes of any litigation that we may file or that may be filed against us by third parties; and
- the product revenue, if any, derived from our sales of approved products.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us or the possibility of such issuance may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute the share ownership of our existing shareholders. The incurrence of indebtedness could result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or for specific strategic considerations. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. In addition, the perception that we may not be able to continue as a going

If we are unable to obtain sufficient funding on a timely basis and on acceptable terms and continue as a going concern, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates or to otherwise reduce or discontinue our operations. In general, we may be unable to expand our operations or otherwise capitalize on business opportunities, and defend against and prosecute litigation necessary to commercialize our product candidates as desired, which could materially affect our business, financial condition and results of operations. If we are ultimately unable to continue as a going concern, we may have to seek the protection of bankruptcy laws or liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that our securityholders will lose all or a part of their investment.

#### We may not be able to obtain sufficient funding on a timely basis, on acceptable terms, or at all.

Given the rising inflation, interest rates and recent volatility on the capital markets, we may be unable to raise sufficient funding on a timely basis, on acceptable terms, or at all. Failure to obtain additional funding could

have a material adverse effect on our business, prospects and financial condition and may require us to significantly curtail, delay or discontinue one or more of our development programs or the commercialization of any product candidates or to otherwise reduce or discontinue our operations. Even if we were able to obtain additional funding, the terms on which such funding could be obtained may be unfavorable to us and our securityholders, including higher interest rates, which would burden us with higher debt service obligations and may impact our prospects of becoming profitable, a lower share price at which new equity would be issued, which may cause significant dilution to existing shareholders, and/or we may be required to provide additional incentives to potential investors, such as penny warrants, which also may cause significant dilution to existing shareholders. See also "— Future issuances of debt securities and equity securities may adversely affect us, including the market price of our Ordinary Shares and may be dilutive to existing shareholders," and "—we have substantial indebtedness and expect to continue to use leverage in executing our business strategy, which could have important consequences on our business and adversely affect the return on our assets."

We have substantial indebtedness and expect to continue to use leverage in executing our business strategy, which could have important consequences on our business and adversely affect the return on our assets.

As of December 31, 2022, we had \$810.4 million in outstanding indebtedness, consisting of \$532.7 million in Senior Bonds, \$81.3 million in the Aztiq Convertible Bond, \$64.6 million from loans issued by Alvogen, \$60.6 million in December 2022 Convertible Bonds, and \$71.2 million in bank loans, including the mortgage on our Reykjavik facility and loans to help finance equipment purchases. Our board of directors will consider a number of factors when evaluating our level of indebtedness and when making decisions regarding the incurrence of new indebtedness, including the purchase price of assets to be acquired with debt financing, the estimated market value of our assets and the ability of particular assets, and our ability as a whole, to generate cash flow to cover the expected debt service. Our articles of incorporation do not contain a limitation on the amount of debt we may incur, and the board of directors may change our target debt levels at any time without the approval of shareholders.

This substantial indebtedness, as well as any future indebtedness we may incur, could have important consequences for our business and holders of our securities, including:

- making it more difficult for us to satisfy our obligations with respect to our debt or to our trade or other creditors;
- causing us to pay higher interest rates upon refinancing indebtedness if interest rates rise;
- increasing our vulnerability to adverse economic or industry conditions;
- limiting our ability to obtain additional financing to fund capital expenditures and acquisitions, particularly when the availability of financing in the capital markets is limited;
- requiring a substantial portion of our cash flows from operations for the payment of interest on our debt and reducing our ability to use our cash flows to fund working capital, capital expenditures, acquisitions, stock repurchases, and general corporate requirements;
- · limiting our flexibility in planning for, or reacting to, changes in our business and the homebuilding industry; and
- placing us at a competitive disadvantage to less leveraged competitors.

We cannot assure you that our business will generate sufficient cash flow from operations or that future borrowings will be available to us through capital markets financings or under our debt or credit facilities or otherwise in an amount sufficient to enable us to pay our indebtedness, or to fund our other liquidity needs. We may need to refinance all or a portion of our indebtedness, on or before its maturity. Our mortgage facility loans expire in December 2027, our Senior Bonds mature in June 2025, the Aztiq Convertible Bond matures in November 2025 and the December 2022 Convertible Bonds in December 2025.

We cannot assure you that we will be able to refinance any of our indebtedness on commercially reasonable terms, or at all. In addition, we may incur additional indebtedness in order to finance our operations, make acquisitions or to repay existing indebtedness. If we cannot service our debt, we may have to take actions such as selling assets, seeking additional debt or equity or reducing or delaying capital expenditures, strategic acquisitions, investments and alliances. We cannot assure you that any such actions, if necessary, could be effected on commercially reasonable terms, or at all, or on terms that would be advantageous to our securityholders or on terms that would not require us to breach the terms and conditions of our existing or future debt agreements.

As a European public company with limited liability with registered office in Luxembourg, we will likely be subject to the sustainability disclosure requirements set out in the EU Taxonomy Regulation after their adoption.

On January 5, 2023, the EU adopted Directive 2022/2464/EU (the "Corporate Sustainability Reporting Directive"), which amends the non-financial reporting requirements set out in Directive 2013/34/EU (the "Accounting Directive"). The CSRD introduces new mandatory reporting obligations that will require in-scope entities to publish audited sustainability information in their Management Reports addressing environmental, social and governance ("ESG") matters in line with new mandatory European sustainability reporting standards ("ESRS") that will be adopted by the European Commission through secondary legislation.

The First Set of ESRS which will apply to EU reporting entities (which may include us) are due to be formally adopted by June 30, 2023. Drafts of these standards have already been published and consulted on. They are currently pending formal approval by the European Commission. The First Set of ESRS cover general requirements (ESRS 1), general disclosures (ESRS 2) and the following 10 ESG topics:

E1	Climate change
E2	Pollution
E3	Water and marine resources
E4	Biodiversity and ecosystems
E5	Resource and circular economy
S1	Own workforce
S2	Workers in the value chain
S3	Affected communities
S4	Consumers and end-users
G1	Business conduct

For each topic, reporting entities will have to include, in their reports, material sustainability information concerning:

- 1. themselves,
- 2. entities in their group whether EU or non-EU, and
- 3. businesses in their value chains (both upstream and downstream).

Certain disclosures for large EU reporting entities are mandatory, even if the entity considers that there are no material impacts, risks or opportunities. For example, disclosure of scopes 1-3 greenhouse gas emissions is always required.

Certain disclosures are only required if 'material' impacts, risks and opportunities are identified. 'Materiality' under the CSRD must be assessed following the double materiality principle. Double materiality means that the reporting entity should consider both financial materiality (i.e., sustainability matters which from the investor perspective are material to the company's development, performance and position) and impact materiality (i.e., the impact of corporate activity on sustainability matters from the perspective of citizens, consumers, employees etc.). Impacts, risks and opportunities are material if they satisfy one or both of these materiality tests.

All EU Reporting Entities must have the sustainability section of their Management Report audited by a third-party accredited auditor to confirm that it has been prepared in accordance with the relevant ESRS and Article 8 of Regulation (EU) 2020/852 ("EU Taxonomy Regulation"). The assurance opinion must be published alongside the Management Report.

As a European public company with limited liability with registered office in Luxembourg, it is likely that we will fall under the scope of application of the new sustainability-related reporting requirements. This will involve setting up processes to gather the relevant data, conduct materiality assessments and prepare a CSRD-compliant report, which will likely be a time-consuming and costly exercise.

The disclosure requirements under the CSRD will apply alongside the EU Taxonomy Regulation, which (a) creates a classification system to determine when an economic activity qualifies as "environmentally sustainable" and (b) requires companies in scope of the EU Accounting Directive, including those brought into scope by the CSRD, to disclose, from January 1, 2022, the proportion of turnover, capital and operational expenditure directed towards activities that qualify as "environmentally sustainable" (this information should be disclosed even if the contribution is none).

The disclosures set out in the CSRD and the EU Taxonomy Regulation should be also considered together with the proposed EU Directive on Corporate Sustainability Due Diligence ("CSDDD"), which, if adopted, will set new due diligence duties for the following entities:

- Large EU-based limited liability companies with (a) more than 500 employees and (b) a net worldwide turnover of over EUR 150 million generated in the last financial year for which financial statements have been prepared.
- Non-EU companies that have generated a net worldwide turnover of more than EUR 150 million in the EU in the financial year preceding the last financial year.
- EU and non-EU companies that do not reach the thresholds set out above but generated a specific amount of their net turnover in high-risk sectors (agriculture, food, textile and extraction of mineral resources).

These entities will be required to identify and, where necessary, prevent, end or mitigate the potential and actual adverse impacts of their activities on human rights, such as child labor and exploitation of workers, and on the environment, for example pollution and biodiversity loss. The CSDDD, if adopted, will impose substantive due diligence obligations and also influence the information gathering process required by entities that are also subject to the CSRD. It will also have an impact on the mandatory disclosures to be made under the CSRD on the entity's due diligence process (which will need to show compliance with the CSDDD if the entity is subject to both the CSRD and CSDDD). It is estimated that the CSDDD will be adopted by the end of Q2 2024 and become enforceable towards 2026-2030.

A disruption at our main manufacturing facility could materially and adversely affect our business, financial condition and results of operations.

On November 16, 2022, we acquired the Reykjavik manufacturing and research facility through the purchase of the shares in Fasteignafélagið Sæmundur hf. ("Saemundur") from ATP Holdings ehf., a related party.

Simultaneously, we entered into a loan facility for \$48.8 million with Landsbankinn hf., secured with a first priority mortgage over the facility, resulting in the extinguishment of the old loan on the manufacturing and research facility. As owners of the manufacturing and research facility, we are responsible for the maintenance, upkeep and improvements of the facility, for obtaining and maintaining all permits related to the facility and activities therein, and a significant disruption at the facility, whether it be due to fire, natural disaster, power loss, intentional acts of vandalism, climate change, war, terrorism, insufficient quality, or cyber-attacks could materially and adversely affect our business. In addition, failure to make timely payments under the loan facility with Landsbankinn hf. may lead disruptions of our manufacturing facility and to the loss of the facility and equipment therein.

Covenants under our existing debt instruments, and any future debt arrangements may result in the acceleration of outstanding indebtedness and limit the manner in which we operate.

Our existing debt instruments, including the Senior Bonds, the Aztiq Convertible Bonds and the December 2022 Convertible Bonds, contain customary terms and covenants, as well as customary events of default, including but not limited to defaults related to payment compliance, undertaking and covenant compliance, bankruptcy and insolvency proceedings, judgments against the Company, and delisting events.

In addition, these bonds contain, and any future indebtedness we incur may contain, various negative covenants that restrict or may restrict, among other things, our ability to:

- incur additional indebtedness, guarantee indebtedness or issue disqualified shares or preferred shares;
- · declare or pay dividends on, repurchase or make distributions in respect of, capital stock or make other restricted payments;
- make certain investments or acquisitions;
- create certain liens;
- enter into agreements restricting certain subsidiaries' ability to pay dividends or make other intercompany transfers;
- · consolidate, merge, sell or otherwise dispose of all or substantially all of our assets and the assets of our restricted subsidiaries;
- enter into certain transactions with affiliates;
- sell, transfer or otherwise convey certain assets; and
- conduct our business and may be unable to engage in favorable business activities, repurchase our ordinary shares or finance future
  operations or capital needs.

Servicing these bonds requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we are unable to make our installment payments in cash, we may be forced to issue a significant number of Ordinary Shares which could dilute existing shareholders. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

#### Risks Related to the Development of Our Product Candidates

The regulatory review and approval processes of the FDA, European Commission and comparable national or regional authorities are lengthy, time consuming and have uncertain outcomes. If we and our collaboration partners are unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. We cannot give any assurance that marketing authorization applications for any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.

Our future success is dependent on our ability to develop, obtain regulatory approval for, and then commercialize and obtain adequate third-party coverage and reimbursement for one or more product candidates. We currently only have marketing authorization for AVT02 in the EEA (comprising the 27 EU Member States, Norway, Liechtenstein, and Iceland), the UK, Switzerland, Canada, Australia and Saudi Arabia. We do not have marketing authorization for other product candidates or in other countries, and may never be able to develop or commercialize a marketable product other than AVT02 in those countries.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, marketing, distribution, post-approval monitoring and reporting and export and import of biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, by the European Commission, the EMA and the National Competent Authorities of the EEA countries, and by other comparable regulatory authorities in other countries, which regulations differ from country to country. Neither we nor any collaboration partner is permitted to market our product candidates before receiving market authorization/approval from the appropriate regulatory authorities.

The time required to seek and obtain market authorization/approval by the FDA and comparable foreign regulatory authorities is unpredictable, may take many years following the completion of clinical studies and depends upon numerous factors. In addition, approval requirements, regulations, or considerations with respect to the type and amount of clinical, nonclinical and analytical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the submission of an application for marketing authorization/approval, the authorization or approval, or the decision not to approve an application. Other than the regulatory approval received in the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia for AVT02, neither we nor any collaboration partner has obtained regulatory approval for any of our product candidates in the United States, the EEA or in additional other countries where We or our partners have commercial rights, and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

These lengthy approval processes, as well as the unpredictability of the results of analytical, nonclinical, and clinical studies, may result in our failure to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, prospects and financial condition. Moreover, any delays in the commencement or completion of product testing could significantly impact our product development costs and could result in the need for additional financing. For example, our clinical trials must use reference products as comparators, and such supplies may not be available on a timely basis to support such trials.

Most of our product candidates are in varying stages of development and will require additional clinical development, management of analytical, nonclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supplies, commercial organization and significant marketing efforts before We may generate any revenue from product sales. Since 2021, we, directly or through our partners, received regulatory approval for AVT02 in the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia. AVT02 is currently marketed in sixteen countries in Europe and in Canada. Our BLA for AVT02 supporting biosimilarity was filed with the FDA in September 2020 and our BLA for AVT02 supporting interchangeability was accepted for review in February 2022. In September 2022, We announced that we had received communication from the FDA detailing our assessment of the March 2022 inspection of our manufacturing facility in Reykjavik, Iceland and our subsequent written responses to the FDA (the "August 2022 CRL"). The August 2022 CRL to the initial

biosimilar BLA for AVT02 noted certain deficiencies related to the Reykjavik facility and stated that satisfactory resolution of the deficiencies is required before FDA may approve this first-filed BLA. In December 2022, we received a complete response letter from the FDA regarding the interchangeability BLA (the "December 2022 CRL"). Under this December 2022 CRL, correction of the same deficiencies identified in the August 2022 CRL with respect to the biosimilarity BLA is required for approval of the interchangeability BLA. In January 2023, we received confirmation from the FDA that the reinspection of our facility in Reykjavik, Iceland is scheduled for March 2023. We are working collaboratively with the FDA to resolve these issues but there can be no guarantee that all deficiencies will be resolved to the satisfaction of the FDA and that the FDA will not find new deficiencies during the March 2023 inspection. In January 2023, we announced that the FDA had accepted for review a BLA for AVT04 and in February 2023, we announced that the EMA had accepted a Marketing Authorization Application for AVT04. We, directly or indirectly through our partners, also submitted marketing applications for AVT04 in, Japan and Canada in the second half of 2022. In July 2022, we announced the initiation of our clinical trials for AVT05 and AVT03 and in January 2023, we announced the initiation of our pharmacokinetic study for AVT05, while AVT23 is in pre-clinical development.

Although some of our employees have prior experience with submitting marketing applications to the FDA and comparable national or regional regulatory authorities, we have not received approval for such applications for our product candidates other than for AVT02 in the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia. We cannot be certain that any of our product candidates will receive additional regulatory approval. If we and our collaboration partners do not receive regulatory approvals for enough of our product candidates in sufficiently large markets, we may not be able to continue our operations.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the data collected from analytical, nonclinical, or clinical studies of our product candidates may not be sufficient to support an application for regulatory approval as a biosimilar;
- the FDA or comparable supranational, national or regional regulatory authorities may disagree with the design or implementation, or sufficiency of our analytical, nonclinical, or clinical studies;
- the FDA or comparable regulatory authorities may disagree with our interpretation of data from analytical and bioanalytical studies, nonclinical studies or clinical studies;
- we may be unable to provide adequate scientific justification to the FDA or comparable regulatory authorities for extrapolation of a
  product candidate to each proposed indication;
- the FDA or comparable regulatory authorities may identify significant deficiencies with the manufacturing processes, test procedures and specifications, facilities or third-party manufacturers with which we contract for clinical and commercial supplies. For example, in September 2022, we announced that we had received the August 2022 CRL, which noted certain deficiencies related to the Reykjavik facility and stated that satisfactory resolution of the deficiencies is required before the FDA may approve the first-filed biosimilarity BLA. In the December 2022 CRL, the FDA noted that correction of the same deficiencies identified in the August 2022 CRL is required for approval of the interchangeability BLA;
- $\bullet \qquad \hbox{the regulatory exclusivity held by a competing manufacturer; and} \\$
- the approval requirements, policies, or regulations of the FDA or comparable regulatory authorities may significantly change in a manner rendering our clinical, nonclinical, analytical, or chemistry, manufacturing, and control data insufficient for approval.

In addition, if we change the regulatory pathway through which we intend to seek approval of any of our product candidates, we may have to conduct additional clinical trials, which may delay our ability to submit a marketing application for the product. Even if we or our collaboration partners were to obtain approval for any of

our product candidates, the FDA or comparable regulatory authorities may limit the scope of such approval, e.g., for fewer or more limited indications than those for which we have sought licensure, may grant approval contingent on the completion of costly additional clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The UK's withdrawal from the EEA on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty and such uncertainty may make it more difficult for us to achieve regulatory approval in the UK. The impact of Brexit on the on-going validity in the UK of current EEA authorizations for medicinal products, whether granted through the centralized procedure, decentralized procedure, or mutual recognition, and on the future process for obtaining marketing authorization for pharmaceutical products manufactured or sold in the UK remains uncertain.

Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the EU, the UK, was subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules continued to apply. The UK and the EU have signed an EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forward though many uncertainties remain. The TCA primarily focuses on ensuring free trade between the EEA and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an annex to the TCA. The annex provides a framework for the recognition of GMP inspections and for the exchange and acceptance of official GMP documents.

The regime does not, however, extend to procedures such as batch-release certification. Among the changes that will now occur is that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will continue to follow the EU regulatory rules. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release.

The UK has unilaterally agreed to accept EEA batch testing and batch release. However, the EEA continues to apply EU laws that require batch testing and batch release to take place in the EEA territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EEA market for commercial use. As regards marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national MA. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EEA countries will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market in Great Britain.

Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU Directives and Regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU, now that UK legislation has the potential to diverge from EU legislation. All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals for our product candidates, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EEA and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EEA. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek

regulatory approvals for our pro in the UK or the EEA for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK.

As a result of the foregoing, among other factors, there can be no assurance that we would be able to achieve our plan to commercialize our product candidates on our expected timeline, or at all.

If we are not able to demonstrate biosimilarity of our biosimilar product candidates to the satisfaction of the FDA or comparable national or regional regulatory authorities, we will not obtain regulatory approval for commercialization of our biosimilar product candidates and our future results of operations and ability to generate revenue would be adversely affected.

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and to commercialize our biosimilar product candidates. Any inability to obtain regulatory approval could impact and delay the development timeline of our product candidates. To obtain regulatory approval for the commercialization of these product candidates, we will be required to demonstrate to the satisfaction of the FDA or comparable national regulatory authorities, among other things, that our proposed products are highly similar to biological reference products already approved by the applicable regulatory authority pursuant to approved marketing applications/authorizations, notwithstanding minor differences in clinically inactive components, and that they have no clinically meaningful differences as compared to the marketed biological products in terms of the safety, purity and potency of the products. Each individual jurisdiction may apply different criteria to assess biosimilarity, based on of the data that can be interpreted subjectively in some cases.

It is uncertain if regulatory authorities will grant the reference biosimilar product candidates the same labeling than the labeling approved for the reference product if the reference biosimilar product candidates are approved. For example, an infliximab (Remicade) biosimilar molecule was approved in the EEA with the same label as the reference product, but it did not receive approval initially for the same labeling reference in Canada. A similar outcome could occur with respect to one or more of our product candidates.

In the event that the FDA or comparable regulatory authorities require us to generate additional data, including by conducting additional clinical trials or other lengthy processes or otherwise change their criteria and requirements for the approval of biosimilar products, the approval and commercialization of our proposed biosimilar products could be delayed or prevented. Delays in the commercialization of or the inability to obtain regulatory approval for these products could adversely affect our operating results by restricting or significantly delaying the introduction of new biosimilars.

The structure of complex proteins used in protein-based therapeutics is inherently variable and highly dependent on the processes and conditions used to manufacture them. If we are unable to develop manufacturing processes that demonstrate that our product candidates are highly similar to their reference products, and within a range of variability considered acceptable by regulatory authorities, we may not be able to obtain regulatory approval for our products.

Protein-based therapeutics are inherently heterogeneous and their structures are highly dependent on the manufacturing process and conditions. Products from one manufacturing facility can differ from those produced in another facility. Similarly, physicochemical differences can also exist among different lots produced within a single facility. The physicochemical complexity and size of biologic therapeutics can create significant technical and scientific challenges in the context of their replication as biosimilar products.

The inherent variability in protein structure from one production lot to another is a fundamental consideration with respect to establishing biosimilarity to a reference product to support regulatory approval

requirements. For example, the glycosylation of the protein, meaning the manner in which sugar molecules are attached to the protein backbone of a therapeutic protein when it is produced in a living cell, is critical to half-life (how long the drug stays in the body), efficacy and even safety of the therapeutic and is therefore a key consideration for biosimilarity. Defining and understanding the variability of a reference product in order to match its glycosylation profile requires significant skill in cell biology, protein purification and analytical protein chemistry. Variations in the glycosylation profile and other analytical characterizations important for determining biosimilarity to the reference product molecule are risks unique to biosimilar manufacturers.

There are extraordinary technical challenges in developing complex protein-based therapeutics that not only must achieve an acceptable degree of similarity to the reference product in terms of relevant quality attributes such as glycosylation patterns, but also the ability to develop manufacturing processes that can replicate the necessary structural characteristics within an acceptable range of variability sufficient to satisfy regulatory authorities.

For example, the manufacturing process of our products may be susceptible to non-ideal product variability without well-characterized and well-controlled master and working cell banks. A cell bank is a collection of ampoules of uniform composition stored under defined conditions, each containing an aliquot of a single pool of cells. The master cell bank is generally derived from the selected cell clone containing the expression construct that has been encoded to produce the protein of interest, such as a specific monoclonal antibody with a defined amino acid sequence. This unique aliquot of cells allows for a consistent high quality biologic medicine to be produced. The working cell bank is derived by expansion of one or more ampoules of the master cell bank and is used for routine manufacturing. Both the master cell bank and working cell bank are central to obtaining regulatory approval for manufacturing and marketing biologic medicine. The quality of the manufactured biologic product is dependent on the quality of the cells used for its manufacturing, and having a sufficient supply of master and working cell banks is important for a consistent manufacturing process. Should our cell banks be compromised, we would be unable to produce usable products for patients in any market.

Given the challenges caused by the inherent variability in protein production, we may not be successful in our application for approval of our products if regulators conclude that we have not demonstrated that our product candidates are highly similar to their reference products, or that the processes we use to manufacture our products are unable to produce the products within an acceptable range of variability (including situations where the reference product sponsor changes its manufacturing process and such changes impact the characteristics of the product).

Additionally, the foregoing factors complicate scaling of our manufacturing capabilities. To the extent that we are unable to scale our manufacturing capabilities to produce sufficient quantities of our products at the required specifications and at an acceptable cost, we may be unable to meet demand for our approved product candidates and our business, financial condition, reputation and results of operations may suffer.

Clinical drug development involves a lengthy and expensive process, and we may encounter substantial delays in our clinical studies or may fail to demonstrate safety, purity and efficacy/potency to the satisfaction of applicable regulatory authorities. Additionally, the impact of public health emergencies, such as the COVID-19 pandemic, or the occurrence of unforeseen geopolitical events such as the Russia-Ukraine conflict and the resulting instability in the region, may delay the conduct and completion of clinical studies.

Before obtaining regulatory approval from regulatory authorities for the sale of our product candidates, we (and/or our collaboration partners) must conduct clinical studies to demonstrate the safety, purity, and potency (safety and efficacy) of the product candidates in humans.

Clinical studies are expensive and can take many years to complete, and their outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies, including comparative analytical assessments of our product candidates, may not be predictive of the results of clinical studies. The success of clinical studies cannot be predicted.

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. As a result of public health emergencies, such as the COVID-19 pandemic, including the surge in COVID-19 cases in China at the end of 2022 and the beginning of 2023, and/or the occurrence of unforeseen geopolitical events, such as the Russia-Ukraine conflict and the resulting instability in the region, timelines could be extended. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory authorities on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites:
- delays in obtaining required Institutional Review Board, or IRB, approval or Ethics Committee positive opinion as part of the single
  decision on the authorization of the clinical trial issued by EU Member States including input from the national competent authorities and
  Ethics Committee in relation each clinical study site;
- imposition of a clinical hold by regulatory authorities, after review of an investigational new drug, or IND, application or amendment or equivalent application or amendment, or an inspection of its clinical study operations or study sites or as a result of adverse events reported during a clinical trial;
- delays in administering studies as a result of adverse events or complaints;
- delays in recruiting suitable or sufficient numbers of patients to participate in its clinical studies sponsored by us or our partners;
- difficulty collaborating with patient groups and investigators;
- failure by its CROs, clinical study sites, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices requirements or applicable regulatory guidelines and good clinical practice requirements in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up, or patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- difficulties justifying the scientific relevance of non-U.S. comparators for use in studies intended to support regulatory approval by FDA;
- questions with regard to the scientific justification for extrapolation of findings across indications;
- changes in regulatory requirements or policies that require amending or submitting new clinical protocols;
- the cost of clinical studies of its product candidates being greater than what we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding or regulators requiring us to conduct additional clinical studies or to abandon product development programs;
- delays in manufacturing, testing, releasing, validating or importing/exporting and/or distributing sufficient stable quantities of our product candidates and reference products for use in clinical studies or the inability to do any of the foregoing;

- staffing shortages and limitation on the movement of people as a result of public health emergencies, such as the COVID-19 pandemic, the Russia-Ukraine conflict and the resulting instability in the region, and local, national or international governmental restrictions imposed or enforced as a result of these or other health-related or geopolitical events; and
- delays or interruptions to preclinical studies, clinical trials, our receipt of services from third-party service providers or our supply chain
  due to public health emergencies, such as the COVID-19 pandemic, including the surge in COVID-19 cases in China at the end of 2022
  and the beginning of 2023, or the occurrence of unforeseen geopolitical events such as the Russia-Ukraine conflict and the resulting
  instability in the region, or otherwise.

Any inability to successfully complete analytical, nonclinical, or clinical development could result in additional costs to us or impair our ability to achieve regulatory approval and generate revenue. Even if we are successful, the regulatory approval processes and action dates of the FDA, EMA and comparable regulatory authorities may be delayed or continue to be delayed due to impact of public health emergencies, such as the COVID-19 pandemic. As a result, we may be delayed in obtaining regulatory approvals for our products. Further, the global economic slowdown, the overall disruption of global supply chains and distribution systems, effects of this on the work of appropriate regulatory authorities in different regions and the other risks and uncertainties associated with public health emergencies, such as the COVID-19 pandemic, including the surge in COVID-19 cases in China at the end of 2022 and the beginning of 2023 and its potential impact on business operation of the Joint Venture and elsewhere, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, the Russia-Ukraine conflict, and the sanctions and retaliatory measures that have been taken, or could be taken in the future, by the United States, the European Union, the United Kingdom, and other countries against Russia and Belarus have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could adversely affect our ability to conduct ongoing and future clinical trials of our product candidates in Ukraine, Russia and Eastern European countries. In addition, in 2022, we had planned to begin our AVT03 clinical trial, that included planned trial sites in Ukraine, and our AVT06 clinical trial, that included planned trial sites in Ukraine and Russia. For the AVT03 and AVT06 trials, we replaced these Ukrainian and Russian trial sites with trial sites in different jurisdictions. The evolving situation of this conflict, the current and potential future sanctions that may be imposed by the United States or other jurisdictions against Russia and Belarus as a result, and the countersanctions that may be imposed by Russia and Belarus are unpredictable and could negatively impact the anticipated timing and completion of our clinical trials and/or analyses of clinical results, including our clinical trials for AVT03 or AVT06, which could limit our ability to obtain regulatory approval for these candidates on anticipated timelines or at all and materially harm our business.

In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. If we intend to alter the manufacturing process for a particular product candidate, we will need to provide data to the FDA and comparable regulatory authorities demonstrating the comparability of the pre- and post-change product candidate. If we are unable to make that demonstration to the FDA or comparable regulatory authorities, we could face significant delays or fail to obtain regulatory approval to market the product, which could significantly harm our business, prospects and financial condition.

Our product candidates may cause unexpected side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if granted.

As with most pharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity (from minor reactions to death) and frequency (infrequent or

prevalent). Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or when a product is commercialized. Undesirable or unexpected side effects caused by our product candidates that must be reported to the FDA or other regulators could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable regulatory authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or other safety issues and, if different from the severity and prevalence of side effects for the reference products, could preclude the demonstration of biosimilarity. Such adverse event findings also could require us or our collaboration partners to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business, prospects and financial condition. In such an event, we may be precluded from seeking licensure through the regulatory pathway for biosimilars, or could be required by the FDA or other comparable regulatory authorities to conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated or our studies could be suspended, varied or terminated, and the FDA or comparable regulatory authorities could order us to cease further development of or deny, vary, or withdraw approval of our product candidates for any or all intended indications. There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any comparable regulatory authority in a timely manner, if ever, which could harm our business, prospects and financial condition.

Drug-related side effects could affect patient recruitment for clinical trials, the ability of enrolled patients to complete our studies or result in potential product liability claims against which we would need to mount a defense. We currently carry product liability insurance, and we are required to maintain clinical trial insurance pursuant to certain of our license agreements. We believe our product liability insurance coverage is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect the results of our operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such products (or caused by the reference products or other biosimilars based on the applicable reference products), a number of potentially significant negative consequences could result, including but not limited to:

- · regulatory authorities may suspend, withdraw or vary approvals of such product;
- regulatory authorities may request or require that the product be recalled or removed from the market;
- · regulatory authorities may require additional warnings on the label or otherwise require labeling to be updated or narrowed;
- we may be required to agree to a Risk Evaluation and Mitigation Strategy ("REMS"), or a shared system REMS, or comparable foreign strategy, which could include a medication guide for distribution to patients outlining the risks of side effects, a communication plan for healthcare providers and/or other elements to assure safe use;
- · we could be sued and potentially held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, prospects and financial condition.

If any of our product candidates receives approval, regulatory authorities including the FDA, European Commission, IMA, EMA, National Competent Authorities of EEA countries and other comparable foreign regulatory authorities regulations will require that we regularly report certain information, including information about adverse events that may have been caused by or contributed by those products. The timing of adverse event reporting obligations would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA, European Commission, the IMA, the EMA, the National Competent Authorities of EEA countries or other comparable foreign regulatory authorities could take action that may include criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or suspension or variation of market approval, and delay in approval or clearance of future products.

As a condition to granting marketing authorization or approval of a product, the FDA or other comparable foreign regulatory authorities may require additional clinical trials or other studies. The results generated in these trials could result in the loss of regulatory approval, changes in labeling, and/or new or increased concerns about the side effects, efficacy or safety. Regulatory authorities in countries outside the United States often have similar regulations and may impose comparable requirements. Post-marketing studies, whether conducted by us or by others, whether mandated by regulatory authorities or conducted voluntarily, and other emerging data about products, such as adverse event reports, may also adversely affect the availability or commercial potential of our products. Any of the foregoing risks could render us unable to achieve our plan of commercializing five products by the end of 2025.

Our reliance on certain participants for our clinical trials could cause delays in ongoing studies or the development of our products if such participants prove to be too limited or a substantial portion of participants in the studies withdraw.

In order to be successful and pursue market authorization for our products in various countries, we must be able to gather health data on the basis of populations from around the world. To the extent participants in clinical trials are too limited to certain populations, our clinical research may be adversely affected. Additionally, we depend on the willingness of these volunteers to participate in studies, and there is always the risk that they may no longer be willing to participate or revoke the consents necessary for us to process their medical data. For example, due to reasons beyond our control, including public health emergencies, such as the COVID-19 pandemic, and the Russia-Ukraine conflict and the resulting instability in the region, participants and our key employees and advisors may no longer be able to travel or cross country borders to participate in our studies. If, for any reason, a substantial portion of participants in the studies were to withdraw their consent or discontinue their participation, we may not be able to continue our clinical studies for some or all of our product candidates which may cause delays in the development or approval of our product candidates. If our ability to gather and use sufficient data is impaired, we also may not be able to fulfill some contractual obligations with our partners.

The development, manufacture and commercialization of biosimilar products under various regulatory pathways pose unique risks related to regulatory approvals across various jurisdictions.

U.S. Regulatory Framework for Biosimilars

We and our collaboration partners intend to pursue market authorization globally. In the United States, an abbreviated pathway for approval of biosimilar products was established by the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), enacted on March 23, 2010, as part of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (together, the "PPACA"). The BPCIA established this abbreviated pathway under section 351(k) of the Public Health Service Act (the "PHSA") for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Subsequent to the enactment of the BPCIA, the FDA has issued numerous guidance documents

explaining its current thinking regarding the demonstration of biosimilarity and interchangeability as well as the submission and review of such BLA. Market success of biosimilar products will depend on demonstrating to patients, physicians, payors and relevant authorities that such products are similar in quality, safety and efficacy as compared to the reference product. If biosimilar product applications do not continue to be approved and the markets in which we operate do not widely accept the commercialization of biosimilar products, our business will be harmed. How the BPCIA is applied and interpreted by the FDA may have a material impact on our chances of obtaining FDA approval for our biosimilar product candidates, and our business operations after obtaining approval.

We will continue to analyze and incorporate into our product development plans any additional final regulations issued by the FDA, pharmacy substitution policies enacted by state governments and other applicable requirements. The costs of development and approval, along with the probability of success for our biosimilar product candidates, will be dependent upon application of any laws and regulations issued by the relevant regulatory authorities. The costs of developing our products may increase due to uncertainties or changes in guidance provided by regulatory authorities like the FDA, and we may not have adequate funding and resources to pursue market authorization for all of our biosimilar products.

Biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which may delay and could prevent the commercial launch of a product. Moreover, the PHSA prohibits the FDA from filing an application for a biosimilar candidate to a reference product for four years of the date of first licensure of the reference product by the FDA, and from approving an application for a biosimilar candidate for 12 years from the date of first licensure of the reference product. For example, the FDA would not be able to approve a BLA submitted for a biosimilar that references a specific drug until 12 years after the date of first licensure of the BLA, i.e., the date that reference product BLA was approved. Depending on the product, that regulatory exclusivity period may be further extended by a six-month pediatric exclusivity. The US regulatory exclusivity in the case of AVT02, a biosimilar to Humira (adalimumab), would be December 31, 2014, in the case of AVT04, a biosimilar candidate to Stelara (ustekinumab), would be September 25, 2021, in the case of AVT05, a biosimilar candidate to Eylea (aflibercept), would be May 18, 2024. Interchangeable biosimilar approvals may also be blocked by periods of first interchangeable exclusivity ranging from 12 to 42 months in duration.

Regulatory Framework for Biosimilars Outside the United States

The European Commission approved the first biosimilar medicinal product in 2006. Since then the European Commission and the EMA have acquired extensive experience in the review and approval of biosimilars, and developed guidelines related to the authorization procedure for these products, including data requirements needed to support approval.

The EU provides opportunities for data and market exclusivity related to certain types of marketing authorizations. Upon grant of related marketing authorization, innovative medicinal products generally benefit from eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EEA from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization applicant from commercializing its product in the EEA until 10 years have elapsed from the initial marketing authorization of the reference product in the EEA. The overall ten year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

Innovative products in the EEA benefit from eight years of data exclusivity and 10 years of marketing exclusivity following grant of marketing authorization. As a result, an application for regulatory approval of a biosimilar drug cannot be submitted to the EMA until expiration of the eight-year data exclusivity period for the reference product, measured from the date of grant of authorization for the reference product. Furthermore, even if the biosimilar is authorized in the subsequent two years it cannot be marketed in the EEA until expiration of the 10-year marketing exclusivity period. This 10-year period may be extendible to 11 years if approval is granted in relation to the reference product for an additional therapeutic indication, within the first eight years following its initial marketing authorization, representing a significant clinical benefit in comparison with existing therapies. A new pharmaceutical form does not trigger a new data exclusivity. It could trigger orphan exclusivity, provided, however, that the targeted disease is a rare disease and that the new pharmaceutical form meets the high threshold for being considered as bringing a significant benefit to patients.

Other regions, including Canada, China, Japan and Korea, also have their own legislation outlining a regulatory pathway for the approval of biosimilars. In some cases, other countries have either adopted European Union guidance (Singapore and Malaysia) or are following guidance issued by the World Health Organization (Cuba and Brazil). While there is overlap in the regulatory requirements across regions, there are also some areas of non-overlap. Additionally, we cannot predict whether countries that we may wish to market in, which do not yet have an established or tested regulatory framework could decide to issue regulations or guidance and/or adopt a more conservative viewpoint than other regions. Therefore, it is possible that even if we obtain agreement from one health authority to an accelerated or optimized development plan, we will need to defer to the most conservative view to ensure global harmonization of the development plan. Also, for regions where regulatory authorities do not yet have sufficient experience in the review and approval of a biosimilar product, these authorities may rely on the approval from another region (for example, the United States), which could delay its approval in that region. In addition, regulatory approval may be delayed as a result of laws in any applicable jurisdiction that provide for stay of regulatory approval related to patent coverage and subsequent litigation.

If other companies' biosimilar candidates for certain reference products are determined to be interchangeable and biosimilar product candidates for these same reference products are not, our business could be negatively impacted.

The FDA may determine that a proposed biosimilar product is "interchangeable" with a reference product, meaning that the biosimilar product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product, if the application includes sufficient information to show that the product is biosimilar to the reference product and that it can be expected to produce the same clinical result as the reference product in any given patient. In addition, if the biosimilar product may be administered more than once to a patient, the applicant must demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between the biosimilar product candidate and the reference product is not greater than the risk of using the reference product without such alternation or switch. To make a final determination of biosimilarity or interchangeability, the FDA may require additional confirmatory information beyond what we plan to initially submit in our applications for approval, such as more in-depth analytical characterization, animal testing or further clinical studies. Provision of sufficient information for approval may prove difficult and expensive.

We cannot predict whether any of our biosimilar product candidates will meet regulatory requirements for approval as a biosimilar product or as an interchangeable product.

The concept of "interchangeability" is important because, in the United States for example, the first biosimilar approved as interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity during which time the FDA cannot approve a second or subsequent biosimilar product interchangeable with that reference product for any condition of use. The relevant period of exclusivity will end upon the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(1)(6) against the

applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). Thus, a determination that another company's product is interchangeable with the reference biologic made before we obtain approval of our corresponding biosimilar product candidates may delay the potential approval of our products as interchangeable with the reference product, which could materially adversely affect the results of operations and delay, prevent or limit our ability to generate revenue. Even if we are awarded interchangeable exclusivity for a product, that award may be challenged by third parties. Any successful challenge to our exclusivity will negatively impact our ability to market and sell the related product.

In the EEA, the approval of a biosimilar for marketing is based on a positive opinion issued by the EMA and a related decision issued by the European Commission. The regulatory approval is valid throughout the entire EEA. However, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. In addition, rules governing the interchangeability, switching and substitution of a reference medicinal products by its biosimilar are provided by the national law of individual EEA countries, and many of them do not permit the automatic substitution of a reference medicinal products by its biosimilar. Therefore, even if we obtain regulatory approval for one of our product candidates in the EEA, we may not receive a positive decision from the National Competent Authorities of EEA countries in relation to the interchangeability, switching or substitution of a reference products with our approved product candidate in one or more EEA countries, thereby restricting our ability to market our products in those jurisdictions.

## Even if we obtain regulatory approval for a product candidate, our products will remain subject to continuous subsequent regulatory obligations and scrutiny.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for pharmacovigilance, manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies (if any) and submission of other post-market information, including both federal and state requirements in the United States and equivalent requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices ("cGMP"), regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing authorization application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we or our collaboration partners receive for our product candidates may be subject to limitations on the approved conditions of use for which the product may be marketed or to the conditions of approval or may contain requirements for potentially costly additional data generation, including clinical trials. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities, and to conduct surveillance to monitor the safety and efficacy of the product candidate. Any new legislation addressing drug safety or biologics or biosimilars issues could result in delays in product development, approval or commercialization or increased costs to assure compliance.

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions that vary throughout the world and must be consistent with the information in the product's approved label. As such, we may not promote our products in ways that are not consistent with FDA-approved labeling, e.g., for indications or uses for which they do not have approval. Equivalent limitations are provided both at EU level and national level in the individual EU Member States.

If our product candidates are approved, the company must submit new or supplemental applications and obtain prior approval for certain changes to the licensed approved, therapeutic indications, product labeling and manufacturing process. These changes may require submission of substantial data packages that may include clinical data.

If a regulatory authority discovers previously unknown problems with a biosimilar product (or with the reference product or related biosimilars) such as adverse events of unanticipated severity or frequency, or if there are problems with the facility where the product is manufactured or the regulatory authority disagrees with the advertising, promotion, marketing or labeling of a product, such regulatory authority may impose restrictions on that product or us. If we fail to comply with applicable regulatory requirements, a regulatory authority such as FDA may, among other things:

- issue warning or untitled letters;
- refer a case to the U.S. Department of Justice, or comparable authorities, to impose civil or criminal penalties;
- begin proceedings to suspend or withdraw regulatory approval;
- issue an import alert;
- · suspend our ongoing clinical studies or put our investigational new drug application ("IND") on clinical hold;
- refuse to approve pending applications (including supplements to approved applications) submitted by us;
- ask us to initiate a product recall; or
- refer a case to the U.S. Department of Justice, or comparable authorities, to seize and forfeit products or obtain an injunction imposing restrictions on our operations.

Failure to comply with EU and EU Member State laws that govern conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Any government investigation of alleged violations of law or regulations could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, our value and our operating results will be adversely affected.

Adverse events involving a reference product, or other biosimilars of such reference product, may result in negative publicity for our biosimilar product or ultimately result in the removal of our biosimilar product from the market.

In the event that use of a reference product, or another biosimilar for such reference product, results in unanticipated side effects or other adverse events, it is likely that our biosimilar product candidate will be viewed comparably and may become subject to the same scrutiny and regulatory actions as the reference product or other biosimilar, as applicable. Accordingly, we may become subject to, for example, safety labeling change orders, clinical holds, voluntary or mandatory product recalls or other regulatory actions for matters outside of our control that affect the reference product, or other biosimilars, as applicable, potentially until we are able to demonstrate to the satisfaction of our regulators that our biosimilar product candidate is not subject to the same issues leading to the regulatory action as the reference product or other biosimilar, as applicable. Any recall or safety alert or safety labeling change relating to our product (either voluntary or required by regulatory bodies) could ultimately result in the removal of our product from the market. Any recall could result in significant cost as well as negative publicity that could reduce overall demand for our products.

We are highly dependent on the services of our key executives and personnel, and if we are not able to retain these members of our management or recruit additional management, clinical and scientific personnel, our operations and future performance will suffer.

We are highly dependent on the principal members of our management and scientific and technical staff. The loss of service of any of our management or key scientific and technical staff could harm our business, prospects and financial condition. In addition, we will need to expand and effectively manage our managerial, scientific, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. The pharmaceutical industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to retain our management and to attract, retain and motivate on acceptable terms, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future regulatory approvals, sales of our product candidates and results of operations. Additionally, we do not currently maintain "key person" life insurance on the lives of our executives or any of our employees.

We have been and will need to continue to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2022, we had 947 employees, including 30 contractors. Additionally, we rely on a number of temporary workers from time to time, as needed. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. In addition, our success depends on our ability to attract and retain a talented workforce with a specialized set of skills. A significant part of our employees are expatriates and may need to obtain work visas in the country of operations. Changes to immigration laws or other restrictions on the movement of persons might make it more difficult for us to attract and retain talented employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the

development of our current and potential future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected and our ability to generate and/or grow revenue could be reduced and our ability to implement business strategy may suffer. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

#### **Risks Related to Our Reliance on Third Parties**

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plans to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with relevant practices that may include cGMP, current good clinical practices ("cGCP") and Good Laboratory Practices ("GLP"), which are regulations and guidelines required by the FDA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities monitor these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we, any of our CROs, service providers or investigators fail to comply with applicable regulations or cGCPs, the data generated in our nonclinical and clinical studies may be deemed unreliable and the FDA, European Commission, EMA or comparable regulatory authorities may require us to perform additional nonclinical and clinical studies before approving our marketing applications. We cannot provide assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any clinical investigator for any of our clinical studies comply with cGCP regulations. In addition, our clinical studies must be conducted with product produced in compliance with cGMP regulations. Failure to comply with these regulations by us or any of the participating parties may require us to generate new data, repeat clinical studies, and potentially undergo re-inspection, which would delay the regulatory approval process. Further, if any accidents occur or there are process mistakes at the facilities of CROs or other vendors that handle reference products, there may be product loss which could further delay our nonclinical and clinical programs. Moreover, our business may be implicated if our CRO or any other participating parties violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws whether in the United States or equivalent foreign laws and obligations.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under the agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going nonclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to protocols, regulatory requirements, delays caused by public health emergencies, such as the COVID-19 pandemic, or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, the results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional costs and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which

can materially impact our ability to meet desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We partly rely on third parties to manufacture clinical and commercial supplies of our product candidates and to store critical components of our product candidates (including procuring and providing reference product). Our business could be harmed if those third parties fail to provide us with sufficient quantities of product candidates or fail to do so at acceptable quality levels, prices and agreed upon time frame.

We partly rely on third-party manufacturers (contract manufacturing organizations, or "CMOs") to manufacture and supply our product candidates for our preclinical and clinical studies. We also rely on third parties to manufacture nonclinical and clinical supplies of our product candidates, to store critical components of our product candidates and perform various services related to the product candidates' compliance with regulatory requirements. Successfully transferring complicated manufacturing techniques to contract manufacturing organizations and scaling up these techniques for commercial quantities is time consuming, and we may not be able to achieve such transfer or do so in a timely manner. Moreover, the availability of contract manufacturing services for protein-based therapeutics is highly variable and there are periods of relatively abundant capacity alternating with periods in which there is little available capacity. If our need for contract manufacturing services increases during a period of industry-wide production capacity shortage, we may not be able to produce our product candidates on a timely basis or on commercially viable terms. Moreover, our manufacturing processes utilize single-use processing technology to manufacture drug substance and drug product. Although we will plan accordingly and generally does not begin a clinical study unless we believe we have a sufficient supply of a product candidate to complete such study, any significant delay, whether due to supply chain interruptions in connection with public health emergencies, such as the COVID-19 pandemic or otherwise, or discontinuation in the supply of a product candidate for an ongoing clinical study due to the need to replace a third-party manufacturer could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

Reliance on third-party manufacturers entails additional risks, including reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, commercial manufacturing must be produced in compliance with cGMP regulations. Failure to comply by any CMO may require us to generate new data, repeat clinical studies, and potentially undergo re-inspection, which would delay the regulatory approval process. In addition, if a CMO does not comply with cGMP, our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, license suspension or revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or any other product candidates or products that we may develop. Any failure or refusal to supply the components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or product candidates could be delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and the expenses relating to the transfer of necessary technology and processes could be significant. In addition, any changes in our manufacturers could necessitate generation of new data and pre-license facility inspections. Changes made during the pendency of a BLA before FDA, or during the marketing authorization application, could result

If any of our product candidates are approved, in order to produce the quantities necessary to meet anticipated market demand, any contract manufacturer that we engage may need to increase manufacturing

capacity. If we are unable to produce our product candidates in sufficient quantities to meet the requirements for the launch of these products or to meet future demand, our revenue and gross margins could be adversely affected. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements for our product candidates or materials used to produce them on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development or commercialization of or products.

In addition, we engage external transport companies to ship our products between the different supply points used to manufacture the finished product. Delays in shipment, damage of materials during shipment or any other events leading to late delivery or not full amount of ordered quantities could have a significant impact on project timelines, stock on markets and sales.

We have entered into collaborations with third parties in connection with the development of certain of our product candidates. Even if we believe that the development of our technology and product candidates is promising, our partners may choose not to proceed with such development if we materially deviate from the original program timelines, the contractual terms, or breach the contractual terms.

We have or may have future collaborations with various partners for the development and commercialization of some of our biosimilar candidates. Our existing and future agreements with our collaboration partners are generally subject to termination by the counterparty under certain circumstances. Accordingly, even if we believe that the development of certain product candidates is worth pursuing, our partners may choose not to continue with such development, if we materially deviate from the original program timelines, the contractual terms, or breach the contractual terms. If any of our collaborations are terminated, we may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establishes may not be favorable to us, available under commercially reasonable terms or available at all.

We are also at risk that our collaborations or other arrangements may not be successful. Factors that may affect the success of our collaborations include the following:

- our collaboration partners may incur financial, legal or other difficulties that force them to limit or reduce their participation in our joint projects;
- our collaboration partners may be pursuing alternative technologies or developing alternative products that are competitive to our technology and products, either on their own or in partnership with others;
- our collaboration partners may terminate the collaborations, which could make it difficult for us to attract new partners or adversely affect our reputation in the business and financial communities; and
- our collaboration partners may pursue higher priority programs or change the focus of their development programs, which could affect their commitment to us.

If we cannot maintain successful collaborations, our business, financial condition and operating results may be adversely affected.

We are dependent on our partners, such as Teva and STADA, for the commercialization of our biosimilar product candidates in certain major markets, and their failure to commercialize in those markets could have a material adverse effect on our revenue, business and operating results.

We do not currently have direct sales, marketing, and distribution capabilities. Instead, we have chosen to market and commercialize our products through partnerships with multiple regional partners. For example, Teva is responsible for commercialization of, among other product candidates, AVT02, AVT04 and AVT06 in the United States, and STADA is responsible for commercialization of, among other product candidates, AVT02, AVT04 and AVT06 in Europe. If our commercial partners fail to exercise commercially reasonable efforts to

market and sell our products in their respective licensed jurisdictions (timely or at all) or are otherwise ineffective in doing so, our business will be harmed and we may not be able to adequately remedy the harm through negotiation, litigation, arbitration or termination of the license agreements. Moreover, any disputes with our collaboration partners concerning the adequacy of their commercialization efforts will substantially divert the attention of our senior management from other business activities, and will require us to incur substantial legal costs to fund litigation or arbitration proceedings, and perhaps lead to delayed license-related payments to us.

We are subject to a multitude of risks related to manufacturing. Any adverse developments affecting the manufacturing operations of our biosimilar products could substantially increase costs and limit supply.

The process of manufacturing our products is complex, highly regulated and subject to several risks, including but not limited to:

- raw material and/or consumable shortages from external suppliers;
- · product loss due to contamination, equipment failure, or operator error; and
- equipment installation and qualification failures, equipment breakdowns, labor shortages, natural disasters, power failures and numerous other factors associated with the manufacturing facilities in which our products are produced.

Even minor deviations from normal manufacturing processes for any of our products could result in reduced production yields, product defects and other supply disruptions; additionally, FDA will inspect our manufacturing facilities for these issues, and ensure that the processes are satisfactory, before it licenses a BLA made at these facilities. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, manufacturing facilities for an extended period of time to investigate and remedy the contamination, and any such findings pre-licensure could impact FDA's ability to license a BLA. Further, any defects or contaminations, or inadequate disclosure relating to the risk of using our products post-approval could lead to recalls or safety alerts, or other enforcement action by regulatory authorities.

Any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We currently engage single suppliers for some manufacture, clinical trial services, formulation development and product testing of our product candidates. The loss of any of these suppliers or vendors could materially and adversely affect our business.

The biologic drug substance used in all of our programs is currently manufactured at the facility of Alvotech hf. in Reykjavik, as is the pre-filled syringe (bulk drug product) for AVT02. In addition, we rely on certain single third-party suppliers for the safety device assembly and associated finished packaging of the AVT02 pre-filled syringe for all clinical supplies and future commercial supplies and for the combination product assembly and finished packaging of the AVT02 pre-filled syringe for all clinical supplies and future commercial supplies. In addition, we have engaged a future second contract manufacturer of the combination product and packaging for AVT02. We have engaged a single contract manufacturer for clinical supplies of AVT06, to conduct the fill and finish manufacturing step for vial presentations. Prior to engaging any contract manufacturer for services, we perform a qualification of the site, including a verification of our status with regard to the relevant regulations. In addition, we perform regular audits as per our contractor management procedures once the contractor is qualified. Prior to any approval inspection, we engage external partners to help prepare for a successful inspection. We do not currently have any other suppliers or vendors for the above-mentioned requirements for our product candidates and, although we believe that there are alternate sources that could satisfy these

requirements, we cannot assure you that identifying and establishing relationships with such would not result in significant delay in the development of our product candidates. Additionally, we may not be able to enter into arrangements with alternative vendors on commercially reasonable terms or at all. A delay in the development of our product candidates or having to enter into a new agreement with a different third-party on less favorable terms than what we have with our current suppliers could have a material adverse impact upon on our business.

Our failure to obtain or renew certain approvals, licenses, permits and certificates required may result in our inability to continue our operations or may result in enforcement actions with the respective regulatory authorities which would materially and adversely affect our business.

We are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including the relevant regulatory authorities ordering us to cease operations, implement potentially costly corrective measures or any other action which could materially disrupt our business operations.

In addition, some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. We cannot give reassurance that we will be able to successfully procure such renewals and/or reassessment when due, and any failure to do so could severely disrupt our business.

Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect requiring us to obtain any additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, we cannot provide assurance that we will successfully obtain them, which in turn could restrict the scope of permitted business activities and constrain our drug development and revenue generation capability.

Any of the above developments could have a material adverse effect on our business, financial condition and results of operations.

We and our collaboration partners and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not meet or continue to meet regulatory requirements or may not be able to meet supply demands.

All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaboration partners or our contract manufacturers must supply all necessary documentation in support of a market application on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA and other comparable foreign regulatory authorities through their facilities inspection program. Not all contractors supporting our product candidates may be registered or approved for commercial pharmaceutical production. The facilities and quality systems of some or all of our collaboration partners and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. For example, in September 2022, we announced that we had

received the August 2022 CRL from the FDA detailing its assessment of the March 2022 inspection of our manufacturing facility in Reykjavik, Iceland and our subsequent written responses to the FDA. The August 2022 CRL noted certain deficiencies related to the Reykjavik facility and stated that satisfactory resolution of the deficiencies is required before FDA may approve the biosimilar BLA for AVT02. In December 2022, we received the December 2022 CRL regarding the interchangeability BLA for AVT02, in which the FDA noted that correction of the same deficiencies identified in the August 2022 CRL with respect to the biosimilarity BLA is required for approval of the interchangeability BLA. In January 2023, we received confirmation from the FDA that the reinspection of our facility in Reykjavik, Iceland is scheduled for March 6-17, 2023.

Although we oversee our contract manufacturers, we cannot control the implementation of the manufacturing process by the contract manufacturing partners. If these facilities do not pass a pre-approval plant inspection, regulatory approval of our products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaboration partners and third-party contractors to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the invalidation of drug product lots or processes, the temporary or permanent suspension of a clinical study or commercial sales or import or the temporary or permanent closure of a facility and that may require re-inspection thereby causing delays. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market products. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, prospects and financial condition.

If we, our collaboration partners or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable foreign regulatory authority can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new biologic product, or suspension, variation or revocation of an approval. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, registration of an alternative manufacturer would require submissions of variations to the marking authorization which could result in further delay. The regulatory authorities may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and prior regulatory approval and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could incur higher costs and cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we is unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue from sales of an approved product.

Our expected benefits from the Joint Venture may not materialize as expected or at all, either of which could have adverse effects on our business.

In September 2018, we entered into a joint venture agreement with Changchun High & New Technology Industries (Group) Inc., a Chinese corporation (the "Joint Venture Partner"). Under the joint venture agreement, we created Alvotech & CCHN Biopharmaceutical Limited Liability Company in 2019 (the "Joint Venture"), of

which we own a 50% ownership interest. The purpose of the Joint Venture is to research, develop, manufacture and sell high quality biosimilar products, to become a Chinese market leader in the biosimilar space and to deliver high quality competitive cost products to patients in China through the introduction of appropriate technology and adoption of scientific management systems and marketing methods, as well as to realize biopharmaceutical internationalization through providing international OEM (Original Equipment Manufacturer) service and innovate biosimilar development. For that purpose, the Joint Venture Partner is assisting the Joint Venture to build manufacturing facilities in the City of Changchun, Jilin Province, completing registration and filing procedures, obtaining and maintaining necessary permits and certifications, and assisting in hiring personnel with appropriate expertise and experience. In 2019, the Joint Venture broke ground on its manufacturing facility, which became operational in 2022. The Joint Venture began completion of system certifications and quality controls in the second quarter of 2022 and is expected to be ready to start producing commercial batches before the end of 2023.

The Joint Venture may not provide us the benefits and results it expects, or at all. Adverse changes in U.S. or European economic and political policies relating to China, or the surge in COVID-19 cases in China at the end of 2022 and the beginning of 2023, could have a material adverse effect on the Joint Venture or our expectations with respect to, or relationship with, the Joint Venture. Further, any decision to modify the business or growth strategy with respect to the Joint Venture or China by us or the Joint Venture Partner, or dispute with the Joint Venture Partner, could have a material adverse effect on our business, the Joint Venture, or our expectations with respect to, or relationship with, the Joint Venture or its broader approach to the Chinese market.

These uncertainties are further exacerbated by larger geopolitical, economic and health related trends. For example, an escalation of recent trade tensions between the United States and China has resulted in trade restrictions that could harm our ability to participate in Chinese markets and numerous additional such restrictions have been threatened by both countries. We may find it impossible to comply with these or other conflicting regulations in the United States and China, which could make it difficult or impossible to achieve our business objectives in China or realize a return on our investment in this market. Sustained uncertainty about, or worsening of, current global economic conditions and further escalation of trade tensions between the United States and its trading partners, especially China, could result in a global economic slowdown and long-term changes to global trade, including retaliatory trade restrictions that could further restrict our ability to operate in China.

The Chinese economic, legal, and political landscape differs from other countries in many respects, including the level of government involvement and regulation, control of foreign exchange and allocation of resources, and uncertainty regarding the enforceability and scope of protection for intellectual property rights among others. The Chinese government has exercised and continues to exercise substantial control over virtually every sector of the Chinese economy through regulation and state ownership. The laws, regulations and legal requirements in China are also subject to frequent changes and the exact obligations under and enforcement of laws and regulations are often subject to unpublished internal government interpretations and policies which makes it challenging to ascertain compliance with such laws. This uncertainty includes investigations and inquiries into graft, corruption and other crimes, the nature of which are difficult to predict. If one or more of the senior executives of the Joint Venture Partner or the Joint Venture or related entities are questioned or come under investigation under such an inquiry, for example, the Joint Venture's performance could be materially adversely impacted and in turn the realization of our investment in such joint ventures and facilities, even if the claims underlying such questions or inquiry are proven false or challenging to verify.

Furthermore, our ability to operate in China may be harmed by changes in its laws and regulations, including those relating to taxation, import and export tariffs, environmental regulations, land use rights, property and other matters. We believe that our operations in China are in material compliance with all applicable legal and regulatory requirements. However, the central Chinese government or the local government of the jurisdiction in which we operate may impose new, stricter regulations or interpretations of existing regulations

that would require additional expenditures and efforts on our part to ensure compliance with such regulations or interpretations. For example, certain Joint Venture permits and certifications could be withdrawn, which could significantly impair or eliminate the Joint Venture's ability to operate in China. Any actions and policies adopted by the Chinese government, or any prolonged slowdown in China's economy, could have an adverse effect on our business, results of operations and financial condition.

The relationship between China and the United States is subject to periodic tension. Relations may also be compromised if the United States pressures the Chinese government regarding its monetary, economic, or social policies. Changes in political conditions in China and changes in the state of China-U.S. relations are difficult to predict and could adversely affect the operations or financial condition of the Joint Venture.

# We rely on third parties to construct the Joint Venture's manufacturing facility in China and, to the extent such third parties do not perform as expected, we may be unable to complete the Joint Venture's facility on time or at all.

We have no construction capabilities and has partnered with the Joint Venture Partner to develop the Joint Venture's manufacturing facilities. We expect substantially all of the Joint Venture's construction work to be outsourced to the Joint Venture Partner. We are exposed to risks that the performance of the Joint Venture Partner and third parties supporting the facility construction may not meet our standards or specifications or on our timeline. Negligence or poor work quality by any contractors may result in defects in the Joint Venture's building, which could in turn cause us to suffer financial losses, harm our reputation or expose us to third-party claims. Although contracts executed in connection with the construction contain provisions designed to protect us, we may be unable to successfully enforce these rights and, even if we are able to successfully enforce these rights, the Joint Venture Partner may not have sufficient financial resources to compensate us. Moreover, the Joint Venture Partner may undertake projects from other property developers, engage in risky undertakings or encounter financial or other difficulties, such as supply shortages, labor disputes or work accidents, which may cause delays in the completion of the Joint Venture's property projects or increases in our costs. We may be unable to complete the Joint Ventures manufacturing facilities development, complete system certifications and quality controls, or obtain a manufacturing license on time, with sufficient workmanship or at all, which may prevent us from scaling our manufacturing capabilities sufficiently or at all, and meeting demand for, and successfully commercializing, any products, which may materially adversely affect our business, financial condition, reputation and results of operations.

## Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaboration partners, advisors, employees and consultants prior to beginning research or disclosing proprietary information, such as trade secrets. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

### We may not be successful in our efforts to identify, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued testing, potential approval and commercialization of our existing product candidates, the success of our business also depends upon our ability

to identify, develop and commercialize additional product candidates (in addition to the lead candidates). Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our development efforts may fail to yield additional product candidates suitable for development and/or commercialization for a number of reasons, including but not limited to the following:

- we may not be successful in identifying potential product candidates that pass our strict screening criteria;
- we may not be able to overcome technological hurdles to development or a product candidate may not be capable of producing commercial quantities at an acceptable cost or at all;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- · our product candidates may not succeed in analytical, nonclinical, or clinical testing;
- our potential product candidates may fail to show biosimilarity to reference products;
- · we may not be successful in overcoming intellectual property obstacles in a timely manner or at all; and
- competitors may develop alternatives that render our product candidates obsolete or less attractive or the market for a product candidate may change such that a product candidate may not justify further development.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs or we may not be able to identify, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

## We rely on certain significant shareholders and affiliated entities for certain key services in the execution of our strategy and business operations.

We have entered into various service agreements with our direct and indirect significant shareholders and related entities, such as Alvogen, Aztiq, Alvogen Malta (Out-Licensing) Ltd. ("Adalvo") and Floki Invest ehf. ("Floki"). These services include, among others, marketing and IT services, corporate administrative, legal, financial, facility management, salary processing, supply chain management, portfolio and market intelligence research, regulatory compliance, quality audit, and publishing services, and certain administrative and financial services related to our Reykjavik facility. These services are key to our ability to continue to execute on our business strategy and to keep our business operations uninterrupted. Any interruption in the provision of these services may materially harm our business. In addition, because the providers of the services are direct or indirect significant shareholders and related entities, we may not be able or willing to enforce our contractual rights under the service agreements the same way we would if the service providers were unrelated third-party providers. See also "—We currently rely on Alvogen's ERP solution and other components of Alvogen's IT infrastructure and will continue to do so for the foreseeable future".

## **Risks Related to Our Competition and Industry**

Our biosimilar product candidates, if approved, will face significant competition from the reference products, other biosimilars, and from other medicinal products approved for the same indication(s) as the reference products. Our failure to effectively compete may prevent us from achieving significant market penetration and expansion.

We expect to enter highly competitive markets. We expect other companies to seek approval to manufacture and market biosimilars to Humira, Prolia/Xgeva, Stelara, Simponi/Simponi Aria, Eylea or Xolair. If other

biosimilars to Humira, Prolia/Xgeva, Stelara, Simponi/Simponi Aria, Eylea or Xolair, or other non-reference products in the same therapeutic spaces are approved and successfully commercialized before AVT02, AVT03, AVT04, AVT05, AVT06 or AVT23, respectively, we may never achieve significant market share for these products, our revenue would be reduced and, as a result, our business, prospects and financial condition could suffer.

Successful competitors in the market have demonstrated the ability to effectively discover, obtain patents, develop, test and obtain regulatory approvals for products, as well as an ability to effectively commercialize, market and promote approved products. Numerous companies, universities and other research institutions are engaged in developing, patenting, manufacturing and marketing of products competitive with those that we are developing. Many of these potential competitors are large, experienced pharmaceutical companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources. These companies also have greater brand recognition and more experience in conducting preclinical testing and clinical trials of product candidates and obtaining FDA and other regulatory approvals of products.

If an improved version of a reference product, such as Humira, Prolia or Xgeva, Stelara, Simponi/Simponi Aria, Eylea or Xolair is developed or if the market for the reference product significantly declines, sales or potential sales of our biosimilar product candidates may suffer.

Companies may develop improved versions, treatment regimens, combinations and/or doses of a reference product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental BLA, or equivalent foreign procedure, filed with the applicable regulatory authority. Should the company manufacturing the reference product for any of our candidate products succeed in obtaining an approval of an improved biologic product, it may capture a significant share of the market for the reference product in the applicable jurisdiction and significantly reduce the market for the reference product and thereby the potential size of the market for our biosimilar product candidates. In addition, the improved product may be protected by additional regulatory exclusivity or patent rights that may subject our follow-on biosimilar to claims of infringement.

Biologic reference products may also face competition as technological advances are made that may offer patients a more convenient form of administration or increased efficacy or as new products are introduced. As new products are approved that compete with the reference product for our biosimilar product candidates, sales of the reference products may be adversely impacted or rendered obsolete. If the market for the reference product is impacted, we may lose significant market share or experience limited market potential for our approved biosimilar products or product candidates, and the value of our product pipeline could be negatively impacted. As a result of the above factors, our business, prospects and financial condition could suffer.

If efforts by manufacturers of reference products to prevent, delay or limit the use of biosimilars are successful, our business may be negatively affected, including but not limited to the sales of our biosimilar products.

Many manufacturers of reference products have increasingly used legislative, regulatory and other means to prevent or delay regulatory approval and to seek to restrict competition from manufacturers of biosimilars. These efforts may include or have included:

- · settling patent lawsuits with biosimilar companies, resulting in such patents remaining an obstacle for biosimilar approval by others;
- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted biosimilar applications or to elaborate or amend the standard of review for such biosimilar applications;

- appealing denials of Citizen Petitions in U.S. federal district courts and seeking injunctive relief to reverse approval of biosimilar applications;
- restricting access to reference brand products for equivalence and biosimilarity testing that interferes with timely biosimilar development plans;
- attempting to influence potential market share by conducting medical education with physicians, payors, regulators and patients claiming that biosimilar products are too complex for biosimilar approval or are too dissimilar from reference products to be trusted as safe and effective alternatives;
- implementing payor market access tactics that benefit their brands at the expense of biosimilars;
- seeking state law restrictions on the substitution of biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;
- seeking federal or state regulatory restrictions, or equivalent foreign restrictions, on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;
- seeking changes to the U.S. Pharmacopeia, an industry recognized compilation of drug and biologic standards, or equivalent international or foreign standards;
- obtaining new patents covering existing products or processes which could extend patent exclusivity for a number of years or otherwise delay the launch of biosimilars;
- originator could compete with us by manufacturing or commercializing their own proprietary biosimilar product to the reference product they sponsor; and
- influencing legislatures so that they attach special patent extension amendments to unrelated federal legislation.

In 2012, Abbott Laboratories filed a Citizen Petition with the FDA asking the agency to refrain from accepting biosimilar applications under the BPCIA arguing that to approve such applications, without compensation to the reference product sponsor, would constitute an unconstitutional taking of a reference company's valuable trade secrets under the fifth amendment of the U.S. constitution. The FDA denied this citizen petition in 2016. Other reference companies may file Citizen Petitions in an effort to restrict or prevent the introduction of biosimilars. If the FDA or a federal court determines that biosimilar applications under the BPCIA should be limited, our business may be negatively impacted.

We face intense competition and rapid technological changes and the possibility that our competitors and originators such as AbbVie and Janssen may develop therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and the ability to successfully commercialize our product candidates.

We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Some of the pharmaceutical and biotechnology companies developing biosimilars We expect to compete with include, for example, Celltrion Healthcare Co., Ltd. ("Celltrion"), Coherus, Amgen, Pfizer Inc. ("Pfizer"), Samsung Bioepis, Ltd. ("Samsung Bioepis"), and Sandoz International GmbH ("Sandoz"), as well as other companies. These companies may develop biosimilars or other products in the same therapeutic space as our products. For example, based on publicly available information, we expect AbbVie (the originator), Amgen, Boehringer Ingelheim GmbH, Biocon/Fujifilm, Celltrion, Fresenius Kabi, Pfizer, Samsung Bioepis, Coherus, and Sandoz to be our main competitors for AVT02, a biosimilar product candidate to Humira (adalimumab); Janssen (the originator), Amgen, Celltrion, Bio-Thera, Formycon, Dong-A/Meiji Seika, Samsung Bioepis, and Biocon to be our main competitors for AVT04, a biosimilar candidate to Stelara (ustekinumab); Amgen (the originator), Sandoz, Celltrion, Fresenius Kabi, Samsung Bioepis, Gedeon Richter, mAbxience, Biocon, Henlius and Teva to

be our main competitors for AVT03, a biosimilar candidate to Prolia / Xgeva (denosumab); Janssen (the originator), and Bio-thera to be our main competitors for AVT05, a biosimilar candidate of Simponi and Simponi Aria (golimumab); and Regeneron/Bayer Health Care (the originator), Amgen, Celltrion, Formycon, Altos, Sam Chun Dang, Samsung Bioepis, Sandoz, and Viatris/Biocon, to be our main competitors for AVT06, a biosimilar candidate to Eylea (aflibercept); and Genentech (the originator), Celltrion and Teva, to be our main competitors for AVT23, a biosimilar candidate to Xolair (omalizumab).

Some of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop; they may also obtain patent protection that could block our products; and they may obtain regulatory approval, product commercialization and market penetration earlier than we do. Additionally, our competitors may have more resources in order to effectively pursue, defend against or settle with regard to potential or ongoing litigation. Biosimilar product candidates developed by our competitors may render our potential product candidates uneconomical, less desirable or obsolete, and we may not be successful in marketing our product candidates against competitors. Competitors may also assert in their marketing or medical education programs that their biosimilar products demonstrate a higher degree of biosimilarity to the reference products than do our or other competitors's biosimilar products, thereby seeking to influence health care practitioners to select their biosimilar products, versus those of us or other competitors.

If we are unable to establish effective sales and marketing capabilities in jurisdictions for which we choose to retain commercialization rights or if we are unable to enter into agreements with third parties to market and sell our product candidates, and we are unable to establish and maintain a marketing and sales organization, we may be unable to generate substantial or any revenue.

We currently have no marketing or sales organization. We as a company have no experience selling and marketing our product candidates. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we might establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets where we may choose to retain commercialization rights. Doing so will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

Further, given our lack of prior experience in marketing and selling biopharmaceutical products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of our product candidates or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaboration partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We expect competition from companies such as Celltrion, Sandoz, Amgen, Pfizer, Fresenius Kabi, Boehringer Ingelheim, Samsung Bioepis, Coherus and Viatris that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our product candidates. If we are unsuccessful in forming or maintaining these alliances on sufficiently favorable terms, our business could be adversely affected.

We expect our manufacturing facility in Reykjavik to be able to scale up its capabilities for commercial production. Nevertheless, We are expected to retain contract manufacturing organization services as a second source of supply, including for business continuity risk mitigation. In addition, because we have limited capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we have found it necessary to enter into alliances with other companies. We entered into a collaboration agreement with Teva for the development and commercialization of AVT02 in the United States. Similarly, we entered into a collaboration agreement with STADA for the development and commercialization of AVT02 in Europe. In the future, we may also find it necessary to form alliances or joint ventures with major pharmaceutical companies to jointly develop and/or commercialize specific biosimilar product candidates. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we are unable to secure or maintain such alliances we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to product development and commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this may substantially harm our business, prospects and financial condition. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be adversely affected.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical studies and through the demonstration of biosimilarity;
- any potential advantages over competing biosimilars and/or other treatments in the same therapeutic space(s);
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- the possibility that a competitor may achieve interchangeability in the United States, and we may not;
- relative convenience and ease of administration;
- the extent to which our product may be more or less similar to the reference product than competing biosimilar product candidates;

- policies and practices governing the naming of biological product candidates;
- prevalence of the disease or condition for which the product is approved;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the extent to which third-party payors provide adequate third-party coverage and reimbursement for our product candidates, if approved;
- · patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and
- our ability to maintain compliance with regulatory requirements.

Even if a potential biosimilar product is expected to have a highly similar efficacy and safety profile to the reference product, as demonstrated through analytical, nonclinical, and clinical studies, market acceptance of the product will not be fully known until after it is launched and may be negatively affected by a potential poor safety experience and the track record of other biosimilar product candidates. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources, may be under-resourced compared to large well-funded pharmaceutical entities and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

The third-party coverage and reimbursement status of newly-approved products is uncertain. Failure of our third-party commercial partners to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and generate revenue.

Pricing, coverage and reimbursement of our biosimilar product candidates, if approved, may not be adequate to support our commercial infrastructure. Our per-patient prices may not be sufficient to recover our development and manufacturing costs and potentially achieve profitability. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as our products, if approved. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government authorities, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to allow us to establish or maintain pricing sufficient to realize a return on investment.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our biosimilar product candidates, if approved. In addition, in the United States,

no uniform policy of coverage and reimbursement for biologics exists among third-party payors. Therefore, coverage and reimbursement for biologics can differ significantly from payor to payor. As a result, the process for obtaining favorable coverage determinations often is time-consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, pharmaceutical companies, products and distributors are generally subject to extensive governmental price controls and other market regulations. We believe the increasing emphasis on cost-containment initiatives in EEA, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to control healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Certain cost containment practices may adversely affect our product sales. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

If our third-party commercial partners are unable to establish or sustain coverage and adequate reimbursement for any of our product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect our ability to market or sell those product candidates, if approved.

Our biosimilar product candidates, if approved, could face price competition from other biosimilars of the same reference products for the same indication. This price competition could exceed our capacity to respond, detrimentally affecting its market share and revenue as well as adversely affecting the overall financial health and attractiveness of the market for the biosimilar.

We expect to enter highly competitive biosimilar markets. Successful competitors in the biosimilar market have the ability to effectively compete on price through payors and their third-party administrators who exert downward pricing pressure. It is possible our biosimilar competitors' compliance with price discounting demands in exchange for market share could exceed our capacity to respond in kind and reduce market prices beyond our expectations. Such practices may limit our and our collaboration partners' ability to increase market share and will also impact profitability.

## **Risks Related to Our Intellectual Property**

If we or one of our partners infringes or is alleged to infringe the intellectual property rights of third parties, our business could be harmed. Avoiding and defending against infringement claims could be expensive and time consuming, which may in turn prevent or delay our development and commercialization efforts.

Our commercial success depends in large part on avoiding infringement of the valid and enforceable patents and proprietary rights of third parties and invalidating or rendering unenforceable other patent and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other

intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the U.S. Patent and Trademark Office ("USPTO"), and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights, or other intellectual property rights, of third parties.

Our research, development and commercialization activities may be claimed or held to infringe or otherwise violate patents owned or controlled by other parties. The companies that originated the products for which we intend to introduce biosimilar versions, such as AbbVie, Amgen, Janssen, Genentech and Regeneron as well as other competitors (including other companies developing biosimilars) often have developed worldwide patent portfolios of varying sizes and breadth, many of which are in fields relating to our business, and it may not always be clear to industry participants, including us, which patents cover various types of products, methods of use, methods of manufacturing, etc.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. While we have conducted freedom to operate analyses with respect to our lead product candidates, we cannot guarantee that any of our analyses will ensure that claims will not be brought or won against us, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Moreover, because patent applications can take up to 18 months after initial priority filing date to publish and issue, there may be currently pending patent applications with claims not yet filed that may later result in issued patents covering our product candidates. We have not yet completed a freedom-to-operate analysis on products we are evaluating for inclusion in our future biosimilar product pipeline, and therefore we do not know whether or to what extent that development of these products may be influenced by unexpired patents and pending applications.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions which typically do not publish patent applications until 18 months from the application's prior date. Moreover, we may face claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. In addition, coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to convince a judicial authority that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid and/or unenforceable, and we may not be able to do this. Proving to a judicial authority that a patent claim is invalid or unenforceable can be difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Also in proceedings before courts in Europe, the burden of proving invalidity of the patent usually rests on the party alleging invalidity. Further, proving the invalidity or unenforceability of a patent claim in the jurisdictions in which we operate may also depend on changes in the relevant law. Attempts to resolve intellectual property disputes may require substantial efforts including, but not limited to, validity challenges in patent offices, court litigation and arbitration. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on us. In addition, we may not ha

Third parties could bring claims against us that would cause us to incur substantial expenses to defend against and, if successful against us, could cause us to pay substantial monetary damages if our product candidate is on the market. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the

suit. Ultimately, we could be prevented from commercializing a product or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, We are unable to enter into licenses on commercially acceptable terms or at all. If, as a result of patent infringement claims or to avoid potential claims, we choose or is required to seek licenses from third parties, these licenses may not be available on acceptable terms or at all. Even if we are able to obtain a license, the license may obligate us to pay substantial license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively delay or block our ability to further develop and commercialize one or more of our product candidates. For example, companies that originated the products for which we intend to introduce biosimilar versions may seek damages for their loss of profits and/or market share. Defense of these claims, regardless of their merit, would likely involve substantial litigation expense and would likely be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may, in addition to being blocked from the market, have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. An unfavorable outcome in any such proceedings could require us to delay or cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. For example, we may jointly develop intellectual property with certain parties, and disagreements may therefore arise as to the ownership of the intellectual property developed pursuant to these relationships. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

BLA holders may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EEA countries, and an equivalent process in Switzerland, seeking to extend certain patent protection which, if approved, may interfere with or delay the launch of one or more of our biosimilar products. Further, patent laws in the various jurisdictions in which we do business are subject to change and any future changes in patent laws may be less favorable for us.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. The companies that originated the products for which we intend to introduce biosimilar versions, as well as other competitors (including other biosimilar companies) may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings (either filed against Alvotech or one of its partners) could impair our ability to compete in the applicable marketplace. For example, we were in legal proceedings adverse to AbbVie, and our Canadian partner JAMP continues to be, relating to AVT02.

So called "submarine" patents may be granted to our competitors that may significantly alter our launch timing expectations, reduce our projected market size, cause us to modify our product or process or block us from the market altogether.

The term "submarine" patent has been used in the pharmaceutical industry and in other industries to denote a patent issuing from an application that was not published, publicly known or available (including unfiled

continuation, continuation-in-part, and divisional applications, and the like) at a critical time during which development and/or commercial decisions are made. Submarine patents add uncertainty to our business, e.g., because key decisions may be made during a period of time during which a pending applications has not yet published and such applications may only become known after those key decisions have already been made and perhaps even acted on. Submarine patents may issue to our competitors covering key aspects of our biosimilar product candidates or our pipeline candidates and thereby cause significant market entry delay, lead to unexpected licensing fees, defeat our ability to market our products or cause us to abandon development and/or commercialization of a molecule.

The issuance of one or more submarine patents may harm our business by causing substantial delays in our ability to introduce a biosimilar candidate into the U.S. market.

We may not timely identify, or identify at all, relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are 100% accurate and/or exhaustive, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction (timely or at all). The scope of a patent claim is determined by a judicial authority's interpretation under controlling law. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect and/or different from that of a judicial authority, which may negatively impact our ability to market our products or pipeline molecules. We may determine that our products are not covered by a third-party patent, but a judicial authority may hold otherwise.

Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction and interactive monitoring and analyzing of the patent landscape. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or abroad that we consider (timely or at all) relevant may be incorrect which may negatively impact our ability to develop and market our products. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

### Legal proceedings that carry risk may occur from time to time, and their outcome may be uncertain.

We may be involved in various legal proceedings, including patent litigation and challenges, other intellectual property disputes, product liability and other product-related litigation, including personal injury, consumer, off-label promotion, securities, antitrust and breach of contract claims, commercial, environmental, government investigations, employment, tax litigation and other legal proceedings that arise from time to time in the ordinary course of our business. See, for example, "—We may be involved in lawsuits to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Litigation is inherently unpredictable, and excessive verdicts do occur. We could incur judgments and/or enter into settlements, which could require us to make payments to the proceedings' counterparties or limit or discontinue certain of our activities, or could otherwise have a material adverse effect on our business operations. In addition, even if such legal proceedings are ultimately resolved in our favor, they may be costly and time-consuming to conduct, which may materially adversely affect our business, financial condition and results of operations. The cost and resource requirements, including management attention, associated with conducting such legal proceedings may lead us to settle certain actions on terms that are materially adverse to us, even if we believe that the ultimate resolution of the proceedings is likely to be favorable.

An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if we cannot obtain a license from the prevailing party on commercially reasonable terms. Our defense of litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

# We may be involved in lawsuits to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful.

We may discover that competitors are infringing one or more of our patents after they issue. Expensive and time-consuming litigation may be required to abate such infringement. Although we are not currently involved in any litigation to enforce patents, if we or one of our collaboration partners, such as Teva or STADA, were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone involved in the prosecution of the patent withheld relevant or material information related to the patentability of the invention from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, and although there are protections in place, there is a risk that some of our confidential information could be compromised by disclosure during any litigation we initiate to enforce our patents. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, they could have a material adverse effect on the price of Ordinary Shares.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers or third parties.

We employ individuals, retains independent contractors and consultants and members on our board of directors or scientific advisory board who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. For example, Joe McClellan, our Chief Scientific Officer, is a former employee of Pfizer where he held the position of Global Head of Biosimilars Development and Medicine/Asset Team Leader of IXIFI (biosimilar infliximab). Our Chief Technical Officer, Sean Gaskell, is a former employee of Novartis where he held a leading role in the development of a number of commercial medicines and drug products, including innovators and biosimilars. Although we have several mechanisms in place to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. For example, in March 2021, AbbVie brought a suit, which is now dismissed, against Alvotech hf. alleging that Alvotech hf. misappropriated trade secrets through the hiring of a former AbbVie employee. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs or delay and be a distraction to management and other employees.

If we are unable to obtain and maintain effective intellectual property rights, including patent rights, for our product candidates or any future product candidates, we may not be able to prevent competitors from using technologies we consider important to successful development and commercialization of our product candidates, resulting in loss of any potential competitive advantage our intellectual property rights may have otherwise afforded us.

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also rely upon a combination of intellectual property protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. Our ability to enjoy any competitive advantages afforded by our own intellectual property depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar, or any, patent protection covering our products in all jurisdictions where we file patent applications.

The patent positions of biopharmaceutical companies generally are highly uncertain and involve complex legal and factual questions for which legal principles remain unresolved. As a result, the patent applications that we own or licenses may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications have been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patent claims being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. From time to time, we may be involved in these anonymous or "straw man" oppositions. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates. In addition, changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to prevent competitive products using our proprietary technology. Further, because patent applications in the United States and most

other countries are confidential for a period of time, typically for 18 months after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013 or patents issuing from such applications, an interference proceeding can be provoked by a third-party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications claiming the same invention are filed by different parties. A third-party that files a patent application in the USPTO before us could therefore be awarded a patent covering our invention.

The change to "first-inventor-to-file" from "first-to-invent" is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011. Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the USPTO. We have filed patent applications, which are in various stages of prosecution/issuance, and plan to pursue additional applications, covering various aspects of our product candidates (e.g., formulations and bioprocesses). We cannot offer any assurances about which or where, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened or infringed by third parties. Any successful actions by third parties to challenge the validity or enforceability of any patents which may issue to us could deprive us the ability to prevent others from using the technologies claimed in such issued patents. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

Our business is based primarily on the timing of our biosimilar product launches to occur after the expiration of relevant patents and/or regulatory exclusivity. We file patent applications directed to our proprietary formulations for our product candidates when we believe securing such patents may afford a competitive advantage. For example, the company that originated Humira (AbbVie) owns patents directed to formulations for these products. We have developed our own proprietary formulations for this product and have filed patent applications covering our formulations. We cannot guarantee that our proprietary formulations will avoid infringement of third-party patents, or that the patent applications filed on our proprietary formulations will be found patentable and/or upheld as valid. Moreover, because competitors may be able to develop their own proprietary product formulations, it is uncertain whether issuance of any of our pending patent applications directed to formulations of ATV02, a biosimilar candidate to Humira (adalimumab), would cover the formulations of any competitors.

We do not consider it necessary for us or our competitors to obtain or maintain a proprietary patent position in order to engage in the business of biosimilar development and commercialization. Hence, while our ability to secure patent coverage on our own proprietary developments may improve our competitive position with respect to the product candidates we intend to commercialize, we do not view our own patent filings as a necessary or essential requirement for conducting our business nor do we rely on patent filings or the potential for any commercial advantage they may provide us as a basis for our success.

Obtaining and maintaining our patent protection depends on compliance with various procedural requirements, document submissions, actions within prescribed deadlines, overcoming substantial and procedural examination requirements, fee payments and other requirements imposed by governmental patent agencies. Our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

#### We may not be able to adequately protect our intellectual property rights throughout the world.

Filing, prosecuting, defending and enforcing patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent applications in certain jurisdictions in which we may obtain commercial rights (to the extent those partners have a contractual right to do so), thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in obtaining, protecting and defending intellectual property rights in certain non-U.S. jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us (not timely or not at all). Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license in certain jurisdictions.

Changes in the patent laws of the United States and other jurisdictions in which we do business could diminish the value of patents obtainable in such jurisdictions, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success for any given product could be heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain.

Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we are unable to maintain effective (non-patent) proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or

trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, for example, our employees, consultants, scientific advisors, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties, or that any such agreements would not be violated. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Further, from time-to-time we may be subject to anonymous Freedom of Information Act ("FOIA"), requests. To the extent the company needs to respond to such requests, our management's attention and the company's resources may be diverted from normal business operations. As a result of either security breaches or FOIA requests, our confidential information and trade secrets thus may become known by our competitors in ways we cannot prevent or remedy.

Although we require all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States (and in other jurisdictions), such unauthorized patent application filings may defeat our attempts to obtain patents on our inventions.

## We may be subject to claims challenging the inventorship or ownership of our patent filings and other intellectual property.

Although we are not currently aware of any claims challenging the inventorship of our patent applications or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates, or which result from an improper assignment of ownership. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

# We may not be successful in obtaining or maintaining necessary intellectual property rights to our product candidates through acquisitions and in-licenses.

We currently have or are pursuing rights to certain intellectual property, through licenses from third parties for various technologies relevant to the manufacture and commercialization of biologics. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or

in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on investment.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, our business and financial condition could suffer.

# Our ability to market our products in the United States may be significantly delayed or prevented by the BPCIA patent information exchange mechanism.

The Biologics Price Competition and Innovation Act of 2009, Title VII, Subtitle A of the PPACA, Pub.L.No.111-148, 124 Stat.119, Sections 7001-02 signed into law March 23, 2010 (the "BPCIA"), created an elaborate and complex, private, pre-litigation patent information exchange mechanism for biosimilars to focus issues for patent litigation and/or facilitate dispute resolution with the reference product sponsor before litigation commences/ends.

The BPCIA provides for a detailed and complex mechanism for exchange of confidential and business-sensitive information between a reference product sponsor and a biosimilar candidate (pre-approval) that is demanding, time-sensitive and, to date, not fully tested and therefore unpredictable. This pre-litigation private information exchange is colloquially known as the "patent dance."

The patent dance requires the biosimilar applicant to disclose not only the regulatory application but also the applicant's manufacturing process before litigation (and therefore significantly earlier than would normally be required in patent litigation), has the potential to afford the reference product sponsor an easier path than traditional infringement litigation for developing any factual grounds they may require to support allegations of infringement. The rules established in the BPCIA's patent dance procedures could place biosimilar firms at a significant disadvantage by affording the reference product sponsor a much easier mechanism for factual discovery, thereby increasing the risk that a biosimilar product could be blocked from the market more quickly than under traditional patent infringement litigation processes and in certain cases could outweigh advantages provided to biosimilar firms by the patent dance.

Preparing for and conducting the patent information exchange, briefing and negotiation process under the BPCIA will require sophisticated legal counseling and extensive planning, all under extremely tight deadlines. We cannot guarantee the outcome of the patent dance will be a successful path to commercialization of our biosimilar products.

It is possible for a biosimilar firm to skip the patent dance before any corresponding patent litigation. But this too could place a biosimilar firm at a significant disadvantage by ceding all control of the number of patents and the timing for the start of litigation to the reference product sponsor, thereby increasing the uncertainty before approval and launch and increasing the chances for possible delays. In certain circumstances, the advantages of participating in the patent dance could outweigh the advantages of skipping the patent dance.

Regardless of whether a biosimilar firm chooses to participate in the patent dance, the BPCIA's information disclosure procedure adds significantly to expense, complexity, uncertainty, and risk. For example, a biosimilar firm may be subject to an allegation of violating the BPCIA independent of the patent issues, given that what could be a violation still has not been fully vetted. Moreover, the complexity of the patent dance and subsequent biosimilar litigation requires highly qualified law firms and the conflict space for such firms is very crowded,

with biosimilar firms competing not only with other biosimilar firms but also with reference product sponsors for the engagement of suitable law firms. It may be difficult for us to secure such legal support if large, well-funded references have already entered into engagements with highly qualified law firms or if the most highly qualified law firms choose not to represent biosimilar applicants due to their long-standing relationships with references.

# Our Canadian partner, JAMP, is involved in legal proceedings adverse to AbbVie that may have an impact on our AVT02 product in Canada.

While our legal proceedings adverse to AbbVie related to our biosimilar adalimumab product, AVT02, have been settled or otherwise resolved in the United States, the Netherlands, and Japan, and before the European Patent Office, proceedings between our Canadian partner JAMP and AbbVie are pending in Canada.

On March 31, 2021, AbbVie filed four actions in the Federal Court of Canada (T-557-21, T-559-21, T-560-21 and T-561-21, collectively, the "NOC Actions") against JAMP Pharma Corporation ("JAMP Pharma"), which is our exclusive Canadian partner for AVT02 (adalimumab solution for injection). No Alvotech entity is a named party in the NOC Actions. AbbVie is seeking declarations pursuant to the Patented Medicines (Notice of Compliance) Regulations and the Patent Act that JAMP Pharma's adalimumab solution for subcutaneous injection (the "JAMP Pharma Products") would directly or indirectly infringe the asserted claims of Canadian Patent Nos. 2,898,009; 2,904,458; 2,504,868; 2,847,142; 2,801,917 and 2,385,745. JAMP Pharma counterclaimed, in each of the four actions, alleging that the asserted claims of each of the six patents are invalid.

On April 6, 2021, JAMP Pharma commenced four actions in the Federal Court of Canada (T-572-21, T-573-21, T-577-21 and T-581-21, collectively, the "Impeachment Actions") seeking declarations that all claims of Canadian Patent Nos. 2,898,009; 2,904,458; 2,504,868; 2,847,142; 2,801,917 and 2,385,745 are invalid, void and of no force or effect, and declarations that the making, using or selling of the JAMP Pharma Products by JAMP Pharma in Canada will not infringe any valid claim of Canadian Patent Nos. 2,898,009; 2,904,458; 2,504,868; 2,847,142; 2,801,917 and 2,385,745. No Alvotech entity is a named party in the Impeachment Actions.

On June 4, 2021, JAMP Pharma amended its Statements of Claim in the Impeachment Actions to only seek declarations that the specific claims asserted in the NOC Actions are invalid, void and of no force or effect, and declarations that the making, using or selling of the JAMP Pharma Products by JAMP Pharma in Canada will not infringe the asserted claims. AbbVie has counterclaimed for declarations that the asserted claims of the patents are valid and that they will be infringed by JAMP Pharma.

The trial of the Impeachment Actions and the NOC Actions commenced on November 14, 2022, and concluded with closing arguments on December 14, 2022. During the course of the proceedings, the patents-at-issue were limited to Canadian Patent Nos. 2,904,458; 2,504,868; and 2.801.917.

In the event of a successful claim of patent infringement against JAMP Pharma, JAMP Pharma may be blocked from the market, and we may have to redesign our infringing products or obtain a license from AbbVie, which may be impossible or require substantial time and monetary expenditure. Even if JAMP Pharma is successful in defending against AbbVie's patent infringement claims, litigation could result in substantial cost and distraction to management and other employees.

In December 2021, Health Canada informed JAMP Pharma that the 40 mg/0.4 mL and 80 mg/0.8 mL presentations of SIMLANDI are not subject to the 24-month statutory stay pursuant to the Patented Medicines (Notice of Compliance) Regulations because AbbVie elected to not market the equivalent high-concentration versions to Canadian patients. In January 2022, JAMP Pharma received notices of compliance for the 40 mg/0.4 mL and 80 mg/0.8 mL presentations of SIMLANDI. AbbVie has commenced applications to judicially review Health Canada's decision in the Federal Court of Canada, and a hearing took place on May 16-17, 2022. On

August 17, 2022, the court issued a decision, finding that Health Canada's interpretation of the regulations was reasonable and dismissing AbbVie's applications for judicial review. On October 3, 2022, AbbVie issued a Notice of Appeal.

In the event that an appellate court finds in AbbVie's favor, then market access of SIMLANDI in Canada may be impacted. In addition, we, directly or through our partners, may become involved in legal proceedings adverse to other originators or market participants.

#### Risks Related to Legal and Regulatory Compliance Matters

Recently enacted and future legislation, including healthcare legislative reform measures, may have a material adverse effect on our business and results of operations.

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system, including initiatives to contain healthcare costs. For example, in March 2010, the PPACA, was passed, which substantially changed the way health care is financed by both governmental and private insurers and continues to significantly impact the U.S. pharmaceutical industry. The PPACA, among other things, created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, added a provision to increase the Medicaid rebate for line extensions or reformulated drugs, established annual fees and taxes on manufacturers of certain branded prescription drugs and promotes a new Medicare Part D coverage gap discount program. The PPACA also includes the BPCIA, which created, among other things, a regulatory framework for the approval of biosimilars and interchangeables.

There have been executive, judicial and Congressional challenges to repeal or replace certain aspects of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, starting January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance and eliminating the implementation of certain PPACA-mandated fees. Additionally, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the PPACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the PPACA marketplace, which began February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challe

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to

reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect until 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to COVID-19 relief legislation, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals and cancer treatment centers. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Further, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," which expressed its intent to pursue certain policy initiatives to reduce pharmaceutical prices. For example, the executive order expressed the Biden administration's support of legislative reforms to lower prescription drug prices, including by allowing Medicare's negotiation of drug prices. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the HHS Secretary to establish a Drug Price Negotiation Program (the "Program") to lower prices for certain high-expenditure, single-source prescription drugs and biologics covered under Medicare Part B and Part D that have been approved by the FDA for at least 7 years for prescription drugs and at least 11 years for biologics. Under the Program, the HHS Secretary will publish a list of "selected drugs," and will then negotiate maximum fair prices ("MFP") with their manufacturers. The Program will be implemented in stages. Beginning in 2026, 10 Medicare Part D "selected drugs" will be subject to price negotiations. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Medicare Part B and Part D. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and potential civil monetary penalties. Further, beginning in October 2023, the IRA will require manufacturers that increase prices of certain Medicare Part B and Part D drugs or biologics at a rate greater than inflation to pay rebates to the Centers for Medicare & Medicaid Services or be subject to civil monetary penalties. The IRA also provides certain incentives for the development and manufacture of biosimilars. For example, the Secretary can grant a one-year delay from price negotiations for biosimilars that have a "high likelihood" of a competing biosimilar product entering the market within the requested delay period. In addition, certain Part B biosimilars qualify for an increase in Medicare payments, to 8% of the 5-year Average Sales Price, from 6% under current law. The HHS Secretary has been directed to promulgate regulations to implement the Program and other IRA health reform measures. Further, the Biden administration released an additional executive order on October 14. 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future.

At the state level, individual states have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some EEA countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the European Commission and other comparable regulatory authorities with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. By January 31, 2025. all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, the Retained EU Law (Revocation and Reform) Bill

published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK.

On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

We may be subject to federal and state healthcare laws, including those governing fraud and abuse, false claims, physician payment transparency and health information privacy and security laws, and comparable foreign law equivalents. If we are unable to comply or have not fully complied with such laws, we could face substantial penalties including administrative, civil and criminal penalties, damages, fines, and exclusion from participation in government health care programs.

Our operations may be subject to various civil and criminal fraud and abuse laws. In the United States, federal fraud and abuse laws include, without limitation, the False Claims Act ("FCA"), the Anti-Kickback Statute ("AKS"), the Exclusions Law, and the Civil Monetary Penalties Law ("CMPL"). Many states have similar state laws. These laws may impact, among other things, our research activities as well as our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any individual or entity from knowingly and willfully soliciting, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce another individual or entity to: (a) refer an individual to a person for the furnishing (or arranging for the furnishing) of any item or service for which payment may be made under a federal health care program; (b) purchase or order any covered item or service; (c) arrange for the purchase or order of any covered item or service; or (d) recommend the purchase or order of any covered item or service;
- federal civil and criminal false claims laws and civil monetary penalties laws, including the FCA and the CMPL, which prohibit, among
  other things, individuals or entities from knowingly presenting or causing to be presented false, fictitious, or fraudulent claims for payment
  to the U.S. government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that
  prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to
  healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing
  regulations, which imposes certain requirements relating to the privacy, security and transmission of health information that allows
  identification of individual patients on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses,
  and their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of
  individually identifiable health information, as well as their covered subcontractors;

- Federal and state transparency laws and regulations, such as the federal Physician Payments Sunshine Act. The federal Physician Payment Sunshine Act which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value made by such manufacturers to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members in such manufacturers; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the national or federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; national or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and national or state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Outside the United States, interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, health care reform legislation has strengthened these laws. For example, in the United States the PPACA, among other things, amended the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes, such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Moreover, one or more of our commercial partners may be subject to the above law and may be investigated or sued for any one or more of the previous concerns which may in turn materially impact us by virtue of our association with such commercial partner(s).

The international aspects of our business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We currently have international operations and a number of international collaborations. Doing business internationally involves a number of risks, including but not limited to:

• multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- failure by us or our collaboration partners to obtain and maintain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations by us or our collaboration partners;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems by our collaboration partners;
- limits in our ability or our collaboration partners' ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products;
- foreign exchange risk, as we have significant asset and liabilities denominated in foreign currencies (mainly in EUR, GBP, ISK, and CHF), and a 10% fluctuation of the exchange rate of ISK against the USD can significantly impact us;
- natural disasters, political and economic instability, including wars such as the Russia-Ukraine conflict, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- · certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, specifically our books and records provisions or its anti-bribery provisions.

We are subject to anti-corruption laws and regulations, export and import controls, and sanctions laws and regulations of the United States and other countries. Compliance with these legal standards could impair our ability to compete in international markets. We could face criminal liability and other serious consequences for violations, which could harm our business, prospects and financial condition.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in jurisdictions in which we may conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value improperly to or from recipients in the public or private sector. We have engaged third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which requires such companies to maintain complete and accurate books and records and maintain a system of internal accounting controls.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, as well as by comparable import, export, and sanctions laws and regulations in other jurisdictions. Compliance with applicable regulatory requirements regarding the import and export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export our products to some countries or persons altogether.

Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions.

Any changes in the laws and regulations described above, shift in the enforcement or scope of existing laws and regulations, or change in the countries, governments, persons, or technologies targeted by such laws and regulations, could result in decreased ability to export our product candidates internationally. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our confidential information in internal systems or those used by third party collaborator partners or other contractors or consultants, could compromise the confidentiality, integrity and availability of our confidential information in information technology systems, network-connected control systems and/or our data, interrupt the operation of our business and/or affect our reputation.

To achieve our business objectives, we rely on sophisticated information technology systems, including software, mobile applications, cloud services and network-connected control systems, some of which are managed, hosted, provided or serviced by third parties. Internal or external events that compromise the confidentiality, integrity and availability of our systems and data may significantly interrupt the operation of our business, result in significant costs and/or adversely affect our reputation and/or place us at a competitive disadvantage resulting from the improper disclosure or theft of confidential information or intellectual property.

Our information technology systems are highly integrated into our business, including our research and development ("R&D") efforts, our clinical and commercial manufacturing processes and our product sales and distribution processes. Further, as certain employees are working remotely, our reliance on our and third-party information technology systems has increased substantially and is expected to continue to increase. The complexity and interconnected nature of our systems make them potentially vulnerable to breakdown or other service interruptions. Our systems are subject to frequent attempted cyberattacks. As the cyber-threat landscape evolves, these attacks are growing in frequency, sophistication and intensity and are becoming increasingly difficult to detect. Such attacks could include the use of harmful and virulent malware, including ransomware or other denials of service, that can be deployed through various means, including the software supply chain, e-mail, malicious websites and/or the use of social engineering. Attacks such as those experienced by governmental entities (including those that approve and/or regulate our products, such as the FDA, the European Commission or EMA) and other multi-national companies, including some of our peers, could leave us unable to utilize key business systems or access or protect important data, and could have a material adverse effect on our ability to operate our business, including developing, gaining regulatory approval for, manufacturing, selling and/or distributing our products.

Our systems and possibly those of permissible third parties also contain and utilize a high volume of sensitive data, including intellectual property, trade secrets, financial information, regulatory information, strategic plans, sales trends and forecasts, litigation materials and/or personal information belonging to us, our staff, customers and/or other parties. In some cases, we and/or permissible third parties may use third-party service providers to process, store, manage or transmit such data, which may increase our risk. Intentional or inadvertent data privacy or security breaches (including cyberattacks) or lapses by employees, service providers (including providers of information technology-specific services), nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations, "hacktivists" or others, create risks that our sensitive data may be exposed to unauthorized persons, our competitors, or the public.

Domestic and global government regulators, our business partners, suppliers with whom it does business, vendors and law firms that host our documents and information in connection with transactions or proceedings, companies that provide us or our partners with business services and companies that we may acquire may face

similar risks, and security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. As a part of our business, we share confidential information with third parties, such as commercial partners, consultants, advisors and vendors. We are at risk of our confidential data being disclosed without our consent or lost if these third parties' servers or databases experience security breaches of their systems.

We have experienced system downtime, attacks and information security breaches, but we do not believe such downtime, attacks and breaches have had, either individually or in the aggregate, a material adverse effect on our business or results of operations. We continue to invest in the monitoring, protection and resilience of our critical and/or sensitive data and systems. However, there can be no assurances that our efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks, and/or breaches of our systems that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in material financial, legal, business or reputational harm or negatively affect our share price. While we maintain cyber-liability insurance, our insurance is not sufficient to cover it against all losses that could potentially result from a service interruption, breach of our systems or loss of critical or sensitive data.

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, in the EEA, we are subject to the General Data Protection Regulation ("GDPR"), which became effective in May 2018, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting and which provides for substantial penalties for non-compliance. Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations. Failure to comply with these current and future laws could result in significant penalties, liability for damages incurred by individuals whose privacy is violated, and could have a material adverse effect on our business and results of operations.

We and our service providers may be subject to evolving data protection and security laws, including in the EEA and the UK, in relation to certain processing of personal data. The actual or perceived failure to comply with such laws could harm our financial condition and operating results and involve distraction from other aspects of our business.

We are also subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The legislative and regulatory environment regarding privacy and data protection is continuously evolving and developing and the subject of significant attention globally. For example, in the EEA we are subject to the EU's General Data Protection Regulation ("EU GDPR"), which became effective in May 2018, and in the United Kingdom, to the United Kingdom's GDPR ("UK GDPR"). Both regulations impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting and which provides for substantial penalties for non-compliance.

Data privacy and security laws are rapidly evolving, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, related obligations may be subject to interpretations which may vary from one country to another. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully

transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the EU and UK GDPR, require our customers to impose specific contractual restrictions on their service providers.

In addition, because of the remote work policies we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal data, including health data. We may also need to collect more extensive health-related information from our employees to manage our workforce.

Other jurisdictions where we operate have enacted or proposed similar legislation and/or regulations. If we or our third-party partners fail to comply or are alleged to have failed to comply with data protection and privacy laws and regulations, or if we were to experience a data breach involving personal data, we could be subject to government enforcement actions. In addition, under the EU GDPR, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

# We currently rely on Alvogen's ERP solution and other components of our IT infrastructure and will continue to do so for the foreseeable future.

We currently rely on certain IT infrastructure and software owned and/or operated by Alvogen. A service agreement is in place between us and Alvogen addressing confidentiality, service and fees and other customary matters, and the two companies have entered into an agreement regarding the ownership, access rights and retention of shared data, pursuant to which Alvogen stores our data separate from Alvogen data.

We have signed a separate license agreement for our own ERP system and are in the process of implementing and migrating to the new platform in an environment separate from Alvogen's. This environment set up is underway and the system is expected to go live during the second half of 2023. However, in the meantime, we are relying on Alvogen's platform and licenses. In addition, we also use a small number of applications related to ERP, that are licensed through Alvogen. We plan to stop using these applications during the second half of 2023.

We are also currently relying on Alvogen's Azure (cloud) environment and is in the process of migrating into a dedicated separate environment. While our components of the environment have been logically separated from Alvogen's components and are operated by us, a limited number of Alvogen IT administrators continue to

have read-only access to our Azure subscriptions for to monitor usage billing purposes. Although we plan to physically separate the remaining resources and have our ERP platform go live by the end of 2023, following the migration of the Azure environment, there can be no assurance that this project will be successful at all or will be achieved on schedule.

There is a risk that other issues due to the shared infrastructure between the companies have not yet been identified, posing a risk to our business operations which are currently relying on the confidentiality, integrity and availability of critical information systems and our data stored on Alvogen's IT infrastructure. For more information on the service agreements between us and Alvogen, please see the section entitled "Certain Relationships and Related Person Transactions."

The implementation of an ERP system is a complex and time-consuming project that requires transformations of business and finance processes to reap the benefits of the ERP system. Any such transformation involves risk inherent in the conversion to a new system, including loss of information and potential disruption to normal operations. Delays or the failure to fully implement the ERP system and fully separate the IT infrastructure, or interruptions in service or operational difficulties during or following the full implementation of the ERP system, may adversely impact our financial results and could lead to business disruption and loss of business. In addition, the failure or abandonment of any part of the ERP system could result in a write-off of part or all of the costs that have been capitalized on the project, which could adversely affect our results of operations and financial condition. Further, if the ERP system does not operate as intended, the effectiveness of our internal control over financial reporting could cause us to fail to comply with SEC reporting obligations related to our management's assessment of internal control over financial reporting.

Our IT Governance (ITG) and Information Security Management System (ISMS) may not be sufficient to ensure the effective and efficient use of IT in enabling the organization to achieve business objectives and secure the confidentiality, integrity and availability of critical information technology systems and data.

We currently do not have a fully implemented ITG and ISMS in place. At the end of 2022, we hired an Information Security Officer who reports to the General Counsel to strengthen ISMS. The Information Security Officer will introduce an information security ("InfoSec") program, which includes revising and updating the ISMS, and, together with the CIO, the ITG. The InfoSec program plans to introduce enhanced policies and procedures. We currently have in place ITIL aligned procedures, covering access management, change management, incident management, business continuity and disaster recovery, which will be further reviewed and revised and aligned to the ISO 27001 framework.

We do not currently have a data retention policy in place. We have established procedures for IT business continuity and disaster management, with restore tests conducted quarterly. The full implementation of ITG and ISMS may not be successfully completed during 2023, or at all, due to lack of capabilities, resources or funding, prioritization, or other reasons.

Some of our critical systems and data are hosted on premise in one data center, without a secondary data center for redundancy. Force majeure events impacting the data center such as fire, flood, earthquake, or power outage can therefore pose a risk to our operation and may compromise the confidentiality, integrity and availability of those systems and data. A new data center is under construction as part of the extension build at Saemundargata 19, Reykjavik, which is expected to be completed in the second half of 2023.

While we have invested, and continue to invest, in ITG and ISMS, there can be no assurance that our efforts will be sufficient to ensure the effective and efficient use of IT, which could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business or reputational harm.

Our ISMS may be subject to security breaches or other incidents that could result in misappropriation of funds, disruption to operations, disclosure of commercially or personally sensitive information, legal or regulatory breaches and liability, as well as other costs and reputational damage. Given the increasing sophistication and evolving nature of these threats, the possibility of security breaches occurring in the future cannot be ruled out. An extended failure of critical system components, caused by accidental or malicious actions, including those resulting from a cybersecurity attack, could result in a significant commercial loss, interruption to operations, loss of access to critical data or systems, unfavorable publicity, damage to reputation, regulatory investigations, fines or penalties, litigation or other claims by affected parties and possible financial obligations for liabilities and damages related to the theft or misuse of our information and other business delays or disruptions, any of which could have an adverse effect on our business, financial condition, results of operations and reputation. Further, we may be forced to expend significant financial and operational resources in response to a security breach, including repairing system damage, increasing security protection costs by deploying additional personnel and modifying or enhancing protection technologies, investigating and remediating any information security vulnerabilities and defending against and resolving legal and regulatory claims, all of which could divert resources and the attention of management and key personnel away from business operations and adversely affect our business, financial condition and results of operations. See also "A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our confidential information in information in information in information in information in information in information of our business and/or affect our reputation."

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our facilities and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect from a serious disaster. Our manufacturing facility and inventories are located at a single site in Reykjavik, Iceland and any severe natural or other disaster or disruption at this site could have a material adverse effect on our financial condition and results of operations.

Our corporate headquarters, manufacturing site and a large part of our R&D division are located in Reykjavik, Iceland. Iceland is geographically isolated and has in the past experienced severe earthquakes and other natural disasters, such as volcanic eruptions. Earthquakes or other natural disasters could severely disrupt

our operations or those of our collaboration partners and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure (such as the manufacturing facilities of our third-party providers of power or water supplies) or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our current lack of business continuity insurance, could have a material adverse effect on our business.

## Our business could be materially disrupted by strikes, work stoppages or other labor actions in Iceland or elsewhere.

Under applicable Icelandic labor laws, members of a labor union are required to participate in a strike called by the labor union or work stoppage called by an employers association. As many of our employees in Iceland are members of Icelandic labor unions, we may be faced with strikes, work stoppages or other labor actions in Iceland which may materially disrupt our business at our headquarters, manufacturing site, and the local part of our R&D division. Work stoppages, strikes or other labor actions at other companies or industries within Iceland, including international air traffic, could also have an adverse effect on our ability to operate and may impact earnings and other key business metrics. In addition, work stoppages, strikes or other labor actions of our employees outside of Iceland may affect our operations at those sites outside of Iceland, and work stoppages, strikes or other labor actions of employees of our vendors, suppliers or partners may affect the performance of our partners, our supply chain, our ability to sell our products and our operations generally.

# Iceland's implementation of EEA rules may not be comprehensive or may be delayed, which may result in certain risks and uncertainty for us and our business.

We have significant assets, including our subsidiary Alvotech hf., in Iceland. Many of our assets and material agreements are therefore governed by Icelandic law and subject to the jurisdiction of the Icelandic courts. As an EEA country, Iceland is obligated to implement important parts of EU law relating to the "four freedoms" within the EU single market. Certain aspects of our operations are subject to laws originating from such implementation. If the Icelandic state fails to draft national legislation which conforms with such EU rules, Icelandic individuals and legal persons may not be able to rely on the relevant EU rules and the Icelandic courts could be restricted from applying them unless the Icelandic legislation can be interpreted in a way which conforms with EEA rules. This could negatively affect us or other individuals or legal persons who conduct business with us in Iceland.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise are unable to develop and maintain an effective system of internal controls in the future, we may not be able to produce timely and accurate financial statements or comply with applicable laws and regulations, which may adversely affect investor confidence in us and, as a result, the value of Ordinary Shares.

We have identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the preparation of the consolidated financial statements covered by this report, we identified material weaknesses as follows: (i) control environment driven by the lack of a sufficient number of trained professionals with an appropriate level of internal control knowledge, training and experience; (ii) control activities, as we did not have adequate formal documentation of certain policies and procedures, implementation of all required business

process controls, including effective review process of key financial information, and documentation to evidence the design and operating effectiveness of the control activities; (iii) information and communication as we did not implement effective controls over the segregation of duties and certain information technology general controls for information systems that are relevant to the preparation of our financial statements; and (iv) monitoring activities, as we did not have the evidence to support evaluation of the effectiveness of monitoring controls to ascertain whether the components of internal control are present and functioning. These material weaknesses could result in a misstatement of our accounts or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

Upon identifying the material weaknesses, we began taking steps intended to address the underlying causes of the control deficiencies in order to remediate the material weaknesses, which included the following activities during 2021 and 2022: (i) performed risk assessment to identify and communicate appropriate objectives and to identify and assess changes in the business that could affect our system of internal controls; (ii) implemented and/or redesigned entity level, business process level controls and information technology controls to mitigate key risks identified, this included designing and implementing detailed management review procedures in addition to establishing an audit committee; (iii) implemented a compliance tool to provide workflow and electronic approval capabilities as well as to maintain control evidence; (iv) engagement of outside consultants to assist in evaluating the internal controls, develop remediation plans to address control deficiencies identified, and provide training to control owners; (v) continued implementation of a new enterprise resource planning ("ERP") system, which includes increased automated functionality and controls.

In addition to the above actions, we expect to engage in additional activities to enhance our control environment including but not limited to:
(i) continue to implement and/or redesign entity level controls, business process-level controls across all significant accounts and information technology general controls across all relevant domains, as needed, (ii) continued engagement of outside consultants to assist in evaluating the internal controls, and developing a remediation plans to address control deficiencies; (iii) continued training to control owners to establish clear expectations as it relates to the control design, execution and monitoring of such controls, including enhancements to the documentation to evidence the execution of the controls; (iv) incremental hiring of more accounting resources; (v) continued implementation of a new ERP system including the engagement of outside consultants to help design and implement automated controls and enhance our information technology general controls environment as part of the ERP system implementation; and (vi) implement a Governance, Risk and Control tool to monitor the segregation of duties in the new ERP system.

We cannot assure that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses identified and avoid potential future material weaknesses. If the steps we take do not remediate the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weaknesses, identify new material weaknesses in our internal controls over financial reporting, are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of the Ordinary Shares could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchanges on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and shareholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

#### Risks Related to Ownership of our Ordinary Shares and Warrants and our Status as a Public Company

We have and will incur increased costs as a result of operating as a public company, and our management will devote substantial time to new compliance initiatives.

We will incur significant legal, accounting and other expenses that it did not incur as a private company, and these expenses may increase even more if and when we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board advisors or as executive officers.

## Our management has limited experience in operating a public company.

Our executive officers have limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage the transition to a public company that will be subject to significant regulatory oversight and reporting obligations under federal and European securities laws. Their limited experience in dealing with the increasingly complex laws pertaining to public companies could be a disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities. This in turn may result in less time being devoted to the management and our growth. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices or internal controls over financial reporting required of public companies in the United States and in Europe. The development and implementation of the standards and controls necessary for us to achieve the level of accounting standards required of a public company in the United States and Europe may require costs greater than expected. It is possible that we will be required to expand our employee base and hire additional employees to support our operations as a public company, which will increase our operating costs in future periods.

## The market price and trading volume of our Ordinary Shares and Warrants may be volatile and could decline significantly.

The stock markets, including Nasdaq and Nasdaq Iceland Main Market on which Ordinary Shares and Warrants are listed under the symbols ALVO and ALVOW, respectively, have from time to time experienced significant price and volume fluctuations. The market price of Ordinary Shares and Warrants may be volatile and could decline significantly. In addition, the trading volume in Ordinary Shares and Warrants may fluctuate and cause significant price variations to occur. Additionally, any substantial amount of trading or sales in Ordinary Shares could make it difficult for us to raise capital through the issuance of debt or equity securities in the future. Generally, securities of biopharmaceutical companies tend to be volatile and experience significant price and volume fluctuations. We cannot guarantee that the market price of Ordinary Shares and Warrants will not fluctuate widely or decline significantly in the future in response to a number of factors, including, among others, the following:

- the realization of any of the risk factors presented in this prospectus;
- actual or anticipated differences in our estimates, or in the estimates of analysts, for our revenues, results of operations, liquidity or financial condition;
- additions and departures of key personnel;

- failure to comply with the requirements of Nasdaq U.S. and Nasdaq Iceland Main Market;
- failure to comply with the Sarbanes-Oxley Act or other laws or regulations in the United States, Luxembourg and Iceland;
- future issuances, sales or resales, or anticipated issuances, sales or resales, of Ordinary Shares;
- publication of research reports about us;
- the performance and market valuations of other similar companies;
- · broad disruptions in the financial markets, including sudden disruptions in the credit markets;
- material and adverse impact of public health emergencies, such as the COVID-19 pandemic, on the markets and the broader global economy;
- speculation in the press or investment community;
- actual, potential or perceived control, accounting or reporting problems; and
- changes in accounting principles, policies and guidelines.

In the past, securities class-action litigation has often been instituted against companies following periods of volatility in the market price of their shares. This type of litigation could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on us.

## The dual listing of Ordinary Shares may adversely affect the liquidity and value of those ordinary shares.

Our Ordinary Shares are listed on both The Nasdaq Stock Market in the United States ("Nasdaq") and Nasdaq Iceland Main Market in Iceland. The trading of Ordinary Shares in these markets takes place in different currencies (U.S. dollars on Nasdaq and Icelandic Krona on Nasdaq Iceland Main Market), at different times (resulting from different time zones, different trading days and different public holidays in the United States and Iceland) and with different settlement mechanics. The trading prices of Ordinary Shares on these two markets may differ due to these and other factors. Any decrease in the price of Ordinary Shares on Nasdaq Iceland Main Market could cause a decrease in the trading price of Ordinary Shares on Nasdaq and vice versa. Investors could seek to sell or buy Ordinary Shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both the trading prices on one exchange and Ordinary Shares available for trading on the other exchange. Further, the dual listing of Ordinary Shares may reduce the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for Ordinary Shares in the United States.

The listing of Ordinary Shares on Nasdaq Iceland Main Market may result in increased additional compliance risk, which could have a material effect on our business, results of operations and financial condition, or may delay or discourage a takeover attempt.

Our ordinary shares are listed on both the Nasdaq and Nasdaq Iceland Main Market. Nasdaq Iceland Main Market a regulated market in Iceland operated by Nasdaq Iceland, the Icelandic stock exchange. Issuers on Nasdaq Iceland Main Market are subject to the rules of Nasdaq Iceland Main Market and the relevant rules and regulations given the fact that the securities of the issuer are admitted to trading on a regulated market.

As a dual-listed Luxembourg company listed on Nasdaq Iceland Main Market and Nasdaq, we are subject to reporting requirements and certain other applicable requirements under Luxembourg law, U.S. law and Icelandic law, including, but not limited to, Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse, as amended ("MAR"), the Directive 2004/109/EC of the European Parliament and of the Council of December 15, 2004 on the harmonization of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market, as amended

(the "Transparency Directive") the Luxembourg law of December 23, 2016, on market abuse, as amended ("Luxembourg Market Abuse Law"), and the Luxembourg law of 11 January 2008 (coordinated version) on transparency requirements for issuers, as amended (the "Luxembourg Transparency Law") and the Luxembourg Grand-Ducal regulation of January 11, 2008, on transparency requirements for issuers of securities, as amended ("Luxembourg Transparency Regulation"), and Directive 2004/25/EC of the European Parliament and of the Council of April 21, 2004, on takeover bids, as amended ("Takeover Directive") has been implemented in the Luxembourg law of May 19, 2006, on takeover bids, as amended ("Luxembourg Takeover Law").

# Transparency Regime

Holders of shares and other financial instruments may be subject to notification obligations pursuant to the Luxembourg Transparency Law. The following description summarizes these obligations. Holders are advised to consult with their own legal advisors to determine whether the notification obligations apply to them.

The Luxembourg Transparency Law and Luxembourg Transparency Regulation provide that, once the Shares are admitted to listing and trading on Nasdaq Iceland Main Market, if a person acquires or disposes of a shareholding in the Company, and if following the acquisition or disposal the proportion of voting rights held by the person reaches, exceeds or falls below one of the thresholds of 5%, 10%, 15%, 20%, 25%, 33 1/3%, 50% and 66 2/3% (each a "Relevant Threshold") of the total voting rights existing when the situation giving rise to a declaration occurs, such person must simultaneously notify the Company and the *Luxembourg Commission de Surveillance du Secteur Financier* (the "CSSF") of the proportion of voting rights held by it further to such event.

A person must also notify the Company and the CSSF of the proportion of his or her voting rights if that proportion reaches, exceeds or falls below a Relevant Threshold as a result of events changing the breakdown of voting rights and on the basis of the information disclosed by the Company.

The same notification requirements apply to a natural person or legal entity to the extent he/she/it is entitled to acquire, to dispose of, or to exercise voting rights in any of the cases or a combination of them stated in Article 9 of the Luxembourg Transparency Law. The notification requirements set out above also apply to a natural person or legal entity that holds, directly or indirectly: (i) financial instruments that, on maturity, give the holder, under a formal agreement, either the unconditional right to acquire or the discretion as to his or her right to acquire the Ordinary Shares, to which voting rights are attached, already issued by the Company; or (ii) financial instruments which are not included in point (i) but which are referenced to the Ordinary Shares referred to in that point and with an economic effect similar to that of the financial instruments referred to in that point, whether or not they confer a right to a physical settlement.

The number of voting rights shall be calculated as specified in Article 12 and 12a of the Luxembourg Transparency Law.

The notification to the Company and the CSSF must be effected promptly, but not later than four trading days after the date on which the shareholder, or the natural person or legal entity referred to above learns of the acquisition or disposal or of the possibility of exercising voting rights, or on which, having regard to the circumstances, should have learned of it, regardless of the date on which the acquisition, disposal or possibility of exercising voting rights takes effect, as specified in the Luxembourg Transparency Law and the related guidelines of the CSSF. Upon receipt of the notification, but not later than three trading days thereafter, the Company must make public all the information contained in the notification as regulated information within the meaning of the Luxembourg Transparency Law.

As long as the notifications have not been made to the Company in the manner prescribed, the exercise of voting rights relating to the shares exceeding the fraction that should have been notified is suspended. The suspension of the exercise of voting rights is lifted as of the moment the shareholder makes the notification. In addition, the CSSF can impose administrative sanctions on holders of securities for lack of filings or for belated filings.

Where within the fifteen days preceding the date for which the general meeting has been convened, the Company receives a notification or becomes aware of the fact that a notification has to be or should have been made in accordance with the Luxembourg Transparency Law, the board of directors may postpone the general meeting.

## Market Abuse Regime

The rules on preventing market abuse set out in the MAR and the Luxembourg Market Abuse Law are applicable to the Company, persons discharging managerial responsibilities within the Company (including the members of the board of directors) (the "PDMRs"), persons closely associated with PDMRs (as defined in Article 1 (26) of the MAR), other insiders and persons performing or conducting transactions in the Company's financial instruments. Certain important market abuse rules set out in the MAR and the Luxembourg Market Abuse Law that are relevant for investors are described hereunder.

The Company is required to make inside information public. Pursuant to the MAR, inside information is information of a precise nature, which has not been made public, relating, directly or indirectly, to the Company or to one or more financial instruments, and which, if it were made public, would be likely to have a significant effect on the prices of those financial instruments or on the price of related derivative financial instruments. Unless an exception applies, the Company must without delay publish the inside information by means of a press release and post and maintain it on its website for at least five years. The Company must also provide Nasdaq Iceland and the CSSF with its press release that contains inside information at the time of publication.

It is prohibited for any person to make use of inside information by acquiring or disposing of, for its own account or for the account of a third party, directly or indirectly, financial instruments to which that information relates, as well as an attempt thereto (insider dealing). In addition, it is prohibited for any person to disclose inside information to anyone else (except where the disclosure is made in the normal exercise of an employment, profession or duties) or, whilst in possession of inside information, to recommend or induce anyone to acquire or dispose of financial instruments to which the information relates. Furthermore, it is prohibited for any person to engage in or attempt to engage in market manipulation, for instance by conducting transactions which give, or are likely to give, false or misleading signals as to the supply of, the demand for or the price of a financial instrument.

Non-compliance with the notification obligations under the Market Abuse Regulation, set out in the paragraphs above, is an economic offense and could lead to the imposition of criminal prosecution, administrative fines, imprisonment or other sanctions. Nasdaq Iceland Main Market may impose administrative penalties or a cease-and-desist order under penalty for non-compliance. If criminal charges are pressed, Nasdaq Iceland Main Market is no longer allowed to impose administrative penalties and vice versa, Nasdaq Iceland Main Market is no longer allowed to seek criminal prosecution if administrative penalties have been imposed.

Pursuant to Article 19 of the MAR and the Luxembourg Market Abuse Law, PDMRs must notify the CSSF and the Company of any transactions conducted for his or her own account relating to shares or any debt instruments of the Company or to derivatives or other financial instruments linked thereto.

A PDMR within the Company shall not conduct any transactions on its own account or for the account of a third party, directly or indirectly, relating to the Ordinary Shares or debt instruments of the Company or to derivatives or other financial instruments linked to them during a closed period of 30 calendar days before the announcement of an interim financial report or a year-end report which must be made publicly available.

In addition, pursuant to the MAR and the regulations promulgated thereunder as well as the Luxembourg Market Abuse Law, certain persons who are closely associated with persons discharging managerial responsibilities (PDMRs) as defined in Article 1 (26) of the MAR, are also required to notify the CSSF and the Company of any transactions conducted for their own account relating to shares or any debt instruments of the Company or to derivatives or other financial instruments linked thereto in accordance with MAR.

Takeover Regime and Squeeze-out and Sell-out Procedures

The Takeover Directive has been implemented in Luxembourg in the Luxembourg Takeover Law. The Luxembourg Takeover Law provides that if a person, acting alone or in concert, acquires shares in a company which, when added to any existing holdings of a company's shares, result in such person having voting rights representing at least 33 1/3% of all of the voting rights attached to the issued and outstanding shares in a company, this person is obliged to make a mandatory takeover bid, at a fair price, for the remaining shares in the company. Where the aforementioned percentage-threshold is met, the person acquiring such voting rights will be deemed to have control over the Issuer in accordance with Luxembourg Takeover Law.

The Luxembourg Takeover Law provides that, when a mandatory or voluntary takeover offer is made to all holders of voting shares in a company and after such offer the offeror holds at least 95% of the capital of that company carrying voting rights and 95% of the voting rights of the company, the offeror may require the holders of the remaining shares to sell those shares to the offeror. The price offered for such shares must be a fair price. The price offered in a voluntary offer would be considered a fair price in the squeeze-out proceedings if 90% of the shares of the company carrying voting rights were acquired in such a voluntary offer, in accordance with Luxembourg Takeover Law. The price paid in a mandatory takeover offer is deemed to be a fair price pursuant to Luxembourg Takeover Law.

The Luxembourg Takeover Law provides that, when a mandatory or voluntary takeover bid is made to all holders of voting shares in a company and if after such offer the offeror (together with any person acting in concert with the offeror) holds shares carrying more than 90% of the voting rights, the remaining shareholders may require that the offeror purchase the remaining shares. The price offered in a voluntary offer would be considered a fair price in the sell-out proceedings if 90% of the shares of the company carrying voting rights were acquired in such a voluntary takeover offer, in accordance with Luxembourg Takeover Law. Where the offeree company has issued more than one class of shares, the right of squeeze-out and sell-out referred to above can be exercised only in the class in which the relevant threshold has been reached.

Even if there has not been an offer pursuant to the Luxembourg Takeover Law, the Luxembourg law of July 21, 2012 on the squeeze-out and sell-out of securities of companies admitted or having been admitted to trading on a regulated market or which have been subject to a public offer (the "Luxembourg Mandatory Squeeze-Out and Sell-Out Law") provides that if any individual or legal entity, acting alone or in concert with another, becomes the direct or indirect holder (otherwise than by way of a voluntary or mandatory takeover bid pursuant to the Luxembourg Takeover Law) of shares or other voting securities representing at least 95% of the voting share capital and 95% of the voting rights of a company, (i) such shareholder may require the holders of the remaining shares or other voting securities; and (ii) the holders of the remaining shares or securities may require such shareholder to purchase those remaining shares or other voting securities (the "Mandatory Sell-Out"). The Mandatory Squeeze-Out and the Mandatory Sell-Out must be exercised at a fair price according to objective and adequate methods applying to asset disposals in accordance with the Luxembourg Mandatory Squeeze-Out and Sell-Out Law.

Adherence to the requirements of these rules and regulations may increase our legal, accounting and financial compliance costs, make certain activities more difficult, time consuming and costly, place additional strain on resources and divert management's attention away from other business matters.

In addition, the applicable legal requirements or the interpretation of such requirements by regulators and courts in each of these jurisdictions may differ or conflict which could expose us to additional costs, sanctions and/or fines. Any of these factors could have a material effect on our business, results of operations and financial condition.

The issuance by us, or the resale by our shareholders or Yorkville, of a substantial number of Ordinary Shares in the public market could occur at any time. These issuances and sales, or the perception in the market that these issuances or sales may occur, could increase the volatility of the market price of Ordinary Shares or result in a significant decline in the public trading price of Ordinary Shares.

Future issuances of debt securities and equity securities may adversely affect us, including the market price of our Ordinary Shares and may be dilutive to existing shareholders.

Significant additional capital will be needed in the future to continue our planned research, development and business operations. In the future, we may incur debt or issue equity ranking senior to our ordinary shares. Those securities will generally have priority upon liquidation. Such securities also may be governed by an indenture or other instrument containing covenants restricting our operating flexibility. Additionally, any convertible or exchangeable securities that we issue in the future may have rights, preferences and privileges more favorable than those of Ordinary Shares. Because our decision to issue debt or equity in the future will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, nature or success of our future capital raising efforts. As a result, future capital raising efforts may reduce the market price of Ordinary Shares and be dilutive to existing shareholders.

The sale and issuance of our Ordinary Shares to Yorkville, current and former employees or holders of warrants or convertible bonds will cause dilution to our existing shareholders, and the sale of Ordinary Shares acquired by them, or the perception that such sales may occur, could cause the price of our Ordinary Shares to fall.

The purchase price for Ordinary Shares that we may sell to Yorkville under the SEPA will fluctuate based on the price of our Ordinary Shares. Depending on a number of factors, including market liquidity, sales of such shares may cause the trading price of our Ordinary Shares to fall. If and when we do sell shares to Yorkville, Yorkville may resell all, some, or none of those shares at its discretion, subject to the terms of the SEPA. Therefore, sales to Yorkville by us could result in substantial dilution to the interests of other holders of our Ordinary Shares. Additionally, the sale of a substantial number of Ordinary Shares to Yorkville, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a desirable time and price. The resale of Ordinary Shares by Yorkville in the public market or otherwise, or the perception that such sales could occur, could also harm the prevailing market price of our Ordinary Shares.

In addition, we agreed to issue up to 3,660,582 Ordinary Shares to certain current and former employees as a result of the settlement of their existing share appreciation rights agreements. Pursuant to these settlement agreements, 3,510,582 Ordinary Shares will be issued June 16, 2023, and 150,000 Ordinary Shares may be issued on this date if the individual elects to receive shares in lieu of cash.

Furthermore, on November 16, 2022, we and the bondholders amended and restated certain terms and conditions of existing senior bonds and issued new senior bonds in an aggregate principal amount equal to \$70,000,000 (the "Senior Bonds"). Pursuant to the terms of the amended Senior Bonds, we are required to use commercially reasonable endeavors to raise new funding through issuance of additional Ordinary Shares (by way of ordinary shares, structured equity and/or preference shares) and/or unsecured convertible bond(s), for net proceeds of at least \$75.0 million by December 15, 2022, and \$150.0 million by March 31, 2023. If we failed to raise at least \$75.0 million in net proceeds by December 15, 2022, we were required to grant penny warrants representing 1.5% of the ordinary share capital to the bondholders, and if we fail to raise at least \$150.0 million by March 31, 2023, we are required to grant penny warrants representing 1.0% of the ordinary share capital to the bondholders. Since we had not raised \$75.0 million by December 15, 2022, we issued 4,198,807 warrants to the bondholders on December 31, 2022. Each new warrant entitles the bondholders, upon exercise, to receive from us one fully paid and non-assessable Ordinary Share, at the exercise price of one cent (\$0.01) per share. Pursuant to the terms of the warrant, we required to register Ordinary Shares underlying the warrants for resale on or before July 15, 2023. Following the issuance of the December 2022 Convertible Bonds and the closing of the private placement of Ordinary Shares for gross proceeds of \$137.0 million on February 10, 2023, we are not obligated to issue the additional 1.0% warrants to the bondholders.

Finally, we issued convertible bonds, such as the Aztiq Convertible Bond and the December 2022 Convertible bond, that may be converted into Ordinary Shares at the option of the bondholders. The Aztiq

Convertible Bond and December 2022 Convertible Bonds include conversion features for the bondholders. Under the terms of these convertible bond agreements, bondholders have the right to convert their bonds into Ordinary Shares credited as fully paid on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date, for a conversion price of \$10.00 per share. If the bondholders decide to convert the debt into Ordinary Shares, the share ownership of our existing shareholders will be diluted as a result of the issuance of new Ordinary Shares to the bondholders.

Given the substantial number of Ordinary Shares expected to be registered for potential resale by bondholders, the sale of shares by the bondholders, or the perception in the market that the holders of a large number of shares intend to sell their shares, could increase the volatility of the market price of Ordinary Shares or result in a significant decline in the public trading price of Ordinary Shares. In addition, if the holders of the Senior Bonds exercise their warrants and/or holders of our convertible bonds elect to convert the bonds into ordinary shares and we issue new Ordinary Shares, the existing shareholders will be diluted. See also "Our Warrants are exercisable for Ordinary Shares, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our shareholders."

Following these issuances described above and following the expiration of lock-ups of certain other restricted shareholders and as restrictions on resale end and registration statements are available for use, the market price of our Ordinary Shares could decline if the holders of restricted or locked up shares sell them or are perceived by the market as intending to sell them. As such, sales of a substantial number of Ordinary Shares in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of Ordinary Shares.

Sales of Ordinary Shares, or the perception of such sales, by us or the Selling Securityholders pursuant to this prospectus in the public market or otherwise could cause the market price for our Ordinary Shares to decline and certain Selling Securityholders still may receive significant proceeds.

The sale of shares Ordinary Shares in the public market or otherwise, including sales pursuant to this prospectus, or the perception that such sales could occur, could harm the prevailing market price of our Ordinary Shares. These sales, or the possibility that these sales may occur, also might make it more difficult for Alvotech to sell equity securities in the future at a time and at a price that it deems appropriate. Resales of Ordinary Shares may cause the market price of our securities to drop significantly, even if Alvotech's business is doing well.

Although the Sponsor and certain Alvotech Holdings Shareholders will be prohibited from transferring any Ordinary Share (subject to certain exceptions) until: (i) with respect to the Ordinary Shares held by the Sponsor after the closing of the Business Combination, 365 days after the closing of the Business Combination, (ii) with respect to the Ordinary Shares held by Robert Wessman, the founder of Alvotech and chairman of the board of directors (the "Chairman Shares"), (x) 180 days following the closing of the Business Combination, with respect to one-third of the Chairman Shares, (y) 365 days following the closing of the Business Combination, with respect to one-third of the Chairman Shares, and (z) 545 days following the closing of the Business Combination, with respect to the Ordinary Shares held by the other investors party to the IRA, 180 days after the closing of the Business Combination, the Ordinary Shares may be sold after the expiration or early termination or release of the respective applicable lock-up provisions. In addition, we agreed to issue up to 3,660,582 Ordinary Shares to certain current and former employees as a result of the settlement of their existing share appreciation rights agreements. Pursuant to these settlement agreements, 3,510,582 Ordinary Shares will be issued June 16, 2023 and 150,000 Ordinary Shares may be issued on this date if the individual elects to receive shares in lieu of cash.

Following the expiration of the applicable lock-ups described above and as restrictions on resale end and registration statements are available for use, the market price of our Ordinary Shares could decline if the holders of restricted or locked up shares sell them or are perceived by the market as intending to sell them. As such, sales of a substantial number of Ordinary Shares in the public market could occur at any time. These sales, or the

perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of Ordinary Shares.

In connection with the Business Combination, holders of 24,023,495 OACB Class A Ordinary Shares, or 96% of the shares with redemption rights, exercised their right to redeem their shares for cash at a redemption price of approximately \$10.00 per share, for an aggregate redemption amount of \$240,234,950. The Ordinary Shares being offered for resale pursuant to this prospectus by the Selling Securityholders represent approximately 80.35% of Alvotech's outstanding shares as of February 15, 2023 (after giving effect to the issuance of shares upon exercise of outstanding Warrants). Given the substantial number of Ordinary Shares being registered for potential resale by Selling Securityholders pursuant to this prospectus, the sale of shares by the Selling Securityholders, or the perception in the market that the Selling Securityholders of a large number of shares intend to sell shares, could increase the volatility of the market price of Ordinary Shares or result in a significant decline in the public trading price of Ordinary Shares.

Even if our trading price is significantly below \$10.00, the offering price for the units offered in the IPO, certain of the Selling Securityholders may still have an incentive to sell Ordinary Shares because they purchased the shares at prices lower than the public investors or the current trading price of Ordinary Shares. For example, based on the closing price of our Ordinary Shares of \$13.22 as of March 10, 2023, the Sponsor and other holders of the Founder Shares would experience a potential profit of up to approximately \$12.10 per share, or up to approximately \$75.63 million in the aggregate. Public investors may not experience a similar rate of return on the securities they purchase due to differences in the purchase prices and the current trading price.

We have issued and expect to issue in the future additional Ordinary Shares, including under our Management Incentive Plan. Any such issuances would dilute the interest of our shareholders and likely present other risks.

On December 1, 2022, our Remuneration Committee authorized the grant of restricted stock units ("RSUs") to certain employees, executive officers and directors under the Alvotech Management Incentive Plan (the "2022 Plan"). Subject to certain vesting and other terms and conditions, the RSUs may be settled in Ordinary Shares. If all RSUs vest and are exchanged for Ordinary Shares, the combined grants may result in an aggregate of 7,659,049 Ordinary Shares.

Ordinary Shares reserved issued under the 2022 Plan become eligible for sale in the public market once those shares are allocated, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. The aggregate number of Ordinary Shares initially reserved for issuance under the 2022 Plan is 16,802,386 shares. In August 2022, we filed a registration statement on Form S-8 under the Securities Act to register Ordinary Shares or other securities convertible into or exchangeable for Ordinary Shares pursuant to the 2022 Plan, and we may file additional registration statements on Form S-8 in the future.

Accordingly, shares registered under such registration statements may be immediately available for sale in the open market.

Any such issuances of additional Ordinary Shares or securities convertible into Ordinary Shares:

- may significantly dilute the equity interests of our investors;
- · may subordinate the rights of holders of Ordinary Shares if securities are issued with rights senior to those afforded Ordinary Shares; and
- may adversely affect prevailing market prices for Ordinary Shares.

We expect to issue a substantial number of Ordinary Shares or other securities convertible into or exchangeable for Ordinary Shares, including under our 2022 Plan.

Our Warrants are exercisable for Ordinary Shares and certain Bonds are convertible into Ordinary Shares, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our shareholders.

As a result of the Business Combination being consummated, outstanding warrants to purchase an aggregate of 10,916,647 Ordinary Shares became exercisable in accordance with the terms of the Warrant Agreement. These warrants became exercisable on July 15, 2022. The exercise price of these warrants is \$11.50 per share, or approximately \$125.5 million, assuming none of the warrants are exercised through "cashless" exercise. To the extent such warrants are exercised, additional ordinary shares will be issued, which will result in dilution to the holders of Ordinary Shares and increase the number of shares eligible for resale in the public market. We believe the likelihood that warrant holders will exercise their warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our ordinary shares. If the trading price for our ordinary shares is less than \$11.50 per share, we believe holders of our Public Warrants and Private Placement Warrants will be unlikely to exercise their warrants. On March 10, 2023, the last reported sales price of our ordinary shares was \$13.22 per share and the last reported sales price of our Public Warrants was \$2.44 per warrant. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of ordinary shares. As of February 15, 2023, holders of 258,350 Public Warrants, representing 258,350 Ordinary Shares, had elected to exercise their Public Warrants. However, there is no guarantee that the Public Warrants will continue to be in the money prior to their expiration, and as such, the warrants may expire worthless. See "—The warrants may not continue to be in the money, and they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment."

In addition, on November 16, 2022, we and the bondholders amended and restated certain terms of existing Senior Bonds and issued new senior bonds in an aggregate principal amount equal to \$70.0 million. Pursuant to the terms of the amended Senior Bonds, we were required to use commercially reasonable endeavors to raise new funding through issuance of additional Ordinary Shares (by way of ordinary shares, structured equity and/or preference shares) and/or unsecured convertible bond(s), for net proceeds of at least \$75.0 million of net proceeds by December 15, 2022, and are required to raise \$150.0 million in net proceeds by March 31, 2023. We failed to raise at least \$75.0 million by December 15, 2022, so we were required to grant penny warrants representing 1.5% of the ordinary share capital to the bondholders, and if we had failed to raise at least \$150.0 million by March 31, 2023, we would have been required to grant penny warrants representing 1.0% of the ordinary share capital to the bondholders. Since we had not raised \$75.0 million of net proceeds by December 15, 2022, we issued 4,198,807 warrants to the bondholders on December 31, 2022. Each new warrant entitles the bondholders, upon exercise, to receive from us one fully paid and non-assessable Ordinary Share, at the exercise price of one cent (\$0.01) per share. If the bondholders exercise their warrants and we issue new Ordinary Shares, the existing shareholders will be diluted. As of February 15, 2023, holders of 1,924,251 warrants, representing 1,924,251 Ordinary Shares, had elected to exercise their warrants. Following the issuance of the December 2022 Convertible Bonds and the closing of the private placement of Ordinary Shares for gross proceeds of \$137.0 million on February 10, 2023, we are not obligated to issue the additional 1.0% warrants to the bondholders.

The Aztiq Convertible Bond and December 2022 Convertible Bonds include conversion features for the bondholders. Under the terms of these convertible bond agreements, bondholders have the right to convert their bonds into Ordinary Shares credited as fully paid on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date, for a conversion price of \$10.00 per share. If the bondholders decide to convert the debt into Ordinary Shares, the share ownership of our existing shareholders will be diluted as a result of the issuance of new Ordinary Shares to the bondholders.

The Warrants may not continue to be in the money, and they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment.

The exercise price for our Warrants is \$11.50 per Ordinary Share. We believe the likelihood that warrant holders will exercise their Public Warrants and Private Placement Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Ordinary Shares. If the trading price for our Ordinary Shares is less than \$11.50 per share, we believe warrant holders will be unlikely to exercise their Warrants. There is no guarantee that the Warrants will continue to be in the money following the time they become exercisable and prior to their expiration, and as such, the Warrants may expire worthless.

The Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and OACB, and were assumed at the time of the Closing by us, pursuant to a warrant assignment, assumption and amendment agreement by and between us, OACB, Continental Stock Transfer & Trust Company, Computershare Inc. and Computershare Trust Company. Computershare is currently the warrant agent. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity, correct any defective provision or correct any mistake, amend the definition of "Ordinary Cash Dividend" or add or change any provisions with respect to matters or questions arising under the warrant as the parties may deem necessary or desirable and that the parties deem shall not adversely affect the rights of the warrant holders, but requires the approval by the holders of at least 50% of the then-outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment and, solely with respect to any amendment to the terms of the Private Placement Warrants or any provision of the warrant agreement with respect to the private placement warrants, 50% of the number of the then outstanding Private Placement Warrants. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then-outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the warrants, convert the warrants into cash, shorten the exercise period or decrease the number of Ordinary Shares purchasable upon exercise of a warrant.

## We may redeem the Warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making such warrants worthless.

We may redeem the Warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making such warrants worthless. We have the ability to redeem outstanding Public Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the closing price of Ordinary Shares equals or exceeds \$18.00 per share (as adjusted for share subdivisions, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading day period ending on the third trading day prior to the date on which a notice of redemption is sent to the warrant holders. We will not redeem the warrants as described above unless a registration statement under the Securities Act covering Ordinary Shares issuable upon exercise of such warrants is effective and a current prospectus relating to those Ordinary Shares is available throughout the 30-day redemption period. If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force holders (i) to exercise the Public Warrants and pay the exercise price therefor at a time when it may be disadvantageous to do so, (ii) to sell the Public Warrants at the then-current market price when holders might otherwise wish to hold the Public Warrants, or (iii) to accept the nominal redemption price which, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of the Public Warrants.

In addition, we will have the ability to redeem the outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.10 per warrant if, among other things, the closing price

of Ordinary Shares equals or exceeds \$10.00 per share (as adjusted for share sub-divisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) on the trading day prior to the date on which a notice of redemption is sent to the warrant holders. Recent trading prices for Ordinary Shares have exceeded the \$10.00 per share threshold at which the Warrants would become redeemable. In such a case, the holders will be able to exercise their Warrants prior to redemption for a number of Ordinary Shares determined based on the redemption date and the fair market value of Ordinary Shares.

The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time when the underlying share price is higher and (2) may not compensate the holders for the value of the Warrants.

The JOBS Act permits "emerging growth companies" like Alvotech to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, which may make our Ordinary Shares less attractive to investors.

We currently qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Its Business Startups Act of 2012, which is referred to as the "JOBS Act." As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act. As a result, our shareholders may not have access to certain information they deem important.

We cannot predict if investors will find Ordinary Shares less attractive because we rely on these exemptions. If some investors find Ordinary Shares less attractive as a result, there may be a less active trading market and share price for Ordinary Shares may be more volatile. We may incur increased legal, accounting and compliance costs associated with Section 404 of the Sarbanes-Oxley Act.

We have issued and expect to issue in the future additional Ordinary Shares, including under our Management Incentive Plan. Any such issuances would dilute the interest of our shareholders and likely present other risks.

On December 1, 2022, our Remuneration Committee authorized the grant of restricted stock units ("RSUs") to certain employees, executive officers and directors under the Alvotech Management Incentive Plan (the "2022 Plan"). Subject to certain vesting and other terms and conditions, the RSUs may be settled in Ordinary Shares. If all RSUs vest and are exchanged for Ordinary Shares, the combined grants may result in an aggregate of 7,659,049 Ordinary Shares.

Ordinary Shares reserved issued under the 2022 Plan become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. The aggregate number of Ordinary Shares initially reserved under the 2022 Plan is 16,802,386 shares. In August 2022, we filed a registration statement on Form S-8 under the Securities Act to register Ordinary Shares or other securities convertible into or exchangeable for Ordinary Shares pursuant to the 2022 Plan, and we may file additional registration statements on Form S-8 in the future.

Accordingly, shares registered under such registration statements may be immediately available for sale in the open market.

Any such issuances of additional Ordinary Shares or securities convertible into Ordinary Shares:

may significantly dilute the equity interests of our investors;

- may subordinate the rights of holders of Ordinary Shares if securities are issued with rights senior to those afforded Ordinary Shares; and
- may adversely affect prevailing market prices for Ordinary Shares.

We expect to issue a substantial number of Ordinary Shares or other securities convertible into or exchangeable for Ordinary Shares, including under our 2022 Plan.

Our Warrants are exercisable for Ordinary Shares and certain Bonds are convertible into Ordinary Shares, the exercise of which would increase the number of shares eligible for future resale in the public market and result in dilution to our shareholders.

As a result of the Business Combination being consummated, outstanding warrants to purchase an aggregate of 10,916,647 Ordinary Shares became exercisable in accordance with the terms of the Warrant Agreement. These warrants became exercisable on July 15, 2022. The exercise price of these warrants is \$11.50 per share, or approximately \$125.5 million, assuming none of the warrants are exercised through "cashless" exercise. To the extent such warrants are exercised, additional ordinary shares will be issued, which will result in dilution to the holders of Ordinary Shares and increase the number of shares eligible for resale in the public market. We believe the likelihood that warrant holders will exercise their warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our ordinary shares. If the trading price for our ordinary shares is less than \$11.50 per share, we believe holders of our Public Warrants and Private Placement Warrants will be unlikely to exercise their warrants. On March 10, 2023, the last reported sales price of our ordinary shares was \$13.22 per share and the last reported sales price of our Public Warrants was \$2.44 per warrant. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of ordinary shares. However, there is no guarantee that the Public Warrants will continue to be in the money prior to their expiration, and as such, the warrants may expire worthless. See "—The warrants may not continue to be in the money, and they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment."

In addition, on November 16, 2022, we and the bondholders amended and restated certain terms of existing Senior Bonds and issued new senior bonds in an aggregate principal amount equal to \$70.0 million. Pursuant to the terms of the amended Senior Bonds, we were required to use commercially reasonable endeavors to raise new funding through issuance of additional Ordinary Shares (by way of ordinary shares, structured equity and/or preference shares) and/or unsecured convertible bond(s), for net proceeds of at least \$75.0 million of net proceeds by December 15, 2022, and are required to raise \$150.0 million in net proceeds by March 31, 2023. We failed to raise at least \$75.0 million by December 15, 2022, so we were required to grant penny warrants representing 1.5% of the ordinary share capital to the bondholders, and if we had failed to raise at least \$150.0 million by March 31, 2023, we would have been required to grant penny warrants representing 1.0% of the ordinary share capital to the bondholders. Since we had not raised \$75.0 million of net proceeds by December 15, 2022, we issued 4,198,807 warrants to the bondholders on December 31, 2022. Each new warrant entitles the bondholders, upon exercise, to receive from us one fully paid and non-assessable Ordinary Share, at the exercise price of one cent (\$0.01) per share. If the bondholders exercise their warrants and we issue new Ordinary Shares, the existing shareholders will be diluted. Following the issuance of the December 2022 Convertible Bonds and the closing of the private placement of Ordinary Shares for gross proceeds of approximately \$137.0 million on February 10, 2023, we are not obligated to issue the additional 1.0% warrants to the bondholders.

The Aztiq Convertible Bond and December 2022 Convertible Bonds include conversion features for the bondholders. Under the terms of these convertible bond agreements, bondholders have the right to convert their bonds into Ordinary Shares credited as fully paid on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date, for a conversion price of \$10.00 per share.

If the bondholders decide to convert the debt into Ordinary Shares, the share ownership of our existing shareholders will be diluted as a result of the issuance of new Ordinary Shares to the bondholders.

The Warrants may not continue to be in the money, and they may expire worthless and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50% of the then outstanding Public Warrants approve of such amendment.

The exercise price for our Warrants is \$11.50 per Ordinary Share. We believe the likelihood that warrant holders will exercise their Public Warrants and Private Placement Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Ordinary Shares. If the trading price for our Ordinary Shares is less than \$11.50 per share, we believe warrant holders will be unlikely to exercise their Warrants. There is no guarantee that the Warrants will continue to be in the money following the time they become exercisable and prior to their expiration, and as such, the Warrants may expire worthless.

The Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and OACB, and were assumed at the time of the Closing by us, pursuant to a warrant assignment, assumption and amendment agreement by and between us, OACB, Continental Stock Transfer & Trust Company, Computershare Inc. and Computershare Trust Company. Computershare is currently the warrant agent. The warrant agreement provides that the terms of the warrants may be amended without the consent of any holder to cure any ambiguity, correct any defective provision or correct any mistake, amend the definition of "Ordinary Cash Dividend" or add or change any provisions with respect to matters or questions arising under the warrant as the parties may deem necessary or desirable and that the parties deem shall not adversely affect the rights of the warrant holders, but requires the approval by the holders of at least 50% of the then-outstanding Public Warrants to make any change that adversely affects the interests of the registered holders of Public Warrants. Accordingly, we may amend the terms of the Public Warrants in a manner adverse to a holder if holders of at least 50% of the then-outstanding Public Warrants approve of such amendment and, solely with respect to any amendment to the terms of the Private Placement Warrants or any provision of the warrant agreement with respect to the private placement warrants, 50% of the number of the then outstanding Private Placement Warrants. Although our ability to amend the terms of the Public Warrants with the consent of at least 50% of the then-outstanding Public Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the warrants, convert the warrants into cash, shorten the exercise period or decrease the number of Ordinary Shares purchasable upon exercise of a warrant.

#### We may redeem the Warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making such warrants worthless.

We may redeem the Warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making such warrants worthless. We have the ability to redeem outstanding Public Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the closing price of Ordinary Shares equals or exceeds \$18.00 per share (as adjusted for share subdivisions, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading day period ending on the third trading day prior to the date on which a notice of redemption is sent to the warrant holders. We will not redeem the warrants as described above unless a registration statement under the Securities Act covering Ordinary Shares issuable upon exercise of such warrants is effective and a current prospectus relating to those Ordinary Shares is available throughout the 30-day redemption period. If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force holders (i) to exercise the Public Warrants and pay the exercise price therefor at a time when it may be disadvantageous to do so, (ii) to sell the Public Warrants at the then-current market price when holders might otherwise wish to hold the Public Warrants, or (iii) to accept the nominal redemption price which, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of the Public Warrants.

In addition, we will have the ability to redeem the outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.10 per warrant if, among other things, the closing price of Ordinary Shares equals or exceeds \$10.00 per share (as adjusted for share sub-divisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) on the trading day prior to the date on which a notice of redemption is sent to the warrant holders. Recent trading prices for Ordinary Shares have exceeded the \$10.00 per share threshold at which the Warrants would become redeemable. In such a case, the holders will be able to exercise their Warrants prior to redemption for a number of Ordinary Shares determined based on the redemption date and the fair market value of Ordinary Shares.

The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time when the underlying share price is higher and (2) may not compensate the holders for the value of the Warrants.

The JOBS Act permits "emerging growth companies" like Alvotech to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, which may make our Ordinary Shares less attractive to investors.

We currently qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Its Business Startups Act of 2012, which is referred to as the "JOBS Act." As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act. As a result, our shareholders may not have access to certain information they deem important.

We cannot predict if investors will find Ordinary Shares less attractive because we rely on these exemptions. If some investors find Ordinary Shares less attractive as a result, there may be a less active trading market and share price for Ordinary Shares may be more volatile. We may incur increased legal, accounting and compliance costs associated with Section 404 of the Sarbanes-Oxley Act.

# Risks Related to Investment in a Luxembourg Company and Our Status as a Foreign Private Issuer

As a foreign private issuer, we are exempt from a number of U.S. securities laws and rules promulgated thereunder and is permitted to publicly disclose less information than U.S. public companies must. This may limit the information available to holders of Ordinary Shares.

We qualify as a "foreign private issuer," as defined in the SEC's rules and regulations, and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. For example, some of our key executives may sell a significant amount of Ordinary Shares and such sales are not required to be disclosed as promptly as public companies organized within the United States would have to disclose. Accordingly, once such sales are eventually disclosed, the price of Ordinary Shares may decline significantly.

Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. We are also not subject to Regulation FD under the Exchange Act, which prohibits companies from selectively disclosing material nonpublic information to certain persons without concurrently making a widespread public disclosure of such information. Accordingly, there may be less publicly available information concerning Alvotech than there is for U.S. public companies.

As a foreign private issuer, we will file an Annual Report on Form 20-F within four months of the close of each fiscal year ended December 31 and furnish reports on Form 6-K relating to certain material events promptly after we publicly annuance these events. However, because of the above exemptions for foreign private issuers, which we rely on, our shareholders are not afforded the same information generally available to investors holding shares in public companies that are not foreign private issuers.

As a foreign private issuer, we are also permitted to follow home country practice in lieu of certain corporate governance rules of the Nasdaq, including those that require listed companies to have a majority of independent directors and independent director oversight of executive compensation, nomination of directors and corporate governance matters. For example, as of December 31, 2022, only three of our eight directors are independent as defined in Nasdaq listing standards and applicable SEC rules. As long as we rely on the foreign private issuer exemption, a majority of our board of directors will not be required to be independent directors and our compensation committee will not be required to be composed entirely of independent directors. Accordingly, holders of our securities may not have the same protections afforded to shareholders of listed companies that are subject to all of the applicable corporate governance requirements.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses. This would subject us to U.S. GAAP reporting requirements which may be difficult for us to comply with.

As a "foreign private issuer," we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. Under those rules, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter, and, accordingly, the next determination will be made with respect to our status on June 30, 2023.

In the future, we could lose our foreign private issuer status if a majority of our ordinary shares are held by residents in the United States and we fail to meet any one of the additional "business contacts" requirements. Although we intend to follow certain practices that are consistent with U.S. regulatory provisions applicable to U.S. companies, our loss of foreign private issuer status would make such provisions mandatory. The regulatory and compliance costs to us under U.S. securities laws if we are deemed a U.S. domestic issuer may be significantly higher. If we are not a foreign private issuer, we will be required to file periodic reports on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. For example, we would become subject to the Regulation FD, aimed at preventing issuers from making selective disclosures of material information.

We also may be required to modify certain policies to comply with good governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements of Nasdaq that are available to foreign private issuers. For example, Nasdaq's corporate governance rules require listed companies to have, among other things, a majority of independent board members and independent director oversight of executive compensation, nomination of directors, and corporate governance matters. As a foreign private issuer, we are permitted to follow home country practice in lieu of the above requirements. We intend to follow Luxembourg practice with respect to quorum requirements for shareholder meetings in lieu of the requirement under Nasdaq Listing Rules that the quorum be not less than 33 1/3% of the outstanding voting shares. Under our articles of association, at an ordinary general meeting, there is no quorum requirement and resolutions are adopted by a simple majority of validly cast votes. In addition, under our articles of association, for any resolutions to be considered at an extraordinary general meeting of shareholders, the quorum shall be at least one half of our issued share capital unless otherwise mandatorily required by law and resolutions are adopted with a majority of at least two thirds of the validly cast votes. As long as we rely on the foreign private issuer exemption to certain of Nasdaq's corporate governance standards, a majority of the directors on our board of directors are not required to be independent directors, our remuneration committee is not required to be comprised entirely of

independent directors, and we will not be required to have a nominating and corporate governance committee. Also, we would be required to change our basis of accounting from IFRS to U.S. GAAP, which may be difficult and costly for us to comply with. If we lose our foreign private issuer status and fail to comply with U.S. securities laws applicable to U.S. domestic issuers, we may have to de-list from Nasdaq and could be subject to investigation by the SEC, Nasdaq and other regulators, among other materially adverse consequences.

We are organized under the laws of Luxembourg and a substantial amount of our assets are not located in the United States. It may be difficult to obtain or enforce judgments or bring original actions against us or the members of our board of directors in the United States.

We are organized under the laws of Luxembourg. In addition, a substantial amount of our assets are located in Iceland and elsewhere outside the United States.

Furthermore, some of the members of our board of directors and officers reside outside the United States and a substantial portion of our assets are located in Iceland and elsewhere outside the U.S. Investors may not be able to effect service of process within the United States upon us or these persons or enforce judgments obtained against us or these persons in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the U.S. federal securities laws. Likewise, it also may be difficult for an investor to enforce in U.S. courts judgments obtained against us or these persons in courts located in jurisdictions outside the United States, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws. Awards of punitive damages in actions brought in the United States or elsewhere are generally not enforceable in Luxembourg.

As there is no treaty in force on the reciprocal recognition and enforcement of judgments in civil and commercial matters between the United States and Luxembourg other than arbitral awards rendered in civil and commercial matters, courts in Luxembourg will not automatically recognize and enforce a final judgment rendered by a U.S. court. A valid judgment obtained from a court of competent jurisdiction in the United States may be entered and enforced through a court of competent jurisdiction in Luxembourg, subject to the applicable enforcement procedures (*exequatur*) as set out in the relevant provisions of the Luxembourg New Civil Procedure Code and in Luxembourg case law. Pursuant to Luxembourg case law, the granting of *exequatur* is subject to the following requirements:

- the judgment of the U.S. court is final and enforceable (*exécutoire*) in the United States and has not been fully enforced in the United States and/or in any other jurisdiction;
- the U.S. court had full jurisdiction over the subject matter leading to the judgment (that is, its jurisdiction was in compliance both with Luxembourg private international law rules and with the applicable domestic U.S. federal or state jurisdictional rules);
- the U.S. court applied to the dispute the substantive law which is designated by the Luxembourg conflict of laws rules or, at least, such court's order must not contravene the principles underlying those rules (based on recent case law and legal doctrine, it is not certain that this condition would still be required for an exequatur to be granted by a Luxembourg court);
- the judgment was granted following proceedings where the counterparty had the opportunity to appear and, if it appeared, to present a
  defense, and the decision of the foreign court must not have been obtained by fraud, but in compliance with the rights of the defendant;
- the U.S. court acted in accordance with its own procedural laws;
- · the judgment of the U.S. court does not contradict an already issued judgment of a Luxembourg court, and
- the decisions and the considerations of the U.S. court must not be contrary to Luxembourg international public policy rules (as such term is interpreted under the laws of Luxembourg) or have been given in

proceedings of a tax or criminal nature or rendered subsequent to an evasion of Luxembourg law (*fraude à la loi*). Awards of damages made under civil liabilities provisions of the U.S. federal securities laws, or other laws, which are classified by Luxembourg courts as being of a penal or punitive nature (for example, fines or punitive damages), might not be recognized by Luxembourg courts. Ordinarily, an award of monetary damages would not be considered as a penalty, but if the monetary damages include punitive damages, such punitive damages may be considered a penalty and therefore not enforceable in Luxembourg.

Similarly, as Alvotech hf., a subsidiary of Alvotech, has significant assets in Iceland, investors may seek to enforce judgments obtained in the United States against Alvotech in Iceland. As there is no treaty in force on the reciprocal recognition and enforcement of judgments in civil and commercial matters between the United States and Iceland other than arbitral awards entered in civil and commercial matters, courts in Iceland will not automatically recognize and enforce a final judgment rendered by a U.S. court. Based on recent Icelandic case law, a valid judgment obtained from a court of competent jurisdiction in the United States will not be directly recognized and enforceable in Iceland. Instead, the judgment creditor would need to issue fresh legal proceedings against the judgment debtor in Iceland in which the U.S. judgment would serve as evidence, in addition to other evidence and legal arguments regarding the merits of the case, which will be adjudicated by the Icelandic courts.

If an original action is brought in Luxembourg or Iceland, without prejudice to specific conflict of law rules, Luxembourg courts or Icelandic courts may refuse to apply the designated law (i) if the choice of such foreign law was not made bona fide or (ii) if the foreign law was not pleaded and proved or (iii) if pleaded and proved, such foreign law is contrary to mandatory Luxembourg or Icelandic laws or incompatible with Luxembourg or Icelandic public policy rules. In an action brought in Luxembourg or Iceland on the basis of U.S. federal or state securities laws, Luxembourg courts or Icelandic courts may not have the requisite power to grant the remedies sought. Also, an *exequatur* may be refused by a Luxembourg court in respect of punitive damages.

In practice, Luxembourg courts tend not to review the merits of a foreign judgment, although there is no clear statutory prohibition of such review. A contractual provision allowing the service of process against a party to a service agent could be overridden by Luxembourg or Icelandic statutory provisions allowing the valid serving of process against a party in accordance with applicable laws at the domicile of the party. Further, in the event any proceedings are brought in a Luxembourg court in respect of a monetary obligation payable in a currency other than the Euro, a Luxembourg court would have the power to give judgment as an order to pay the obligation in a currency other than the Euro. However, enforcement of the judgment against any party in Luxembourg would be available only in Euros and, for such purposes, all claims or debts would be converted into Euros. Similarly, in the event any proceedings are brought in an Icelandic court in respect of a monetary obligation payable in a currency other than the Icelandic Krona, an Icelandic court would have the power to give judgment as an order to pay the obligation in a currency other than the Icelandic Krona.

In addition, actions brought in a Luxembourg court against Alvotech, the members of our board of directors, our officers, or the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, Luxembourg courts generally do not award punitive damages. Litigation in Luxembourg also is subject to rules of procedure that differ from the U.S. rules, including, with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Luxembourg would have to be conducted in the French or German language, and all documents submitted to the court would, in principle, have to be translated into French or German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a Luxembourg court predicated upon the civil liability provisions of the U.S. federal securities laws against Alvotech, the members of our board of directors, our officers, or the experts named herein. In addition, even if a judgment against Alvotech, the non-U.S. members of our board of directors, our officers, or the experts named in this prospectus based on the civil liability provisions of the U.S. federal securities laws is obtained, a U.S. investor may not be able to enforce it in United States or Luxembourg courts.

Our directors and officers have entered into, or will enter into, indemnification agreements with Alvotech. Under such agreements, the directors and officers will be entitled to indemnification from Alvotech to the fullest extent permitted by Luxemburg law against liability and expenses reasonably incurred or paid by him or her in connection with any claim, action, suit, or proceeding in which he or she would be involved by virtue of his or her being or having been a director or officer and against amounts paid or incurred by him or her in the settlement thereof. Luxembourg law permits us to keep directors indemnified against any expenses, judgments, fines and amounts paid in connection with liability of a director towards Alvotech or a third-party for management errors i.e., for wrongful acts committed during the execution of the mandate (mandat) granted to the director by Alvotech, except in connection with criminal offenses, gross negligence or fraud. The rights to and obligations of indemnification among or between Alvotech and any of our current or former directors and officers are generally governed by the laws of Luxembourg and subject to the jurisdiction of the Luxembourg courts, unless such rights or obligations do not relate to or arise out of such persons' capacities listed above. Although there is doubt as to whether U.S. courts would enforce this indemnification provision in an action brought in the United States under U.S. federal or state securities laws, this provision could make it more difficult to obtain judgments outside Luxembourg or from non-Luxembourg jurisdictions that would apply Luxembourg law against our assets in Luxembourg.

Luxembourg, Icelandic and European Union insolvency and bankruptcy laws are substantially different from U.S. insolvency and bankruptcy laws and may offer our shareholders less protection than they would have under U.S. insolvency and bankruptcy laws.

As a company organized under the laws of Luxembourg and with its registered office in Luxembourg, we are subject to Luxembourg insolvency and bankruptcy laws in the event any insolvency proceedings are initiated against us including, among other things, Council and European Parliament Regulation (EU) 2015/848 of May 20, 2015, on insolvency proceedings (recast). Should courts in another EU Member State determine that the insolvency and bankruptcy laws of that country apply to us in accordance with and subject to such EU regulations, the courts in such EU Member State could have jurisdiction over the insolvency proceedings initiated against us.

We are the parent company of Alvotech hf., our main operating subsidiary. As a company organized under the laws of Iceland and with its registered office in Iceland, Alvotech hf. is subject to Icelandic insolvency and bankruptcy laws in the event any insolvency proceedings are initiated against it.

Insolvency and bankruptcy laws in Luxembourg, Iceland or the relevant other EU Member State, if any, may offer our shareholders less protection than they would have under U.S. insolvency and bankruptcy laws and make it more difficult for them to recover the amount they could expect to recover in a liquidation under U.S. insolvency and bankruptcy laws.

The rights of our shareholders and responsibilities of our directors and officers are governed by Luxembourg or Icelandic law and differ in some respects from the rights and responsibilities of shareholders under other jurisdictions, including jurisdictions in the United States or Iceland.

Our corporate affairs are governed by our articles of association, and by the laws governing companies incorporated in Luxembourg, including the Luxembourg Company Law. The rights of our shareholders and the responsibilities of our directors and officers under Luxembourg law differ in some respects from those of a company incorporated under other jurisdictions, including jurisdictions in the U.S. corporate laws governing Luxembourg companies may not be as extensive as those in effect in U.S. jurisdictions and the Luxembourg Company Law in respect of corporate governance matters might not be as protective of shareholders as the corporate law and court decisions interpreting the corporate law in Delaware, where the majority of U.S. public companies are incorporated. Further, under Luxembourg law there may be less publicly available information about us than would otherwise be published by or about U.S. issuers. In addition, we anticipate that all of our shareholder meetings will take place in Luxembourg. Our shareholders may have more difficulty in protecting

their interests in connection with actions taken by our directors and officers or our principal shareholders than they would as shareholders of a corporation incorporated in a jurisdiction in the United States.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding Ordinary Shares and Warrants adversely, then the price and trading volume of Ordinary Shares and Warrants could decline.

The trading market for Ordinary Shares and Warrants is influenced by the research and reports that industry or securities analysts may publish about us, our business, our market, or our competitors. If any of the analysts who may cover us change their recommendation regarding Ordinary Shares and Warrants adversely, cease to provide coverage or provide more favorable relative recommendations about our competitors, the price of Ordinary Shares and Warrants would likely decline. If any analyst who may cover OACB were to cease coverage of us or fail to regularly publish reports on it, we could lose visibility in the financial markets, which could cause price or trading volume of our Ordinary Shares and Warrants to decline.

Only two majority shareholders may have significant influence over the outcome of matters submitted to shareholders for approval, which may prevent us from engaging in certain transactions.

As of the date hereof, our two largest shareholders, Alvogen and Aztiq, own approximately 73.2% of our Ordinary Shares. As a result of their ownership interest and other contractual rights, these shareholders exercise significant influence over all matters requiring shareholder approval, including the appointment of directors and the approval of significant corporate transactions. Such corporate action might be taken even if other shareholders oppose them. This ownership and control may also have the effect of delaying or preventing a future change in control, impeding a merger, consolidation, takeover or other business combination that may be in the best interest of us and any other shareholder. This ownership and control may be used to prevent us from raising additional funds through the sale of equity which may make it more difficult for us to finance our operations.

We rely on certain significant shareholders and affiliated entities for certain key services in the execution of our strategy and business operations.

We have entered into various service agreements with our direct and indirect significant shareholders and related entities, such as Alvogen, Aztiq, Alvogen Malta (Out-Licensing) Ltd. ("Adalvo") and Floki Invest ehf. ("Floki"). These services include, among others, marketing and IT services, corporate administrative, legal, financial, facility management, salary processing, supply chain management, portfolio and market intelligence research, regulatory compliance, quality audit, and publishing services, and certain administrative and financial services related to our Reykjavik facility. These services are key to our ability to continue to execute on our business strategy and to keep our business operations uninterrupted. Any interruption in the provision of these services may materially harm our business. In addition, because the providers of the services are direct or indirect significant shareholders and related entities, we may not be able or willing to enforce our contractual rights under the service agreements the same way we would if the service providers were unrelated third-party providers. See also "—We currently rely on Alvogen's ERP solution and other components of Alvogen's IT infrastructure and will continue to do so for the foreseeable future".

# **Risks Related to Taxation**

If we are treated as a "passive foreign investment company" for any taxable year, U.S. investors could be subject to adverse U.S. federal income tax consequences.

A non-U.S. corporation generally will be treated as a "passive foreign investment company" ("PFIC") for U.S. federal income tax purposes if either (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by

value, is passive income or (ii) at least 50% of its assets in a taxable year (ordinarily determined based on fair market value and averaged quarterly over the year), including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business), and gains from the disposition of passive assets.

Based on our analysis of our income, assets, activities and market capitalization, we believe that we were not treated as a PFIC for our taxable year ended December 31, 2022. However, the determination of whether a non-U.S. corporation is a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, the total value of our assets for PFIC testing purposes may be determined in part by reference to our market capitalization from time to time, which may fluctuate considerably. As a result, there can be no assurance with respect to our status as a PFIC for any taxable year, and our U.S. counsel expresses no opinion with respect to our PFIC status for any taxable year.

If we are treated as a PFIC, U.S. investors may be subject to certain adverse U.S. federal income tax consequences, including additional reporting requirements. For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, as well as certain elections that may be available to U.S. investors, see "Material U.S. Federal Income Tax Considerations – Passive Foreign Investment Company Rules." U.S. investors should consult their tax advisors regarding the application of the PFIC rules in their particular circumstances.

# If we or any of our subsidiaries is treated as a "controlled foreign corporation," certain U.S. investors could be subject to adverse U.S. federal income tax consequences.

Generally, under the Code, if a U.S. investor owns or is treated as owning, directly, indirectly, or constructively, 10% or more of the total value or total combing voting power of our stock, the U.S. investor may be treated as a "United States shareholder" with respect to each controlled foreign corporation ("CFC") in our corporate structure, if any. A non-U.S. corporation generally will be a CFC if United States shareholders own, directly, indirectly, or constructively, 10% or more of the total value or total combined voting power of the stock of such corporation. Because our corporate structure includes a U.S. corporate subsidiary, our non-U.S. corporate subsidiaries, including any non-U.S. corporate subsidiaries that may be formed or acquired in the future, will be treated as CFCs, regardless of whether we are treated as a CFC. A United States shareholder of a CFC may be required to annually report and include in its U.S. taxable income its pro rata share of the CFC's "Subpart F income", "global intangible low-taxed income," and investments of earnings in U.S. property, regardless of whether the CFC makes any distributions to its shareholders. Furthermore, an individual United States shareholder with respect to a CFC generally will not be allowed certain tax deductions and foreign tax credits that are allowed to a corporate United States shareholder. Failure to comply with CFC reporting obligations may also subject a United States shareholder to significant penalties. There can be no assurance that the Company will provide to any United States shareholder information that may be necessary for the United States shareholder to comply with its CFC reporting and tax paying obligations. U.S. investors should consult their tax advisors regarding the application of the CFC rules in their particular circumstances.

# Changes in tax laws and unanticipated tax liabilities could adversely affect us.

We are subject to taxes in Luxembourg and numerous other jurisdictions. Alvotech hf., our operating subsidiary, is subject to taxes in Iceland and other foreign jurisdictions. Our tax liabilities could be adversely affected in the future by a number of factors, including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and the outcome of tax audits in various jurisdictions around the world. Many of the countries in which we and our subsidiaries do business have or are expected to adopt changes to tax laws, including as a result of the Base

Erosion and Profit Shifting final proposals from the Organization for Economic Co-operation and Development and specific country anti-avoidance initiatives. For instance, the IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations. Such tax law changes increase uncertainty and may adversely affect our tax provision, possibly with retroactive effect. We regularly assess all of these matters to determine the adequacy of our tax provision, which is subject to significant judgment.

# We may not be able to utilize a significant portion of our Iceland NOL carryforwards.

As of December 31, 2022, Alvotech hf., the Icelandic operational entity, had net operating loss ("NOL") carryforwards. There can be no certainty that we will generate revenue from sales of products outside the sixteen countries in Europe and Canada, where AVT02 is currently marketed, in the foreseeable future, if ever, and we may never achieve profitability. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. In the absence of profitability, any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

# **USE OF PROCEEDS**

We could potentially receive up to an aggregate of \$125.5 million if all the Warrants are exercised to the extent such Warrants are exercised for cash. We expect to use the net proceeds from the exercise of the Warrants for general corporate purposes. The exercise price of our Public Warrants and Private Placement Warrants is \$11.50 per warrant. We believe the likelihood that Warrant holders will exercise their Warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the trading price of our Ordinary Shares. If the trading price for our Ordinary Shares is less than \$11.50 per share, we believe holders of our Public Warrants and Private Placement Warrants will be unlikely to exercise their Warrants. To the extent that the Warrants are exercised on a "cashless basis," the amount of cash we would receive from the exercise of the Warrants will decrease.

All Ordinary Shares offered by the Selling Securityholders pursuant to this prospectus will be sold by the Selling Securityholders for their respective amounts. We will not receive any of the proceeds from these sales.

#### DIVIDEND POLICY

From the annual net profits of Alvotech, at least 5% shall each year be allocated to the reserve required by applicable laws (the "Legal Reserve"). That allocation to the Legal Reserve will cease to be required as soon and as long as the Legal Reserve amounts to 10% of the amount of the share capital of Alvotech The legal reserve is not available for distribution.

We do not anticipate paying any cash dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business and product candidates.

In accordance with the Luxembourg law of August 10, 1915, on commercial companies, as amended ("Luxembourg Company Law"), the general meeting of shareholders, by a simple majority vote and based on the recommendation of our board of directors, shall resolve how the remainder of the annual net profits, after allocation to the Legal Reserve, will be disposed of by allocating the whole or part of the remainder to a reserve or to a provision, by carrying it forward to the next following financial year or by distributing it, together with carried forward profits, distributable reserves or share premium to the shareholders, each Ordinary Share entitling to the same proportion in such distributions.

The board of directors may resolve that Alvotech pays out an interim dividend to the shareholders, subject to the conditions of article 461-3 of the Luxembourg Company Law and Alvotech's articles of association. The board of directors shall set the amount and the date of payment of the interim dividend.

Any share premium, assimilated premium or other distributable reserve may be freely distributed to the shareholders subject to the provisions of the Luxembourg Company Law and Alvotech's articles of association.

Distributions may be lawfully declared and paid only if our net profits and/or distributable reserves are sufficient under Luxembourg Company Law.

Thus, in case of a dividend payment, each shareholder is entitled to receive a dividend right pro rata according to his or her respective shareholding. The dividend entitlement lapses upon the expiration of a five-year prescription period from the date of the dividend distribution. The unclaimed dividends return to Alvotech's accounts. However, Alvotech does not anticipate paying cash dividends on our Ordinary shares in the foreseeable future.

A Luxembourg withholding tax of 15% is generally due on dividends and similar distributions made by us to our shareholders, unless a reduced treaty rate or the participation exemption applies. No withholding tax is levied on capital gains and liquidation proceeds.

There is no law, governmental decree or regulation in Luxembourg that would affect the remittance of dividends or other distributions by us to non-resident holders of our Ordinary Shares, other than withholding tax requirements. In certain limited circumstances, the implementation and administration of international financial sanctions may affect the remittance of dividends or other distributions. There are no specified procedures for non-resident holders to claim dividends or other distributions.

We are a holding company and have no material assets other than our ownership of shares in our subsidiaries. To the extent we pay a dividend or other distribution on our Ordinary Shares in the future, we will generally cause our operating subsidiaries to make distributions to us in an amount sufficient to cover any such dividends or distributions. Our subsidiaries' ability to make distributions to us is subject to their capacity to generate sufficient earnings and cash flow, and may also be affected by statutory accounting and tax rules.

# **CAPITALIZATION**

The following table sets out our consolidated capitalization and indebtedness as of December 31, 2022. The information below should be read together with the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	Alvotech As of December 31, 2022 (USD in thousands)
Cash and cash equivalents and restricted cash	
Cash and cash equivalents	66,427
Restricted cash	25,187
Total Cash and cash equivalents and restricted cash	91,614
Borrowings and other financial liabilities	
Borrowings	744,654
Current maturities of borrowings	19,916
Liabilities to related parties	1,131
Total Borrowings and other financial liabilities	765,701
Equity	
Share capital	2,126
Share premium	1,058,432
Other reserves	30,582
Translation reserve	(1,442)
Accumulated deficit	(1,654,114)
Total Equity	(564,416)
Total Capitalization	201,285

#### **BUSINESS**

# **Company Overview**

We are a vertically integrated biotech company focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Our purpose is to improve the health and quality of life of patients around the world by improving access to proven treatments for various diseases. Since our inception, we have built our company with key characteristics we believe will help us capture the substantial global market opportunity in biosimilars: a leadership team that has brought numerous successful biologics and biosimilars to market around the world; a purpose-built biosimilars R&D and manufacturing platform; commercial partnerships in global markets; and a diverse, expanding portfolio and pipeline addressing many of the largest disease areas and health challenges globally.

A biosimilar is a biological medicine that is highly similar to and has no clinically meaningful differences from an existing approved biological, or reference product. Much as generics do for off-patent small-molecule drugs, biosimilars provide a cost-effective alternative with no clinically meaningful difference to biologic medicines whose patent exclusivity has expired. Many patient, policy, industry and regulatory organizations share our view that the availability of quality, affordable biosimilars is critical to the long-term sustainability of health systems and medical innovation globally. Cost savings generated by biosimilars can be used to treat more people and to sustain the cost of investment in the next generations of innovative therapies. We see both the discovery of novel therapies, which is the focus of many biopharmaceutical companies, and innovating access to medicines, which is our core focus, as critical to the purpose of the pharmaceutical industry as a whole—to deliver breakthrough, life-changing medicines to as many patients as possible, whoever and wherever they are.

We aim to achieve our mission by becoming a leading supplier of biosimilars globally. To do this, we have built a distinctive and comprehensive platform for developing and manufacturing biosimilars at scale. Our platform is designed to enable us to execute the product development and scale-up process in-house: from identifying therapeutic areas and target product candidates with significant unmet patient and market need through R&D, leveraging gold-standard host cell lines, cell-culture processes and Good Manufacturing Practice ("GMP") manufacturing, clinical testing, and regulatory approvals. In order to give our products global reach with local expertise, we have formed strategic commercialization partnerships with leading pharmaceutical companies covering global markets. We license our intellectual property to partners in exchange for milestone payments and royalties.

Developing and manufacturing biosimilars is a time-consuming, capital intensive, complex and historically uncertain undertaking. We currently have eight product candidates in our portfolio and pipeline targeting serious diseases with unmet patient and market need. Product candidates in our pipeline address reference products treating autoimmune, eye, and bone disorders, as well as cancer.

# **Our History**

Alvotech hf. was founded in 2013 in Reykjavik, Iceland with the aim of creating a highly integrated platform company focused exclusively on developing and manufacturing biosimilars for the global market. Over the past ten years, we have invested steadily and methodically in building a fully integrated platform, enabling us to control quality, cost and speed to market of our developed products, representing a key competitive advantage in the biosimilar business.

Alvotech, previously known as Alvotech Lux Holdings S.A.S., was incorporated under the laws of the Grand Duchy of Luxembourg on August 23, 2021, as a simplified joint stock company (*société par actions simplifiée*) solely for the purpose of effectuating the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech (the "Business Combination"), which was consummated on June 15, 2022. Immediately after the effectiveness of the first merger and the redemption in the process of the Business

Combination, the legal form of Alvotech changed from a simplified joint stock company (*société par actions simplifiée*) to a public limited liability company (*société anonyme*) under Luxembourg law. We own no material assets other than our interests in Alvotech hf., acquired in the Business Combination through the merger with Alvotech Holdings S.A., and do not operate any business. Following and as a result of the Business Combination, our business is conducted through Alvotech hf., our direct, wholly-owned subsidiary and its subsidiaries.

# Our Pipeline

# Product selection

We believe that the nature and quality of our platform enable us to innovate and systematically produce high quality biosimilars for treating a broad range of serious diseases. We believe that our ability to generate and capture efficiencies across research and development, manufacturing and commercialization gives us key advantages in quality, cost and speed to market when competing with both originator and other biosimilar companies.

Our fully integrated capabilities provide us wide breadth and flexibility in deciding which biosimilar opportunities to pursue, optimizing the commercial, scientific and medical impact of each program as part of our portfolio. We evaluate a rigorous set of six criteria to select our candidates:

- Competitive situation: Evaluates originator value, brand and longevity, as well as competition from biosimilars and originators alike, on an ongoing basis.
- Launch timing: Aims to be among the first wave of biosimilars to every reference product.
- Portfolio fit: Seeking balance across the portfolio, assesses volume/price ratio and the ability to leverage the breadth of our R&D and manufacturing capabilities.
- Differentiation: Seeks opportunities where platform differentiation can be applied and exploited, for example, in potential for interchangeability (for the U.S. market), delivery device and product presentations.
- *Feasibility and cost*: Ongoing assessment for technical, clinical, intellectual property and regulatory issues as well as cost and time analysis for CMC, clinical and potential for interchangeability.
- Partner insights: Strategic input from commercial partners taken into account at every stage.

In addition to the above, our platform is built for flexibility that may allow us to expand into other healthcare products areas such as respiratory and primary care products.

# Our Pipeline

Through our rigorous product selection and development platform, we have been able to build a pipeline comprising five disclosed biosimilar products covering a variety of therapeutic areas, including autoimmune, eye, and bone disorders, as well as cancer. Our lead program, AVT02, a high concentration formulation biosimilar to Humira, received regulatory approval in the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia. It is currently marketed in sixteen countries in Europe and in Canada and dossiers are under review in multiple countries, including in the United States. We expect to launch AVT02, if approved by the FDA, in the United States on July 1, 2023. We also have a second clinical program, AVT04, which uses the same SP2/0 host cell line as Stelara. In January 2023, we announced that the FDA had accepted for review a BLA for AVT04. We anticipate that the FDA's review will be completed in the second half of 2023. We, directly or indirectly through our partners, also submitted marketing applications for AVT04 in the EU and in Japan in the second half of 2022. We announced the initiation of clinical programs for AVT06 and AVT03 in July 2022 and the initiation of the pharmacokinetic study for AVT05 in January 2023. Beyond our registrational and clinical programs, we have

one additional product, AVT23, that is in late-stage development, and two undisclosed programs in pre-clinical development.

# Our Programs

# AVT02, our high-concentration biosimilar to Humira

Humira (adalimumab) inhibits tumor necrosis factor ("TNF"), which is a protein in the body that can cause inflammation. Developed and predominantly marketed by AbbVie, adalimumab is prescribed to treat a variety of inflammatory conditions including, rheumatoid arthritis, psoriatic arthritis, Crohn's disease, ulcerative colitis, plaque psoriasis among other indications. Humira is approved and marketed in a high concentration formation (100 mg/mL) across four doses (10 mg, 20 mg, 40 mg, 80 mg) which account for roughly 80% of the U.S. Humira market. In 2021, Humira worldwide net revenues were approximately \$20.7 billion. A lower concentration formulation (50 mg/mL) is also approved and marketed across three strengths (10 mg, 20mg, 40mg). Adalimumab has many of the core characteristics we look for in selecting a candidate for development. We are aiming to be in the first wave of launches in the United States, as there are currently only two other companies developing high concentration formulation biosimilars to Humira, and have launched AVT02 in sixteen countries in Europe and in Canada in 2022. Additionally, adalimumab fits well within our immunology portfolio and manufacturing capabilities. The competitive landscape and broad market opportunity for adalimumab is attractive to us and our commercial partners as we are aware of only one other company that is pursuing an interchangeability designation referencing the high concentration form of the product, and others that are doing low concentration.

- Since 2021, we, directly or through our partners, received regulatory approval for AVT02 in the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia. AVT02 is currently marketed in sixteen countries in Europe and in Canada. Dossiers are under review in multiple countries, including in the United States.
- In February 2022, the FDA accepted our BLA supporting interchangeability for review. In December 2022, the FDA issued a CRL for the February 2022 BLA requesting a correction of the same deficiencies identified on the August 2022 CRL with respect to the original BLA in order for approval.
- In addition, we also successfully conducted a switching study to support a potential designation for interchangeability in the U.S. Pursuant to the U.S. AbbVie Agreement, we settled all U.S. litigation related to AVT02 with AbbVie, and, subject to regulatory approval from the FDA, expect to launch AVT02 in the United States on July 1, 2023.
- Pursuant to the various settlement agreements with AbbVie, we resolved all intellectual property disputes with AbbVie relating to AVT02, except in Canada, in 2022.

We have conducted five clinical studies to date for AVT02, comprising of over 1,500 subjects. In September of 2021, we announced that topline results from a randomized study in patients demonstrate no increased risk in terms of safety or decreased efficacy from repeated switches between the administration of Humira (adalimumab) and our high-concentration interchangeable biosimilar candidate AVT02, compared to the administration of Humira without switching (AVT02-GL-302). The study has been conducted in 568 patients with Chronic Plaque Psoriasis across five countries and 25 sites in Central and Eastern Europe. Further, no significant differences were observed in clinical pharmacokinetics (which was the primary endpoint), or the clinical efficacy, safety or immunogenicity between the switching cohort and the reference product cohort. During the lead-in period (Week 1 to Week 12), only one patient reported a serious Treatment Emergent Adverse Event ("TEAE"). During the switching module phase (Week 12 to Week 28), six patients (1.1%) reported serious TEAEs, of which five patients (1.8%) were in the AVT02/EU-Humira/AVT02 group, and one patient was in the EU-Humira group. During the extension phase, three patients reported TEAEs. All ten of the TEAEs were assessed by the investigator as non-drug related. Two of the TEAEs were assessed by the sponsor as drug related: one event was COVID-19 pneumonia, which was resolved in the patient with sequelae, and the other event was

extrapulmonary tuberculosis. Only one TEAE was fatal and the cause was determined to be unexpected and non-drug related (accidental carbon monoxide poisoning). None of the drug related serious TEAEs were unexpected. The most commonly reported serious TEAE was COVID-19 (30%). Statistical analysis for this study was conducted in line with the scientific standards and in agreement with relevant regulatory guidelines and the specific advice received from major agencies during the course of development.

# AVT04, our proposed biosimilar to Stelara

Stelara (ustekinumab) is a human IgG1k monoclonal antibody against the human interleukin-12 and -23 cytokines. Marketed by Janssen, Stelara is prescribed to treat a variety of inflammatory conditions including psoriatic arthritis, Crohn's disease, ulcerative colitis, plaque psoriasis among other indications. In 2021, Stelara's worldwide net revenues were nearly \$14.1 billion.

We are using an SP2/0 host cell line, which is the same manufacturing host cell line as Stelara. The infrequent dosing for Stelara is enabled by an extended half-life that is partially achieved due to the high levels of sialic acid on the monoclonal antibody. The SP2/0 host cell line allows for more efficient sialyation of the molecule as compared to CHO. Therefore, matching of the post-translational modifications and structure in a biosimilar development program for Stelara also, in our view, requires matching of the host cell line. Developing our biosimilar in the same host cell line as the originator for a product that requires such a long half-life, de-risks the approval process and creates potential differentiation relative to other biosimilar developers. In July 2021, we announced the initiation of clinical studies for AVT04. A pharmacokinetic (PK) comparability study (AVT04-GL-101) is being conducted in healthy volunteers and is being conducted simultaneously in New Zealand and Australia. This is a single dose, 3-arm, parallel design to compare pharmacokinetic, safety, tolerability and immunogenicity of a single 45mg/0.5mL subcutaneous dose of AVT04, European-sourced Stelara (EU-Stelara) and U.S. sourced Stelara (US-Stelara). The study is being conducted in Australia and New-Zealand and the enrollment of all 294 participants was completed in the fourth quarter of 2021. The primary endpoints for this PK study are peak concentration (Cmax) and the total area under the curve (AUC0-inf). The secondary endpoints for the study include (but are not limited to) additional PK parameters, adverse events and clinical laboratory assessments, tolerability and immunogenicity parameters. This study is still ongoing, therefore allocation to either one of the treatment arms is not possible until the database lock, when the study will be unblinded. Statistical analysis for this study is being conducted in line with the scientific standards and in agreement with relevant regulatory guidelines and the specific advice receiv

Simultaneously, we are conducting a comparative, confirmatory efficacy and safety clinical study (AVT04-GL-301) in patients with chronic plaque psoriasis. The clinical study is conducted at approximately 30 investigational sites in five countries across Central and Eastern Europe. The enrollment (581 patients) was completed in September 2021. The primary efficacy endpoint for AVT04-GL-301 study is Psoriasis Area and Severity Index (PASI) percent improvement from Baseline at Week 12. The key secondary endpoints include additional efficacy parameters, adverse events and clinical laboratory assessments, tolerability, immunogenicity and pharmacokinetic parameters as well as quality of life scores. The safety extension phase of the study has recently been completed and full readout of the results will take place in the near future. Statistical analysis for this study is being conducted in line with the scientific standards and in agreement with relevant regulatory guidelines and the specific advice received from major agencies during the course of development. In May 2022, we reported positive topline results for AVT04-GL-301.

In January 2023, we announced that the FDA had accepted for review a BLA for AVT04. We anticipate that the FDA's review will be completed in second half of 2023. In February 2023, we announced that the EMA had accepted a Marketing Authorization Application for AVT04. We, directly or indirectly through our partners, also submitted marketing applications for AVT04 in Japan and Canada in the second half of 2022.

# AVT06, our proposed biosimilar to Eylea

Eylea (aflibercept) is a recombinant fusion protein formulated for intravitreal administration consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1. Developed and marketed by Bayer and Regeneron, Eylea is prescribed to treat conditions including age-related macular degeneration, macular edema, and diabetic retinopathy. In 2022, Eylea worldwide net revenues were nearly \$10.3 billion.

Both the reference product as well as our proposed biosimilar AVT06 are produced in recombinant Chinese hamster ovary cells.

We originally planned to conduct the AVT06 trial, in part, in ten sites (for 44 patients) located in Ukraine and eight sites (for 19 patients) in Russia. Due to the Russia-Ukraine conflict, we replaced these Ukrainian and Russian sites with sites in new countries with similar patient enrollment projections. As of today, we do not expect the conflict in Ukraine to have a material impact on us as a whole or on the development or clinical trial of AVT06.

In July 2022, we initiated the confirmatory clinical study for AVT06. The objective of the study is to compare AVT06 and Eylea in terms of efficacy, safety, and immunogenicity in adult patients with neovascular (wet) age-related macular degeneration (AMD). The study (ALVOEYE) is a randomized, double-masked, parallel-group, multicenter, therapeutic equivalence study, and is expected to enroll approximately 444 participants in approximately 16 different countries in Europe, South America, Asia (India and Japan) and South Africa. The study's primary endpoint is change from baseline to week 8 in best-corrected visual acuity (BCVA). Statistical analysis for this study will be conducted in line with the scientific standards and in agreement with relevant regulatory guidelines and the specific advice received from major agencies during the course of development. We have engaged with global regulatory authorities on our development strategy in order to align our program with expectations from regulatory authorities and further limit development risk. We target the release of topline data in the second half of 2023.

# AVT03, our proposed biosimilar to both Xgeva and Prolia

Xgeva and Prolia have the same active ingredient, denosumab, but the products are approved for different indications, patient populations, doses and frequencies of administration. Denosumab is a human IgG2 monoclonal antibody with affinity and specificity for human RANKL, receptor activator of nuclear factor kappa-B ligand. Developed and predominately marketed by Amgen, Xgeva is prescribed to prevent bone fracture, spinal cord compression or the need for radiation or bone surgery in patients with certain types of cancer, and Prolia is prescribed to prevent bone loss and increase bone mass. In 2022, Xgeva and Prolia worldwide net revenues were over \$6.1 billion.

Both the reference product as well as our proposed biosimilar AVT03 are produced in recombinant Chinese hamster ovary cells.

AVT03 is in the pre-clinical phase and has been developed to have a high degree of analytical similarity to the originator. Further we have engaged with global regulatory authorities on our development strategy in order to align our program with expectations from regulatory authorities and further limit development risk.

Our clinical program consists of a pharmacokinetic (PK) study in healthy volunteers and a confirmatory efficacy and safety study in patients with post-menopausal osteoporosis.

We originally planned to conduct the AVT03 trial, in part, in five sites (for a projected 40 patients) in Ukraine. Due to the Russia-Ukraine conflict, we replaced these Ukrainian trial sites with sites elsewhere. As of today, we do not expect the conflict in Ukraine to have a material impact on us as a whole or on the development or clinical trial of AVT03.

In July 2022, we announced the initiation of the pharmacokinetic (PK) study (AVT03-GL-P01) in healthy volunteers aimed to compare the pharmacokinetic, safety, tolerability and immunogenicity between AVT03 and the reference product Prolia after administration of 60mg single subcutaneous dose. The study is expected to have a 2-arm, double-blind, parallel design and to be conducted at selected pharmacology units in Australia and New Zealand. We aim to recruit approximately 206 participants for this study. The primary endpoints for this PK study are peak concentration (Cmax) and the total area under the serum concentration-time curve (AUC0-inf). The secondary endpoints for this study include (but are not limited to) additional PK parameters, adverse events and clinical laboratory assessments, tolerability and immunogenicity parameters. Statistical analysis for this study will be conducted in line with the scientific standards and in agreement with relevant regulatory guidelines and the specific advice received from major agencies during the course of development. We target the release of topline data in second half of 2023. In August of 2022, we announced the initiation of a confirmatory patient study for AVT03. The objective of the study is to demonstrate clinical similarity of AVT03 to Prolia in terms of efficacy, safety, immunogenicity, and pharmacokinetics in postmenopausal women with osteoporosis. We target the release of topline data in 2024.

# AVT05, our proposed biosimilar to Simponi and Simponi Aria

Simponi / Simponi Aria (golimumab), inhibits TNF, which is a protein in the body that can cause inflammation. Simponi / Simponi Aria are prescribed to treat a variety of inflammatory conditions including, RA, psoriatic arthritis, ulcerative colitis among others. Simponi is a sterile solution of golimumab antibody supplied for subcutaneous use. Simponi Aria injection is a sterile solution supplied for intravenous use. We are developing both forms of the product. In 2022, Simponi and Simponi Aria generated over \$3.3 billion in sales. AVT05 is expressed in an SP2/0 host cell line, which matches the cell used by the developer of the originator. AVT05 is in early phase development. We have developed AVT05 to match the host cell line used by the developer of the originator and we intend to pursue interchangeability designation. In January 2023, we announced the initiation of our pharmacokinetic study for AVT05 in January 2023. We target the release of topline data in the first half of 2024.

# AVT23 (also called BP001), our proposed biosimilar to Xolair

Xolair (omalizumab) is an antibody that targets free IgE and is used to treat patients with allergic asthma, chronic spontaneous urticaria (CSU) and nasal polyp. Xolair, the only currently approved product containing omalizumab, was first approved in 2003. In 2022, global sales of Xolair reached \$3.7 billion.

AVT23 is in late-stage development. AVT23 will be produced using Biosana's proprietary 3C process technology, a fully continuous operation to allow for highly productive, low-cost manufacturing. A pharmacokinetic (PK) comparability study has been completed showing that AVT23's bioavailability, safety, tolerability and immunogenicity are comparable to those of Xolair.

# Undisclosed programs, AVT16 and AVT33

We are currently in early phase development for two additional products that have not yet been publicly disclosed, AVT16, a proposed biosimilar to an immunology product, and AVT33, a proposed biosimilar to an oncology product. We expect the estimated combined originator market opportunity for these two products to exceed \$30 billion.

# **Our Market Opportunity**

Background on Biologics

Biologic medicines (biologics) are complex pharmaceutical products that typically contain one or more active substances made by or derived from a biological source. Conventional medicines are typically chemically

synthesized small molecules that are easily identified and characterized; in contrast, biologics are large, complex molecules that require unique characterization techniques and generally tend to be sensitive to heat and microbial contamination. The creation innovation and advancement of biologics are the result of cutting-edge research and these medicines have provided novel treatments for a variety of illnesses such as rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis, multiple sclerosis, age-related macular degeneration, diabetic macular edema and numerous types of cancer. Biologics are designed to have very specific effects and to interact with specific targets in the patient's body, mainly on the outside of cells. A more targeted mechanism of action leads to a greater chance of the medicine having the desired effect against the disease and results in fewer side effects compared to traditional medicines. The effectiveness of biologics has led to an increase of investment in R&D within the pharmaceutical sector for biologic medicines.

# Background on Biosimilars

A biosimilar is a biological medicine that is highly similar to and has no clinically meaningful differences from an existing approved biological, or reference product. Biosimilars are approved according to the same standards of pharmaceutical quality, safety and efficacy that apply to all biological medicines and typically have the same amino acid sequence.

Biosimilars offer a lower cost alternative to their name-brand reference products, and have no clinically meaningful difference in terms of safety, purity or potency when compared to reference products. Because they are designed to be highly similar to already approved biologics, the success rate for developing biosimilars is considerably higher, and the R&D cost proportionally much lower. While the average originator biologic takes an average of 12 years to develop at a cost of more than \$2.5 billion, the average biosimilar can usually be developed six to nine years and at a cost of between \$100.0 to 200.0 million. Further, this is significantly different to generics, which are simpler to manufacture, can typically developed in two years or less at a cost of less than \$10 million, and without needing clinical trials.

The availability of biologics and their rapidly increasing prices have forced healthcare systems and payors around the world, public and private alike, into difficult tradeoffs in the effort to balance the best quality of care, accessibility, sustainability and cost. As biosimilars provide a more affordable alternative to payors and patients, they offer the potential to improve the accessibility of many life-altering treatments to many more patients. More broadly, lower costs for existing treatments can make healthcare systems more sustainable and free up resources to pay for the next generation of innovative brand-name therapies, and the R&D infrastructure that sustains future drug discovery. In this way, we believe that biosimilars can also help to sustain the global biomedical innovation ecosystem as a whole.

While biosimilars share similarities with generics, there are significant differences, including the complexity of development and manufacturing. For traditional medications, generic products can generally be considered identical to the branded product in form and function. In the case of biologics and biosimilars, the complexity of a biologic molecule means that the biosimilar product is not identical in form to the branded product, and some variability from the branded reference product is considered inherent to the process. However, there is no clinically meaningful functional difference between a biosimilar and the reference product in safety, purity or potency.

# Our Strategy

Our strategy is to leverage our integrated platform to develop and manufacture high quality biosimilars and to then work with our global network of partners to commercialize the portfolio and pipeline into markets around the world. We are advancing multiple product candidates towards regulatory approval and intend to launch our portfolio and pipeline into over 90 markets around the world. Our strategy can be summarized by the following;

 Platform: At the heart of our strategy is our fully integrated biosimilars platform. We have a purpose-built facility with a footprint of approximately 280,000 square feet that includes R&D, process, quality,

manufacturing and headquarters in Reykjavik, Iceland. Additionally, we have cell line, process, analytics and glycoprotein characterization sites in Germany; a regulatory, legal and government affairs office in the United States; and an R&D, clinical, and regulatory strategy center in Switzerland. This infrastructure and know-how enables us to have a full set of capabilities and control, from analysis of reference products and cell line development through fill-and-finish GMP manufacturing and regulatory approvals. Further, it provides us the ability to innovate efficiencies in every step of the process and project those cost-savings throughout our portfolio. We have demonstrated manufacturing capabilities using both of the two most widely-used host cell lines — Chinese hamster ovary ("CHO") and SP2/0 — as well as cell culture processes, fed batch and perfusion.

- Portfolio and Pipeline: We are currently advancing a portfolio and pipeline of 8 biosimilars and biosimilar candidates through the development and global regulatory process. Our portfolio and pipeline covers a variety of therapeutic areas, including autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Where possible, we seek to develop differentiated products as is the case with the company's lead candidate, AVT02, a biosimilar to Humira. For the U.S. market, our proposed biosimilar has been developed as a high-concentration form, which is the predominant product profile that is marketed by the originator company. Additionally, we are seeking an interchangeability designation for the proposed biosimilar in the U.S. market. In 2022, we have begun commercialization of AVT02, through our commercial partners, of our first biosimilar into Canada and 16 markets across Europe.
- Commercial Partnerships: We have formed a global network of strategic commercial partnerships to ensure that our products can reach the patients in geographies across the world. Our partners include Teva (US), STADA (EU), Yangtze (China), Fuji Pharma Co., Ltd (Japan), Cipla/Cipla Gulf/Cipla Medpro (Australia, New Zealand, South Africa/Africa), JAMP Pharma (Canada), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS (Middle East and Africa), Abdi Ibrahim (Turkey), Kamada (Israel), Biosana (Australia, Netherlands, Singapore), and MegaLabs, Stein, Libbs, Tuteur and Saval (Latin America), Advanz Pharma (EEA, U.K., Switzerland, Canada, Australia and New Zealand), among others. Our partners' deep knowledge of the markets and economic, regulatory, payor and reimbursement landscapes in the countries they serve optimizes our commercial opportunity and ability to reach patients in these markets in a way we could not do on our own. We partner only with trusted, market leaders and develop close strategic relationships with these partners that align our interests and the partners' interests for success.
- *People:* As of December 31, 2022, we employ over 900 people around the world. Over 85% of our workforce is dedicated to manufacturing and development of biosimilars. We seek to attract and retain the highest quality talent in order to achieve our mission and execute our strategy.
- ESG and corporate responsibility: We aim to maintain and further develop our commitment to sustainability and corporate responsibility beyond our fundamental mission of expanding access to medicines while lowering costs for patients. We are developing and implementing a comprehensive environmental, social and governance ("ESG") framework to collect, monitor and report data that assess our environmental and social impact as well as provide transparent disclosures on governance. We believe that we have certain intrinsic business and operational qualities that may favorably position us to optimize our ESG impact, including the location of our headquarters and manufacturing in Iceland. This enables us to minimize our environmental impact by conducting our principal operations using nearly 100% renewable energy and in a geography with abundant cold and hot water. We intend to make a difference for patients around the world by working strategically towards increasing patient access to medicines, supporting the sustainability of health systems and, where feasible, conducting clinical trials in areas with relatively lower access to healthcare.

# **Our Platform**

We believe that the nature and quality of our platform enable us to innovate and systematically develop and manufacture biosimilar medicines. We consider this ability, and that our platform can generate and capture

efficiencies all along the research and development, manufacturing and sales and marketing chain, to be fundamental advantages when competing with both originator and other biosimilar companies in quality, cost and speed to market.

# The challenges of biosimilars development

Making biosimilars—biologic medicines that are highly similar to and without clinically meaningful differences from their reference products in terms of safety, purity and potency—is a fundamentally complex task. It requires, among other things, highly specialized expertise and infrastructure, time, and significant capital. Success in the biosimilar space is largely determined by the ability to make biosimilars efficiently and consistently.

We believe that these same barriers to entry also create opportunities for differentiation. The capital investment, sophisticated infrastructure and scientific/technical expertise required are principal reasons that the biosimilar divisions of large originator biopharmaceutical companies, who have access to all of these, have dominated the sector's early years. But these biosimilars divisions within larger organizations have competing internal demands for resources, including people, R&D and manufacturing facilities. As a result, biosimilars are often viewed as a secondary business. Such internal competition makes consistent and replicable operational control and efficiencies more difficult and costly to achieve, and biosimilars also tend to receive less focus in marketing and distribution. Conversely, smaller companies may not have all of the internal capabilities needed for development or the capital resources to invest in such capabilities. These constraints may require these smaller companies to outsource key parts of the R&D and manufacturing process, thereby potentially losing control over quality or the ability to innovate and control costs.

# Research & Development

Our research and development is solely focused on the development of biosimilar medicines, which require considerable time and substantial financial investment. We intend to continue to commit significant resources in financial and human capital to development activities going forward, with the aim of offering more affordable biologic medicines, globally. We also strive to identify opportunities where a level of differentiation can be applied to the development program to enable improved commercial success.

Biosimilar medicines are highly similar to their reference products and typically have identical primary amino acid structure. They are held to the same high-quality standards as innovative biopharmaceuticals. The ultimate goal in the development of biosimilar medications is to develop therapeutics that are highly similar to and have no clinically meaningful difference from their reference products. In order to demonstrate this, we apply rigorous processes in the development of our product candidates.

A biosimilarity claim must demonstrate totality of evidence with respect to physiochemical characteristics, biologic activity, pharmacokinetics, clinical safety and efficacy, and therapeutic indication. Extensive analytical comparisons to the reference products are conducted, followed by nonclinical and clinical pharmacokinetic ("PK") and pharmacodynamic ("PD") studies, as required. Finally, a clinical efficacy and safety study is conducted to resolve any remaining uncertainty that the product is biosimilar. This process is described in more detail below.

# Early phase development

In this phase of development it is vital to establish a manufacturing process that delivers highly similar product to the reference product. This starts with cell line development activities, where clones having characteristics similar to the reference product with acceptable productivity are selected. Following this a competitive commercial manufacturing process for drug substance and drug product is developed to deliver a product that is highly similar to the reference product, enabling future investment in GMP manufacturing.

Numerous characterization methods are also applied to ensure our biosimilar candidate is highly similar to the reference product in structure and function. Significant time and effort is spent on this similarity evaluation to enable a streamlined clinical program in subsequent development phases with a higher probability of success.

# Pre-clinical development and GMP manufacturing

In this phase, the manufacturing process is scaled-up up from small pilot scale batches to commercial scale in a commercial site. The goal is to manufacture product with a high degree of analytical similarity to the reference product while also confirming the highest quality product is produced.

In parallel, regulatory authorities in the United States, EU and other geographies are engaged to discuss the overall development strategy, in order to ensure the ultimate submission package is approvable in all major regions. Non-clinical studies may also be conducted as required, based on the individual biosimilar program and alignments with regulatory authorities.

# Clinical studies

Clinical studies are conducted in this phase to support product registration. Typically, a PK study is performed to demonstrate PK equivalence of the proposed biosimilar to the approved reference products such as those available in both the U.S. and EU. A global, confirmatory clinical efficacy and safety study is typically also performed to demonstrate that there are no clinically meaningful differences between the proposed biosimilar and the reference product. Depending on the specific program, these two studies may be conducted within one larger study or, conversely, additional small studies may need to be performed to support registration. When both a PK and confirmatory efficacy and safety study is required, we take the calculated risk to execute these studies in parallel (where feasible), which enables the fast track to licensing application submission for the program.

In parallel to the clinical studies being conducted, manufacturing process characterization and validation is completed, in addition to completion of the analytical similarity assessment supporting registration.

# **Interchangeability**

When practical and commercially relevant in the U.S. market and other countries and regions, we seek interchangeability designation such as is the case with our lead product, AVT02, our biosimilar candidate to Humira. Interchangeability is a U.S. regulatory construct and according to the FDA, an interchangeable product will have met additional data requirements and so may be substituted for the reference product without the intervention of a prescriber. The substitution may occur at the pharmacy, much as generic drugs are substituted for brand name drugs, subject to varying U.S. state pharmacy laws. Biosimilars, including those designated as interchangeable products, have the potential to reduce health care costs. The concept of interchangeability for biosimilars was signed into law through the Biologics Price Competition and Innovation Act in 2010. In order to be considered interchangeable, a biosimilar must meet additional requirements, including the execution of a "switching study," utilizing the reference product and biosimilar product in patients. The vast majority of states have passed laws regarding substitution for interchangeable products.

# Submission and approval

The ultimate goal is to submit a globally vetted, high-quality dossier that enables first-pass approval based on the totality of evidence for the comparative analytical, Chemistry, Manufacturing and Controls, ("CMC"), and clinical data. Extrapolation principles also allow for attaining a full label matching the reference product other than indications specifically protected by regulatory exclusivity. We work closely with health authorities through the review process to enable approval at the earliest possible time after dossier submission, ensuring we can remain competitive with market entry.

Manufacturing & Supply

# **Manufacturing Facilities**

Our corporate headquarters, main manufacturing site and a large part of our R&D division are located in Reykjavik, Iceland. This facility provides us with purpose-built GMP and has highly integrated capabilities for producing biosimilars at scale. The facility is currently approximately 140,000 square feet and utilizes single-use technology to manufacture drug substance and drug product. It houses our R&D, quality control and quality assurance teams and has an active and valid GMP certificate issued by the Icelandic Medicines Authority authorizing Investigational Medicinal Product and commercial manufacturing. In December 2020, we broke ground on an expansion of our Reykjavik facility that will double the total footprint, adding another 140,000 square feet. The expansion is expected to be completed in 2023 and will give additional redundancy in drug product capacity, assembly of combination products and devices, and secondary packaging. Additionally, the expansion will support increased warehousing and other supportive functions. With the expansion of the Reykjavik facility's manufacturing capabilities, we expect our capabilities to be able to meet the demand for our products, after obtaining regulatory approval and commercial launch, in the near future.

On November 16, 2022, we purchased the facility from ATP Holdings ehf. See "Certain Relationships and Related Party Transactions—Aztiq Facility Contribution" for a description of this transaction.

# Third Party Suppliers, Manufacturers and Raw Materials

Our manufacturing processes utilize single-use processing technology for both drug substance and drug product. Our manufacturing is therefore reliant on the availability of single-use components to complete production. We source these components from various reputable third-party suppliers. However, the price of these materials and components is subject to market forces and competing demands. Increases in the cost of components would have an adverse effect on our forecasted cost of goods. In certain cases, we may rely on only one approved source for a particular component and shortages may significantly impact our ability to manufacture drug substance and drug product. Finding alternative suppliers may not be possible or cause material delay to development plans or commercial production. We have the ability and are currently evaluating opportunities for redundancies in our manufacturing processes in order to mitigate risk and control costs.

We also require the use of certain reagents and materials in order to develop and produce biologic medicines. We acquire these reagents and materials through reputable third parties that specialize in the production and sourcing of these reagents and materials. These materials are widely available commodities. However, unforeseen shortages in these materials may have an adverse effect on either the price of these materials or could cause delays in our development or commercialization timelines.

AVT02 and certain other products within our pipeline require the use of auto-injector devices. We work closely with our vendor in order to assure availability and manage risk through inventory management and relationship management. Our current arrangement with our supplier utilizes a proprietary design.

Master cell banks and working cell banks are critical components in biologic medicine manufacturing. A cell bank is a collection of ampoules of uniform composition stored under defined conditions, each containing an aliquot of a single pool of cells. The master cell bank is generally derived from the selected cell clone containing the expression construct that has been encoded to produce the protein of interest, such as a specific monoclonal antibody with a defined amino acid sequence. This unique aliquot of cells allows for a consistent high quality biologic medicine to be produced. The working cell bank is derived by expansion of one or more ampoules of the master cell bank and is used for routine manufacturing. Both the master cell bank and working cell bank are central to obtaining regulatory approval for manufacturing and marketing biologic medicine. Without well-characterized and well-controlled master and working cell banks, the manufacturing process could be susceptible to non-ideal product variability. The quality of the manufactured biologic product is dependent on the quality of the cells used for our manufacturing, and having a sufficient supply of master and working cell banks is

important for a consistent manufacturing process. The master cell banks and working cell banks for our lead product candidates are produced at either an EU or U.S.-based contract manufacturing organization and then transferred internally to both the Reykjavik site in Iceland and J lich site in Germany for supply continuity and redundancy. The availability of master cell banks is critical to our ability to manufacture products for the commercial market. Should our cell banks (despite any redundancies) be compromised, we would be unable to produce usable products for patients in any market.

# Sales and Marketing

To date, we have chosen to market and commercialize our products through numerous strategic partnerships rather than sell a single global license to an individual commercial partner. By partnering with multiple leading regional partners who would likely be able place a higher value on licenses due to their core market(s) focus, we believe we can achieve higher return for the rights of our products. This also better ensures focus from partners on our portfolio. Additionally, by partnering with multiple partners, we are able to enhance local market knowledge and expand our geographic reach by mitigating our risk of being dependent on one single partner.

By outsourcing sales and marketing, we believe we are able to realize and leverage the following benefits:

- Global reach: By commercializing through best-in-class partners, we can reach nearly all markets around the world, including key markets in the U.S., Europe, Japan, Canada, Australia, and various international markets across regions such as Latin America and Asia. This global approach provides diversification and opportunities for growth often overlooked by companies that focus solely on the U.S. and Europe.
- Local expertise: Our commercial strategy allows us to leverage the expertise from our partners. Our partners' expertise in managing numerous local regulatory and commercial landscapes has been built up over many years and would be difficult, to replicate internally across all global markets. We believe our partners will enable us to bring our products to market more effectively, than if we were to pursue a commercial strategy on our own.
- *Portfolio scale:* Our commercial strategy also allows us to combine our products with larger portfolios (via our partners) which, through the benefit of cross-selling, should enhance the attractiveness of our products. Furthermore, through a portfolio approach, we are able to receive the benefits of our partners established relationships with payors and providers.
- Product selection flexibility: As a company focused only on developing and manufacturing biosimilars, our product selection model is not complicated by an in-house set of innovator products, nor is it confined to specific therapeutic areas. We do not need to make product selection decisions to fit a pre-existing commercial strategy or sales and marketing infrastructure, but rather we can take a flexible approach to product selection, evaluating candidates based on their clinical merits, partner preferences and commercial opportunity. We are able to access markets through an existing network or create a new network through our partnership model in various therapeutic areas and various geographies.
- *Platform leveragability:* Our commercial strategy also allows for the creation of a highly leverageable platform. Products may be added without significant changes in Sales and Marketing or G&A infrastructure. We believe this leveragability, after achieving critical mass through our launches, can create a company more profitable than we would otherwise be, had we decided to create a global commercial infrastructure and distribute our product through that network.
- *Milestones:* We expect to receive milestone payments from our partners at the time of signature of the commercial agreement and at various points in time through development and in some cases, post approval. Milestones offset the cost of development and create a shared risk alignment with our partners. We further view milestones as a consistent and repeating revenue opportunity, as we fully expect to continue to add product candidates to our pipeline, and subsequently out-license them in order to maximize the value of our dedicated biosimilar development and manufacturing infrastructure.

As a result of our strategic decision to form commercial partnerships, we do not currently have direct sales, marketing, and distribution capabilities. In order for us to commercialize any product on our own, we would need to either develop an infrastructure to facilitate sales, marketing and distribution or contract with third parties that have the requisite capabilities. Our in-house strategic sales and marketing expertise is currently focused on relationships with our existing partners and finding new partner relationships. As of December 31, 2022, we have contracted with 18 partners to sell, market, and distribute our products in certain agreed upon territories.

# Commercial partnerships

We have formed strategic commercialization partnerships with leading pharmaceutical companies covering global markets. A commercialization partnership generally consists of two components. First, under the licensing component, we and the partner agree that we will develop the product candidate and that the partner will have the exclusive right to market, distribute and sell our product in a certain territory once the product has been approved by the relevant regulator. In return, the partner agrees to make certain upfront or milestone payments to us, which can be any or a combination of the following:

- Upfront payments upon the signing of the agreement;
- Milestone payments related to the development of the products, for example upon the completion of a clinical trial with respect to the relevant product candidate;
- Milestone payments related to the regulatory approval process of the products, for example upon submitting an application for approval with or receiving approval from the relevant regulator for the relevant product candidate;
- Milestone payments related to the launch or first commercial sale of the product in the relevant territory; and
- Milestone payments related to achieving sales targets in the territory.

Under the supply component of the partnership agreements, we will generally manufacture, supply and deliver the product to each partner, and the partner will exclusively buy the product from us. The purchase price for each commercial partner, unless specifically noted otherwise in the description of the partnership agreements below, is a royalty of approximately 40% (between 35% and 45%) of the estimated net selling price or an agreed-upon applicable floor price, whichever is higher, for the duration of the agreements. The floor price is a minimum price per unit specific to each presentation to be paid by the commercial partner for the product, and is determined per each presentation and product taking into consideration Cost of Goods of manufacturing, supply and commercial market environment. Under certain partnership agreements, we may be eligible to receive additional royalty payments in periods where sales exceed certain targets. As is customary, the partnerships are concluded for durations of ten to twenty years. We recognized \$24.8 million of product revenue and \$58.2 million of license and other revenue, resulting from the commercial partnerships, for the year ended December 31, 2022. Refer to Note 5 of the consolidated financial statements included elsewhere in this prospectus for further details on the revenue recognized under these agreements.

The amounts in upfront and milestone payments and the royalty rates are negotiated between parties and depend in part on the estimated addressable market for the product and the size of the territory.

As a principal matter, we grant our partners access to the dossier, which includes our dossier of data, information and know-how relating to the relevant products that enable our partners to apply for and obtain marketing authorization in the various territories. Marketing authorizations obtained with the help of the dossier remain with the partners after the expiry of the partnership. Partners only return the marketing authorization to us when we terminate the agreement for cause. Certain partners may also get access to our trademarks.

Our principal partners and partnerships include:

# United States—Teva

License and Development Agreement with Teva Pharmaceuticals International GmbH

In August 2020, we entered into a license and development agreement with Teva which was amended in June 2021, and again in February 2023, for the commercialization of certain biosimilar products in certain territories (the "LDA"). Under the LDA, we granted Teva an exclusive license (even as to us and our affiliates), with the right to sublicense through multiple tiers, to use, import, commercialize, and market products containing AVT02, AVT04, AVT05, AVT06 and AVT16 in the United States and each of its territories, districts and possessions, including the Commonwealth of Puerto Rico. Under the LDA, Teva has the exclusive right to reference (i) our registration dossiers of certain biosimilar products for its BLA approval, and (ii) all clinical studies conducted by or on our behalf with respect to the development of certain biosimilar products for purposes of obtaining applicable BLA approvals. Under the LDA, we granted Teva the right of first negotiation for commercialization and marketing rights in certain territories for our future biosimilar products (with some exceptions) for five (5) years from the effective date of the agreement.

As consideration for the rights granted to Teva under the LDA, Teva made upfront payments of \$40.0 million and \$35.0 million in development milestone payments. Additionally, we are eligible to receive aggregate payments of up to an additional \$425.0 million upon the achievement of certain regulatory, commercial, manufacturing and sales milestones. See Note 5 of the consolidated financial statements included elsewhere in this prospectus for further details on the revenue recognized under these agreements.

The LDA expires on a product-by-product basis ten (10) years from the first commercial sale of a product, subject to possible one-year extensions. Either party may terminate the LDA on a product-by-product basis for any material breach by the other party that is not remedied within a specified time period, if either party reasonably believes that there is a material safety issue with respect to such product, or in certain other circumstances. Teva may terminate the LDA on a product-by-product basis within certain time periods, if Teva reasonably demonstrates a lack of commercial viability for such product in which case we retain already paid milestone payments and are allowed to partner with someone else. Either party may also terminate the LDA upon the insolvency of the other party. The LDA will automatically terminate as a whole upon the termination of the Teva Product Supply Agreement, or in part with respect to any product if the Teva Product Supply Agreement is terminated with respect to such product.

In January 2023, we and Teva announced that the FDA had accepted the biologics license application for AVT04. We anticipate that the FDA's review will be completed in the second half of 2023.

On February 27, 2023, Alvotech and Teva signed an amendment to the LDA. As part of that amendment, Alvotech agreed to provide future financial consideration to Teva to assist with the cost of launching and marketing the licensed biosimilar products.

Product Supply Agreement with Teva Pharmaceuticals International GmbH

In addition to the LDA, we entered into a product supply agreement with Teva in August 2020 for the exclusive manufacture and supply of each product during such product's respective product supply term (the "PSA"). Under the PSA, we will manufacture and supply each product exclusively to Teva for marketing in the territory. We will meet purchase orders for the product that have been accepted or deemed accepted by us. Teva has agreed to a minimum order quantity for each product. Subject to some limitations, as consideration for supply of product Alvotech will receive 40% of the value of Teva's net sales of the products.

The PSA remains in force on a product-by-product basis for 10 years from launch, then continuing until terminated by either party with 12 months' notice. Either party may terminate the PSA on a product-by-product

basis for any material breach by the other party that is not remedied within a specified time period. Either party may terminate the agreement with respect to a product if the BLA approval for a product in the territory is revoked by a regulatory authority due to a health, safety or efficacy concern. With exceptions, Teva may require us to purchase any and all unsold quantities of products ordered by Teva prior to termination. We may terminate the PSA if Teva fails to purchase certain minimum quantities of each product. Additionally, either party may terminate the PSA with respect to a product if a margin split event occurred which results in a negative margin for a period of four (4) consecutive calendar quarters.

# Europe—STADA

From August to November of 2019, we entered into similar license and supply agreements ("out-license contracts") with STADA which were amended in March 2020, pursuant to which we granted STADA exclusive licenses (even as to us and our affiliates) to import, commercialize and market certain products containing AVT02, AVT03, AVT04, AVT05, AVT06 and AVT16 in the European Union and certain other countries. Under the amended agreements, STADA also received joint ownership of certain of our intellectual property covering such products in the EU and certain other countries under certain conditions. Pursuant to the amended agreements, we are required to provide, and STADA is required to obtain, all of STADA's requirements of the licensed products for a defined period of time. We are also obligated to develop the licensed products, including performing all pre-clinical and clinical activities required to submit grants to obtain marketing authorizations for the licensed products in the EU and certain other countries, whereas STADA is required to use all commercially reasonable efforts to sell, market, import and store the licensed products and we have the right to terminate if STADA does not launch after fulfillment of certain conditions. STADA will remit approximately 40% of its in-market sales to us in the form of sales-based royalties.

Subject to certain conditions, the consideration paid to us is subject to a partial or full refund to STADA on a product-by-product basis if (i) the net sales of a product fall below certain specified thresholds, (ii) the manufacture, marketing or sale of such product would result in patent infringement, or (iii) we materially breach the agreement and fail to cure within 60 days of receiving notice from STADA. The licenses granted to STADA will remain exclusive until the fifth anniversary of STADA's first sale of a product in a country, on a product-by-product and country-by-country basis. STADA may extend the exclusivity period up to three times for an additional five years by providing written notice one year prior to the expiration of the exclusivity period. Upon expiration of the exclusivity period for a product in a country, STADA will retain a non-exclusive license to import, commercialize and market such product in the country, and will be granted a worldwide, non-exclusive license to manufacture such product for sale in such country.

In May 2021, we entered into a second amendment of the AVT02 agreement to, among other things, expand the agreement to include an additional product and provide certain additional terms for the development, licensing and commercialization of such product. Under the amended agreement, we granted STADA a perpetual, exclusive license to import, commercialize and market the additional product in the EU and certain other countries. If STADA grants us a non-exclusive license to import, commercialize and market the additional product, we will be required to reimburse a portion of the milestone payments received for the development of the additional product. Upon expiration of the exclusive license of any AVT02 product in a country, STADA will be granted a worldwide, non-exclusive license to manufacture the additional product for sale in such country. Prior to the completion of development of the additional product, STADA may terminate its rights to the additional product upon 10 days written notice. Upon such termination, we would no longer be eligible for payments for the subsequent completion of milestones for the additional product.

Under the terms of these agreements, STADA made upfront payments of \$5.9 million and \$78.6 million in development milestone payments. Additionally, we are eligible to receive aggregate payments of up to an additional \$202.8 million upon the achievement of certain, regulatory, commercial, manufacturing and sales milestones. Refer to Note 5 of the consolidated financial statements included elsewhere in this prospectus for further details on the revenue recognized under these agreements.

# <u>Japan – Fuji Pharma</u>

On April 2, 2019, Alvotech and Fuji Pharma entered into a license agreement, as amended on June 23, 2020 to reflect a delay in the development process and therefore, among others, amended and restated the milestone payments, (the "Fuji Pharma AVT04 License Agreement") and a supply agreement (the "Fuji Pharma AVT04 Supply Agreement"). Under the Fuji Pharma AVT04 License Agreement, Alvotech will develop AVT04 and compile and provide a dossier of data, information and know-how relating to AVT04 to Fuji Pharma. Alvotech retains full ownership of all intellectual property rights in AVT04 and the AVT04 dossier. Fuji Pharma has the exclusive right to use the dossier to obtain and maintain regulatory approvals for AVT04 and to import, finish, market, promote, sell and distribute AVT04 in Japan. Fuji Pharma made a one-time payment on the signature date of \$4.6 million and will make an additional milestone payment to Alvotech upon the launch of the product, subject to certain conditions. If Fuji Pharma achieves annual sales in excess of certain target volumes, it will pay Alvotech an additional royalty on the net sales above the target. Under the Fuji Pharma AVT04 Supply Agreement, Alvotech will manufacture, supply and deliver the AVT04 product. Fuji Pharma will pay Alvotech a royalty or the applicable floor price, whichever is higher, for the duration of the agreement. All invoices are payable within thirty business days, in U.S. dollar and by wire transfer. The agreements terminate 20 years after the first commercial sale of AVT04 in Japan. They can be terminated by either party if the other party: (i) withholds any monies due to the other party for more than two months; (ii) commits or permits any substantial breach of any material term of the agreement; (iii) has a receiver or administrator appointed in respect of any of its assets or enters into any agreement with its creditors; or (iv) goes into liquidation. The agreements can be terminated by Fuji Pharma if (i) a competing product obtains reimbursement approval (Fuji Pharma AVT04 License Agreement) before AVT04 obtains reimbursement approval; (ii) AVT04 does not obtain reimbursement approval by November 30, 2023; or (iii) AVT04 obtains reimbursement approval at the same time two competing products obtain reimbursement approval.

On November 18, 2020, Alvotech and Fuji Pharma entered into four binding term sheets with respect to AVT06, two proposed AVT03 biosimilar products and AVT05. On February 10, 2022, Alvotech and Fuji Pharma expanded their strategic partnership and entered into an additional binding term sheet with respect to a new undisclosed biosimilar candidate currently in early phase development, and in January 2023 we announced the expansion with another undisclosed biosimilar candidate. Under the binding term sheets, Alvotech will develop the product candidates and provide a dossier of data, information and know-how relating to the relevant product to Fuji Pharma. Fuji Pharma has the exclusive right to use the dossier to obtain and maintain regulatory approvals and to import, finish, market, promote, sell and distribute the relevant product in Japan. As of December 31, 2022, Fuji Pharma made one-time payments on the signing dates of the binding term sheets of \$3.0 million and agreed to make additional payments upon the achievement of certain regulatory and development milestones. Alvotech and Fuji Pharma will enter into license and supply agreements for each product at a later date, subject to fulfilling of certain conditions related to the development of that product and the absence of the commercial launch of competing products in Japan at that time. Fuji Pharma will exclusively buy the relevant biosimilar candidate from Alvotech at a royalty or the applicable floor price, whichever is higher, for the duration of the agreement. The license and supply agreements will terminate 20 years after the first commercial sale of the relevant product in Japan. They can be terminated by either party in case a party (i) withholds any monies due to the other party for more than two months; (ii) commits or permits any substantial breach of any material term of the agreement; (iii) has a receiver or administrator appointed in respect of any of its assets or enters into any agreement with its creditors; or (iv) goes into liquidation.

In November 2022, Fuji Pharma submitted an application to the Japanese Ministry of Health, Labor and Welfare for the marketing approval of AVT04.

# Canada – JAMP Pharma

JAMP Pharma has a portfolio with more than 290 molecules and is a leader in the pharmaceutical industry in Canada. In December 2019, Alvotech entered into five license and supply agreements with JAMP Pharma

with respect to AVT02, AVT03, AVT04, AVT05 and AVT06. Under the terms of the agreements, Alvotech will develop the product candidates and provide the dossier of data, information and know-how relating to the relevant product candidate to JAMP Pharma. Alvotech retains full ownership of all intellectual property rights in the product candidates and the dossiers. JAMP Pharma has the exclusive right and obligation to use the dossier to try to obtain and maintain regulatory approvals for the relevant product and to market, sell, and distribute the products in Canada. Alvotech will manufacture, supply and deliver the product to JAMP Pharma and JAMP Pharma will exclusively buy the relevant biosimilar candidate from Alvotech at a royalty or the applicable floor price, whichever is higher, for the duration of the agreement. If the agreed remittance is less than the floor price, JAMP Pharma has the option to turn the supply price for that product into a profit share arrangement. All invoices are payable within sixty days, in euros and by wire transfer. The agreements terminate 20 year after the first commercial sale of the relevant product and are subject to certain customary early termination rights. They can be terminated by either party if the other party (i) commits or permits any substantial breach of any material term or provision of the agreement; (ii) has a receiver or administrator appointed in respect of any of its assets, or enter into any arrangement or composition with its creditors; or (iii) goes into liquidation. The agreements can be terminated by JAMP Pharma (i) in case of Phase III study failure; (ii) in case the dossier is delayed by more than 12 months from the target date; (iii) if, following the agreed launch date, Alvotech's formulation of the product or the process used in the manufacture of the product violates any third-party patent in Iceland or Canada; (iv) in case of GMP or quality failures hindering registration or launch in the Canada; (v) if Health Canada rejects or does not provide regulatory approval within 18 months of filing; (vi) if the results of due diligence performed by JAMP Pharma are not satisfactory; (viii) if 50% of the market for the product is not converted to certain product specifications at the time of launch by JAMP Pharma; or (ix) if Alvotech fails to deliver the launch order for the product within 12 months from the placing of the launch and, due to Alvotech's non- or late delivery of products, JAMP Pharma is out of stock for more than 12 consecutive months.

In January 2022, Health Canada granted marketing authorization to JAMP Pharma for AVT02. In April 2022, JAMP Pharma launched AVT02, under the trade name Simlandi, in Canada.

On August 29, 2022, Alvotech and JAMP Pharma entered into additional license and supply agreements on substantially the same terms and thereby expanded their partnership with two additional biosimilar candidates, AVT16 and AVT33. Under these agreements, JAMP Pharma made upfront payments of \$15.0 million and \$0.5 million in development milestone payments. Additionally, we are eligible to receive aggregate payments of up to an additional \$62.0 million upon the achievement of certain regulatory, commercial, manufacturing and sales milestones.

In addition, Alvotech has partnerships with, among others, Yangtze (China), Cipla/Cipla Gulf/Cipla Medpro (Australia, New Zealand, South Africa/Africa), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS (Middle East and Africa), Abdi Ibrahim (Turkey), Kamada (Israel), Biosana (Australia, Netherlands, Singapore), and MegaLabs, Stein, Libbs, Tuteur and Saval (Latin America), Advanz Pharma (EEA, U.K., Switzerland, Canada, Australia and New Zealand).

# Biosana for AVT23

*Biosana*. In December 2021, Alvotech entered into an exclusive global licensing agreement with Biosana Pharma ("Biosana") for the co-development of AVT23, which will be produced using Biosana's proprietary 3C manufacturing process technology. Under the terms of the agreement, Biosana will develop AVT23, compile part of the dossier of data, information and know-how related to AVT23 and provide the dossier to Alvotech.

Alvotech will conduct the comparative study and update the dossier, and, when completed, has the exclusive right (and, for the U.S., the U.K., France, Germany, Italy and Spain, the obligation) to use the dossier to obtain regulatory approvals and to market, promote, distribute and sell AVT23. In each case limited to the extent necessary and solely for the purpose of (i) developing, registering, marketing, offering for sale, importing, storage, distributing, selling and using the property; and (ii) manufacturing the product, Biosana grants Alvotech

(i) exclusive, perpetual and irrevocable, assignable and sub-licensable rights to its intellectual property rights related to AVT23, including in the dossier, that existed prior to or are created during the collaboration; and (ii) the non-exclusive, perpetual and irrevocable, assignable and sub-licensable right with respect to the 3C manufacturing process. Alvotech made a one-time payment of \$7.5 million upon the signing of the agreement with an additional \$7.5 million paid during the year ended December 31, 2022, and agreed to make additional payments upon the achievement of certain development and regulatory milestones. Biosana will manufacture, supply and deliver AVT23 and Alvotech will exclusively buy AVT23 from Biosana (i) for five years, on a country-by-country basis, from the launch for supply for the EEA market; and (ii) for the term of the agreement for all other markets. In addition to the supply price, Alvotech will make tiered royalty payments to Biosana of 0% of product revenue in the first three years after the launch, 5% for the next three years, and 10% for as long as Alvotech continues to commercialize AVT23, unless the agreement is terminated for cause. All invoices are payable within 60 days in U.S. dollar and by wire transfer. The agreement terminates 15 years after the launch of AVT23 in a given country on a country-by-country basis, unless the parties agree to a renewal term. Either party may terminate the agreement for cause at any time if the other party (i) is two or more months overdue on a payment; (ii) commits or permits a substantial breach of any material term of the agreement; or (iii) is subject to certain bankruptcy proceedings. Alvotech may terminate the agreement in its entirety in a certain territory if (i) the intellectual property rights of a third party may be infringed; (ii) there is an unacceptable product liability risk; (iii) a regulatory authority prohibits, prevents, or restricts the products developed under the agreement for more than 90 days; (iv) the product fails to achieve real time stability; or (v) its gross margin is below a certain threshold in that country. Alvotech may further terminate the agreement if (i) Biosana fails to ship clinical trial material by the target date; (ii) the regulatory approval for the U.S. has not been submitted or granted by certain target dates for reasons attributable to Biosana; or (iii) a supply failure occurs. Biosana may terminate the agreement if Alvotech, its affiliates, or customers institutes or actively participates with a third party in challenging any of the patents under the agreement.

# Material Agreements, Partnerships and Suppliers

# China Joint Venture

In September 2018, Alvotech created a 50-50 joint venture with the Joint Venture Partner to develop, manufacture and commercialize Alvotech's biosimilar medicines in China and for the China market. Pursuant to a joint venture agreement, as amended on February 17, 2019, the Joint Venture Partner is investing \$100 million in cash to build a state-of-the-art biologic medicine manufacturing facility in Changchun, and Alvotech is contributing the same value via a combination of additional capital and the granting of market licenses for six of its biosimilar medicines in the China market under a separate technology license contract. These capital contributions are made in installments pursuant to the contribution schedule in the joint venture agreement. There are no other anticipated payments under the joint venture agreement aside from the aforementioned capital contributions.

The Joint Venture Partner's responsibilities include building the manufacturing facility, hiring employees, and obtaining the requisite approvals, permits and licenses for the operation of the facility. Alvotech's responsibilities include providing the Joint Venture with technical support for the construction of the facility, procuring equipment, and providing technical experts and training. Profit distributions from the Joint Venture shall be made to Alvotech and the Joint Venture Partner in proportion to their respective paid-up capital contributions. The duration of the Joint Venture is infinite, but the joint venture agreement is subject to certain customary termination rights. Upon termination of the joint venture agreement, the Joint Venture shall be dissolved, or if terminated pursuant to a breach, the non-breaching party may opt to buy out the other party pursuant to the terms of the joint venture agreement.

This joint venture provides Alvotech with the ability to expeditiously enter its products into the Chinese market, leveraging the Joint Venture Partner's experience and reputation in the China market as well as expertise in local registration, certification, and approval processes. In 2019, the Joint Venture broke ground on its

manufacturing facility, which became operational in 2022. The Joint Venture began completion of system certifications and quality controls in the second quarter of 2022 and is expected to be ready to start producing commercial batches before the end of 2023.

# U.S. AbbVie Agreement

On March 8, 2022 Alvotech entered into the AbbVie U.S. Agreement with AbbVie Inc. and AbbVie Biotechnology Ltd with respect to AVT02 for the U.S. market. Pursuant to the settlement component of the AbbVie U.S. Agreement, the parties agreed to stipulate to the dismissal of all claims, counterclaims and potential claims in the pending litigation, with each party to bear its own fees and costs, in the U.S. For more information about the U.S. litigation that was terminated, please refer to "—Legal Proceedings—U.S. Litigations." The parties further agreed to release each other from certain claims and demands. Under the licensing component of the AbbVie U.S. Agreement, AbbVie granted Alvotech a license effective July 1, 2023 to make, import, use, distribute, sell and offer for sale AVT02 in the U.S. and a license to manufacture, import and store a reasonable amount of AVT02 in anticipation of the commercial launch of AVT02 in the U.S. Under the agreement, Alvotech may sublicense certain rights to Teva, as a commercialization partner, and may also sublicense to other parties subject to certain conditions. In return, Alvotech is obligated to pay a royalty to AbbVie in the single-digits of the net sales of AVT02 in the U.S. The agreement does not provide for upfront or milestone payments. The obligation of Alvotech to pay royalties shall terminate on the earlier of (i) February 11, 2025; or (ii) a determination that licensed patents are invalid or unenforceable, at which time the license granted will be deemed fully paid up and irrevocable. Each party has the right to terminate the agreement upon breach of certain terms of the agreement that remains uncured for a certain period of time. Additionally, AbbVie may terminate the agreement if Alvotech takes certain actions concerning the patentability, validity, or enforceability of AbbVie's patents in the U.S. with respect to AVT02.

# European AbbVie Agreement

On April 4, 2022, Alvotech entered into the European AbbVie Agreement with AbbVie Biotechnology Ltd with respect to the sale of AVT02 in Europe and selected markets outside of Europe (the "European AbbVie Agreement"). Pursuant to the settlement component, the parties resolved all intellectual property disputes between Alvotech and AbbVie relating to AVT02 in those territories. For more information about those legal disputes, please refer to "-Legal Proceedings." The parties further agreed to release each other from certain claims and demands. Under the licensing component of the European AbbVie Agreement, AbbVie granted Alvotech a license effective immediately to make, import, use, distribute, sell and offer for sale AVT02 in Europe and selected markets outside of Europe. Under the agreement, Alvotech may sublicense certain rights to STADA, as a commercialization partner, and may also sublicense to other parties subject to certain conditions. In return, Alvotech is obligated to pay royalties to AbbVie with respect to certain indications that are covered by AbbVie patents, on an indication-by-indication and territory-by-territory basis. For purposes of calculating royalties due under the agreement, the parties agreed that in any territory, a certain percentage of AVT02 sold in such territory is covered by the indication, bringing the effective royalty rate in the single-digit to low-teens percentage range of net sales of AVT02 in the territories. The agreement does not provide for upfront or milestone payments. The royalty payments terminated or will terminate, on an indication-by-indication basis, on June 5, 2022, April 11, 2025 and June 3, 2031, respectively, at which time the license granted for that indication will be deemed fully paid up and irrevocable. Alvotech's royalty obligation will terminate earlier if, on a territory-by-territory and indication-by-indication basis, no valid AbbVie patent rights remain. Each party has the right to terminate the agreement upon breach of certain terms of the agreement that remains uncured for a certain period of time. Additionally, AbbVie may terminate the agreement if Alvotech takes certain actions concerning the patentability, validity, or enforceability of AbbVie's patents in Europe with respect to AVT02.

For the year ended December 31, 2022, we paid \$0.1 million in royalties to AbbVie.

# Competition

We believe our focus on biosimilars, investment in our platform, and global market reach endow us with a differentiated set of strategic advantages in the dynamic and competitive biosimilars marketplace. These features include substantial control over quality and capacity allocation; the ability to find and exploit operational and process efficiencies across R&D and manufacturing; and the agility to rapidly, flexibly and efficiently pivot to new opportunities to advance a broad portfolio of product candidates. We believe these advantages expand our opportunity and support our commercial and medical goals of accelerating the development of cost-effective biosimilars that are as close to the reference products as possible, and then getting them to the patients around the world who need them.

The specific characteristics of the competitive landscape for each of our publicly announced product development programs include but are not limited to:

AVT02. We expect AbbVie (the originator) as well as Amgen, Boehringer Ingelheim GmbH, Biocon/FujiFilm, Celltrion, Fresenius Kabi Pfizer, Samsung Bioepis, Coherus, and Sandoz to be our main competitors for AVT02, a biosimilar product candidate to Humira (adalimumab). Most of these companies have either launched or disclosed development plans for a 50 mg/mL Humira biosimilar in the U.S., EU, or both, as well as in some other global markets. Celltrion, Sandoz and Alvotech are the only companies with regulatory approval in the EU for a 100 mg/mL biosimilar version of adalimumab. In the US, Samsung Bioepis received approval from FDA for a 100 mg/mL biosimilar version of adalimumab. Celltrion and Sandoz announced they have BLAs for a 100 mg/mL biosimilar version of adalimumab under review by FDA. Other companies that disclosed development plans for a 100 mg/mL Humira biosimilar in the US include Amgen and Boehringer Ingelheim. Companies that announced plans to seek interchangeability designation for a 100 mg/mL biosimilar version of adalimumab include Amgen, Samsung Bioepis, and Celltrion.

*AVT04*. We expect Janssen (the originator) as well as Amgen, Celltrion, Bio-Thera, Formycon, Dong-A/Meiji Seika, Samsung Bioepis and Biocon to be our main competitors for AVT04, a biosimilar candidate to Stelara (ustekinumab), all of which have disclosed development plans for a Stelara biosimilar. Janssen is also attempting to defend against biosimilar competition by expanding the label for Stelara and by launching follow-on drugs.

*AVT06*. We expect Regeneron (the originator) Amgen, Celltrion, Formycon, Altos, Sam Chun Dang, Samsung Bioepis, Sandoz and Viatris/Biocon to be our main competitors for AVT06, a biosimilar candidate to Regeneron's Eylea (aflibercept). As the originator, Regeneron is currently working to expand the label for Eylea and developing higher-concentration formulations.

*AVT03*. We expect Amgen (the originator), Sandoz, Celltrion, Fresenius Kabi, Samsung Bioepis, Gedeon Richter, mAbxience, Biocon, Henlius and Teva to be our main competitors for AVT03, a biosimilar candidate to Prolia/Xgeva (denosumab), as they have all disclosed development plans for a Prolia/Xgeva biosimilar.

*AVT05*. We expect Janssen (the originator), and Bio-Thera to be our main competitors for AVT05, a biosimilar candidate to Janssen's Simponi (golimumab). The originator, Janssen, is solidifying the reference product's market position by actively expanding the label and by winning approvals in Japan and China. We believe that the originator's success in expanding the market for the reference product will prove to be a benefit to AVT05's commercial positioning.

*AVT23*. We expect Genentech (the originator), Celltrion and Teva to be our main competitors for AVT23, a biosimilar candidate to Genentech's Xolair (omalizumab), as they have all disclosed development plans for a Xolair biosimilar. As the originator, Genentech is currently working to expand the label for Xolair.

# **Intellectual Property**

The branded pharmaceutical industry relies on patent protection as one of several means to maintain exclusivity on the market. As a biosimilar-focused company, our success will depend in part on our ability to avoid infringement of, to invalidate, and/or to license any relevant and material intellectual property rights of third parties. We expect all branded companies that market products in which we are developing a biosimilar to vigorously protect what they view as their proprietary rights. We fully understand that efforts to market our products may result in patent litigation, which may determine whether a particular patent at issue is valid and whether we have infringed such a patent. Timelines for resolution to patent disputes are difficult to estimate and are very specific to a particular situation (including, for example, the jurisdiction).

While our principal focus in matters relating to intellectual property is to avoid infringing the valid and enforceable rights of third parties, we also use a combination of intellectual property protection and confidentiality agreements to protect our own intellectual property related to our product candidates and development programs. We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including by seeking, maintaining, enforcing and defending trademarks, trade secrets, patent rights, and other intellectual property rights for our products and processes, whether developed internally or licensed from third parties.

We are actively building our own intellectual property portfolio around our product candidates and platform technologies, including our manufacturing processes, and intend to identify and obtain, directly or through a license, as appropriate, patents that provide protection to our intellectual property and technology base. As of December 31, 2022, our patent portfolio consists of several pending patent applications for composition of matter (formulations) related to our AVT02 product:

- We have patent applications entitled "pharmaceutical formulations for adalimumab" that are pending in Europe, Canada, Australia, Japan, New Zealand, China, and the United States, all owned by us. Any patents issuing from these pending applications would be expected to expire no earlier than 2038.
- We also have patent applications entitled "Aqueous Formulations of TNF-alpha Antibodies in High Concentrations" that are pending in Australia, New Zealand, Japan, Israel, Europe, China, the United States and Canada, all owned by us. Any patents issuing from these pending applications would be expected to expire no earlier than 2040.

With respect to these pending and any future applications, we cannot be sure that patents will be granted in any or all jurisdictions, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products. In addition to patents, We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and IP assignment agreements in place with our employees to develop and maintain our proprietary position and ensure the future commercial success of our products.

# Regulatory Landscape

# Government Regulation and Product Approval

Government authorities at the federal, state and local level in the United States and in other countries extensively regulate, among other things, the research, development, testing, clinical trials manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in other countries, along with subsequent obligation of compliance with applicable statutes and regulations, can vary widely and can require the expenditure of substantial time and financial resources.

# FDA Approval Process

All of our current product candidates are subject to extensive pre- and post-market regulation in the United States by the FDA as biological products, or biologics. The Public Health Service Act, or PHSA, the Federal

Food, Drug and Cosmetic Act, or FFDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, post-approval changes, and import and export of biologics. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending Biologics License Applications, or BLAs, withdrawal of approvals or revocation or suspension of licenses, clinical holds, warning letters, product recalls, product seizures, injunctions, fines, civil penalties or criminal penalties. The PHSA and its implementing regulations provides FDA authority to immediately suspend licenses in certain situations where FDA determines that there exists a danger to health, and to promulgate and enforce regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

The process required by the FDA before a new biologic may be marketed in the United States is long, expensive and inherently uncertain. In order to establish the safety, purity and potency (effectiveness) of the biologic, biologics development in the United States typically involves, among other things, pre-clinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before U.S. clinical investigations in humans may commence, and adequate and well-controlled clinical trials to establish the safety, purity and potency of the biologic for the conditions of use for which FDA approval is sought. Developing the data to satisfy FDA approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and toxicology, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements, including good laboratory practices. An IND must be submitted to the FDA to administer an investigational new drug to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies, although the IND must also include safety data, e.g., the results of pre-clinical testing and animal testing assessing the toxicology and pharmacology of the product along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

An IND must become effective before United States clinical trials may begin. There is generally a 30-day waiting period after the IND submission, after which clinical investigations can begin, unless the FDA notifies the sponsor of concerns or questions related to a clinical hold. If that happens, the sponsor and the FDA must resolve the hold issue(s) before the clinical investigation can begin. Otherwise, the clinical trial proposed in the IND may begin at the conclusion of this 30-day period.

Clinical trials involve the administration of the investigational new drug to volunteers or patients all under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations on good clinical practice, or GCP, including, for example, regulations regarding the protection of human subjects, defining, the roles of clinical trial sponsors, administrators and monitors, and governing protocols detailing the objectives of the trial and, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients, among other reasons. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions. The study sponsor may also suspend a clinical trial

at any time on various grounds, including a determination that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials to support BLAs for regulatory approval of a reference biologic product under the 351(a) pathway are typically conducted in three sequential phases, but the phases may overlap or be combined. In Phase 1, the biologics are initially introduced into patients or healthy human subjects and the biologic is tested to assess the safety/tolerability, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the biologic for a particular indication, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a product candidate demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites. These Phase 3 clinical trials are intended to establish data sufficient to demonstrate substantial evidence of the efficacy and safety of the product to permit the FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the biologic. Trials conducted outside of the United States under similar, GCP-compliant conditions in accordance with local applicable laws may also be acceptable to the FDA in support of product licensing.

Sponsors of clinical trials for investigational drugs generally must publicly disclose certain clinical trial information, including detailed trial design and trial results in a public database administered by the U.S. Department of Health and Human Services. These requirements are subject to specific timelines and apply to most clinical trials of FDA-regulated products.

After completion of the required clinical testing in accordance with all applicable regulatory requirements, detailed information regarding the investigational product is prepared and submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications or conditions of use. FDA review and approval of the BLA is required before marketing of the product may begin in the United States. The BLA will include the results of pre-clinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls and must demonstrate the continued safety, purity, and potency (efficacy) of the product based on these data.

Manufacturing controls and conformance to current good manufacturing practices ("cGMPs") are considered very important for biological products. The BLA must also contain extensive manufacturing information. The FDA will inspect the facility or the facilities at which the biologic is manufactured to ensure conformance to cGMPs. The COVID-19 pandemic has impacted the FDA's ability to complete timely inspections of manufacturing sites. FDA is using alternative tools, where available, to determine or mitigate the need for an inspection and to support the application assessment. This can include reviewing a firm's previous compliance history, using information sharing from trusted foreign regulatory partners through mutual recognition agreements and other confidentiality agreements, requesting records "in advance of or in lieu of" facility inspections or voluntarily from facilities and sites, and conducting remote interactive evaluations where appropriate.

The cost of preparing and submitting a BLA is substantial. Under federal law, the submission of most original BLAs is subject to a multi-million dollar application user fee, as well as annual fees, both of which are typically increased annually.

The FDA has agreed to certain performance goals in the review of BLAs. First, the FDA has agreed to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to enable substantive review within 60 days from its receipt of a BLA. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA's stated goal is to review most original BLA applications for standard review biologics within ten months from the date the application is accepted for filing. Although the FDA often meets its user fee performance goals, the review goal date can be

extended in the event of a "major amendment," or can be extended by requests for additional information or clarification, and FDA review may not occur on a timely basis at all. Additionally, as a result of public health emergencies, such as the COVID-19 pandemic, review timelines may be delayed even further.

The FDA often refers applications for novel biologics or biologics which present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation and a recommendation as to whether the application should be approved and/or specific use and approvability questions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. After the FDA evaluates the BLA, including the facilities listed in the BLA, it issues either an approval letter or a complete response letter. A complete response letter outlines the deficiencies in the submission. Remedying those deficiencies may require substantial additional testing or information in order for the FDA to consider the resubmitted application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction such that a resubmitted BLA is approvable, the FDA will issue an approval letter. The FDA has committed to user fee goals of reviewing such resubmissions in two or six months depending on the type of information included. The FDA approval is never guaranteed, and the FDA may refuse to approve a BLA if applicable regulatory criteria are not satisfied. Additionally, while the agency may utilize alternative approaches such as records requests in lieu of inspections for certain facilities, the agency is also deferring actions (i.e., missing the goal dates) on BLAs for which they have been unable to conduct site inspections due to the COVID-19 pandemic as FDA regulations generally require a pre-approval inspection for biologics in addition to the BLA's demonstration the biologic is safe, pure and potent (effective) under the conditions of use sought. For BLAs where FDA defers action, there is no submission or communication needed by the applicant to ensure that an inspection will be scheduled to support approval.

Under the PHSA, the FDA will approve a BLA if it determines, among other things, that the product is safe, pure and potent and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. The approval for a biologic may be significantly more limited than requested in the application, including limitations on the specific conditions of use, which could restrict the commercial value of the product. The FDA may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, under certain circumstances, the FDA may require a risk evaluation and mitigation strategy, or REMS, as a condition of approval, if necessary to ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the biologic. Moreover, product approval may include post-marketing commitments and/or post-marketing-requirements, including, for example, pediatric studies, safety monitoring, and Phase 4 trials.

Certain types of biologics may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. After approval of biologics, manufacturers must address any safety issues that arise, may be subject to recalls or a halt in manufacturing under certain circumstances, and are subject to periodic inspection after approval.

Because biologically-sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Abbreviated Licensure Pathway of Biological Products as Biosimilars under 351(k)

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA and created an abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed reference biological products. This pathway was established as a way to provide more treatment options, increase access to lifesaving medications, and potentially lower health care costs through competition. Under the 351(k) (biosimilar) approval pathway, an application for licensure of a biosimilar product must include information demonstrating biosimilarity based upon the following (unless a specific element is waived by FDA):

- analytical studies demonstrating that the proposed biosimilar product is highly similar to the approved product notwithstanding minor differences in clinically inactive components;
- · animal studies (including the assessment of toxicity and immunogenicity); and
- a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product.

In addition, an application submitted under the 351(k) pathway must include information demonstrating that:

- the proposed biosimilar product and reference product utilize the same mechanism of action for the condition(s) of use prescribed, recommended or suggested in the proposed labeling, but only to the extent the mechanism(s) of action are known for the reference product;
- the condition or conditions of use prescribed, recommended or suggested in the labeling for the proposed biosimilar product have been previously approved for the reference product;
- the route of administration, the dosage form and the strength of the proposed biosimilar product are the same as those for the reference product; and
- the facility in which the biological product is manufactured, processed, packed or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

Biosimilarity, as defined in PHSA §351(i), means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product. In addition, section 351(k)(4) of the PHSA provides for a designation of "interchangeability" between the reference and biosimilar products if certain additional criteria are met, whereby the biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. An application seeking licensure as an interchangeable must include information sufficient to demonstrate that:

- the proposed product is biosimilar to the reference product;
- the proposed product is expected to produce the same clinical result as the reference product in any given patient; and
- for a product that is administered more than once to an individual, the risk to the patient in terms of safety or diminished efficacy of alternating or switching between the biosimilar and the reference product is no greater than the risk of using the reference product without such alternation or switch.

As with other biological products, FDA approval of a BLA is required before a biosimilar may be marketed in the United States. Biosimilar BLAs (or "351(k) BLAs") are not required to duplicate the entirety of the data

package used to establish the safety and effectiveness of the reference product. Rather, a 351(k) BLA will be approved based on a demonstration of biosimilarity to the reference product, including the information outlined above, and does not require an independent showing of safety and effectiveness. Because a biosimilar can rely in part on FDA's previous determination of safety and effectiveness for the reference product for approval, biosimilar applicants generally do not need to conduct as many clinical trials. Biosimilar products also may be approved for an indication without direct studies of the biosimilar in that indication, with sufficient scientific justification for extrapolation. However, the FDA may not approve a 351(k) BLA if there is insufficient information to show that the biosimilar is "highly similar" to the reference product or that there are no clinically meaningful differences between the biosimilar product and the reference product. In addition, as with innovator BLAs, biosimilar BLAs will not be approved unless the product is manufactured in facilities designed to assure and preserve the biological product's safety, purity and potency.

The process for filing and review of a BLA submitted through the 351(k) pathway is very similar to that of a BLA submitted through the 351(a) pathway, although there is a period of statutory exclusivity during which time the FDA is precluded from filing a 351(k) BLA that references a protected reference product. Subsequently, the FDA will accept the application for filing if it meets the regulatory criteria. The FDA may refuse to file applications that it finds are incomplete. The FDA will treat a biosimilar application or supplement as incomplete if, among other reasons, any applicable user fees assessed under the Biosimilar User Fee Act of 2012 have not been paid. In addition, the FDA may accept an application for filing but deny approval on the basis that the sponsor has not demonstrated biosimilarity, in which case the sponsor may choose to conduct further analytical, preclinical or clinical studies and resubmit the BLA to demonstrate biosimilarity under section 351(k).

The timing of final FDA approval of a biosimilar for commercial distribution depends on a variety of factors, including whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which time the FDA is prohibited from approving any products that are biosimilar to the branded product. The FDA cannot approve a biosimilar application for 12 years from the date of first licensure of the reference product. A reference product may also be entitled to exclusivity under other statutory provisions. For example, a reference product with orphan drug exclusivity for a particular orphan "disease or condition" may be entitled to seven years of exclusivity, in which case no product that is biosimilar to the reference product may be approved until either the end of the 12-year period provided under §351(k)(7), and no biosimilar may be approved for the orphan disease or condition until the end of the seven-year orphan drug exclusivity period. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent and thus block §351(k) applications from being approved on or after the patent expiration date.

The first biological product determined to be interchangeable with a branded reference product for any condition of use is also eligible for a period of exclusivity, during which time the FDA may not determine that another product is interchangeable with the same reference product for any condition of use. This exclusivity period lasts until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l) (6).

# Advertising and Promotion

The FFDCA prohibits the marketing, promotion, or advertising of an investigational drug as if it has been demonstrated to be safe and effective for the uses for which it is being studied. Once a BLA is approved, a product will be subject to continuing post-approval regulatory requirements, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and

promotion and reporting of adverse events. For instance, the FDA closely regulates the post-approval advertising, marketing and promotion of drugs, including biologics, including, for example, direct-to-consumer advertising, off-label promotion, and industry-sponsored scientific and educational activities. Violations of the FDA's requirements around advertising, marketing, and promotion of drugs can result in significant enforcement activities, including the issuance of warning letters or untitled letters, which may direct a company to correct deviations from FDA, and federal and state investigations, which can lead to civil and criminal penalties, lawsuits, and prosecutions.

As with all drugs, biologics may be marketed only as consistent with FDA-approved labeling. After approval, most changes require submission and FDA approval supplemental BLA before the change can be implemented. This includes changes to labeling or manufacturing processes (including changes to facilities), which typically require prior approval of a supplement. A supplement for a 351(a) BLA seeking to add a new indication typically requires new clinical data, and the FDA generally uses the same procedures and actions in reviewing BLA supplements with clinical data as it does in reviewing BLAs. There are also continuing reporting requirements for marketed drug products.

# Adverse Event Reporting and GMP Compliance

In addition to regular periodic reports following FDA approval of a BLA and compliance with any post-marketing commitments or post-marketing requirements, license-holders also must comply with adverse event reporting requirements and must continue to conform to cGMPs, as described above. Manufacture, packaging, labeling, storage, and distribution procedures must continue to conform to cGMP after approval, and FDA conducts periodic surveillance inspections intended to ensure such ongoing compliance. Biologics manufacturers and their manufacturing subcontractors are generally required to register their establishments with the FDA and certain state agencies. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMP.

Post-approval discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency or issues with manufacturing processes or cGMP compliance, or other failures to comply with regulatory requirements, may lead the FDA to, for example:

- require revisions to approved labeling to add new safety information;
- require post-market studies to assess new safety risks;
- issue fines, warning letters, or untitled letters;
- place post-approval clinical trials on hold;
- · detain or refusal to permit the import or export of products;
- request voluntary calls;
- seek injunctions, civil forfeiture, civil money penalties, or other civil relief; or
- seek criminal penalties or prosecution.

Under certain circumstances, FDA may initiate proceedings to suspend or revoke a license or recall the product from the market.

# Other Healthcare Laws and Compliance Requirements

Although we currently do not have any products on the market or engage with any licensed health care providers in the United States, our current and future business operations are subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute ("AKS") prohibits any individual or entity from knowingly and willfully offering or paying "remuneration," directly or indirectly, overtly or covertly, in cash or in kind to induce another individual or entity to: (a) refer an individual to a person for the furnishing (or arranging for the furnishing) of any item or service for which payment may be made under a federal health care program; (b) purchase or order any covered item or service; (c) arrange for the purchase or order of any covered item or service. It also is illegal under the Anti-Kickback Statute to solicit or receive remuneration for such purposes. "Remuneration" is generally defined to include any transfer of value, in cash or in kind, including gifts or free product, meals, discounts, rebates, and other price concessions. Courts have broadly construed the AKS to include virtually anything of value given to an individual or entity if one purpose of the remuneration is to influence the recipient's reason or judgment relating to referrals.

There are statutory exceptions and regulatory safe harbors specifying certain payment practices that will not be considered to violate the AKS. Such exceptions and safe harbors include, among others, protection for payments for personal services and management contracts, and for certain discounts. If a payment practice falls squarely within one of the exceptions or safe harbors, it will be immune from criminal prosecution and civil exclusion under the AKS. Importantly, the failure of an arrangement to fall within a statutory exception or regulatory safe harbor does not mean that it necessarily violates the AKS; however, the legality of such arrangements may be closely scrutinized by federal authorities on a facts and circumstances basis and are not protected.

Additionally, states have enacted similar kickback statutes that may apply to healthcare services reimbursed by private insurance, not just those reimbursed by a federal or state health care program. The specific scope of these laws vary. However, in many instances, activities that are protected from scrutiny under the federal statute would not violate the state statutes.

Further, pursuant to changes made under the PPACA, any claims submitted to Medicare or Medicaid as a result of an illegal kickback constitutes a false or fraudulent claims under the federal False Claims Act ("FCA"). Additionally, the ACA amended the intent requirement of the AKS so that a person or entity no longer needs to have actual knowledge of the AKS, or the specific intent to violate it, to have violated the statute.

The civil false claims laws, including the FCA, prohibits, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the FCA may be brought by the government or as a qui tam action by a private individual in the name of the government. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free products to customers with the expectation that the customers would bill federal programs for the products; providing consulting fees and other benefits to physicians to induce them to prescribe products; and engaging in promotion for unapproved uses. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of some of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. For instance, the federal Physician Payments Sunshine Act ("Sunshine Act") requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with specified exceptions) to report annually information related to specified payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors, other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and to report annually specified ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and their implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity and their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, administrative, civil, and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment.

## **International Regulation**

In addition to regulations in the United States, a variety of foreign regulations govern clinical trials, marketing authorization procedures and commercial sales and distribution of pharmaceutical products. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA approval. In the EU, the approval of a biosimilar for marketing is based on an opinion issued by the European Medicines Agency, or EMA, and a related decision issued by the European Commission. However, the subsequent substitutability of a reference medicinal product for the biosimilar is a decision that is made at the national level on a country-by-country basis in individual EU Member States. Other regions, including Canada, Japan and Korea, also have their own regulatory pathways governing the approval and marketing of biosimilars. Some third countries (such as Singapore and Malaysia) have adopted EU guidance. Other countries (such as (Cuba and Brazil) follow guidance issued by the World Health Organization. While there are some similarities between the regulatory requirements across regions, some areas of substantial difference remain.

#### Clinical Trials in the EU

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20, or CTD, and related national implementing legislation of EU Member States.

The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increasing their transparency. Specifically, the Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the EU portal, the Clinical Trials Information System, or CTIS; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Individual EU Member States retain the power to authorize the conduct of clinical trials on their territory.

The extent to which on-going clinical trials will be governed by the CTR will depend on the duration of the individual clinical trial. Sponsors could choose to submit a clinical trial application under either the CTD or the CTR until January 31, 2023. For clinical trials in relation to which application for approval was made on the basis of the CTD before January 31, 2022, the CTD will continue to apply on a transitional basis for three years. If authorized, those clinical trials will be governed by the CTD until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the clinical trial has already transitioned to the CTR framework.

### EU Review and Approval Process

In the EU, medicinal products can only be commercialized after a related marketing authorization, or MA, has been granted. A company may submit a marketing authorization application, or MAA, either on the basis of the centralized, or decentralized procedure or mutual recognition procedure.

To obtain an MA for a product in the EU, which is valid throughout the EEA, an applicant must submit an MAA either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU Member States. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the

applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

### Post-approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU legislation, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

### Data and marketing exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving an MA in the EU, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for marketing authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

## Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all marketing authorization applications for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which marketing authorization is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity. For other countries outside of the EU, such as certain countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product approval, pricing and reimbursement vary from country to country. In all cases, the clinical trials are to be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

## Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and other countries, sales of our products will depend on the availability and extent of coverage and reimbursement from third-party payors, including government healthcare programs and private insurance plans. Patients who are provided medical treatment for their conditions generally rely on third party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, or comparable foreign programs and commercial payors are critical to new product acceptance. Governments and private payors continue to pursue initiatives to manage drug utilization and contain costs. These payors are increasingly focused on the effectiveness, benefits, and costs of similar treatments, which could result in lower reimbursement rates for our

products or narrower populations for whom payors will reimburse. Continued intense public scrutiny of the price of drugs and other healthcare costs, together with payor dynamics, have limited, and are likely to continue to limit, our ability to set or adjust the price of our products based on their value, which could adversely affect our business.

In the United States, no uniform product coverage and reimbursement policy exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor can be a time-consuming and costly process that can require provision of supporting scientific, clinical and cost-effectiveness data, with no assurance that coverage or specific levels of reimbursement will be obtained. Third-party payors are increasingly examining the medical necessity and cost-effectiveness of products and services in addition to their safety and efficacy. Accordingly, significant uncertainty exists as to the reimbursement status of newly approved products.

Both private and government payors use formularies to manage access and utilization of drugs. A drug's inclusion and favorable positioning on a formulary are essential to ensure patients have access to a particular drug. Even when access is available, some patients abandon their prescriptions for economic reasons. Third-party payors continue to institute cost reduction and containment measures that lower drug utilization and/or spending altogether and/or shift a greater portion of the costs to patients. Such measures include, but are not limited to, more-limited benefit plan designs, higher patient co-pays or coinsurance obligations, limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs), stricter utilization management criteria before a patient may get access to a drug, higher-tier formulary placement that increases the level of patient out-of-pocket costs and formulary exclusion, which effectively encourages patients and providers to seek alternative treatments or pay 100% of the cost of a drug. The use of such measures by pharmacy benefit managers ("PBMs") and insurers has continued to intensify and could limit use and sales of our products.

Over the past few years, many PBMs and insurers have consolidated, resulting in a smaller number of PBMs and insurers overseeing a large portion of total covered lives in the United States. As a result, PBMs and insurers have greater market power and negotiating leverage to mandate stricter utilization criteria and/or exclude drugs from their formularies in favor of competitor drugs or alternative treatments. In highly competitive treatment markets, PBMs are also able to exert negotiating leverage by requiring incremental rebates from manufacturers in order for them to gain and/or maintain their formulary position. Moreover, third-party coverage policies and reimbursement rates are dynamic, meaning that our products could be subject to less favorable coverage policies and/or reimbursement rates over time, making prospective reimbursement and coverage status of our products difficult to predict.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Other countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. For example, some EU Member States may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many EU Member States have increased the amount of discounts that pharmaceutical companies are requirement to offer. These efforts could continue as countries attempt to manage healthcare expenditures. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products onto national markets. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade (arbitrage between low-priced and high-priced member states), can further reduce prices.

### Healthcare Reform

Like third-party payors, the U.S. federal government, state legislatures and foreign governments have continually implemented cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for generic substitution. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. State laws may permit or require substitution of interchangeable products, too, when approved interchangeable products are available in the future. Adoption of price controls and cost-containment measures and adoption of more restrictive policies in jurisdictions with existing controls and measures could further limit our net revenue and results. Decreases in third-party reimbursement for our products or decisions by certain third-party payors to not cover specific products, or implement coverage restrictions (e.g. prior authorization, step-edit requirements) could reduce provider utilization and have a material adverse effect on sales, results of operations and financial condition.

In the United States and some other countries, particularly over the past few years, a number of legislative and regulatory proposals have been introduced in an attempt to lower drug prices and restrict or regulate post-approval activities.

In the United States, in addition to market actions taken by private and government payors, there has been heightened government, media, and public scrutiny over the manner in which drug manufacturers set prices for their marketed products, resulting in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. For example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA directs the HHS Secretary to establish a Drug Price Negotiation Program to lower prices for certain highexpenditure, single-source prescription drugs and biologics covered under Medicare Part B and Part D that have been approved by the FDA for at least 7 years for prescription drugs and at least 11 years for biologics. Under the Program, the HHS Secretary will publish a list of "selected drugs," and will then negotiate maximum fair prices with their manufacturers. The Program will be implemented in stages. Beginning in 2026, 10 Medicare Part D "selected drugs" will be subject to price negotiations. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Medicare Part B and Part D. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and potential civil monetary penalties. Further, beginning in October 2023, the IRA will require manufacturers that increase prices of certain Medicare Part B and Part D drugs or biologics at a rate greater than inflation to pay rebates to the Centers for Medicare & Medicaid Services or be subject to civil monetary penalties. The IRA also provides certain incentives for the development and manufacture of biosimilars. For example, the Secretary can grant a one-year delay from price negotiations for biosimilars that have a "high likelihood" of a competing biosimilar product entering the market within the requested delay period. In addition, certain Part B biosimilars qualify for an increase in Medicare payments, to 8% of the 5-year Average Sales Price, from 6% under current law. The HHS Secretary has been directed to promulgate regulations to implement the Program and other IRA health reform measures. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and

Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future.

In this dynamic environment, we are unable to predict which or how many government policy, legislative, regulatory, executive or administrative changes may ultimately be, or effectively estimate the consequences to our business if, enacted and implemented. However, to the extent that these or other federal government initiatives further decrease or modify the coverage or reimbursement available for our products, require that we pay increased rebates or shift other costs to us, limit or affect our decisions regarding the pricing of or otherwise reduce the use of our products, or limit our ability to offer co-pay payment assistance to commercial patients, such actions could have a material adverse effect on our business and results of operations. Individual states have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In many countries outside the United States, government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure. These measures can include mandatory price controls; price referencing; therapeutic-reference pricing; increases in mandates; incentives for generic substitution and biosimilar usage and government-mandated price cuts. In this regard, many countries have health technology assessment agencies that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies; and these agencies are expanding in both established and emerging markets. For example, some EEA countries may require the completion of studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. In December 2021 the EU HTA Regulation was adopted. The purpose of the Regulation is to introduce joint clinical assessments at EU level. When it enters into application in 2025 the Regulation will be intended to harmonize the clinical benefit assessment of HTA across the EU. Many countries also limit coverage to populations narrower than those specified on our product labels or impose volume caps to limit utilization. We expect that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

#### **Brexit**

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement, or Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the Agreement includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the Agreement.

Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of the Agreement, the EU and the UK will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The Agreement also encourages,

although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, it is currently unclear to what extent the UK will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation on January 31, 2022.

As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. Since January 1, 2021, an applicant for a centralized procedure marketing authorization can no longer be established in the UK. Since this date, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures to obtain an MA to market products in the UK. Until 31 December 2023, MHRA may rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization; or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EU Member States through decentralized and mutual recognition procedures to be granted in the United Kingdom or Great Britain. Post Brexit, the MHRA has been updating various aspects of the regulatory regime for medicinal products in the UK. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicinal products; updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for marketing authorizations in the UK, Great Britain and Northern Ireland and a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission).

## Data Privacy and Security

We are subject to stringent and evolving United States and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security, including the EU's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation ("UK GDPR"). New privacy rules are being enacted in the United States and globally, and existing ones are being expanded, updated and strengthened. For example, the EU GDPR which went into effect in May 2018 introduced strict requirements regarding the processing of personal data, including health-related data.

The collection and use of personal health data in the EEA is governed by the EU GDPR, which became effective on May 25, 2018. The EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The EU GDPR enhances data protection obligations for controllers and processors of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for high-risk processing, limitations on retention of personal data and mandatory data breach notification and privacy by design requirements, and creates direct obligations on service providers acting as data processors. The EU GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, such as the U.S. Failure to comply with the requirements of the EU GDPR and the related national data protection laws of the EEA countries may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the EU GDPR grants data subjects the right to claim compensation for damages resulting from infringement of the EU GDPR.

Following the United Kingdom's withdrawal and the expiration of the transition period, from January 31, 2020, companies doing business in the EU and the UK will be obliged to comply with both the GDPR and the UK GDPR. The UK has implemented legislation similar to the EU GDPR, the UK GDPR, including the UK Data Protection Act, which provides for fines of up to the greater of 17.5 million British Pounds or 4% of a company's worldwide turnover, whichever is higher. Additionally, the relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear following Brexit, including with respect to regulation of data transfers between EU Member States and the UK. On June 28, 2021, the European Commission announced a decision of "adequacy" concluding that the UK ensures an equivalent level of data protection to the EU GDPR, which provides some relief regarding the legality of continued personal data flows from the EEA to the UK. Some uncertainty remains, however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. We cannot fully predict how the Data Protection Act, the UK GDPR, and other UK data protection laws or regulations may develop in the medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the UK will be regulated.

### **Facilities**

We believe that our office, research, laboratory and manufacturing facilities, including the ongoing expansion of the Reykjavik facility, are sufficient to meet our current needs. However, as a high-growth company we are constantly evaluating our needs for expanding and or adding to our facilities. We are not aware of, and do not anticipate, environmental issues that may affect our utilization of the facilities described below.

## Registered Office in Grand Duchy of Luxembourg

Our registered office is at 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg, where it has approximately 19 square meters of office space. This location is used for administrative functions only. We are currently leasing this office space. The lease expires in August 2023 but the agreement provides for automatic renewal for one year until termination of the agreement.

## Offices and Manufacturing Facility in Iceland

Our corporate headquarters, main manufacturing site and a large part of our R&D division are located in Reykjavik, Iceland. This facility provides us with purpose-built GMP, and has highly integrated capabilities for producing biosimilars at scale. The facility is currently approximately 140,000 square feet and utilizes single-use technology to manufacture drug substance and drug product. It houses our R&D, quality control and quality assurance teams and has an active and valid GMP certificate issued by the Icelandic Medicines Authority authorizing Investigational Medicinal Product and commercial manufacturing. In December 2020, we broke ground on an expansion of our Reykjavik facility that will double the total footprint, adding another 140,000 square feet. The expansion is expected to be completed in 2023 and will give additional redundancy in drug product capacity, assembly of combination products and devices, and secondary packaging. Additionally, the expansion will support increased warehousing and other supportive functions. With the expansion of the Reykjavik facility's manufacturing capabilities, we expect our capabilities to be able to meet the demand for our products, after obtaining regulatory approval and commercial launch, in the near future. During this expansion, our R&D functions have temporarily moved to another facility in Reykjavik. Permits from the Icelandic EPA (*Umhverfisstofnun*) and the city of Reykjavik have been granted for the operations in Klettagardar. These facilities have no known additional environmental risks that might impact our operations or utilization of facilities.

In November 2022, we purchased the entity holding the abovementioned manufacturing facility from ATP Holdings ehf., an affiliate of Aztiq, for a purchase price of \$115.0 million, which includes the Aztiq Convertible Bond and assumption of loans related to the facility.

Additionally, we have a warehouse of approximately 36,000 square feet in Reykjavik which is used for warehousing, office space and laboratories to sample incoming materials. We are leasing this office space and

warehouse until 2038. We also rent office space in Kopavogur, Iceland, for approximately 10,000 square feet, on a lease that expires in 2027. Until the expansion of our Reykjavik facility is completed, we also have short term leases for office space, R&D activities and storage space in Reykjavik, for approximately 57,000 square feet in total, with the leases expiring either in 2023 or 2024.

We hold operational permits from the city of Reykjavik for our facilities in Iceland. The permits address potential environmental impact from our operations. They also address factors that could impact our neighboring communities, such as noise pollution, handling of hazardous substances, air emissions, handling of solid waste and wastewater. We are also required to hold permits from the Icelandic EPA (*Umhverfisstofnun*) for the use of GMOs in our facilities. We are subject to Icelandic law and regulations, many of whom are set by the Icelandic EPA (*Umhverfisstofnun*) and the Icelandic Administration of Occupational Safety and Health (*Vinnueftirlitið*).

# Other Offices

We have a facility in J lich, Germany that focuses on cell line, media, process and analytical development, including tailored clone creation and selection. The J lich site also serves as a warehouse for supply continuity of master cell banks and working cell banks for our lead product candidates that are produced at contract manufacturing organizations. This facility is approximately 15,000 square feet and is not used for manufacturing. We are holding the space through seven lease agreements, two of which expire in 2024, one of which expires in December 2023 and provides for automatic renewal until the termination of the agreement, and the other three lease agreements can be terminated at any time with a three-month notice period.

We have a facility in Hannover, Germany that houses our capabilities in analytical glycoprotein characterization. This facility is approximately 14,000 square feet and is not used for manufacturing. We are currently leasing this office space. The lease agreement can be terminated at any time with a 12-month notice period.

Our Virginia, USA office houses our U.S. regulatory, government policy and legal affairs functions. This office is approximately 3,200 square feet and is not used for manufacturing. We are currently leasing this office space. The lease expires in August 2023.

Our office in Zurich, Switzerland features our strategic clinical and Medical Affairs R&D center that focuses on late-stage development and regulatory filings. This facility is approximately 3,800 square feet and is not used for manufacturing. We are currently leasing this office space. The lease expires in August 2026.

We have a facility in Bangalore, India that focuses on research and development. This facility is approximately 6,100 square feet and is not used for manufacturing. We are currently leasing this office space. The lease expires in December 2025.

Additionally, we use a small part of a 566 square meter office in Malta that for administrative functions. We are currently leasing this office space. The leases expire in August 2025.

# **Legal Proceedings**

While Alvotech's legal proceedings adverse to AbbVie related to its biosimilar adalimumab product, AVT02, have been settled or otherwise resolved in the United States, the Netherlands, and Japan, and before the European Patent Office, proceedings between Alvotech's Canadian partner JAMP and AbbVie are pending in Canada. For more information about the settlement agreements with respect to legal proceedings in the United States and Europe, please refer to "—Material Agreements, Partnerships and Suppliers."

The past and present AbbVie proceedings are described further below.

### U.S. Litigations

On March 19, 2021, AbbVie filed an action against Alvotech hf. in the United States District Court for the Northern District of Illinois alleging trade secret misappropriation under the Defend Trade Secrets Act and under the Illinois Trade Secrets Act. The complaint pleaded, among other things, that Alvotech hf. hired a certain former AbbVie employee in order to acquire and access trade secrets belonging to AbbVie. Pursuant to the U.S. AbbVie Agreement, Alvotech and AbbVie settled all U.S. litigation arising out of the development of Alvotech's adalimumab biosimilar, and the filing of the corresponding BLA with the FDA. The case is now dismissed.

On December 17, 2021, AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd. filed a complaint with the U.S. International Trade Commission against Alvotech hf., Alvotech Germany GmbH, Alvotech Swiss AG, Alvotech USA Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc., and Ivers-Lee AG (Certain Adalimumab, Processes for Manufacturing or Relating to Same, and Products Containing Same, Investigation No. 337-TA-1296). The complaint raised trade secret misappropriation allegations similar to those raised in the trade secret litigation that AbbVie previously filed in the Northern District of Illinois. Pursuant to the U.S. AbbVie Agreement, Alvotech and AbbVie jointly sought dismissal of this action for all respondents, with each respondent to bear its own fees and costs. The action is now terminated.

On April 27, 2021, AbbVie filed an action against Alvotech hf. in the United States District Court for the Northern District of Illinois, alleging infringement of four patents, under the patent laws of the United States. On May 28, 2021, AbbVie filed another action against Alvotech hf. in the United States District Court for the Northern District of Illinois alleging infringement of 58 patents, under the patent laws of the United States, the BPCIA, and the Declaratory Judgment Act, and later added three more patents. Pursuant to the U.S. AbbVie Agreement, Alvotech and AbbVie settled all patent litigation regarding AVT02. The cases are now dismissed.

### Canadian Litigations

On March 31, 2021, AbbVie filed four actions in the Federal Court of Canada (T-557-21, T-559-21, T-560-21 and On March 31, 2021, AbbVie filed four actions in the Federal Court of Canada (T-557-21, T-559-21, T-560-21 and T-561-21, collectively, the "NOC Actions") against JAMP Pharma, which is Alvotech's exclusive Canadian partner for AVT02 (adalimumab solution for injection). No Alvotech entity is a named party in the NOC Actions. AbbVie is seeking declarations pursuant to the Patented Medicines (Notice of Compliance) Regulations and the Patent Act that JAMP Pharma's adalimumab solution for subcutaneous injection (the "JAMP Pharma Products") would directly or indirectly infringe the asserted claims of Canadian Patent Nos. 2,898,009; 2,904,458; 2,504,868; 2,847,142; 2,801,917 and 2,385,745. JAMP Pharma counterclaimed, in each of the four actions, alleging that the asserted claims of each of the six patents are invalid. On April 6, 2021, JAMP Pharma commenced four actions in the Federal Court of Canada (T-572-21, T-573-21, T-577-21 and T-581-21, collectively, the "Impeachment Actions") seeking declarations that all claims of Canadian Patent Nos. 2,898,009; 2,904,458; 2,504,868; 2,847,142; 2,801,917 and 2,385,745 are invalid, void and of no force or effect, and declarations that the making, using or selling of the JAMP Pharma Products by JAMP Pharma in Canada will not infringe any valid claim of Canadian Patent Nos. 2,898,009; 2,904,458; 2,504,868; 2,847,142; 2,801,917 and 2,385,745. No Alvotech entity is a named party in the Impeachment Actions.

On June 4, 2021, JAMP Pharma amended its Statements of Claim in the Impeachment Actions to only seek declarations that the specific claims asserted in the NOC Actions are invalid, void and of no force or effect, and declarations that the making, using or selling of the JAMP Pharma Products by JAMP Pharma in Canada will not infringe the asserted claims. AbbVie has counterclaimed for declarations that the asserted claims of the patents are valid and that they will be infringed by JAMP Pharma.

The trial of the Impeachment Actions and the NOC Actions commenced on November 14, 2022, and concluded with closing arguments on December 14, 2022. During the course of the proceedings, the patents-at-issue were limited to Canadian Patent Nos. 2,904,458; 2,504,868; and 2,801,917. In the event of a

successful claim of patent infringement against JAMP Pharma, JAMP Pharma may be blocked from the market, and we may have to redesign its infringing products or obtain a license from AbbVie, which may be impossible or require substantial time and monetary expenditure. Even if JAMP Pharma is successful in defending against AbbVie's patent infringement claims, litigation could result in substantial costs and be a distraction to management and other employees.

In December 2021, Health Canada informed JAMP Pharma that the 40 mg/0.4 mL and 80 mg/0.8 mL presentations of SIMLANDI are not subject to the 24-month statutory stay pursuant to the Patented Medicines (Notice of Compliance) Regulations because AbbVie elected to not market the equivalent high-concentration versions to Canadian patients. In January 2022, JAMP Pharma received notices of compliance for the 40 mg/0.4 mL and 80 mg/0.8 mL presentations of SIMLANDI. AbbVie has commenced applications to judicially review Health Canada's decision in the Federal Court of Canada, and a hearing took place on May 16-17, 2022. On August 17, 2022, the court issued a decision, finding that Health Canada's interpretation of the regulations was reasonable and dismissing AbbVie's applications for judicial review. On October 3, 2022, AbbVie issued a Notice of Appeal.

In the event that an appellate court finds in AbbVie's favor, then market access of SIMLANDI in Canada may be impacted.

## Preliminary Injunction Proceedings in Netherlands

On April 15, 2021, AbbVie Biotechnology Ltd. ("AbbVie Biotech") filed a writ of summons, bringing preliminary injunction proceedings (Case number: C/09/610604 KG ZA 21-366) against Alvotech hf., Alvotech Swiss AG, and STADA Arzneimittel AG (collectively, "Defendants") in the District Court of Amsterdam, relating to the European Union Marketing Authorization Application for AVT02, and asserting European Patent Nos. EP 1 737 491 and EP 2 940 044. AbbVie Biotech sought, after amendment of its claims, an order for the defendants to obtain a Marketing Authorization for AVT02 with a carve-out pursuant to Article 11, second paragraph, of Directive 2001/83/EC, whereby the indications allegedly protected by EP 1 737 491 and/or EP 2 940 044 and the corresponding dosage regimens are removed from certain portions of the SmPC of the Marketing Authorization, before AVT02 is marketed in Iceland, Norway, Liechtenstein and the EU countries where the asserted patents are valid. AbbVie Biotech also sought periodic penalty payments and an order to pay the costs of the proceedings. The Court heard oral argument on June 18, 2021. On July 16, 2021, the Court issued a decision, denying AbbVie Biotech's request for relief and ordering AbbVie Biotech to pay the defendants' costs. AbbVie Biotech did not appeal the Court's ruling.

### Proceedings Before the European Patent Office

On July 15, 2021, Alvotech hf. filed an intervention with the European Patent Office in the appeal opposition proceedings (T1837/19-3.304) relating to EP2940044, assigned to AbbVie Biotech. In 2017, a number of oppositions were filed with the Opposition Division of the European Patent Office ("Opposition Division") against EP2940044. On July 15, 2021, Alvotech hf. also filed an intervention with the European Patent Office in the appeal opposition proceedings (T1039/19-3.304) relating to EP1737491, assigned to AbbVie Biotech. On April 1, 2022 AbbVie and Alvotech entered into the European AbbVie Agreement pursuant to which, among other things, Alvotech and AbbVie settled all European legal proceedings relating to AbbVie's adalimumab patents. Pursuant to that agreement, the interventions have been withdrawn.

## Proceedings Before the Japanese Patent Office

On February 24, 2021, Alvotech hf. filed a petition to invalidate JP5813618, assigned to AbbVie Biotech with the Japanese Patent Office (No. 2021-800014). Alvotech hf.'s grounds for invalidation include that the claims of JP5813618 lack clarify and are unenforceable. AbbVie Biotech has filed its reply to the petition.

On March 16, 2021, Alvotech hf. filed a petition to invalidate JP5840364, assigned to AbbVie Biotech, with the Japanese Patent Office (No. 21-800020). Alvotech hf.'s grounds for invalidation include that the claims of JP5840364 are obvious and unenforceable. AbbVie Biotech has filed its response to the petition. An oral hearing took place in January 2022. In May 2022, the Japanese Patent Office dismissed Alvotech's petition to invalidate JP5840364.

In June 2022, Alvotech entered into a Settlement and License Agreement with AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Bahamas Ltd. with respect to AVT02 in Australia, Japan, Israel, Mexico, New Zealand, Republic of Korea, China, Hong Kong, Indonesia, Malaysia, Philippines, Saudi Arabia, Singapore, South Africa, Taiwan and certain other territories. With that settlement agreement executed, the parties have now resolved all intellectual property disputes before the Japanese Patent Office. In June 2022, Alvotech filed petitions to withdraw its petitions to invalidate JP5813618 and JP5840364.

## **Employees**

As of December 31, 2022, we had 947 employees, including 30 contractors, 86% of whom were devoted to R&D, quality and technical operations, and 14% to administration and support roles.

Many of our Iceland-based employees are members of Icelandic labor unions and as such the bargaining agreements which these unions enter into with the Icelandic Confederation of Employers, of which Alvotech hf. is a member. We have not experienced any work stoppages and consider our relationship with our employees and the labor union to be good.

		At December 31,		
	2020	2021	2022	
Function:				
Manufacturing	261	360	512	
Administrative	77	104	129	
Research and development	214	268	306	
Total	551	732	947	
Geography:		<u> </u>		
Iceland	435	557	745	
European Union	79	94	79	
United States	8	23	28	
Elsewhere	29	58	95	
Total	551	732	947	

#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our audited financial condition and results of operations together with our consolidated financial statements appearing elsewhere in this prospectus. This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," or similar language. All forward-looking statements included in this prospectus are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. In evaluating our business, you should carefully consider the information provided under the section "Risk Factors." Actual results could differ materially from those projected in the forward-looking statements. The terms "Company," "Alvotech," "we," "our" or "us" as used herein refer to Alvotech and its consolidated subsidiaries unless otherwise stated or indicated by context.

All amounts discussed are in U.S. dollars, unless otherwise indicated.

## Company Overview

Alvotech is a highly integrated biopharmaceutical company committed to developing and manufacturing high quality biosimilar medicines for patients globally. Our purpose is to improve the health and quality of life of patients around the world by improving access to proven treatments for various diseases. Since our inception, we have built our company with key characteristics we believe will help us capture the substantial global market opportunity in biosimilars: a leadership team that has brought numerous successful biologics and biosimilars to market around the world; a purpose-built biosimilars R&D and manufacturing platform; top commercial partnerships in global markets; and a diverse, expanding pipeline addressing many of the biggest disease areas and health challenges globally. Alvotech is a company committed to constant innovation: we focus our platform, people and partnerships on finding new ways to drive access to more affordable biologic medicines Alvotech, which was founded in 2013, is led by specialists in biopharmaceutical product creation from around the world that bring extensive combined knowledge and expertise to its mission.

Alvotech currently has eight product candidates in its pipeline for serious diseases with unmet patient and market need. Product candidates in our pipeline address reference products treating autoimmune, eye, and bone disorders, as well as cancer, with combined estimated peak global sales of originator products of more than \$85 billion.

• In April 2022, Alvotech's commercial partner, JAMP Pharma, launched AVT02 under the name SIMLANDI in Canada. In 2022, Alvotech's commercial partner, STADA, launched AVT02 under the name Hukyndra in select European markets. The Company recognized \$24.8 million in product revenue resulting from the commercialization of AVT02.

Alvotech's BLA supporting biosimilarity for AVT02, was filed with the FDA in 2020, and its BLA supporting interchangeability was accepted for review in February 2022. In September 2022, Alvotech announced that it had received communication from the FDA detailing its assessment of the March 2022 inspection of Alvotech's manufacturing facility in Reykjavik, Iceland and Alvotech's subsequent written responses to the FDA. The FDA's August 2022 CRL to the initial biosimilar BLA for AVT02 noted certain deficiencies related to the Reykjavik facility and stated that satisfactory resolution of the deficiencies is required before FDA may approve this first-filed BLA. In December 2022, Alvotech received a complete response letter from the FDA regarding the interchangeability BLA. Under this December 2022 CRL, correction of the same deficiencies identified in the August 2022 CRL with respect to the biosimilarity BLA is required for approval of the interchangeability BLA. In January 2023, Alvotech received confirmation from the FDA that the reinspection of its facility in Reykjavik,

Iceland is scheduled for March 6, 2023. Subject to regulatory approval from the FDA, Alvotech expects to launch AVT02 in the United States on July 1, 2023.

- In May 2022, Alvotech reported positive topline results from two clinical studies for its second product candidate, AVT04, a proposed biosimilar to Stelara (ustekinumab). In January 2023, Alvotech announced that the FDA had accepted for review a BLA for AVT04. Alvotech anticipates that the FDA's review will be completed in October 2023. In February 2023, Alvotech announced that the EMA had accepted a Marketing Authorization Application for AVT04. Alvotech, directly or indirectly through its partners, also submitted marketing applications for AVT04 in, Japan and Canada in the second half of 2022.
- Alvotech is in the earlier stages of development for its other lead product candidates, namely AVT03, a biosimilar candidate to Prolia /
  Xgeva (denosumab) for which Alvotech initiated clinical studies in July 2022, AVT05, a biosimilar candidate to Simponi and Simponi
  Aria (golimumab) for which Alvotech initiated a pharmacokinetic (PK) study in December 2022, AVT06, a biosimilar candidate to Eylea
  (aflibercept) for which Alvotech initiated a clinical study in July 2022, and AVT23, a biosimilar candidate to Xolair (omalizumab) for
  which a PK study has been completed.
- Alvotech also has a number of other programs in earlier phases of development that it plans to advance over the coming years. The two most advanced of these, AVT16 and AVT33, are in early development and with immunology and oncology reference products that have estimated combined global peak sales of approximately \$30 billion.

Since inception, Alvotech has incurred significant operating losses. Alvotech's loss for the years ended December 31, 2022, 2021 and 2020 was \$513.6 million, \$101.5 million and \$170.0 million, respectively. Alvotech's Adjusted EBITDA was (\$205.2) million, (\$180.7) million and (\$91.2) million for the years ended December 31, 2022, 2021, and 2020, respectively. Alvotech expects to continue to incur increasing expenses and operating losses for the immediate future, as it advances its products through preclinical and clinical development and seeks regulatory approvals, manufactures drug product and drug supply, maintains and expands its intellectual property portfolio, hires additional personnel, and pays for accounting, audit, legal, regulatory and consulting services and costs associated with maintaining compliance with exchange listing rules and the requirements of the SEC, director and officer liability insurance premiums, investor and public relations activities and other expenses associated with operating as a public company. See "Risk Factors—We may need to raise substantial additional funding from shareholders or third parties. This additional funding may not be available on acceptable terms or at all. Failure to obtain such necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations."

## Factors Affecting Alvotech's Performance

The pharmaceutical industry is highly competitive and highly regulated. As a result, Alvotech faces a number of industry-specific factors and challenges, which can significantly impact its results. For a more detailed explanation of Alvotech's business and its risks see "*Risk Factors*."

### Competition

The regions in which Alvotech conducts business and the pharmaceutical industry in general is highly competitive. Alvotech faces significant competition from a wide range of companies in a highly regulated industry, including competition from both biosimilar developers and manufacturers as well as competition from branded pharmaceutical developers and manufacturers. In addition, Alvotech is at risk of becoming a party to litigation with respect to patent infringement and other related claims. See "Business—Legal Proceedings" for details related to Alvotech's resolved litigation adverse to AbbVie.

## Research and development uncertainty

Research and development within the pharmaceutical industry has a high degree of uncertainty, and likewise there is uncertainty with respect to the probability of success of Alvotech's biosimilar programs and the timing of the requisite preclinical and clinical steps to achieve regulatory approval of its biosimilar product candidates.

## Reliance on commercial partners

Alvotech has partnered with several third parties to commercialize its biosimilar product candidates, once approved by the appropriate regulatory agencies. Alvotech does not currently have the capabilities or the necessary infrastructure to commercialize its products independently.

### The Business Combination and PIPE Financing

On June 15, 2022 (the "Closing Date"), Alvotech consummated the business combination with Alvotech Holdings and OACB (the "Business Combination") pursuant to the business combination agreement dated December 7, 2021, and as amended by an amendment agreement dated April 18, 2022, and June 7, 2022 (the "Business Combination Agreement"). The Business Combination was accounted for as a capital reorganization.

Concurrently with the execution of the Business Combination Agreement, OACB and Alvotech entered into Subscription Agreements with certain investors (the "PIPE Financing"). On June 15, 2022, immediately prior to the closing of the Business Combination, the PIPE Financing was closed, pursuant to the Subscription Agreements, in which subscribers collectively subscribed for 17,493,000 ordinary shares at \$10.00 per share for an aggregate subscription price equal to \$174.9 million.

The closing of the Business Combination and the PIPE Financing provided the Group with gross proceeds of \$184.7 million that was used to finance the continuing development and commercialization of its biosimilar products. The Company also incurred \$28.5 million of transaction costs, which represent legal, financial advisory, and other professional fees in connection with the Business Combination and PIPE Financing, during the year ended December 31, 2022. Of this amount, \$5.6 million represented equity issuance costs related to the PIPE Financing.

## Impact of COVID-19, the Russia and Ukraine Conflict, and Global Economic Conditions

With the ongoing COVID-19 pandemic, Alvotech created a COVID-19 task force which implemented a business continuity plan to address and mitigate the impact of the pandemic on its business and operations across sites. As a result, in the short-term, the pandemic has not had a material impact on Alvotech's financial condition, results of operations, the timelines for biosimilar product development, expansion efforts or its operations as a whole. However, the extent to which the pandemic will impact Alvotech's business, biosimilar product development and expansion efforts, corporate development objectives and the value of and market for its ordinary shares will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate direction of the pandemic, travel restrictions, quarantines, social distancing, business closure requirements and the effectiveness of other actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global supply chains and distribution systems, the effects of this on the work of appropriate regulatory authorities in different regions and the other risks and uncertainties associated with the pandemic could have a material adverse effect on Alvotech's business, financial condition, results of operations and growth prospects.

In February 2022, Russia began a military invasion of Ukraine. The global response to this invasion could have an adverse impact on the Group's business, including the Group's ability to market and sell products in Europe, by creating disruptions in global supply chain, and potentially having an adverse impact on the global economy, European economy, financial markets, energy markets, currency rates, and otherwise. Currently, the

conflict has not had a material impact on the Group's financial condition, results of operations, the timelines for biosimilar product development, expansion efforts or the Group's operations as a whole.

The Company believes that inflation will have a general impact on the business in line with overall price increases, increases in the cost of borrowing, and operating in an inflationary economy. We cannot predict the timing, strength, or duration of any inflationary period or economic slowdown or its ultimate impact on the Company. If the conditions in the general economy significantly deviate from present levels and continue to deteriorate it could have a material adverse effect on the Group's business, financial condition, results of operations and growth prospects.

## **Components of Operations**

### Product Revenue

During the year ended December 31, 2022, the Company recognized revenue from product sales resulting from the launch of Alvotech's AVT02 product, under the name Hukyndra in select European countries and SIMLANDI in Canada. The Company expects to continue to recognize product revenue as products are successfully launched into the marketplace.

#### License and Other Revenue

Alvotech generates a majority of its revenue from upfront and milestone payments pursuant to long-term out-license contracts which provide its partners with an exclusive right to market and sell Alvotech's biosimilar product candidates in a particular territory once such products are approved for commercialization. These contracts typically include commitments to continue development of the underlying compound and to provide supply of the product to the partner upon commercialization.

In the future, revenue may include new out-license contracts and additional milestone payments. Alvotech expects that any revenue it generates will fluctuate from period to period as a result of the timing and amount of license, research and development services, and milestone and other payments.

### **Operating Expenses**

#### Cost of product revenue

Cost of product revenue includes the cost of inventory sold, labor costs, manufacturing overhead expenses and reserves for expected scrap, as well as shipping and freight costs and royalty costs related to in-license agreements.

## Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with Alvotech's research, development and pre-commercial manufacturing activities prior to the commercialization of AVT02. These costs include:

- personnel expenses, including salaries, benefits and other compensation expenses;
- costs of funding the execution of studies performed both internally and externally;
- costs of purchasing laboratory supplies and non-capital equipment used in designing, developing and manufacturing preclinical study and clinical trial materials;
- expenses related to quality control and other advancement development;
- consultant fees;

- expenses related to regulatory activities, including filing fees paid to regulatory agencies;
- facility costs including rent, depreciation and maintenance expenses;
- fees for maintaining licenses under third party licensing agreements;
- expenses incurred in preparation for commercial launch, such as designing and developing commercial-scale manufacturing capabilities
  and processes, quality control processes, production asset valuation and other related activities; and
- costs related to amortization, depreciation and impairment losses related to software and property, plant and equipment used in research and development activities.

Expenditures related to research and development activities are generally recognized as an expense in the period in which they are incurred. Due to significant regulatory uncertainties and other uncertainties inherent in the development of pharmaceutical products, Alvotech did not capitalize any research and development expenses as internally developed intangible assets during the years ended December 31, 2022, 2021 and 2020.

Research and development activities will continue to be central to Alvotech's business model and will vary significantly based upon the success of its programs. Alvotech plans to substantially increase research and development expenses in the near term, as it continues to advance the development of its biosimilar product candidates.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of development, primarily due to the increased size and duration of later-stage clinical trials.

The duration, costs and timing of clinical trials of Alvotech's products in development and any other product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the number of trials required for approval;
- the per patient trial costs;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the dose that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- any delays in key trial activities and patient enrollment or diversion of healthcare resources as a result of the COVID-19 pandemic;
- production shortages or other supply interruptions in clinical trial materials resulting from the COVID-19 pandemic;
- · the timing and receipt of regulatory approvals; and
- the efficacy and safety profile of the product candidates.

In addition, the probability of success of Alvotech's products in development and any other product candidate will depend on numerous factors, including competition, manufacturing capability and commercial

viability. Alvotech may never succeed in achieving regulatory approval of its product candidates for any indication in any country. As a result of the uncertainties discussed above, the estimated duration and completion costs of any clinical trial that Alvotech conducts is subject to change. Alvotech is also unable to determine with certainty when and to what extent it will generate revenue from the commercialization and sale of products in development or other product candidates, if at all.

## General and administrative expenses

General and administrative expenses primarily consist of personnel-related expenses, including salaries, bonuses and other related compensation expenses, and external consulting service costs for corporate and other administrative and operational functions including finance, human resources, information technology and legal, as well as facility-related costs not otherwise included in research and development expenses. These costs relate to the operation of the business and are not related to research and development initiatives. General and administrative costs are expensed as incurred.

Alvotech expects general and administrative expenses to continue to increase as Alvotech increases its headcount and incurs external costs associated with operating as a public company, including expenses related to legal, accounting, tax, consulting services and regulatory matters, maintaining compliance with requirements of exchange listings and of the SEC, director and officer liability insurance premiums and investor relations activities and other expenses associated with operating as a public company. Though expected to increase, Alvotech expects these expenses to decrease as a percentage of revenue in the long-term, as revenue increases.

## Share of net loss / profit of joint venture

Alvotech currently holds a 50% ownership interest in the Joint Venture. Alvotech accounts for its ownership interest in the Joint Venture using the equity method of accounting. Under the equity method of accounting, investments in joint ventures are initially recognized at cost and the carrying amount is subsequently adjusted for Alvotech's share of the profit or loss of the Joint Venture, as well as any distributions received from the Joint Venture. Alvotech's profit or loss includes its share of the profit or loss of the Joint Venture and, to the extent applicable, other comprehensive income or loss for Alvotech will include its share of other comprehensive income or loss of the Joint Venture.

## Finance income and finance costs

Finance income consists of changes in the fair value of derivative financial liabilities and interest income. Alvotech recognizes interest income from a financial asset when it is probable that the economic benefits will flow to Alvotech, and the amount of income can be measured reliably.

Finance costs consist of interest expenses related to lease liabilities and borrowings, changes in the fair value of derivative financial liabilities, accretion of Alvotech's borrowings and amortization of deferred financing fees.

## Exchange rate differences

Exchange rate differences primarily consist of the translation of certain assets and liabilities that are denominated in foreign currency into U.S. dollars.

## Gain / loss on extinguishment of financial liabilities

Alvotech recognizes a gain / loss on extinguishment of financial liabilities in connection with the substantial modification or extinguishment of outstanding financial liabilities. The gain / loss is calculated as the difference between the carrying amount of the liability extinguished and the fair value of the consideration paid.

Income tax benefit

Income tax benefit consists of current tax and deferred tax benefit recorded in the consolidated statement of profit or loss and other comprehensive income or loss.

## **Operating Results**

Comparison of the Years Ended December 31, 2022, and 2021

The following table sets forth Alvotech's results of operations for the years ended December 31:

USD in thousands	2022	2021
Product revenue	24,836	
License and other revenue	58,193	36,772
Other income	1,988	2,912
Cost of product revenue	(64,095)	_
Research and development expenses	(180,622)	(191,006)
General and administrative expenses	(186,742)	(84,134)
Operating loss	(346,442)	(235,456)
Share of net loss of joint venture	(2,590)	(2,418)
Finance income	2,549	51,568
Finance costs	(188,419)	(117,361)
Exchange rate differences	10,566	2,681
(Loss) / Gain on extinguishment of financial liabilities	(27,311)	151,788
Non – operating (loss) profit	(205,205)	86,258
Loss before taxes	(551,647)	(149,198)
Income tax benefit	38,067	47,694
Loss for the year	(513,580)	(101,504)

## Product revenue

USD in thousands	Year Ended I	December 31.	2021 to 2	
	2022	2021	\$	%
Product revenue	24,836		24,836	nm

## nm = not meaningful, refer to explanation below

The Company successfully launched the AVT02 product in Canada and select European countries resulting in \$24.8 million of product revenue recognized during the year ended December 31, 2022.

# License and other revenue

USD in thousands	Year Ended D	ecember 31.	<u>Chan</u> 2021 to	, -
COD III GIOUSAINO	2022	2021	\$	%
License and other revenue	58,193	36,772	21,421	58.2%

License and other revenue increased by \$21.4 million, or 58.2%, from \$36.8 million for the year ended December 31, 2021, to \$58.2 million for the year ended December 31, 2022. The company recognized \$44.5 million and \$11.6 million resulting from license and milestone payments for AVT04 and AVT05,

respectively, for the year ended December 31, 2022. During the year ended December 31, 2021, the Company recognized \$20.8 million, \$8.6 million, and \$7.2 million from license and milestone payments for AVT06, AVT02, and AVT03, respectively.

### Other income

USD in thousands	Year Ended Do	Year Ended December 31,		
	2022	2021	\$	%
Other income	1,988	2,912	(924)	31.7%

Other income decreased by \$0.9 million, or 31.7%, from \$2.9 million for the year ended December 31, 2021, to \$2.0 million for the year ended December 31, 2022. The decrease in other income was driven by a decrease in income generated from services performed pursuant to Alvotech's support service arrangements with Alvogen, a related party, during the year ended December 31, 2022, as compared to the year ended December 31, 2021.

## Cost of product revenue

			Chang	је
USD in thousands	Year Ende	d December 31,	2021 to 2	2022
	2022	2021	\$	%
Cost of product revenue	64,095		64,095	nm

## nm = not meaningful, refer to explanation below

The Company successfully launched AVT02 in select European countries and Canada during the year ended December 31, 2022. As a result, the Company commenced recognizing cost of product revenue in the same period. Cost of product revenue for the year ended December 31, 2022, was \$64.1 million, which includes both variable and fixed manufacturing costs associated with commercial manufacturing. Cost of product revenue is disproportionate relative to product revenue due to the timing of new launches, resulting in higher costs than revenues recognized for the period. The Company expects this to normalize as it increases in scale and expands on new product launches. Ultimately, the increase in volumes will result in the absorption of fixed manufacturing costs. Prior to the recognition of cost of product revenues, these costs were reported as research and development expenses as pre-commercial manufacturing activities.

### Research and development expenses

			Chang	ge
	Year Ended December 31,		2021 to 2	2022
USD in thousands	2022	2021	\$	%
AVT02 development program expenses	9,986	26,610	(16,624)	62.5
AVT03 development program expenses	15,667	6,631	9,036	136.3
AVT04 development program expenses	23,879	35,770	(11,891)	33.2
AVT05 development program expenses	28,034	2,822	25,212	nm
AVT06 development program expenses	19,044	11,508	7,536	65.5
Salary and other employee expenses	52,962	71,588	(18,626)	26.0
Depreciation, amortization and impairment	6,740	21,764	(15,024)	69.0
Other research and development expenses (1)	24,310	13,766	10,544	76.6
Total research and development expenses	180,622	191,006	(10,384)	5.4%

### nm = not meaningful, refer to explanation below

<sup>(1)</sup> Other research and development expenses include other project costs, facility costs and other operating expenses recognized as research and development expenses during the period.

Research and development expenses decreased by \$10.4 million, or 5.4%, from \$191.0 million for the year ended December 31, 2021, to \$180.6 million for the year ended December 31, 2022. During the year ended December 31, 2022, the following resulted in an overall decrease to total research and development expenses:

- AVT02 development program expenses decreased by \$16.6 million, or 62.5%, as a result of decreased R&D activities. The Company obtained marketing authorization for AVT02 in the EEA, the UK, Switzerland, Canada, Australia and Saudi Arabia, resulting in the conclusion of pre-launch R&D studies and the recognition of cost of product revenue. As a result, the AVT02 development program expenses decreased during the year ended December 31, 2022. The Company expects these expenses to continue to decrease as the Company seeks to obtain marketing authorization in other jurisdictions, including the US.
- AVT04 development program expenses decreased by \$11.9 million, or 33.2%. During the year ended December 31, 2022, the Company completed significant R&D activities related to AVT04. Subsequent to December 31, 2022, in January 2023, Alvotech announced that the FDA had accepted for review a BLA for AVT04. In February 2023, Alvotech announced that the EMA had accepted a Marketing Authorization Application for AVT04. As a result, the company recognized less R&D expense related to AVT04 as R&D studies entered late stages.
- Salary and other employee expenses decreased by \$18.6 million, or 26.0%. This decrease is a result of costs being classified as manufacturing costs subsequent to the Company obtaining marketing authorization for AVT02. Previously, these costs were reported as pre-commercial manufacturing activities within research and development.
- Depreciation, amortization and impairment expenses decreased by \$15.0 million, or 69.0%. This decrease is a result of costs being classified as manufacturing costs subsequent to the Company obtaining marketing authorization for AVT02. Previously, these costs were reported as pre-commercial manufacturing activities within research and development.
- The increases in development program expenses of \$9.0 million, \$25.2 million, and \$7.5 million for AVT03, AVT05, and AVT06, respectively, are a result of these biosimilar candidates initiating the clinical phase of development. The Company expects to continue to incur R&D expense as they seek commercialization of these biosimilar candidates.
- Other research and development expenses increased by \$10.5 million, or 76.6%. The increase is due to an increase in costs of \$4.3 million and \$4.2 million for AVT23 and AVT16, respectively.

Chanae

## General and administrative expenses

	Year Ended De	cember 31,	2021 to 2	
USD in thousands	2022	2021	\$	%
General and administrative expense	186,742	84,134	102,608	122.0

General and administrative expenses increased by \$102.6 million, or 122.0%, from \$84.1 million for the year ended December 31, 2021, to \$186.7 million for the year ended December 31, 2022. The increase in general and administrative expenses was primarily attributable to the \$83.4 million non-cash share listing expense and \$10.4 million of additional transaction costs recognized as a result of the Business Combination. See Note 1.1 of the consolidated financial statements. The Company also recognized \$5.8 million of general and administrative expenses for share-based payments, resulting from the granting of RSUs during the year ended December 31, 2022. Lastly, the company recognized \$3.3 million in salary expense related to severance agreements, associated with a management reorganization, and had an increase of \$13.6 million on other general administrative expenses related to IT and other third-party services. These increases were offset by \$17.4 million less of long-term incentive plan expense recognized during the year ended December 31, 2022.

### Share of net loss of joint venture

			Cha	nge
USD in thousands	Year Ended	l December 31,	2021 to	o 2022
	2022	2021	\$	%
Share of net loss of joint venture	2,590	2,418	172	7.1

Share of net loss of joint venture increased by \$0.2 million, or 7.1%, from \$2.4 million for the year ended December 31, 2021, to \$2.6 million for the year ended December 31, 2022. The increase in the share of net loss of joint venture was due to an increase in losses incurred by the Joint Venture during the year ended December 31, 2022, as compared to December 31, 2021. The increase in losses incurred by the Joint Venture was due to lower interest income combined with higher depreciation and amortization expense for the year ended December 31, 2022.

## Finance income

			Cnai	<u>nge</u>
USD in thousands	Year Ended	Year Ended December 31,		
	2022	2021	\$	%
Finance income	2,549	51,568	(49.0)	95.1

Finance income decreased by \$49.0 million, or 95.1%, from \$51.6 million for the year ended December 31, 2021, to \$2.6 million for the year ended December 31, 2022. The decrease in finance income was primarily attributable to \$48.7 million in income resulting from a favorable fair value remeasurement of derivative financial liabilities associated with the convertible shareholder loans during the year ended December 31, 2021. In connection with the Business Combination Agreement, on December 7, 2021, the Group's shareholders entered into the BCA Framework Agreement resulting in the exercise of the conversion, warrant, and funding rights associated with the convertible shareholder loans.

#### Finance costs

			Chang	je	
USD in thousands	Year Ended December 31,			2021 to 2022	
	2022	2021	\$	%	
Finance costs	188,419	117,361	71,058	60.5	

Finance costs increased by \$71.1 million, or 60.5%, from \$117.4 million for the year ended December 31, 2021, to \$188.4 million for the year ended December 31, 2022. The increase in finance costs is primarily related to a \$94.2 million increase in finance costs resulting from the change in fair value of derivative liabilities. For the year ended December 31, 2022, the Company recognized finance costs for the following derivatives:

- \$48.7 million in finance costs resulting from the increase in fair value of the Predecessor Earn Out Shares
- \$29.9 million in finance costs resulting from the increase in fair value of the Senior Bond Warrants
- \$13.2 million in finance costs resulting from the increase in fair value of the Tranche A Conversion Feature
- \$3.7 million in finance costs resulting from the decrease in fair value of the derivative asset relates to the Senior bond interest feature
- \$1.4 million in finance costs resulting from the increase in fair value of the OACB Earn Out Shares

Additionally, the company recognized \$13.9 million in finance costs related to the consenting fee and remeasurement of the bonds as result of the terms being amended in association with the closing of the Business

Combination with OACB. These increases in finance costs were offset by \$35.0 million less of finance costs related to the interest on debt and borrowings. The company incurred less interest costs on borrowings due to the extinguishment of the convertible shareholder loans on December 7, 2021, resulting in less finance costs for the year ended December 31, 2022. During the year ended December 31, 2021, the Company recognized \$30.7 million of finance costs related to interest on the convertible shareholders loans.

# Exchange rate differences

USD in thousands	Year Ended Do	ecember 31,	2021 to	2022
	2022	2021	\$	%
Exchange rate differences	10,566	2,681	7,885	294.1

Chanaa

Exchange rate differences increased by \$7.9 million, or 294.1%, from \$2.7 million for the year ended December 31, 2021, to \$10.6 million for the year ended December 31, 2022. The increase was primarily driven by a change in financial assets and liabilities denominated in Icelandic Krona and Euros, along with the weakening of the Icelandic Krona compared to the US dollar, during the year ended December 31, 2022.

## (Loss) / Gain on extinguishment of financial liabilities

			Cha	nge
USD in thousands	Year Ended D	ecember 31,	2021 to	o 2022
	2022	2021	\$	%
(Loss) / Gain on extinguishment of financial liabilities	(27,311)	151,788	nm	nm

## nm = not meaningful, refer to explanation below

Alvotech recognized a loss on extinguishment of financial liabilities of \$27.3 million during the year ended December 31, 2022, primarily as a result of the following transactions:

- \$40.9 million loss resulting from the amendment and upsizing of the Senior Bonds.
- \$3.9 million loss resulting from the extinguishment of the lease on the Alvotech facility resulting from the Share Purchase Agreement for the Saemundur manufacturing facility.
- \$17.8 million gain resulting from the settlement of related party loans with Aztiq and Alvogen, in which the parties agreed to settle outstanding loan amounts through the issuance of Ordinary Shares.

Alvotech recognized a gain on extinguishment of financial liabilities of \$151.8 million during the year ended December 31, 2021, in connection with the substantial modification to the terms and conditions of the convertible bonds, as well as the exercise of the conversion, warrant and funding rights associated with the convertible shareholder loans.

## Income tax benefit

USD in thousands	Year Ended De	cember 31,	2021 to 2	
	2022	2021	\$	%
Income tax benefit	38,067	47,694	(9,627)	20.2

Income taxes for the year ended December 31, 2022, resulted in an income tax benefit of \$38.1 million compared to an income tax benefit of \$47.7 million for the year ended December 31, 2021. This decrease in income tax benefit was mainly driven by a \$10.1 million foreign currency impact due to the continued weakening of the Icelandic Krona against the US dollar, decreasing the US dollar value of tax loss carry-forwards that Alvotech expects to fully utilize against future taxable profits.

Comparison of the Years Ended December 31, 2021, and 2020

The following table sets forth Alvotech's results of operations for the years ended December 31:

USD in thousands	2021	2020
Revenue	36,772	66,616
Other income	2,912	2,833
Research and development expenses	(191,006)	(148,072)
General and administrative expenses	(84,134)	(58,914)
Operating loss	(235,456)	(137,537)
Share of net loss of joint venture	(2,418)	(1,505)
Finance income	51,568	5,608
Finance costs	(117,361)	(161,551)
Exchange rate differences	2,681	3,215
Gain on extinguishment of financial liabilities	151,788	_
Non – operating profit (loss)	86,258	(154,233)
Loss before taxes	(149,198)	(291,770)
Income tax benefit	47,694	121,726
Loss for the year	(101,504)	(170,044)

### Revenue

			Chang	ge
USD in thousands	Year Ended D	ecember 31,	2020 to 2	2021
	2021	2020	\$	%
Revenue	36,772	66,616	(29,844)	(44.8)

Revenue decreased by \$29.8 million, or 44.8%, from \$66.6 million for the year ended December 31, 2020, to \$36.8 million for the year ended December 31, 2021. The decrease in revenue was driven by a \$22.6 million decrease in license revenue and a \$7.2 million decrease in research and development service revenue earned pursuant to out-license contracts with commercial partners during 2021 as compared to 2020.

The \$22.6 million decrease in license revenue was primarily attributable to the timing of entering out-license contracts with commercial partners coupled with the stage of development of Alvotech's biosimilar product candidates at the time such out-license contracts were executed. Alvotech's license revenue for the year ended December 31, 2020, primarily relates to milestones reached on out-license contracts entered into for AVT02 whereas Alvotech's license revenue for the year ended December 31, 2021, primarily relates to out-license contracts entered into for AVT04.

The \$7.2 million decrease in research and development service revenue was primarily attributable to the wind down of clinical studies and other development-related activities for AVT02 in 2021.

## Other income

			Cha	inge
USD in thousands	Year Ended De	Year Ended December 31,		
	2021	2020	\$	%
Other income	2,912	2,833	79	2.8

Other income increased by \$0.1 million, or 2.8%, from \$2.8 million for the year ended December 31, 2020, to \$2.9 million for the year ended December 31, 2021. The increase in other income was driven by an increase in

research and development grants from the Icelandic government partially offset by a decrease in income generated from services performed pursuant to Alvotech's support service arrangements with Alvogen, a related party, during the year ended December 31, 2021, as compared to the year ended December 31, 2020.

# Research and development expenses

		Chang	je
Year Ended December 31,		2020 to 2	2021
2021	2020	\$	%
26,610	42,440	(15,830)	(37.3)
35,770	15,148	20,622	136.1
11,508	2,321	9,187	395.8
71,588	49,043	22,545	46.0
21,764	16,358	5,406	33.0
23,766	22,762	1,004	4.4
191,006	148,072	42,934	29.0
	2021 26,610 35,770 11,508 71,588 21,764 23,766	2021         2020           26,610         42,440           35,770         15,148           11,508         2,321           71,588         49,043           21,764         16,358           23,766         22,762	Year Ended December 31, 2020 to 2         2020 to 2           2021 2020 \$         \$           26,610 42,440 (15,830)         35,770 15,148 20,622           11,508 2,321 9,187         71,588 49,043 22,545           21,764 16,358 5,406 23,766 22,762 1,004

(1) Other research and development expenses include manufacturing costs, facility costs and other operating expenses recognized as research and development expenses during the period. In 2020, other research and development expenses includes the payment made to Lotus Pharmaceutical Co. Ltd., a related party, related to the acquisition of rights for the commercialization of Alvotech's biosimilar Adalimumab product in certain territories in Asia.

Research and development expenses increased by \$42.9 million, or 29.0%, from \$148.1 million for the year ended December 31, 2020, to \$191.0 million for the year ended December 31, 2021. The increase in research and development expense was primarily attributable to an increase of \$22.5 million in salary expense as a result of new hires in support of new and existing development programs and ongoing preparation for commercial launch of Alvotech's biosimilar product candidates. Additional drivers include an increase of \$20.6 million in AVT04 development program expenses, an increase of \$9.2 million in AVT06 development program expenses, a \$4.0 million impairment charge on certain software assets previously under development and a \$2.1 million impairment charge on equipment no longer intended for research and development purposes. These expenses were offset by a \$15.8 million decrease in AVT02 development program expenses due to the wind down of clinical studies and other development-related activities throughout 2021.

### General and administrative expenses

	Year Ended December 31,		2020 to	
USD in thousands	2021	2020	\$	%
General and administrative expense	84,134	58,914	25,220	42.8

General and administrative expenses increased by \$25.2 million, or 42.8%, from \$58.9 million for the year ended December 31, 2020, to \$84.1 million for the year ended December 31, 2021. The increase in general and administrative expenses was primarily attributable to \$12.5 million of transaction costs related to the Business Combination incurred in 2021, an increase of \$5.6 million in legal expenses in preparation for, and/or in relation to, litigation with AbbVie in the United States and an increase of \$4.7 million in salary expense as a result of new hires.

### Share of net loss of joint venture

			Cha	ınge
USD in thousands	Year Ended Do	ecember 31,	2020 t	o 2021
	2021	2020	\$	%
Share of net loss of joint venture	2,418	1,505	913	60.7

Share of net loss of joint venture increased by \$0.9 million, or 60.7%, from \$1.5 million for the year ended December 31, 2020, to \$2.4 million for the year ended December 31, 2021. The increase in the share of net loss of joint venture was due to an increase in losses incurred by the Joint Venture during the year ended December 31, 2021, as compared to December 31, 2020. The increase in losses incurred by the Joint Venture was due to higher research and development and administrative expenses incurred by the Joint Venture during the year ended December 31, 2021, partially due to the fact that the Joint Venture commenced operations in the first quarter of 2020, coupled with a decrease in interest income in 2021.

### Finance income

			<u>Char</u> 2020 to	
USD in thousands	Year Ended 1	Year Ended December 31,		
	2021	2020	\$	%
Finance income	51,568	5,608	45,960	819.5

Finance income increased by \$46.0 million, or 819.5%, from \$5.6 million for the year ended December 31, 2020, to \$51.6 million for the year ended December 31, 2021. The increase in finance income was primarily attributable to an increase of \$46.1 million in unrealized gains associated with the fair value remeasurement of derivative financial liabilities, the majority of which relates to the remeasurement of the derivative financial liabilities associated with the convertible shareholder loans on the date of extinguishment of such loans.

#### Finance costs

			Chang	је
USD in thousands	Year Ended	December 31,	2020 to 2	2021
	2021	2020	\$	%
Finance costs	117,361	161,551	(44,190)	(27.4)

Finance costs decreased by \$44.2 million, or 27.4%, from \$161.6 million for the year ended December 31, 2020, to \$117.4 million for the year ended December 31, 2021. The decrease in finance costs was primarily attributable to a decrease of \$58.0 million in unrealized losses associated with the fair value remeasurement of derivative financial liabilities, partially offset by an increase of \$14.5 million in interest on borrowings as result of additional payment-in-kind interest added to the principal balances for the convertible shareholder loans during the year ended December 31, 2021.

## Exchange rate differences

			Cha	nge
USD in thousands	Year Ended De	cember 31,	2020 to	2021
	2021	2020	\$	%
Exchange rate differences	2,681	3,215	(534)	(16.6)

Exchange rate differences decreased by \$0.5 million, or 16.6%, from \$3.2 million for the year ended December 31, 2020, to \$2.7 million for the year ended December 31, 2021. The decrease was primarily driven by a change in financial assets and liabilities denominated in Icelandic Krona and Euros during the year ended December 31, 2021.

### Gain on extinguishment of financial liabilities

			Change	?
USD in thousands	Year Ended Dec	ember 31,	2020 to 20	)21
	2021	2020	\$	%
Gain on extinguishment of financial liabilities	151,788		151,778	nm

## nm = not meaningful, refer to explanation below

Alvotech recognized a gain on extinguishment of financial liabilities of \$151.8 million during the year ended December 31, 2021, in connection with the substantial modification to the terms and conditions of the convertible bonds, and other related, concurrent transactions, as well as the exercise of the conversion, warrant and funding rights associated with the convertible shareholder loans.

The substantial modification of the convertible bonds was accounted for as an extinguishment, resulting in a gain on extinguishment of financial liabilities of \$2.6 million. The gain on extinguishment of financial liabilities was primarily driven by the \$26.7 million difference between the fair value of the post-transaction bonds and the carrying amount of the pre-transaction bonds in addition to the \$7.7 million difference between the carrying amount of pre-transaction bonds converted in connection with the transaction and the fair value of the resulting shares into which such bonds were converted. The gain on extinguishment of financial liabilities was partially offset by \$16.2 million for transaction costs and fees incurred as part of the extinguishment, the acceleration of \$11.0 million of previously deferred debt issue costs incurred in connection with the issuance of the pre-transaction bonds, and the acceleration of \$4.6 million of previously unamortized accretion of the pre-transaction bonds.

The exercise of the conversion, warrant and funding rights associated with the convertible shareholder loans resulted in a gain on extinguishment of financial liabilities of \$149.2 million, primarily driven by the difference between the carrying amount of the pre-transaction convertible shareholder loans and the related derivative financial liabilities and the fair value of the ordinary shares issued, and cash received for the exercise of the conversion, warrant and funding rights.

### Income tax benefit

USD in thousands	Very Ended	December 31.	<u>Chang</u> 2021 to 2	
USD in thousands	2021	2020	\$	%
Income tax benefit	47,694	121,726	(74,032)	(60.8)

### nm = not meaningful, refer to explanation below

Income taxes for the year ended December 31, 2021, resulted in an income tax benefit of \$47.7 million compared to income tax benefit of \$121.7 million for the year ended December 31, 2020. This change was primarily driven by the recognition of an additional \$47.7 million of deferred tax assets in 2021 with respect to current year tax losses that Alvotech expects will be fully utilized against future taxable profits.

## Reconciliation of non-IFRS financial measure

In addition to its operating results, as calculated in accordance with IFRS, Alvotech uses Adjusted EBITDA when monitoring and evaluating operational performance. Adjusted EBITDA is defined as profit or loss for the relevant period, as adjusted for certain items that Alvotech management believes are not indicative of ongoing operating performance. The adjusting items consist of the following:

- 1. Income tax benefit;
- 2. Total net finance costs;

- 3. Depreciation and amortization of property, plant, and equipment, right-of-use assets and other intangible assets;
- 4. Impairment of property, plant, and equipment and other intangible assets;
- 5. Incentive plan expense;
- 6. Share of net loss of joint venture;
- 7. Exchange rate differences;
- 8. Acquisition of rights for Adalimumab from Lotus Pharmaceutical Co. Ltd.;
- 9. Share listing expense;
- 10. Loss / (Gain) on extinguishment of financial liabilities;
- 11. Transaction costs

Alvotech believes that this non-IFRS measure assists its shareholders because it enhances the comparability of results each period, helps to identify trends in operating results and provides additional insight and transparency on how management evaluates the business. Alvotech's executive management team uses this non-IFRS measure to evaluate financial measures to budget, update forecasts, make operating and strategic decisions, and evaluate performance. This non-IFRS financial measure is not meant to be considered alone or as a substitute for IFRS financial measures and should be read in conjunction with Alvotech's consolidated financial statements prepared in accordance with IFRS. Additionally, this non-IFRS measure may not be comparable to similarly titled measures used by other companies. The most directly comparable IFRS measure to this non-IFRS measure is loss for the year.

The following table reconciles loss for the year to Adjusted EBITDA for the years ended December 31, 2022, 2021 and 2020, respectively:

USD in thousands	2022	2021	2020
Loss for the year	(513,580)	(101,504)	(170,044)
Income tax benefit	(38,067)	(47,694)	(121,726)
Total net finance costs	185,870	65,793	155,943
Depreciation and amortization	20,409	18,196	16,419
Impairment of property, plant and equipment	_	2,092	2,142
Impairment of intangible assets	2,755	3,993	_
Incentive plan expense (1)	10,994	17,955	18,053
Share of net loss of joint venture	2,590	2,418	1,505
Exchange rate differences	(10,566)	(2,681)	(3,215)
Acquisition of rights for Adalimumab from Lotus Pharmaceutical Co. Ltd. (2)	_	_	9,300
Share listing expense(3)	83,411	_	_
Loss / (Gain) on extinguishment of financial liabilities	27,311	(151,788)	_
Transaction costs (4)	23,695	12,503	430
Adjusted EBITDA	(205,178)	(180,717)	(91,193)

- (1) Represents expense related to employee incentive plans, reported within cost of product revenue, research and development expenses and general and administrative expenses.
- (2) Represents the expense related to the acquisition of rights for Adalimumab from Lotus Pharmaceutical Co. Ltd., reported within research and development expenses.
- (3) Represents the share listing expense reported within general and administrative expenses, which was recorded in accordance with IFRS 2 as the excess of the fair value of Alvotech shares issued at the Closing Date over the fair value of OACB's identifiable net assets acquired.

(4) Represents transaction costs incurred in connection with the Business Combination and the Icelandic Main Board Listing, reported within general and administrative expenses

## **Liquidity and Capital Resources**

Sources of Liquidity

Alvotech has a limited operating history and to date has primarily funded its operations with proceeds from the issuance of ordinary shares and the issuance of loans and borrowings to both related parties and third parties. Alvotech has also incurred recurring losses since inception, including net losses of \$513.6 million, \$101.5 million and \$170.0 million for the years ended December 31, 2022, 2021 and 2020, respectively, and had an accumulated deficit of \$1,654.1 million and \$1,140.5 million as of December 31, 2022, and 2021, respectively. As of December 31, 2022, and 2021, Alvotech had cash and cash equivalents, excluding restricted cash, of \$66.4 million and \$17.6 million, respectively and current assets less current liabilities of \$63.4 million and \$8.0 million, respectively.

In February and March 2022, Alvotech received \$25.0 million from each of Alvogen and Aztiq pursuant to interest free loan advances provided by both significant shareholders, who agreed to settle these outstanding amounts in Ordinary Shares rather than cash in July 2022. The closing of the Business Combination and the PIPE Financing provided the Group with \$131.9 million of net proceeds that was used to finance the continuing development and commercialization of its biosimilar product candidates. Additionally, during the year ended December 31, 2022, the Company received \$110.0 million in cash proceeds from the loans issued by Alvogen (including the Alvogen Facility), successfully amended and upsized the outstanding Senior Bonds resulting in \$57.9 million of net cash proceeds, along with net cash proceeds of \$73.4 million from the issuance of the Tranche A and Tranche B December 2022 Convertible Bonds and Facility Loans, of which \$50.0 million was used to repay amounts drawn under the Alvogen Facility.

On January 25, 2023, the Company issued an additional \$10.0 million in the December 2022 Convertible Bonds. Holders of the Tranche B December 2022 Convertible Bonds may elect, at their sole discretion, to convert all or part of the principal amount and accrued interest into Alvotech Ordinary Shares at a conversion price of \$10.00 per share on December 31, 2023, or June 30, 2024.

On February 10, 2023, Alvotech completed a private placement for proceeds of \$137.0 million, and transaction costs of and transaction costs of \$4.8 million, at the then-prevailing exchange rates, of its Ordinary Shares at a purchase price of \$11.57 per Ordinary Share.

In addition to the cash received, the Company expects to continue to source its financing during the development of its biosimilar product candidates from new and existing out-license contracts with commercial partners, shareholder equity and related party and third-party debt financing.

For the foreseeable future, Alvotech's Board of Directors will maintain a capital structure that supports Alvotech's strategic objectives through managing the budgeting process, maintaining strong investor relations and managing financial risks. Consequently, management and the Board of Directors believe that Alvotech will have sufficient funds, and access to sufficient funds, to continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the normal course of business. However, although management continues to pursue these plans, there is no assurance that Alvotech will be successful in obtaining sufficient funding on terms acceptable to Alvotech management to fund continuing operations, if at all. Alvotech's future capital requirements will depend on many factors, including the following:

- the progress, results, and costs of preclinical studies for any programs that Alvotech may develop;
- the costs, timing, and outcome of regulatory review of program candidates;
- Alvotech's ability to establish and maintain collaborations, licensing, and other agreements with commercial partners on favorable terms, if at all;

- the achievement of milestones or occurrence of other developments that trigger payments under the agreements that Alvotech has entered
  into or may enter into with third parties or related parties;
- the extent to which Alvotech is obligated to reimburse clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications and maintaining, defending and enforcing Alvotech's intellectual property rights;
- the extent to which Alvotech acquires or invests in businesses, products, technologies, or other joint ventures;
- the costs of performing commercial-scale manufacturing in-house and, if needed, securing manufacturing arrangements for commercial production of its program candidates; and
- the costs of establishing or contracting for sales and marketing capabilities if Alvotech obtains regulatory approvals to market program candidates.

As of December 31, 2022, and 2021, Alvotech had \$810.4 million and \$435.2 million in outstanding borrowings, respectively, including payment-in-kind interest and accrued interest, through its shareholders and third-party investors, as mentioned above.

## Material Cash Requirements for Known Contractual Obligations and Commitments

The following is a description of commitments for known and reasonably likely cash requirements as of December 31, 2022.

## Borrowings

Alvotech's debt consists of interest-bearing borrowings from both financial institutions and related parties. The amount of the outstanding borrowings as of December 31, 2022, was \$810.4 million, including payment-in-kind interest and accrued interest, respectively. The timing of future payments on the outstanding borrowing amounts, by year, as well as additional information regarding Alvotech's borrowings and rights conveyed to the lenders, can be found in Note 20 of the audited consolidated financial statements, included elsewhere in this prospectus.

## Senior Bonds

On June 24, 2021, holders of Alvotech's convertible bonds converted \$100.7 million of principal and accrued interest and \$4.8 million of additional premium offered by Alvotech to the bondholders into 455,687 Class A ordinary shares of Alvotech Holdings. Following the conversion, certain bondholders elected to redeem their remaining bonds for cash, resulting in the payment of \$55.3 million in outstanding principal and accrued interest plus an additional \$6.1 million of premium that the bondholders elected to be paid in cash. The remaining unconverted and unredeemed bonds were rolled over into new bonds with an extended maturity of June 2025 and the elimination of conversion rights, among other amendments to the terms and conditions. Such bonds, including an additional premium of \$2.6 million and an extension premium of \$8.1 million offered to the bondholders in the form of additional bonds, totaled \$280.9 million. Alvotech also issued an additional \$113.8 million of bonds to one previous bondholder and one new bondholder.

In January and June of 2022, the Group amended the terms of the outstanding bonds. The amendments resulted in the interest rate on the bonds ranging from 7.5% to 10.0%, depending on the amount of aggregate net proceeds, following the closing of the Business Combination. Additionally, the Company made a payment of a \$5.0 million consent fee to the bondholders who did not vote against the Business Combination Agreement. The payment was made in July 2022. The amendment also included a requirement for Alvotech to maintain a minimum of \$25.0 million of restricted cash in a separate liquidity account. As a result of the net proceeds from closing of the Business Combination, in the interest rate increased from 7.5% to 10.0%.

On November 16, 2022, the Group amended and upsized the outstanding bonds by \$70.0 million. The amended bond agreement (the "Senior Bonds") resulted in the following:

- An increase in principal from \$455.7 million at the time of the amendment, to \$525.7 million;
- The coupon rate applicable to the Senior Bonds is 12.0% per annum, which may be lowered to 11.375% (if Alvotech raises more than \$75.0 million but less than \$150.0 million in net proceeds from the issuance of new equity) or 10.75% (if Alvotech raises more than \$150.0 million in net proceeds from the issuance of new equity). This step down provision is subject to certain further conditions, including the FDA approval of a biologics license application for AVT02 on or before March 31, 2023;
- Amended the terms of the related party loans from Alvogen, setting forth subordination conditions;
- If the Company failed to raise at least \$75.0 million in net proceeds by December 15, 2022, we were required to grant penny warrants representing 1.5% of the ordinary share capital to the bondholders, and if we fail to raise at least \$150.0 million by March 31, 2023, we are required to grant penny warrants representing 1.0% of the ordinary share capital to the bondholders. Since we had not raised \$75.0 million by December 15, 2022, we issued 4,198,807 warrants to the bondholders on December 31, 2022. Following the issuance of the December 2022 Convertible Bonds and the closing of the private placement of Ordinary Shares for gross proceeds of \$137.0 million on February 10, 2023, we are not obligated to issue the additional 1.0% warrants to the bondholders.

As of December 31, 2022, the outstanding principal balance on the Senior Bonds was \$532.7 million. The carrying amount of the Senior Bonds was \$530.5 million, including accrued interest. The Group has the option, at any time, to prepay all or any part of the outstanding bonds.

## **Aztiq Convertible Bond**

On November 16, 2022, the Group issued a convertible bond (the "Aztiq Convertible Bond") to ATP Holdings ehf. for the Share Purchase Agreement and the acquisition of the Alvotech manufacturing facility. The Aztiq Convertible Bond has a principal amount of \$80.0 million and carries and carries an interest rate of 12.5% per annum. Interest payable in six-month intervals and is capitalized and added to the outstanding principal amount of the bonds. The maturity date of the convertible bond is the later of the (i) November 16, 2025, or (ii) 91 days after the earlier of the full redemption or the final maturity date of the Senior Bonds. Bondholders have the right to convert their outstanding bonds into ordinary shares of Alvotech on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date, for a conversion price of \$10.00 per share.

As of December 31, 2022, the outstanding principal balance on the Aztiq Convertible Bond was \$81.3 million. The carrying amount of the Aztiq Convertible Bond was \$65.8 million.

# **Alvotech Facility Loans**

The company assumed loans on the facility as part of the acquisition of the Alvotech manufacturing facility. On December 9, 2022, the Group refinanced assumed loans from Arion banki hf., with an outstanding balance of \$30.9 million, with new loans from Landsbankinn hf. for \$48.8 million, which carries variable interest rate, currently 8.3% and 9.3% per annum. The refinancing resulted in net cash proceeds of \$17.2 million after transaction costs paid.

As of December 31, 2022, the outstanding balance of the Facility Loans was \$49.0 million, including accrued interest.

## **Alvogen Facility**

On April 11, 2022, Alvotech entered into a loan agreement with Alvogen, as lender, for a loan of up to \$40.0 million bearing an interest rate of 10.0% per annum. The loan was drawable in two separate installments of

\$20.0 million each. On 12 April 2022, Alvotech withdrew the first installment of \$20.0 million. Alvotech withdrew a second installment of \$20.0 million on May 9, 2022, for aggregate indebtedness of \$40.0 million.

On June 1, 2022, Alvotech also entered into a loan agreement with Alvogen, as lender, for a loan of \$20.0 million bearing an interest rate of 10% per annum. Alvotech withdrew the entire loan amount of \$20.0 million on 1 June 2022.

In connection with the November 16, 2022, Senior Bond amendment, Alvotech entered into the Alvogen Facility agreement. As part of the subordinated loan agreement, the Group agreed to the following:

- Rollover the \$63.3 million, which includes \$3.3 million of accrued interest, outstanding under the Alvogen loans, into the new subordinated loan agreement, and upsize the loan facility by \$50.0 million.
- The interest rate was increased from 10.0% per annum to 17.5% per annum on the outstanding amounts under the loan facility.
- A repayment date of 91 days after the full redemption or the final maturity date of the Senior Bonds

The \$50.0 million upsize was repaid on December 20, 2022, with the proceeds from the December 2022 Convertible Bonds (see below for further information). As of December 31, 2022, the outstanding principal balance on the Alvogen Facility was \$64.6 million.

#### December 2022 Convertible Bonds

On December 20, 2022, the Company issued two tranches of convertible bonds, Tranche A is ISK denominated with a principal balance of \$59.1 million, of which \$3.5 million in cash proceeds were received subsequent to December 31, 2022, and carries an annual payment-in-kind interest rate of 15% per year, while tranche B is USD denominated with a principal balance of \$0.6 million and carries an annual payment-in-kind interest rate of 12.5% per year. The maturity date of the convertible bonds is the later of the (i) 20 December 2025 or (ii) 91 days after the earlier of the full redemption or the final maturity date of the Senior Bonds. Holders of both the Tranche A and Tranche B convertible bonds, may elect, at their sole discretion, to convert all or part of the principal amount and accrued interest into Alvotech Ordinary Shares at a conversion price of \$10.00 per share on December 31, 2023, or June 30, 2024.

As of December 31, 2022, the outstanding principal balance on the December 2022 Convertible Bonds was \$60.6 million. The carrying amount of the December 2022 Convertible Bonds was \$32.4 million.

## Other borrowings

On February 22, 2022, the Group entered into a credit facility agreement with Landsbankinn hf. with the ability to draw down an amount up to \$18.3 million. The credit facility is in place to help finance equipment purchases in the future. Per the terms of the credit facility, any borrowings are required to be paid by August 1, 2023, and have a variable interest rate of USD SOFR plus a margin of 4.95%. As of 31 December 2022, the outstanding balance on the credit facility was \$14.0 million, including accrued interest.

# Leases

Alvotech's future undiscounted payments pursuant to lease agreements totaled \$48.4 million as of December 31, 2022. The timing of these future payments can be found in Note 13 of the audited consolidated financial statements included elsewhere in this prospectus.

### Other long-term liability to a related party

Alvotech acquired certain rights for the commercialization of its biosimilar Adalimumab product in certain territories in Asia from Lotus Pharmaceutical Co. Ltd., a related party, during the year ended December 31, 2020.

Pursuant to the terms of the asset acquisition, Alvotech is required to pay \$7.4 million upon the commercial launch of Adalimumab in China. Alvotech concluded that the event triggering future payment is probable and, as such, recorded the full amount of the liability as a non-current liability in the consolidated statements of financial position as of December 31, 2022.

### Other current liabilities

Alvotech entered into an exclusive global licensing agreement with Biosana Pharma (Biosana) for the co-development of AVT23, which is in late-stage development. Pursuant to the terms of the agreement, Alvotech may be obligated to pay Biosana up to an aggregate of \$13.5 million, payable upon the achievement of various development and regulatory milestones, as well as certain tiered royalty payments based on commercial sales of AVT23. Refer to Note 2.18 of the consolidated financial statements included elsewhere in this prospectus.

## Purchase obligations

For the years ended December 31, 2022, 2021 and 2020, Alvotech did not have any purchase obligations.

While Alvotech does not have legally enforceable commitments with respect to capital expenditures, Alvotech expects to continue to make substantial investments in preparation for commercial launch of its biosimilar product candidates.

### Cash Flows

Comparison of the Years Ended December 31, 2022, and 2021

USD in thousands

			Change	<u>:</u>	
	Year Ended D	Year Ended December 31,		2021 to 2022	
	2022	2021	\$	%	
Cash used in operating activities	(312,389)	(228,170)	(84,219)	36.9	
Cash used in investing activities	(63,537)	(40,633)	(22,904)	56.4	
Cash generated from financing activities	424,910	254,831	170,079	66.7	

## Operating activities

Net cash used in operating activities increased by \$84.2 million, or 36.9%, from \$228.2 million for the year ended December 31, 2021, to \$312.4 million for the year ended December 31, 2022. The increase was primarily driven by a \$35.6 million increase in operating cash outflows before considering movements in working capital and \$41.1 million increase in cash outflows from working capital.

The \$35.6 million increase in operating cash outflow before movements in working capital is due a \$412.1 million higher loss for the year, offset by \$376.5 million more of non-cash net expenses.

The \$41.1 million increase in cash outflows from working capital is due to an increase \$28.8 million in cash outflows from other liabilities resulting from cash payments made for the settlement of incentive plans and amounts due under the license agreement with Biosana. The Company also had an increase of \$24.5 million in cash outflows from contract assets as the Company recognized revenue for performance obligations satisfied while payments remained outstanding. There was an increase of \$12.8 million in cash outflows from other assets primarily due to an \$11.3 million increase in prepaid assets. Interest paid also increased by \$7.4 million. These increases in cash outflows were offset by \$25.2 million less in cash outflows resulting from the collection of trade receivables.

### **Investing activities**

Net cash used in investing activities increased by \$22.9 million, or 56.4%, from \$40.6 million for the year ended December 31, 2021, to \$63.5 million for the year ended December 31, 2022. The increase was driven by a \$17.4 million increase in cash outflow for the acquisition of property, plant and equipment as the company continues to expand its facility and the manufacturing and development capabilities. Additionally, the Group had a \$14.9 million cash outflow resulting from the amended bond agreement, whereby Alvotech is required to maintain a minimum of \$25.0 million of restricted cash in a separate liquidity account per the terms of their debt agreements. These increases were offset by a \$9.1 million decrease in cash outflows related to the acquisition of intangible assets as the company acquired intellectual property rights to AVT23 from Biosana during the year ended December 31, 2021.

## Financing activities

Net cash generated from financing activities increased by \$170.1 million, or 66.7%, from \$254.8 million for the year ended December 31, 2021, to \$424.9 million for the year ended December 31, 2022. The increase was attributable to the \$169.4 million in proceeds from the PIPE financing, \$9.8 million in proceeds from the Business Combination, and \$110.0 million in proceeds from loans from related parties. Additionally, the company received \$79.9 million more in proceeds from new borrowings resulting from the upsize of the Senior Bonds, December 2022 Convertible Bonds, and loans related to the manufacturing facility. This increase in proceeds from new borrowings was offset by \$185.9 million less in proceeds from the issuance of equity shares and \$12.1 million in transaction costs paid for the amended borrowing agreements.

Comparison of the Years Ended December 31, 2021, and 2020

USD in thousands

			Change	2
	Year Ended December 31,		2020 to 2021	
	2021	2020	\$	%
Cash used in operating activities	(228,170)	(74,295)	(153,875)	207.1
Cash used in investing activities	(40,633)	(16,903)	(23,730)	140.4
Cash generated from financing activities	254,831	55,402	199,429	360.0

### Operating activities

Net cash used in operating activities increased by \$153.9 million, or 207.1%, from \$74.3 million for the year ended December 31, 2020, to \$228.2 million for the year ended December 31, 2021. The increase was driven by a \$160.8 million decrease in non-cash operating costs, a \$39.3 million decrease in cash flows from operating working capital and a \$22.3 million increase in interest paid, partially offset by a \$68.5 million decrease in net loss for the year.

The decrease in non-cash operating costs was primarily driven by a \$151.8 million gain on extinguishment of financial liabilities and a \$90.2 million increase in net finance income, partially offset by a \$74.0 million decrease in tax benefit and a \$4.0 million increase in impairment charges.

The decrease in cash flows from operating working capital was primarily driven by a net decrease in cash flows from customers of \$26.2 million, comprised of changes in trade receivables, contract assets and contract liabilities, due to the timing of milestone achievement and customer payments and a net decrease in cash flows of \$25.9 million due to purchases of inventory in preparation for commercial launch of certain of Alvotech's biosimilar product candidates. These decreases were partially offset by a net increase in cash flows of \$12.1 million due to the timing of payments to Alvotech's vendors.

#### **Investing activities**

Net cash used in investing activities increased by \$23.7 million, or 140.4%, from \$16.9 million for the year ended December 31, 2020, to \$40.6 million for the year ended December 31, 2021. The increase was primarily driven by a \$15.7 million increase in cash outflows for intangible assets, which include the acquisition of intellectual property rights from Biosana and the development of software, and a \$13.0 million increase in purchases of property, plant and equipment during the year ended December 31, 2021. These increases were partially offset by a \$5.0 million investment in the Joint Venture made in 2020 that did not reoccur in 2021.

## Financing activities

Net cash generated from financing activities increased by \$199.4 million, or 360.0%, from \$55.4 million for the year ended December 31, 2020, to \$254.8 million for the year ended December 31, 2021. The increase was primarily attributable to a \$151.5 million increase in proceeds on issue of equity shares and an \$83.8 million increase in proceeds from new borrowings during the year ended December 31, 2021, partially offset by a \$34.6 million increase in cash outflows related to the redemption and repayments of borrowings during the year ended December 31, 2021.

## Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks that may result in changes of foreign currency exchange rates and interest rates, as well as the overall change in economic conditions in the countries where we conduct business. As of December 31, 2022, and 2021, we had cash and cash equivalents of \$66.4 million and \$17.6 million, respectively, excluding restricted cash. Our cash and cash equivalent include both cash in banks and cash on hand.

## Foreign currency exchange risk

We are subject to foreign exchange risk in our operations, as a majority of its financial assets and financial liabilities are denominated in currencies other than our functional currency. Any strengthening or weakening of our significant foreign currencies against the USD could impact the measurement of financial instruments in a foreign currency and affect equity. Our significant asset and liabilities denominated in foreign currencies as December 31, 2022, and December 31, 2021 are denominated in EUR, GBP, ISK and CHF. We analyze at the end of each year the sensitivity to foreign currency exchange changes. Specifically, we have performed an analysis to understand the impact of an increase or decrease of a 10% strengthening or weakening of each significant foreign currency, keeping all other variables consistent, as of December 31, 2022. Through this analysis, we note that the only foreign currency that had a material impact was ISK, while all other currencies did not significantly fluctuate. Refer to Note 27 of the consolidated financial statements included elsewhere in this prospectus for further information.

#### Interest rate risk

Our interest-bearing investments and borrowings are subject to interest rate risk. Our exposure to the risk of fluctuations in market interest rates primarily relates to the cash in bank that is denominated with floating interest rates. We analyze at the end of each year the sensitivity to interest rate changes. Specifically, we have performed an analysis to understand the impact of an increase or decrease of a one hundred basis point on the interest rates, keeping all other variables consistent, as of December 31, 2022. Through this analysis, we note that the impacts of the interest rate sensitivity did not have a significant effect on loss before tax.

## Credit risk

We are exposed to credit risk from our operating activities, primarily trade receivables, and cash, cash equivalents and deposits held with banks and financial institutions. Cash, cash equivalents and deposits are

maintained with high-quality financial institutions in Iceland and United States. We are also potentially subject to concentrations of credit risk in our trade receivables. Concentrations of credit risk are with respect to trade receivables owed by a limited number of companies comprising our customer base. Our exposure to credit losses is low, however, owing largely to the credit quality of our collaboration partners which are significantly larger than

We continually monitor our positions with, and the credit quality of, the financial institutions and corporations, which are counterparts to our financial instruments and do not anticipate non-performance. The maximum default risk corresponds to the carrying amount of the financial assets shown in the statement of financial positions. We monitor the risk of a liquidity shortage. The main factors considered here are the maturities of financial assets as well as expected cash flows from equity measures.

# Liquidity Risk

Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" and "Risk Factors", including "We may be unable to generate sufficient cash flow to satisfy our significant debt service obligations, which would adversely affect our financial condition and results of operations." of this prospectus.

## Inflation Risk

We believe that inflation will have a general impact on our business in line with overall price increases, increases in the cost of borrowing, and operating in an inflationary economy. We cannot predict the timing, strength, or duration of any inflationary period or economic slowdown or its ultimate impact on the Company. If the conditions in the general economy significantly deviate from present levels and continue to deteriorate it could have a material adverse effect on the Group's business, financial condition, results of operations and growth prospects.

## **Critical Accounting Estimates**

Alvotech has prepared its financial statements in accordance with IFRS. The preparation of these financial statements requires Alvotech to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities and related disclosures at the date of the financial statements, as well as revenue and expense recorded during the reporting periods. Alvotech evaluates its estimates and judgments on an ongoing basis. Alvotech bases its estimates on historical experience and other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably possible could materially impact the financial statements. Alvotech's significant accounting policies are described in more detail in Note 2 of the audited consolidated financial statements as of December 31, 2022, and for the three years ended December 31, 2022, included elsewhere in this filing.

## Revenue recognition

## Product revenue

The Company recognizes revenue from the sale of its biosimilar product to commercial partners, identified as the customer, when control is transferred, and the performance obligations have been satisfied. This is when the title passes to the customer, which is upon shipment of the product. At that point, the commercial partner has

full discretion over the channel and price to sell the products. Revenue is recognized based on the net selling price from the commercial partners, which is considered to be the transaction price and includes estimated rebates, returns and chargebacks, and other forms of variable consideration recognized by the Customer. Variable consideration is accounted for by the Company only to the extent that it is highly probable that a significant reversal in the revenue recognized will not occur. Variable consideration, which includes any adjustments to the net selling price, is estimated based on the most likely amount method on a contract-by-contract basis. The Company uses historical and market data in determining the most likely amount of variable consideration. These estimates are reviewed each reporting period and involve inherent uncertainty and management's judgement.

## Out-licensing revenue

The consideration to which Alvotech is entitled pursuant to these contracts generally includes upfront payments and payments based upon the achievement of development and regulatory milestones. All contracts include a potential refund obligation whereby Alvotech must refund the consideration paid by the partner in the event of a technical failure or the occurrence of certain other matters that result in partial or full cancellation of the contract. As such, the entire transaction price is comprised of variable consideration, which is estimated using the most likely amount method due to the binary nature of the outcomes under these contracts. Such variable consideration is included in the transaction price only when it is highly probable that doing so will not result in a significant reversal of cumulative revenue recognized when the underlying uncertainty associated with the variable consideration is subsequently resolved.

The standalone selling prices of the development services and the license to intellectual property are not directly observable and, therefore, are estimated. The standalone selling price of the development services is estimated using the expected cost plus a margin approach, using various data points such as the underlying development budget, contractual milestones, and performance completed at the time of entering into the contract with a partner. The standalone selling price of the license is estimated using the residual approach on the basis that the Alvotech licenses intellectual property for a broad range of amounts and has not previously licensed intellectual property on a standalone basis. Therefore, Alvotech first allocates the transaction price to the development services and subsequently allocates the remainder of the transaction price to the license. Inputs used to determine the standalone selling price of the development services are reviewed by management each reporting period. Changes to these inputs, including changes to the underlying development budget, could impact the timing in which revenue is recognized. The Company has not made any changes to the inputs used in determining the standalone selling price.

## Valuation of derivative financial instruments

Alvotech recognized derivative financial liabilities related to warrants, earn out shares and conversion features. The fair values of the derivative liabilities were determined using an option pricing-based approach that incorporated a range of inputs that are both observable and unobservable in nature. The observable and unobservable inputs used in the initial and subsequent fair value measurements relate to (i) the fair value of Ordinary Shares, (ii) the volatility of the Ordinary Shares, (iii) a risk-adjusted discount rate corresponding to the credit risk associated with the repayment of the host debt instruments, and (iv) the probabilities of each derivative being exercised by the holder and the timing of such exercises. The probabilities are determined based on all relevant internal and external information available and are reviewed and reassessed at each reporting date.

The assumptions underlying the valuations represent Alvotech's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if Alvotech used significantly different assumptions or estimates, its finance costs for prior periods could have been materially different.

## Valuation of deferred tax assets

Alvotech recognizes deferred tax assets for all deductible temporary differences to the extent that it is probable that taxable profits will be available against the deductible temporary differences that can be utilized

after consideration of all available positive and negative evidence. Estimation of the level of future taxable profits and the application of relevant jurisdictional tax legislation regarding loss expiry rules, non-deductible expenses, and other guidance are required in order to determine the appropriate carrying value of deferred tax assets.

Alvotech's estimation of the level of future taxable profits is primarily driven by an evaluation of executed out-license contracts and the expected timing of revenue recognition from such contracts. Alvotech considers the amount of revenues that relate to the various phases of development for its biosimilar product candidates, with greater certainty attributed to revenues earned upon contract execution and before later-stage clinical trials and no certainty attributed to revenues that relate to future sales targets on the basis that such amounts are dependent on events that are not within Alvotech's control. These forecasts are also evaluated to incorporate potential uncertainty associated with the amount and timing of expected future revenues, driven by factors such as potential competition and the inherent risk associated with biosimilar product development. Changes to these forecasts, and the inputs used in determining the underlying cash flows involve inherent uncertainties and the application of management's judgement. As a result, if Alvotech used significantly different assumptions or estimates, its valuation of deferred tax assets for current and prior periods could have been materially different.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and is reduced to the extent it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered. Recognition of Alvotech's deferred tax asset occurred in 2020 due to the increase in forecasted profit, largely driven by an increase in executed out-license contracts with commercial partners in 2020.

#### BOARD OF DIRECTORS AND EXECUTIVE MANAGEMENT

## Management and Board of Directors

The following table sets forth the executive officers and directors of Alvotech. Unless otherwise noted, the business address of each of the directors and executive officers of Alvotech is 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg.

Name	Age	Title
Executive Officers		
Robert Wessman*	53	Chief Executive Officer and Executive Chairman of the Board of Directors
Tanya Zharov	56	General Counsel
Joseph E. McClellan	49	Chief Scientific Officer
Hafrun Fridriksdottir	61	Chief Operating Officer
Joel Morales	45	Chief Financial Officer
Directors		
Richard Davies	61	Director and Deputy Chairman
Tomas Ekman	55	Director
Faysal Kalmoua	47	Director
Ann Merchant	58	Director
Arni Hardarson	56	Director
Lisa Graver	52	Director
Linda McGoldrick	67	Director

<sup>\*</sup> Mr. Wessman is our Chief Executive Officer since January 1, 2023. Mr. Mark Levick stepped down as our Chief Executive Officer on December 31, 2022. Executive Officers

## **Executive Officers**

Robert Wessman is the founder and has served as Executive Chairman and member of the board of directors of Alvotech since January 2019, and chief executive officer since January 2023. Since November 2018, he has also served as Director at Fuji Pharma and chairman of the board of directors of Lotus Pharmaceuticals and since May 2009, he has served as a member of the board of directors of Aztiq and as a member of the board of directors of Aztiq GP, the general partner of Aztiq Fund I SCSp, a Luxembourg alternative investment fund, and the parent company of Aztiq. Mr. Wessman is also the founder and main partner of the Aztiq group. Mr. Wessman founded Alvogen in July 2009, and served as its Executive Chairman and Chief Executive Officer until June 2022. He continues to serve as Alvogen's chairman since July 2022. Between 1999 and 2008, Mr. Wessman served as the Chief Executive Officer of Actavis. He has a Bachelor of Science degree in Business Administration from the University of Iceland. We believe Mr. Wessman is qualified to serve on Alvotech's board of directors due to the perspective he brings as Alvotech's founder and his experience in top executive positions in the pharmaceutical industry.

Tanya Zharov has served as our General Counsel since January 2023 and Deputy Chief Executive Officer between May 2020 and December 2022. Prior to joining Alvotech, between 2016 and 2020, Ms. Zharov served as Deputy Chief Executive Officer and compliance officer of deCODE genetics. Prior to that, Ms. Zharov held various management positions, including as General Counsel and Deputy Chief Executive Officer at Virding hf from January 2016, as General Counsel and Deputy Chief Executive Officer at Audur Capital from January 2008 to December 2013, as Board Secretary, corporate counsel and Vice President Corporate Governance and Administration at deCODE genetics from July 2003 to December 2007, and as tax partner at PricewaterhouseCoopers from June 1996 to December 1998. Ms. Zharov holds a law degree from the University of Iceland and is a European Patent Attorney.

Joseph E. McClellan has served as our Chief Scientific Officer since October 2019. Prior to joining Alvotech, Mr. McClellan served for over 17 years in various roles at Pfizer Inc., including as Global Head of Biosimilars Development and Medicine/Asset Team Leader of *IXIFI* (biosimilar infliximab). Mr. McClellan holds a PhD degree in Chemistry, with a focus in Analytical Chemistry and Mass Spectrometry, from the University of Florida, and he was a Postdoctoral Fellow in Mass Spectrometry and Analytical Biochemistry at the Boston University School of Medicine.

Joel Morales has served as our Chief Financial Officer since February 2020 after serving as Chief Financial Officer at our affiliated company Alvogen since 2017. Prior to joining Alvotech he held various positions of increasing responsibility with Endo International plc., from January 2015 to September 2017, with his last position as Senior Vice President of the Generics Business Segment and Global Finance Operations. Prior to that, Mr. Morales spent ten years working for large multinational pharmaceutical companies, including Merck and Schering Plough. Mr. Morales began his career at KPMG as a licensed certified public accountant in the State of New Jersey and has a Bachelor of Science degree in Accounting from Rutgers University.

Hafrun Fridriksdottir has served as our Chief Operating Officer since January 2023. Prior to joining Alvotech, Ms. Fridriksdottir served as the Executive Vice President and Head of Global R&D at Teva from 2017 to June 2022. From February 2017 to November 2017, she served as Executive Vice President, President of Global Generics R&D, after serving as Senior Vice President and President of Global Generics R&D from 2016. Prior to joining Teva, Dr. Fridriksdottir served as Senior Vice President and President of Global Generics R&D in Allergan plc from 2015 to 2016. From 2002 to 2015, she held positions of increasing responsibility within the Actavis Group, including Senior Vice President, R&D. From 1997 to 2002, Dr. Fridriksdottir served as Divisional Manager of Development at Omega Pharma, until its merger with Actavis. Dr. Fridriksdottir received an MS degree in pharmacy and a Ph.D. in physical pharmacy from the University of Iceland.

## Non-Executive Directors

*Richard Davies* has served Deputy Chairman of Alvotech's board, previously Chairman of Alvotech's board, and as one of Alvotech's directors since January 2019. Since November 2018, he has served as Chief Executive Officer of Auregen Bio Therapeutics SA. Prior to joining Auregen Bio Therapeutics, Mr. Davies served as Chief Executive Officer of Bonesupport AB between 2016 and 2018, as Senior Vice President and Chief Commercial Officer of Hospira Inc. between 2012 and 2015, and in various leadership roles at Amgen Inc between 2003 and 2012. Mr. Davies holds an MBA from the University of Warwick and Bachelor of Science in applied chemistry from the University of Portsmouth.

Tomas Ekman has served as one of Alvotech's directors since January 2019. Since November 2014 he has served as a partner at CVC Capital Partners where he is a member of the CVC Nordics team and is based in Stockholm. Prior to joining CVC in 2014, Mr. Ekman was a partner and Managing Director at 3i, responsible for its Nordic business. Mr. Ekman holds MSc degrees from the University of Strathclyde and Chalmers University of Technology, and an MBA from IMD, Switzerland.

*Faysal Kalmoua* has served as one of Alvotech's directors since June 2020. Mr. Kalmoua has also served as a partner of the Aztiq group since June 2022. Between April 2020 and June 2022, Mr. Kalmoua served as Executive Vice President of Portfolio, Business Development and Research and Development for Alvogen Iceland ehf. and Alvogen, Inc. Between November 2015 and March 2020, Mr. Kalmoua served as Executive Vice President of Portfolio for Alvogen, Inc. Prior to joining Alvogen, Mr. Kalmoua served in various management positions for Synthon for nearly 16 years. Mr. Kalmoua holds a Master's degree in Chemistry from the Radboud University Nijmegen and an executive MBA from Insead.

Ann Merchant has served as one of Alvotech's directors since June 2022. Since 2018, she has served as Vice President for MorphoSys, and as Head of Global Supply Chain since January 2019. Prior to joining MorphoSys, from September 2011 to August 2018, Ms. Merchant served as the President for Schreiner

Medipharm. Between 1994 and 2011, Ms. Merchant held various roles at Amgen, including Vice President, Head of International Supply Chain and Site Head between 2007 and 2011. Ms. Merchant holds an MBA from the Henley Business School and a Bachelor of Science in Languages from Georgetown University. We believe Ms. Merchant is qualified to serve on Alvotech's board of directors because of her experience in executive positions with several pharmaceutical companies and expertise in financial planning, new product launches and creating and executing international strategies to increase market share.

*Arni Hardarson* has served as one of Alvotech's directors since June 2022. Mr. Hardarson is a co-founder and partner of the Aztiq group. Between 2009 and June 2022, he served as Deputy to the Chief Executive Officer and General Counsel of Alvogen. Prior to joining Alvogen, Mr. Hardarson was Vice President of Tax and Structure at Actavis, and as partner, member of the executive management committee, and served as a head of tax and legal at Deloitte. Mr. Hardarson holds a Master's degree in law from the University of Iceland. We believe Mr. Hardarson is qualified to serve on Alvotech's board of directors because of his extensive expertise in financial and legal matters and his past experience in top executive positions.

Lisa Graver has served as one of Alvotech's directors since June 2022. Ms. Graver has served in various leadership positions for Alvogen since June 2010, including as President of Alvogen Inc, a subsidiary of Alvogen, since August 2015, as Executive Vice President and Deputy to the Chief Executive Officer of Alvogen Inc. since February 2013, and as Vice president Intellectual Property of Alvogen since June 2010. Prior to joining Alvogen, Ms. Graver was Vice President Intellectual Property and Senior Director Intellectual Property at Actavis Inc. between 2006 and 2008. Ms. Graver holds a BSc in Biology from Lakehead University and a law degree from the Case Western Reserve University School of Law. We believe Ms. Graver is qualified to serve on Alvotech's board of directors because of her extensive expertise in intellectual property and the pharmaceutical industry.

Linda McGoldrick has served as one of Alvotech's directors since June 2022. In 1985, Ms. McGoldrick founded, and currently serves as Chairman and Chief Executive Officer of, Financial Health Associates International, a strategic consulting company specializing in healthcare and life sciences. Since January 2020, she has served as the Chief Executive Officer for 2Enable Health LLC. Prior to joining 2Enable Health LLC, Ms. McGoldrick served as interim CEO at Zillion between June 2019 and December 2019. Over her professional career, Ms. McGoldrick has served in a number of leadership roles, including Senior Vice President and National Development Director for the Healthcare and Life Sciences Industry Practices at Marsh-MMC Companies, International Operations and Marketing Director of Veos plc, and Managing Director Europe for Kaiser Permanente International. In 2018, Ms. McGoldrick was appointed by the Governor of Massachusetts to serve on the state's Health Information Technology Commission. Ms. McGoldrick has served as a director of numerous publicly traded and private held companies and non-profit organizations in the U.S., UK and Europe, including as director for Compass Pathways since September 2020. In 2012, Ms. McGoldrick was named as one of the Top 100 Corporate Directors of Fortune 100 Companies by the Financial Times. Ms. McGoldrick holds a Master's Degree in Healthcare from the University of Pennsylvania and an MBA from Wharton. We believe Ms. McGoldrick is qualified to serve on Alvotech's board of directors because of her extensive expertise in financial matters and the healthcare and life sciences industry.

## **Family Relationships**

There are no family relationships among any of our executive officers or directors.

## Foreign Private Issuer Exemption

We are a "foreign private issuer," as defined by the SEC. As a result, in accordance with Nasdaq rules, we comply with home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we expect to voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- Exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events;
- Exemption from Section 16 rules requiring insiders to file public reports of their securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- Exemption from quorum requirements for shareholder meetings. Luxembourg practice with respect to quorum requirements for shareholder meetings in lieu of the requirement under Nasdaq Listing Rules that the quorum be not less than 33 1/3% of the outstanding voting shares;
- Exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers;
- Exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans;
- Exemption from the requirement that our audit and risk committee have review and oversight responsibilities over all "related party transactions," as defined in Item 7.B of Form 20-F;
- Exemption from the requirement that a majority of the board of directors must be comprised of Independent Directors as defined in the
  Nasdaq listing standards. Three of our eight directors are independent as defined in Nasdaq listing standards and applicable SEC rules, and
  our board of directors has an independent audit and risk committee. In addition, the independence rules applicable to companies listed on
  the Icelandic Main Market differ from the rules of Nasdaq.
- Exemption from the requirement that our board have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. We currently have only one (1) director who serves on the compensation committee who meets the heightened independence standards for members of a compensation committee; and
- Exemption from the requirements that director nominees are selected, or recommended for selection by our board, either by (1) independent directors constituting a majority of our board's independent directors in a vote in which only independent directors participate, or (2) a committee comprised solely of independent directors, and that a formal written charter or board resolution, as applicable, addressing the nominations process is adopted.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as Alvotech, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625), the Voting Rights requirement (Rule 5640) and that we have an audit and risk committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although Alvotech is permitted to follow certain corporate governance rules that conform to Luxembourg requirements in lieu of many of the Nasdaq corporate governance rules, we comply with the Nasdaq corporate governance rules applicable to foreign private issuers.

Accordingly, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

## Corporate Governance

We structured our corporate governance in a manner we believe closely aligns its interests with those of our shareholders. Notable features of this corporate governance include:

- We have three independent directors and independent director representation on our audit and risk, compensation and nominating committees immediately following the consummation of the Business Combination, and our independent directors will meet regularly in executive sessions without the presence of our corporate officers or non-independent directors;
- at least one of the independent directors qualifies as an "audit committee financial expert" as defined by the SEC; and
- We implemented a range of other corporate governance practices, including a robust director education program.

Our board of directors is currently composed of eight members. In accordance with our articles of association, the board of directors is not divided into classes of directors. Each director was appointed at the closing of the Business Combination on June 15, 2022, to serve as director until the end of the general meeting of shareholders called to approve our annual accounts for the 2024 financial year.

## Non-Classified Board of Directors

In accordance with our articles of association, our board of directors is not divided into classes of directors. The Directors were appointed until the end of the general meeting of shareholders called to approve our annual accounts for the 2024 financial year.

# Compensation of Directors and Officers

Compensation of Executive Officers

Each of our executive officers has entered into an employment agreement with us for an indefinite period of time. The agreements provide the terms of each individual's employment or service with us, as applicable.

Each employment agreement contains provisions regarding non-competition, non-solicitation, confidentiality of information and assignment of inventions. The enforceability of the non-competition covenants is subject to limitations. Either we or the executive officer may terminate the applicable executive officer's employment or service by giving advance written notice to the other party. We may also terminate an executive officer's employment or services agreement for cause (as defined in the applicable employment or services agreement).

Our executive compensation program reflects its compensation policies and philosophies, as they may be modified and updated from time to time. In addition to a base salary and certain performance-based bonuses, executive officers can be eligible to receive awards under our 2022 equity incentive plan, the Alvotech Management Incentive Plan (the "2022 Plan"), as further described below. Decisions with respect to the compensation of our executive officers, including our named executive officers, are made by the compensation committee of our board of directors.

The following table sets forth information regarding compensation earned by Mark Levick, our former Chief Executive Officer, and our other executive officers during the years ended December 31, 2022 and 2021.

		2022 (In thousands)			
Key employees	Salaries and benefits	Pension contribution	Termination benefits	Other long- term benefits	
Mark Levick CEO	892	162	1,157	_	
Other Executive Team Members (9)	5,400	446	820	5,015	
	6,292	608	1,977	5,015	
	(In th				
		ъ :	Tr	Other long-	
Key employees	Salaries and benefits	Pension contribution	Termination benefits	term benefits	
Mark Levick CEO	877	492			
Other Executive Team Members (9)	4,531	333		985	
	5,408	825		985	

## Compensation of Directors

On June 8, 2022, we adopted our Non-Employee Director Compensation Policy (the "Director Compensation Policy"). Under the Director Compensation Policy, each of our non-employee director will receive an annual retainer of \$50,000, the Executive Chairperson (Mr. Wessman) will receive an additional annual retainer of \$20,000 and the Deputy Chairperson (Mr. Davies) an additional annual retainer of \$25,000. In addition, the chairpersons of the audit and risk committee, compensation committee, and nominating committee will receive a retainer of \$20,000, and non-chair members of the audit and risk committee, compensation committee, and nominating committee will receive a retainer of \$10,000. Non-employee directors who are appointed or elected after the Closing Date will receive an initial award of restricted stock units with a value of \$250,000, which will vest in three equal annual installments on the first three anniversaries of the grant date. Each non-employee director will also receive an automatic annual restricted stock unit award, the value of which will be determined by a third party. The value of such annual grant will be prorated for each individual who has been in service as a non-employee director for less than one year as of such annual meeting. The automatic annual grants will vest on the earlier of the first anniversary of the grant or the date immediately preceding the date of the following annual meeting of shareholders.

All vesting of the restricted stock units is subject to the non-employee director's continuous service on the applicable vesting date. However, for each eligible director who remains in continuous service until immediately prior to the occurrence of a change in control (as such term is defined in the 2022 Plan), the shares subject to his or her then-outstanding restricted stock unit awards will become fully vested immediately prior to the closing of such change in control event.

We will also reimburse our non-employee directors for their reasonable out-of-pocket expenses in connection with attending board and committee meetings.

The following tables sets forth information regarding compensation earned by each of our directors during the years ended December 31, 2022 and 2021.

	20. (In thou		
Board of Directors' fee for the year.	Board fees	Pension contribution	
Robert Wessman, Chairman of the board	740	_	
Richard Davis, Vice-Chairman	68	_	
Ann Merchant	43	_	
Árni Harðarson*	_	_	
Faysal Kalmoua*	_	_	
Linda McGoldrick	38	_	
Lisa Graver	38	_	
Thomas Ekman *	_	_	
Hirofumi Imai, Board member (until 16.6.2022)	_	_	
	927		

\* Waived their board compensation (both cash and equity).

	2021 (In thousands)			
Board of Directors' fee for the year.	Board fees	Pension contribution		
Robert Wessman, Chairman of the board	_	_		
Richard Davis, Vice-Chairman	_	_		
Faysal Kalmoua*	_	_		
Thomas Ekman *	_			
Hirofumi Imai,	_	_		
Tanya Zharov*	_	_		
		_		

<sup>\*</sup> Waived their board compensation (both cash and equity).

# Company Management Incentive Plan

On June 13, 2022, our chairman adopted, and our shareholders approved, a new 2022 equity incentive plan, the Management Incentive Plan (the "2022 Plan"). The 2022 Plan came into existence upon its adoption by our chairman, but no grants were made under the 2022 Plan prior to its effectiveness after Closing.

Awards. The 2022 Plan will provide for the grant of shares, restricted shares units, options or any combination of the foregoing including such other Awards that may be denominated or payable in, value in whole or in part, by reference to or otherwise based upon, or related to, shares (the "Awards") to our employees, directors, and consultants and any of our affiliates' employees and consultants.

*Authorized Shares*. Initially, the maximum number of Ordinary Shares that may be issued under the 2022 Plan after it becomes effective will not exceed 5.79% of our share capital on a fully diluted basis. In addition, the number of Ordinary Shares reserved for issuance under the 2022 Plan may be increased by our board of directors by up to 1% annually over ten (10) years from the date of approval of the 2022 Plan.

*Plan Administration*. Our board of directors, or any person or persons or committee to whom decision-making authority with respect to the 2022 Plan is delegated by our board of directors (the "Administrator") will administer the 2022 Plan.

Plan Amendment or Termination. Our board of directors and the Administrator have the authority to amend or, suspend, the 2022 Plan at any time and from time to time, and our board of directors has the authority to terminate the 2022 Plan provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our shareholders. No Awards may be granted after the tenth anniversary of the date our board of directors adopted the 2022 Plan. No Awards may be granted under the 2022 Plan while it is suspended or after it is terminated. Rights under any Award granted before suspension or termination of the 2022 Plan shall not be impaired by such suspension or termination.

On December 1, 2022, our Remuneration Committee authorized the grant of restricted stock units ("RSUs") to certain employees, executive officers and directors under the 2022 Plan. Subject to certain vesting and other terms and conditions, the RSUs may be settled in Ordinary Shares. If all RSUs vest and are exchanged for Ordinary Shares, the combined grants may result in an aggregate of 7,659,049 Ordinary Shares.

# Management Share Appreciation Rights Agreements

As part of its long-term incentive program, Alvotech hf. had entered into "phantom share agreements," which were defined as Share Appreciation Rights ("SARs") for financial purposes, with certain members of management. The vesting conditions of the SARs under the phantom share agreements were linked to certain milestones in our operations and the payment amounts were determined by the increase in our market value from the grant date of the SARs until the triggering event occurred. The SARs did not give the beneficiaries dividend rights, voting rights or the right to purchase shares of Alvotech but required Alvotech to pay the beneficiaries a cash payment associated with the occurrence of certain designated triggering events. In conjunction with the Business Combination, Alvotech terminated deferred compensation arrangements by entering into settlement agreements with the three former employees and one current employee that had outstanding rights under the phantom share agreements of \$38.1 million as of the Closing. Alvotech agreed with one former employee to settle his claim by paying a one-time lump sum of \$1.5 million, reduced by any applicable tax withholdings and pension fund contribution, on June 16, 2022. Alvotech further agreed with the two other former employees to settle each of their respective claims of \$17.5 million, as may be reduced by any applicable tax withholdings, through the allocation of a number of Ordinary Shares by dividing their respective claims by a per share price of \$10.00, rounded to the nearest whole share. The shares will be allocated to them on June 16, 2023, one year and one day following the Closing. Alvotech also agreed with one current employee to settle his outstanding claim of \$1.5 million in either shares or cash, payable on June 16, 2023, one year and one day from the Closing. Alvotech settled the remaining SARs through the issuance of fully vested RSUs.

## Risk Oversight

The board of directors is responsible for overseeing our risk management process. The board of directors focuses on our general risk management strategy, the most significant risks, and oversees the implementation of risk mitigation strategies by management. The audit and risk committee is also responsible for discussing our policies with respect to risk assessment and risk management. The board of directors believes its administration of its risk oversight function has not negatively affected the board of directors' leadership structure.

# Code of Business Conduct

Our board of directors adopted a Code of Business Conduct applicable to the directors, executive officers and team members that complies with the rules and regulations of Nasdaq and the SEC. The Code of Ethics is available on our website. In addition, we posted on the Corporate Governance section of our website all disclosures that are required by law or Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the Code of Ethics. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

## Composition of Our Board of Directors

Our board of directors is currently composed of eight members. In accordance with our articles of association, the board of directors is not divided into classes of directors. Each director was appointed at the closing of the Business Combination on June 15, 2022, to serve as director until the end of the general meeting of shareholders called to approve our annual accounts for the 2024 financial year. Three of eight directors are independent as defined in Nasdaq listing standards and applicable SEC rules and our board of directors has an independent audit and risk committee, a nominating committee, a compensation committee.

Three of eight directors are independent as defined in Nasdaq listing standards and applicable SEC rules and our board of directors has an independent audit and risk committee, a nominating committee, a compensation committee.

## Non-Executive Director Appointment Letters

Our independent non-executive directors are engaged on letters of appointment that set out their duties and responsibilities. The non-executive directors do not receive benefits upon termination or resignation from their respective positions as directors. Under the non-executive director appointment letters, our non-executive directors are entitled to receive annual fees in accordance with our Director Compensation Policy, as discussed above.

## Committees of our Board of Directors

Our board of directors has five standing committees: an audit and risk committee, a compensation committee, a nominating and corporate governance committee, a strategy committee and a Corporate Sustainability Committee. The board has adopted written charters that are available to shareholders on our website at https://investors.alvotech.com/corporate-governance/documents-charters for the audit and risk committee, the compensation committee, and the nominating and corporate governance committees. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

#### Audit and Risk Committee

The members of our audit and risk committee are Ms. McGoldrick (Chair), Ms. Merchant and Mr. Davies. Each member of our audit and risk committee qualifies as independent directors according to the rules and regulations of the SEC and Nasdaq with respect to audit and risk committee membership. In addition, all audit and risk committee members meet the requirements for financial literacy under applicable SEC and Nasdaq rules and at least one of the audit and risk committee members qualifies as an "audit and risk committee financial expert," as such term is defined in Item 407(d) of Regulation S-K. The audit and risk committee is responsible for, among other things:

- appointing, compensating, retaining, evaluating, terminating and overseeing our independent registered public accounting firm;
- discussing with our independent registered public accounting firm their independence from management;
- · reviewing, with our independent registered public accounting firm, the scope and results of their audit;
- · approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the annual financial statements that we file with the SEC;
- overseeing our financial and accounting controls and compliance with legal and regulatory requirements;

- reviewing our policies on risk assessment and risk management;
- reviewing related party transactions; and
- establishing procedures for the confidential anonymous submission of concerns regarding questionable accounting, internal controls or auditing matters.

## Compensation Committee

The members of our compensation committee are Mr. Davies (Chair), Mr. Hardarson and Mr. Ekman. Mr. Davies qualifies as independent directors according to the rules and regulations of the SEC and Nasdaq with respect to compensation committee membership, including the heightened independence standards for members of a compensation committee. The compensation committee is responsible for, among other things:

- reviewing and approving the corporate goals and objectives, evaluating the performance of and reviewing and approving, (either alone or, if directed by the board of directors, in conjunction with a majority of the independent members of the board of directors) the compensation of our chief executive officer;
- overseeing an evaluation of the performance of and reviewing and setting or making recommendations to our board of directors regarding the compensation of our other executive officers;
- reviewing and approving or making recommendations to our board of directors regarding our incentive compensation and equity-based plans, policies and programs;
- reviewing and approving all employment agreement and severance arrangements for our executive officers;
- making recommendations to our shareholders regarding the compensation of our directors; and
- retaining and overseeing any compensation consultants.

## Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Mr. Davies (Chair), Mrs. Graver and Mr. Ekman. The nominating committee is responsible for, among other things:

- identifying individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors;
- overseeing succession planning for our Chief Executive Officer and other executive officers;
- periodically reviewing our board of directors' leadership structure and recommending any proposed changes to our board of directors;
- overseeing an annual evaluation of the effectiveness of our board of directors and its committees; and
- developing and recommending to our board of directors a set of corporate governance guidelines.

## ESG Committee

The members of our ESG committee are Ms. Merchant (Chair), Mr. Hardarson and Mr. Wessman. The ESG committee is responsible for, among other things:

- · reviewing, monitoring and setting strategy in the area of corporate responsibility;
- overseeing our activities in the area of corporate responsibility that may have an impact on the Company's reputation and operations;
- periodically assess our compliance obligations;

- monitor and review matters of health and safety and report findings to the broader board; and
- review and evaluate environmental, social and political issues and trends and their relevance to our business and make recommendations to the board regarding those trends and issues.

# Strategy Committee

The Strategy committee is responsible for, among other things, reviewing, monitoring and setting strategy for our business. The members of our Strategy committee are Mr. Faysal Kalmoua (Chair), Ms. Lisa Graver and Mr. Wessman.

#### **DESCRIPTION OF SECURITIES**

#### General

Alvotech was incorporated on August 23, 2021 by Floki Holdings S.à r.l., an affiliate of Alvotech Holdings, with an initial share capital of \$40,000, represented by 4,000,000 initial shares with a nominal value of \$0.01 per share. Prior to consummation of the Business Combination, Alvotech's issued share capital equaled \$40,000, represented by 4,000,000 initial shares with a nominal value of \$0.01 per share. All issued shares were fully paid and subscribed for.

Immediately after the effectiveness of the first merger and the redemption in the process of the Business Combination, the legal form of Alvotech changed from a simplified joint stock company (*société par actions simplifiée*) to a public limited liability company (*société anonyme*) under Luxembourg law.

We are registered with the Luxembourg Trade and Companies Register (*Registre de Commerce et des Sociétés*, *Luxembourg*) under number B258884. Our registered office is at 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg,

## **Ordinary Shares**

Share Capital

As of December 31, 2022, Alvotech had 248,649,506 ordinary shares with a nominal value of \$0.01 per share (the "Ordinary Shares"), issued and outstanding. All issued Ordinary Shares are fully paid and subscribed for. In addition, Alvotech Manco ehf. held 27,072,166 Ordinary Shares, the voting and dividend rights of which are suspended.

The authorized capital of Alvotech (excluding the issued share capital) is set at \$59,504,348.33, divided into 5,950,434,833 ordinary shares with a nominal value of \$0.01 each.

A shareholder in a Luxembourg *société anonyme* holding fully paid-up shares is not liable, solely because of his, her or its shareholder status, for additional payments to Alvotech or its creditors.

## Share Issuances

Pursuant to Luxembourg law, the issuance of ordinary shares requires approval by the extraordinary general meeting of shareholders in front of a notary subject to necessary quorum and majority requirements. The extraordinary general meeting of shareholders may approve an authorized capital and authorize the board of directors to increase the issued share capital in one or several tranches with or without share premium, against payment in cash or in kind, by conversion of claims on Alvotech or in any other manner for any reason whatsoever including (i) issue subscription and/or conversion rights in relation to new shares or instruments within the limits of the authorized capital under the terms and conditions of warrants (which may be separate or linked to shares, bonds, notes or similar instruments issued by Alvotech), convertible bonds, notes or similar instruments; (ii) determine the place and date of the issue or successive issues, the issue price, the terms and conditions of the subscription of and paying up on the new shares and instruments and (iii) remove or limit the statutory preferential subscription right of the shareholders in case of issue against payment in cash or shares, warrants (which may be separate or attached to shares, bonds, notes or similar instruments), convertible bonds, notes or similar instruments up to the maximum amount of such authorized capital for a maximum period of five years after the date that the minutes of the relevant general meeting approving such authorization are published in the Luxembourg official gazette (*Recueil Electronique des Sociétés et Associations*, "*RESA*"). The extraordinary general meeting may amend, renew, or extend such authorized capital and such authorization to the board of directors to issue ordinary shares.

In addition, the extraordinary general meeting of shareholders may authorize the board of directors to make an allotment of existing or newly issued shares without consideration to (a) employees of Alvotech or certain categories amongst those; (b) employees of companies or economic interest grouping in which Alvotech holds

directly or indirectly at least 10% of the share capital or voting rights; (c) employees of companies or economic interest grouping which directly or indirectly hold at least 10% of the share capital or voting rights of Alvotech; (d) employees of companies or economic interest grouping in which at least 50% of the share capital or voting rights is held directly or indirectly by a company which holds directly or indirectly at least 50% of the share capital of Alvotech; (e) members of the corporate bodies of Alvotech or of the companies or economic interest grouping listed in point (b) to (d) above or certain categories amongst those, for a maximum period of five years after the date that the minutes of the relevant general meeting approving such authorization are published in the RESA.

Alvotech recognizes only one holder per ordinary share. In case an ordinary share is owned by several persons, they shall appoint a single representative who shall represent them in respect of Alvotech. Alvotech has the right to suspend the exercise of all rights attached to that share, except for relevant information rights, until such representative has been appointed.

Upon the consummation of the Business Combination, the board of directors resolved on the issuance of Ordinary Shares out of the authorized capital (*capital autorisé*) in accordance with the quorum and voting thresholds set forth in the articles of association and applicable law to the PIPE Investors.

The board of directors also resolves on the applicable procedures and timelines to which such issuance will be subjected. If the proposal of the board of directors to issue new Ordinary Shares exceeds the limits of Alvotech's authorized share capital, the board of directors must then convene the shareholders to an extraordinary general meeting to be held in front of a Luxembourg notary for the purpose of increasing the issued share capital. Such meeting will be subject to the quorum and majority requirements required for amending the articles of association. If the capital call proposed by the board of directors consists of an increase in the shareholders' commitments, the board of directors must convene the shareholders to an extraordinary general meeting to be held in front of a Luxembourg notary for such purpose. Such meeting will be subject to the unanimous consent of the shareholders.

## Preferential Rights

Under Luxembourg law, existing shareholders benefit from a preferential subscription right on the issuance of ordinary shares for cash consideration. However, Alvotech's shareholders have, in accordance with Luxembourg law, authorized the board of directors to suppress, waive, or limit any preferential subscription rights of shareholders provided by law to the extent that the board of directors deems such suppression, waiver, or limitation advisable for any issuance or issuances of ordinary shares within the scope of Alvotech's authorized share capital. The general meeting of shareholders duly convened to consider an amendment to the articles of association also may, by a two-thirds majority vote at a quorate meeting, limit, waive, or cancel such preferential subscription rights or renew, amend, or extend the authorization of the board of directors to suppress, waive, or limit such preferential subscription rights, in each case for a period not to exceed five years. Such ordinary shares may be issued above, at, or below market value, and, following a certain procedure, even below the nominal value or below the accounting par value per ordinary share. The ordinary shares also may be issued by way of incorporation of available reserves, including share premium.

# **Share Repurchases**

Alvotech cannot subscribe for its own ordinary shares. Alvotech may, however, repurchase issued ordinary shares or have another person repurchase issued ordinary shares for its account, generally subject to the following conditions and the respect of the principle of equal treatment of shareholders being in the same situation and applicable securities laws:

- prior authorization by a simple majority vote at an ordinary general meeting of shareholders, which authorization sets forth:
- the terms and conditions of the proposed repurchase and in particular the maximum number of ordinary shares to be repurchased;

- the duration of the period for which the authorization is given, which may not exceed five years; and
- in the case of repurchase for consideration, the minimum and maximum consideration per share, provided that the prior authorization shall not apply in the case of ordinary shares acquired by either Alvotech, or by a person acting in his or her own name on its behalf, for the distribution thereof to its staff or to the staff of a company with which it is in a control relationship;
- only fully paid-up ordinary shares may be repurchased; and
- the voting and dividend rights attached to the repurchased shares will be suspended as long as the repurchased ordinary shares are held by
  Alvotech; and the acquisition offer must be made on the same terms and conditions to all the shareholders who are in the same position,
  except for acquisitions which were unanimously decided by a general meeting at which all the shareholders were present or represented.
  However, listed companies like us may repurchase their own shares on the stock exchange without an acquisition offer having to be made
  to Alvotech's shareholders.

The authorization will be valid for a period ending on the earlier of five years from the date of such shareholder authorization and the date of its renewal by a subsequent general meeting of shareholders. Pursuant to such authorization, the board of directors is authorized to acquire Ordinary Shares under the conditions set forth in article 430-15 of the Luxembourg Company law. Such purchases and subsequent sales may be carried out for any authorized purpose or any purpose that is authorized by the laws and regulations in force. The purchase price per ordinary share to be determined by the board of directors or its delegate shall represent not more than the fair market value of such ordinary share.

In addition, pursuant to Luxembourg law, Alvotech may directly or indirectly repurchase ordinary shares by resolution of its board of directors without the prior approval of the general meeting of shareholders if such repurchase is deemed by the board of directors to be necessary to prevent serious and imminent harm to Alvotech in accordance with article 430-15(2) of the Luxembourg Company Law, or if the acquisition of ordinary shares has been made with the intent of distribution to its employees and/or the employees of any entity having a controlling relationship with it (i.e., its subsidiaries or controlling shareholder) in accordance with article 430-15(3) of the Luxembourg Company Law or in any of the circumstances listed in article 430-16 of the Luxembourg Company Law.

## Voting rights

Each Ordinary Share entitles the holder thereof to one vote. Neither Luxembourg law nor Alvotech's articles of association contain any restrictions as to the voting of Ordinary Shares by non-Luxembourg residents. The Luxembourg Company Law distinguishes ordinary general meetings of shareholders and extraordinary general meetings of shareholders with respect to the required quorums and majorities.

## Meetings

Ordinary General Meeting

At an ordinary general meeting, there is no quorum requirement and resolutions are adopted by a simple majority of validly cast votes. Abstentions are not considered "votes."

## Extraordinary General Meeting

Resolutions adopted at an extraordinary general meeting are required for any of the following matters, among others: (i) an increase or decrease of the authorized or issued capital, (ii) a limitation or exclusion of preferential subscription rights, (iii) approval of a statutory merger or de-merger (scission), (iv) Alvotech's dissolution and liquidation, (v) any and all amendments to Alvotech's articles of association and (vi) change of nationality. Pursuant to Alvotech's articles of association, for any resolutions to be considered at an extraordinary

general meeting of shareholders, the quorum shall be at least one half of Alvotech's issued share capital unless otherwise mandatorily required by law. If the said quorum is not present, a second meeting may be convened, for which Luxembourg Company Law does not prescribe a quorum. Any resolution taken at an extraordinary general meeting shall be adopted at a quorate general meeting, except otherwise provided by law, by at least a two-thirds majority of the votes cast on such resolution by shareholders. Abstentions are not considered "votes."

## **Annual Shareholders Meetings**

An annual general meeting of shareholders shall in principle be held in the Grand Duchy of Luxembourg within 6 months of the end of the preceding financial year. Alvotech's first financial year ended on December 31, 2021.

## Warrants

OACB assigned to Alvotech all of OACB's right, title and interest in and to the existing Warrant Agreement and Alvotech assumed, and agreed to pay, perform, satisfy and discharge in full, all of OACB's liabilities and obligations under the existing Warrant Agreement.

## Public Shareholders' Warrants

Each warrant entitles the registered holder to purchase one Ordinary Share at a price of \$11.50 per share, subject to adjustment as discussed below, except as discussed in the immediately succeeding paragraph. Pursuant to the Warrant Agreement, a warrant holder may exercise its warrants only for a whole number of Ordinary Shares. This means only a whole warrant may be exercised at a given time by a warrant holder. The warrants will expire five years after the completion of our initial business combination, at 5:00 p.m., New York City time, or earlier upon redemption or liquidation.

We will not be obligated to deliver any Ordinary Shares pursuant to the exercise of a warrant and will have no obligation to settle such warrant exercise unless a registration statement under the Securities Act with respect to the Ordinary Shares underlying the warrants is then effective and a prospectus relating thereto is current, subject to our satisfying our obligations described below with respect to registration, or a valid exemption from registration is available. No warrant will be exercisable and we will not be obligated to issue an Ordinary Share upon exercise of a warrant unless the Ordinary Share issuable upon such warrant exercise has been registered, qualified or deemed to be exempt under the securities laws of the state of residence of the registered holder of the warrants. In the event that the conditions in the two immediately preceding sentences are not satisfied with respect to a warrant, the holder of such warrant will not be entitled to exercise such warrant and such warrant may have no value and expire worthless. In no event will we be required to net cash settle any warrant.

We have filed with the SEC a registration statement for the registration under the Securities Act of the Ordinary Shares issuable upon exercise of the warrants. We will use our commercially reasonable efforts to maintain the effectiveness of such registration statement, and a current prospectus relating thereto, until the expiration of the warrants in accordance with the provisions of the Warrant Agreement. If a registration statement covering the Ordinary Shares issuable upon exercise of the warrants is not effective, warrant holders may, until such time as there is an effective registration statement and during any period when we will have failed to maintain an effective registration statement, exercise warrants on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act or another exemption. In addition, if our Ordinary Shares are at the time of any exercise of a warrant not listed on a national securities exchange such that it satisfies the definition of a "covered security" under Section 18(b)(1) of the Securities Act, we may, at our option, require holders of our public warrants who exercise their warrants to do so on a "cashless basis" in accordance with Section 3(a)(9) of the Securities Act and, in the event we elect to do so, we will not be required to file or maintain in effect a registration statement, but we will use our commercially reasonable efforts to register or qualify the shares under applicable blue sky laws to the extent an exemption is not available. In such event, each holder would pay the

exercise price by surrendering the warrants for that number of Ordinary Shares equal to the lesser of (A) the quotient obtained by dividing (x) the product of the number of Class A ordinary shares underlying the warrants, multiplied by the excess of the "fair market value" (defined below) less the exercise price of the warrants by (y) the fair market value and (B) 0.361 Class A ordinary shares per whole warrant. The "fair market value" as used in this paragraph shall mean the volume weighted average price of the Ordinary Shares for the 10 trading days ending on the trading day prior to the date on which the notice of exercise is received by the warrant agent.

A holder of a warrant may notify us in writing in the event it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 4.9% or 9.8% (as specified by the holder) of the Ordinary Shares issued and outstanding immediately after giving effect to such exercise.

*Redemption of warrants when the price per Ordinary Share equals or exceeds* \$18.00. Once the warrants become exercisable, we may redeem the outstanding warrants (except as described herein with respect to the private placement warrants):

- in whole and not in part;
- at a price of \$0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption to each warrant holder; and
- if, and only if, the reported closing price of the Ordinary Shares equals or exceeds \$18.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which we send to the notice of redemption to the warrant holders.

We will not redeem the warrants as described above unless a registration statement under the Securities Act covering the issuance of the Ordinary Shares issuable upon exercise of the warrants is then effective and a current prospectus relating to those Ordinary Shares is available throughout the 30-day redemption period. If and when the warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws.

We have established the last of the redemption criterion discussed above to prevent a redemption call unless there is at the time of the call a significant premium to the warrant exercise price. If the foregoing conditions are satisfied and we issue a notice of redemption of the warrants, each warrant holder will be entitled to exercise his, her or its warrant prior to the scheduled redemption date. However, the price of the Ordinary Shares may fall below the \$18.00 redemption trigger price (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) as well as the \$11.50 warrant exercise price after the redemption notice is issued.

Redemption of warrants when the price per Ordinary Share equals or exceeds \$10.00. Once the warrants become exercisable, we may redeem the outstanding warrants:

- in whole and not in part;
- at \$0.10 per warrant upon a minimum of 30 days' prior written notice of redemption provided that holders will be able to exercise their warrants on a cashless basis prior to redemption and receive that number of shares determined by reference to the table below, based on the redemption date and the "fair market value" (as defined below) of our Ordinary Shares except as otherwise described below;
- if, and only if, the reported closing price of our Ordinary Shares equals or exceeds \$10.00 per share (as adjusted per share splits, share dividends, reorganizations, reclassifications, recapitalizations and the like) on the trading day prior to the date on which we send the notice of redemption to the warrant holders; and

• if the closing price of the Ordinary Shares for any 20 trading days within a 30-trading day period ending on the third trading day prior to the date on which we send the notice of redemption to the warrant holders is less than \$18.00 per share (as adjusted for adjustments to the number of shares issuable upon exercise or the exercise price of a warrant as described under the heading "Description of Securities—Warrants—Public Shareholders' Warrants—Anti-dilution Adjustments"), the private placement warrants must also be concurrently called for redemption on the same terms as the outstanding public warrants, as described above.

The numbers in the table below represent the number of Ordinary Shares that a warrant holder will receive upon exercise in connection with a redemption by us pursuant to this redemption feature, based on the "fair market value" of our Ordinary Shares on the corresponding redemption date (assuming holders elect to exercise their warrants and such warrants are not redeemed for \$0.10 per warrant), determined based on the average of the last reported sales price for the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of warrants, and the number of months that the corresponding redemption date precedes the expiration date of the warrants, each as set forth in the table below. We will provide our warrant holders with the final fair market value no later than one business day after the 10 trading day period described above ends.

The stock prices set forth in the column headings of the table below will be adjusted as of any date on which the number of shares issuable upon exercise of a warrant is adjusted as set forth in the first three paragraphs under the heading "—Anti-dilution Adjustments" below. The adjusted stock prices in the column headings will equal the stock prices immediately prior to such adjustment, multiplied by a fraction, the numerator of which is the number of shares deliverable upon exercise of a warrant immediately prior to such adjustment and the denominator of which is the number of shares deliverable upon exercise of a warrant as so adjusted. The number of shares in the table below shall be adjusted in the same manner and at the same time as the number of shares issuable upon exercise of a warrant.

## **Redemption Date**

(period to expiration of warrants)			Fai	r Market V	alue of Or	dinary Sha	ares		
(Francisco)	≤\$10.00	\$11.00	\$12.00	\$13.00	\$14.00	\$15.00	\$16.00	\$17.00	≥\$18.00
60 months	0.261	0.281	0.297	0.311	0.324	0.337	0.348	0.358	0.361
57 months	0.257	0.277	0.294	0.31	0.324	0.337	0.348	0.358	0.361
54 months	0.252	0.272	0.291	0.307	0.322	0.335	0.347	0.357	0.361
51 months	0.246	0.268	0.287	0.304	0.32	0.333	0.346	0.357	0.361
48 months	0.241	0.263	0.283	0.301	0.317	0.332	0.344	0.356	0.361
45 months	0.235	0.258	0.279	0.298	0.315	0.33	0.343	0.356	0.361
42 months	0.228	0.252	0.274	0.294	0.312	0.328	0.342	0.355	0.361
39 months	0.221	0.246	0.269	0.29	0.309	0.325	0.34	0.354	0.361
36 months	0.213	0.239	0.263	0.285	0.305	0.323	0.339	0.353	0.361
33 months	0.205	0.232	0.257	0.28	0.301	0.32	0.337	0.352	0.361
30 months	0.196	0.224	0.25	0.274	0.297	0.316	0.335	0.351	0.361
27 months	0.185	0.214	0.242	0.268	0.291	0.313	0.332	0.35	0.361
24 months	0.173	0.204	0.233	0.26	0.285	0.308	0.329	0.348	0.361
21 months	0.161	0.193	0.223	0.252	0.279	0.304	0.326	0.347	0.361
18 months	0.146	0.179	0.211	0.242	0.271	0.298	0.322	0.345	0.361
15 months	0.13	0.164	0.197	0.23	0.262	0.291	0.317	0.342	0.361
12 months	0.111	0.146	0.181	0.216	0.25	0.282	0.312	0.339	0.361
9 months	0.09	0.125	0.162	0.199	0.237	0.272	0.305	0.336	0.361
6 months	0.065	0.099	0.137	0.178	0.219	0.259	0.296	0.331	0.361
3 months	0.034	0.065	0.104	0.15	0.197	0.243	0.286	0.326	0.361
0 months	_	_	0.042	0.115	0.179	0.233	0.281	0.323	0.361

The exact fair market value and redemption date may not be set forth in the table above, in which case, if the fair market value is between two values in the table or the redemption date is between two redemption dates in the table, the number of Ordinary Shares to be issued for each warrant exercised will be determined by a straight-line interpolation between the number of shares set forth for the higher and lower fair market values and the earlier and later redemption dates, as applicable, based on a 365 or 366-day year, as applicable. For example, if the average last reported sale price of our Ordinary Shares for the 10 trading days ending on the third trading date prior to the date on which the notice of redemption is sent to the holders of the warrants is \$11.00 per share, and at such time there are 57 months until the expiration of the warrants, holders may choose to, in connection with this redemption feature, exercise their warrants for 0.277 Ordinary Shares for each whole warrant. For an example where the exact fair market value and redemption date are not as set forth in the table above, if the average last reported sale price of our Ordinary Shares for the 10 trading days ending on the third trading date prior to the date on which the notice of redemption is sent to the holders of the warrants is \$13.50 per share, and at such time there are 38 months until the expiration of the warrants, holders may choose to, in connection with this redemption feature, exercise their warrants for 0.298 Ordinary Shares for each whole warrant. In no event will the warrants be exercisable on a cashless basis in connection with this redemption feature, since they will not be exercisable for any Ordinary Shares.

This redemption feature differs from the typical warrant redemption features used in many other blank check offerings, which typically only provide for a redemption of warrants for cash (other than the private placement warrants) when the trading price for the Ordinary Shares exceeds \$18.00 per share for a specified period of time. This redemption feature is structured to allow for all of the outstanding warrants to be redeemed when the Ordinary Shares are trading at or above \$10.00 per share, which may be at a time when the trading price of our Ordinary Shares is below the exercise price of the warrants. We have established this redemption feature to provide us with the flexibility to redeem the warrants without the warrants having to reach the \$18.00 per share threshold set forth above under "—Redemption of warrants when the price per Ordinary Share equals or exceeds \$18.00." Holders choosing to exercise their warrants in connection with a redemption pursuant to this feature will, in effect, receive a number of shares representing "fair value" for their warrants based on a Black-Scholes option pricing model with a fixed volatility input as of the of this prospectus. This redemption right provides us with an additional mechanism by which to redeem all of the outstanding warrants, and therefore have certainty as to our capital structure as the warrants would no longer be outstanding and would have been exercised or redeemed. We will be required to pay the applicable redemption price to warrant holders if we choose to exercise this redemption right and it will allow us to quickly proceed with a redemption of the warrants if we determine it is in our best interest to do so. As such, we would redeem the warrants in this manner when we believe it is in our best interest to update our capital structure to remove the warrants and pay the redemption price to the warrant holders.

As stated above, we can redeem the warrants when the Ordinary Shares are trading at a price starting at \$10.00, which is below the exercise price of \$11.50, because it will provide certainty with respect to our capital structure and cash position while providing warrant holders with the opportunity to exercise their warrants on a cashless basis for the applicable number of shares. If we choose to redeem the warrants when the Ordinary Shares are trading at a price below the exercise price of the warrants, this could result in the warrant holders receiving fewer Ordinary Shares than they would have received if they had chosen to wait to exercise their warrants for Ordinary Shares if and when such Ordinary Shares were trading at a price higher than the exercise price of \$11.50.

No fractional Ordinary Shares will be issued upon exercise. If, upon exercise, a holder would be entitled to receive a fractional interest in a share, we will round down to the nearest whole number of the number of Ordinary Shares to be issued to the holder. If, at the time of redemption, the warrants are exercisable for a security other than the Ordinary Shares pursuant to the Warrant Agreement, the warrants may be exercised for such security. At such time as the warrants become exercisable for a security other than the Ordinary Shares, we

(or a surviving company) will use commercially reasonable efforts to register under the Securities Act the security issuable upon the exercise of the warrants.

Anti-dilution Adjustments. If the number of outstanding Ordinary Shares is increased by a capitalization or share dividend payable in Ordinary Shares, or by a split-up of ordinary shares or other similar event, then, on the effective date of such capitalization or share dividend, split-up or similar event, the number of Ordinary Shares issuable on exercise of each warrant will be increased in proportion to such increase in the outstanding ordinary shares. A rights offering to holders of ordinary shares entitling holders to purchase Ordinary Shares at a price less than the fair market value will be deemed a share dividend of a number of Ordinary Shares equal to the product of (i) the number of Ordinary Shares actually sold in such rights offering (or issuable under any other equity securities sold in such rights offering that are convertible into or exercisable for Ordinary Shares) and (ii) one (1) minus the quotient of (x) the price per Ordinary Share paid in such rights offering and (y) the fair market value. For these purposes, (i) if the rights offering is for securities convertible into or exercisable for Ordinary Shares, in determining the price payable for Ordinary Shares, there will be taken into account any consideration received for such rights, as well as any additional amount payable upon exercise or conversion and (ii) fair market value means the volume weighted average price of Ordinary Shares as reported during the ten (10) trading day period ending on the trading day prior to the first date on which the Ordinary Shares trade on the applicable exchange or in the applicable market, regular way, without the right to receive such rights.

In addition, if we, at any time while the warrants are outstanding and unexpired, pay a dividend or make a distribution in cash, securities or other assets to all or substantially all of the holders of Ordinary Shares on account of such Ordinary Shares (or other securities into which the warrants are convertible), other than (a) as described above, (b) any cash dividends or cash distributions which, when combined on a per share basis with all other cash dividends and cash distributions paid on the Ordinary Shares during the 365-day period ending on the date of declaration of such dividend or distribution does not exceed \$0.50 (as adjusted to appropriately reflect any other adjustments and excluding cash dividends or cash distributions that resulted in an adjustment to the exercise price or to the number of Ordinary Shares issuable on exercise of each warrant) but only with respect to the amount of the aggregate cash dividends or cash distributions equal to or less than \$0.50 per share, (c) to satisfy the redemption rights of the holders of Ordinary Shares in connection with a proposed initial business combination, (d) to satisfy the redemption rights of the holders of Ordinary Shares in connection with a shareholder vote to amend our amended and restated memorandum and articles of association (A) to modify the substance or timing of our obligation to redeem 100% of our Ordinary Shares if we do not complete our initial business combination within 24 months from the closing of our initial public offering or (B) with respect to any other provisions relating to the rights of holders of our Ordinary Shares, or (e) in connection with the redemption of our public shares upon our failure to complete our initial business combination, then the warrant exercise price will be decreased, effective immediately after the effective date of such event, by the amount of cash and/or the fair market value of any securities or other assets paid on each Ordinary Share in respect of such event.

If the number of outstanding Ordinary Shares is decreased by a consolidation, combination, reverse share split or reclassification of Ordinary Shares or other similar event, then, on the effective date of such consolidation, combination, reverse share split, reclassification or similar event, the number of Ordinary Shares issuable on exercise of each warrant will be decreased in proportion to such decrease in outstanding Ordinary Shares.

Whenever the number of Ordinary Shares purchasable upon the exercise of the warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of Ordinary Shares purchasable upon the exercise of the warrants immediately prior to such adjustment and (y) the denominator of which will be the number of Ordinary Shares so purchasable immediately thereafter.

In case of any reclassification or reorganization of the outstanding Ordinary Shares (other than those described above or that solely affects the par value of such Ordinary Shares), or in the case of any merger or

consolidation of us with or into another corporation (other than a consolidation or merger in which we are the continuing corporation and that does not result in any reclassification or reorganization of our outstanding Ordinary Shares), or in the case of any sale or conveyance to another corporation or entity of the assets or other property of us as an entirety or substantially as an entirety in connection with which we are dissolved, the holders of the warrants will thereafter have the right to purchase and receive, upon the basis and upon the terms and conditions specified in the warrants and in lieu of the Ordinary Shares immediately theretofore purchasable and receivable upon the exercise of the rights represented thereby, the kind and amount of Ordinary Shares or other securities or property (including cash) receivable upon such reclassification, reorganization, merger or consolidation, or upon a dissolution following any such sale or transfer, that the holder of the warrants would have received if such holder had exercised their warrants immediately prior to such event. However, if such holders were entitled to exercise a right of election as to the kind or amount of securities, cash or other assets receivable upon such consolidation or merger, then the kind and amount of securities, cash or other assets for which each warrant will become exercisable will be deemed to be the weighted average of the kind and amount received per share by such holders in such consolidation or merger that affirmatively make such election, and if a tender, exchange or redemption offer has been made to and accepted by such holders (other than a tender, exchange or redemption offer made by the company in connection with redemption rights held by shareholders of the company as provided for in the company's amended and restated memorandum and articles of association or as a result of the redemption of Ordinary Shares by the company if a proposed initial business combination is presented to the shareholders of the company for approval) under circumstances in which, upon completion of such tender or exchange offer, the maker thereof, together with members of any group (within the meaning of Rule 13d-5(b)(1) under the Exchange Act) of which such maker is a part, and together with any affiliate or associate of such maker (within the meaning of Rule 12b-2 under the Exchange Act) and any members of any such group of which any such affiliate or associate is a part, own beneficially (within the meaning of Rule 13d-3 under the Exchange Act) more than 50% of the issued and outstanding Ordinary Shares, the holder of a warrant will be entitled to receive the highest amount of cash, securities or other property to which such holder would actually have been entitled as a shareholder if such warrant holder had exercised the warrant prior to the expiration of such tender or exchange offer, accepted such offer and all of the Ordinary Shares held by such holder had been purchased pursuant to such tender or exchange offer, subject to adjustment (from and after the consummation of such tender or exchange offer) as nearly equivalent as possible to the adjustments provided for in the Warrant Agreement. If less than 70% of the consideration receivable by the holders of Ordinary Shares in such a transaction is payable in the form of Ordinary Shares in the successor entity that is listed for trading on a national securities exchange or is quoted in an established over-the-counter market, or is to be so listed for trading or quoted immediately following such event, and if the registered holder of the warrant properly exercises the warrant within thirty days following public disclosure of such transaction, the warrant exercise price will be reduced as specified in the Warrant Agreement based on the Black-Scholes value (as defined in the Warrant Agreement) of the warrant. The purpose of such exercise price reduction is to provide additional value to holders of the warrants when an extraordinary transaction occurs during the exercise period of the warrants pursuant to which the holders of the warrants otherwise do not receive the full potential value of the warrants. The purpose of such exercise price reduction is to provide additional value to holder of the warrants when an extraordinary transaction occurs during the exercise period of the warrants pursuant to which the holders of the warrants otherwise do not receive the full potential value of the warrants.

The warrants have been issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and Oaktree Acquisition Corp. II, and amended by an assignment, assumption and amendment agreement between us and Oaktree Acquisition Corp. II, Continental Stock Transfer & Trust Company, as existing warrant agent, Computershare Trust Company, N.A. and Computershare Inc., as new warrant agent"). The Warrant Agreement provides that the terms of the warrants may be amended without the consent of any holder for the purpose of (i) curing any ambiguity or correct any mistake, including to conform the provisions of the Warrant Agreement to the description of the terms of the warrants and the Warrant Agreement set forth in this prospectus, or defective provision, (ii) amending the provisions relating to cash dividends on ordinary shares as contemplated by and in accordance with the Warrant Agreement or (iii) adding or changing any provisions with respect to matters or questions arising under the Warrant Agreement as the

parties to the Warrant Agreement may deem necessary or desirable and that the parties deem to not adversely affect the rights of the registered holders of the warrants, provided that the approval by the holders of at least 50% of the then outstanding public warrants is required to make any change that adversely affects the interests of the registered holders You should review a copy of the Warrant Agreement, which has been filed with the SEC, for a complete description of the terms and conditions applicable to the warrants.

The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of ordinary shares and any voting rights until they exercise their warrants and receive Ordinary Shares. After the issuance of Ordinary Shares upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by shareholders.

No fractional shares will be issued upon exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of Ordinary Shares to be issued to the warrant holder.

## Private Placement Warrants

Except as described below, the private placement warrants have terms and provisions that are identical to those of the warrants sold as part of the units in our initial public offering. are not redeemable by us so long as they are held by Oaktree Acquisition Holdings II, L.P. or its permitted transferees (except for a number of Ordinary Shares as described under "—Public Shareholders' Warrants—Redemption of warrants when the price per Ordinary Share equals or exceeds \$10.00"). If the private placement warrants are held by holders other than Oaktree Acquisition Holdings II, L.P. or its permitted transferees, the private placement warrants are redeemable by us in all redemption scenarios and exercisable by the holders on the same basis as the warrants included in the units sold in our initial public offering.

Oaktree Acquisition Holdings II, L.P., or its permitted transferees, has the option to exercise the private placement warrants on a cashless basis. If holders of the private placement warrants elect to exercise them on a cashless basis, they would pay the exercise price by surrendering his, her or its warrants for that number of Ordinary Shares equal to the quotient obtained by dividing (x) the product of the number of Ordinary Shares underlying the warrants, multiplied by the difference between the exercise price of the warrants and the "fair market value" (defined below) by (y) the fair market value. The "fair market value" will mean the average reported closing price of the Ordinary Shares for the 10 trading days ending on the third trading day prior to the date on which the notice of warrant exercise is sent to the warrant agent. The reason that we have agreed that these warrants will be exercisable on a cashless basis so long as they are held by Oaktree Acquisition Holdings II, L.P. and permitted transferees is because it is not known at this time whether they will be affiliated with us following a business combination. If they remain affiliated with us, their ability to sell our securities in the open market will be significantly limited. We expect to have policies in place that prohibit insiders from selling our securities except during specific periods of time. Even during such periods of time when insiders will be permitted to sell our securities, an insider cannot trade in our securities if he or she is in possession of material non-public information. Accordingly, unlike public shareholders who could exercise their warrants and sell the Ordinary Shares received upon such exercise freely in the open market in order to recoup the cost of such exercise, the insiders could be significantly restricted from selling such securities. As a result, we believe that allowing the holders to exercise such warrants on a cashless basis is appropriate.

# Dividends

From the annual net profits of Alvotech, at least 5% shall each year be allocated to the reserve required by applicable laws (the "Legal Reserve"). That allocation to the Legal Reserve will cease to be required as soon and

as long as the Legal Reserve amounts to 10% of the amount of the issued share capital of Alvotech. The general meeting of shareholders shall resolve how the remainder of the annual net profits, after allocation to the Legal Reserve, will be disposed of by allocating the whole or part of the remainder to a reserve or to a provision, by carrying it forward to the next following financial year or by distributing it, each Ordinary Share entitling to the same proportion in such distributions.

The board of directors may resolve that Alvotech pays out an interim dividend to the shareholders, subject to the conditions of article 461-3 of the Luxembourg Company Law and Alvotech's articles of association. The board of directors shall set the amount and the date of payment of the interim dividend.

Any share premium, assimilated premium or other distributable reserve may be freely distributed to the shareholders subject to the provisions of the Luxembourg Company Law and Alvotech's articles of association. In case of a dividend payment, each shareholder is entitled to receive a dividend right pro rata according to his or her respective shareholding. The dividend entitlement lapses upon the expiration of a five-year prescription period from the date of the dividend distribution. The unclaimed dividends return to Alvotech's accounts.

# Registrar, Transfer and Warrant Agent

The registrar and transfer agent for the Shares and the warrant agent for the Warrants is Computershare Trust Company, N.A.

## Stock Exchange Listing

Our Ordinary Shares and Warrants are currently listed on the Nasdaq under the symbols "ALVO" and "ALVOW," respectively. Our Ordinary Shares are also listed on the Nasdaq Iceland Main Market under the ticker symbol "ALVO."

# Comparison of Luxembourg Corporate Law and Delaware Corporate Law

## SHAREHOLDER RIGHTS PLAN

Delaware

Under the DGCL, the certificate of incorporation of a corporation may give the board of directors the right to issue new classes of preferred shares with voting, conversion, dividend distribution, and other rights to be determined by the board of directors at the time of issuance, which could prevent a takeover attempt and thereby preclude stockholders from realizing a potential premium over the market value of their shares.

In addition, Delaware law does not prohibit a corporation from adopting a stockholder rights plan, or "poison pill," which could prevent a takeover attempt and also preclude stockholders from realizing a potential premium over the market value of their shares.

Pursuant to Luxembourg law, the shareholders may create an authorized share capital which allows the board of directors to increase the issued share capital for a price defined by the board of directors of Alvotech (which may or may not include an issue premium) against payment in cash or in kind, including by conversion of claims on Alvotech for any reason whatsoever including (i) issue subscription and/or conversion rights in relation to new shares or instruments within the limits of the authorized capital under the terms and conditions of warrants (which may be separate or linked to shares, bonds, notes or similar instruments issued by Alvotech),

Luxembourg

Delaware Luxembourg

convertible bonds, notes or similar instruments; (ii) determine the place and date of the issuance or successive issuances, the issue price, the terms and conditions of the issuance of and paying up on the new shares and instruments and (iii) remove or limit the statutory preferential subscription right of the shareholders in case of issue against payment in cash or shares, warrants (which may be separate or attached to shares, bonds, notes or similar instruments), convertible bonds, notes or similar instruments within the limits of such authorized share capital. The board of directors may be further authorized to, under certain conditions, limit, restrict, or waive preferential subscription rights of existing shareholders when issuing new shares within the authorized share capital. The rights attached to the new shares issued within the authorized share capital will be equal to those attached to existing shares and set forth in the articles of association.

The authorization to the board of directors to issue additional shares or other instruments as described above within the authorized share capital (and to limit, restrict, or waive, as the case may be preferential subscription rights) as well as the authorization to allot shares without consideration may be valid for a period of up to five years, starting from either the date of the minutes of the extraordinary general meeting resolving upon such authorization or starting from the date of the publication of the minutes of the extraordinary general meeting resolving upon such authorization in the Luxembourg official electronic gazette (RESA). The authorization

Delaware \_\_\_\_\_ Luxembourg

may be renewed, increased or reduced by a resolution of the extraordinary general meeting of shareholders, with the quorum and majority rules set for the amendment of the articles of association.

Alvotech's articles of association authorize its board of directors to issue Ordinary Shares within the limits of the authorized share capital at such times and on such terms as the board of directors or its delegates may decide for a period ending five years after the date of the creation of the authorized share capital or its publication date unless such period is extended, amended or renewed. Accordingly, the board of directors is authorized to issue Ordinary Shares up to the limits of authorized share capital until such date. Alvotech currently intends to seek renewals and/or extensions as required from time to time.

holder of a corporation Neither Luxembourg law nor Alvotech's articles of association provide for appraisal rights.

APPRAISAL RIGHTS

Under the DGCL, a stockholder of a corporation participating in some types of major corporate transactions may, under varying circumstances, be entitled to appraisal rights pursuant to which the stockholder may receive cash in the amount of the fair market value of his or her shares in lieu of the consideration he or she would otherwise receive in the transaction.

A shareholder meeting must always be called if the matter to be considered requires a shareholder resolution under Luxembourg law

or Alvotech's articles of association.

SHAREHOLDER CONSENT TO ACTION WITHOUT MEETING

Under the DGCL, unless otherwise provided in a corporation's certificate of incorporation, any action that may be taken at a meeting of stockholders may be taken without a meeting, without prior notice, and without a vote if the holders of outstanding stock, having not less than the minimum number of votes that would be necessary to authorize such action, consent in writing.

Pursuant to Luxembourg law, shareholders of a public limited liability company may not take actions by written consent. All shareholder actions must be

Delaware	Luxembourg

approved at an actual meeting of shareholders held before a notary public or under private seal, depending on the nature of the matter. Shareholders may vote in person, by proxy or, if the articles of association provide for that possibility, by correspondence.

The articles of association of Alvotech provide for the possibility of vote by correspondence, via proxy, and conference or videoconference call (to the extent made available by Alvotech).

Pursuant to Luxembourg law, at least one general meeting of shareholders must be held each year, within six months as from the close of the financial year. The purpose of such annual general meeting is to approve the annual accounts, allocate the results, proceed to statutory appointments and resolve on the

Other general meetings of shareholders may be convened.

discharge of the directors.

Luxembourg law distinguishes between ordinary resolutions to be adopted and extraordinary resolutions to be adopted by the general meeting of shareholders. Extraordinary resolutions relate to proposed amendments to the articles of association and other limited matters. All other resolutions are ordinary resolutions.

Pursuant to Luxemburg law, there is no requirement of a quorum for any ordinary resolutions to be considered at a general meeting and such ordinary resolutions shall be adopted by a simple majority of votes validly cast on such resolution. Abstentions are not considered "votes."

Under the DGCL, a special meeting of stockholders Pursuant to Luxembourg law, at least one may be called by the board of directors or by any other person authorized to do so in the certificate of incorporation or the bylaws.

Pursuant to Luxembourg law, at least one general meeting of shareholders must be leach year, within six months as from the continuous of the financial year. The purpose of such

Under the DGCL, a corporation's certificate of incorporation or bylaws can specify the number of shares that constitute the quorum required to conduct business at a meeting, provided that in no event shall a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Delaware Luxembourg

Extraordinary resolutions are required for any of the following matters, among others: (i) an increase or decrease of the authorized or issued share capital, (ii) a limitation or exclusion of preferential subscription rights, (iii) approval of a statutory merger or de-merger (scission), (iv) dissolution, (v) an amendment of the articles of association and (vi) change of nationality.

Pursuant to Luxembourg law, for any extraordinary resolutions to be approved at a general meeting, the quorum shall be at least one half (50%) of the issued share capital. If the said quorum is not present, a second meeting may be convened at which Luxembourg law does not prescribe a quorum. Any extraordinary resolution shall be adopted at a quorate general meeting (except as otherwise provided by mandatory law) by a two-thirds majority of the votes cast on such resolution by shareholders. Abstentions are not considered "votes."

The Luxembourg Company Law provides that if, as a result of losses, net assets fall below half of the share capital of the company, the board of directors shall convene an extraordinary general meeting of shareholders so that it is held within a period not exceeding two months from the time at which the loss was or should have been ascertained by them and such meeting shall resolve on the possible dissolution of the company and possibly on other measures announced in the agenda. The board of directors shall, in such situation, draw up a special report which sets out the causes of that situation and justify its proposals made available eight days before the extraordinary

Delaware Luxembourg

## DISTRIBUTIONS AND DIVIDENDS; REPURCHASES AND REDEMPTIONS

Under the DGCL, the board of directors, subject to any restrictions in the corporation's certificate of incorporation, may declare and pay dividends out of:

- surplus of the corporation, which is defined as net assets less statutory capital; or;
- if no surplus exists, out of the net profits of the corporation for the year in which the dividend is declared and/or the preceding year.

If, however, the capital of the corporation has been diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets, the board of directors shall not declare and pay dividends out of the corporation's net profits until the deficiency in the capital has been repaired.

Under the DGCL, any corporation may purchase or redeem its own shares, except that generally it may not purchase or redeem these shares if such repurchase or redemption would impair the capital of the corporation. A corporation may, however, purchase or redeem out of

general meeting at the registered office. If it proposes to continue to conduct business, it shall set out in the report the measures it intends to take in order to remedy the financial situation of the company. The same rules apply if, as a result of losses, net assets fall below one-quarter of the share capital provided that in such case dissolution shall take place if approved by one-fourth of the votes casts at the extraordinary general meeting.

Under Luxembourg law, the amount and payment of dividends or other distributions is determined by a simple majority vote at a general shareholders' meeting based on the recommendation of the board of directors, except in certain limited circumstances. Pursuant to Alvotech's articles of association, the board of directors has the power to pay interim dividends or make other distributions in accordance with applicable Luxembourg law. Distributions may be lawfully declared and paid if Alvotech's net profits and/or distributable reserves are sufficient under Luxembourg law. All Ordinary Shares rank pari passu with respect to the payment of dividends or other distributions unless the right to dividends or other distributions has been suspended in accordance with Alvotech's articles of association or applicable law.

Under Luxembourg law, at least 5% of Alvotech's net profits per year must be allocated to the creation of a legal reserve until such reserve has reached an amount equal to 10% of Alvotech's issued share capital. The allocation to the legal reserve becomes compulsory again when

Delaware

capital any of its own shares which are entitled upon any distribution of its assets to a preference over another class or series of its shares if such shares will be retired and the capital reduced. Luxembourg

the legal reserve no longer represents 10% of Alvotech's issued share capital. The legal reserve is not available for distribution.

Pursuant to Luxembourg law, Alvotech (or any party acting on its behalf) may repurchase its own shares and hold them in treasury, provided that:

- the shareholders at a general meeting have previously authorized the board of directors to acquire its ordinary shares.
   The general meeting shall determine the terms and conditions of the proposed acquisition and in particular the maximum number of shares to be acquired, the period for which the authorization is given (which may not exceed five years), and, in the case of acquisition for value, the maximum and minimum consideration;
- the acquisitions, including shares
   previously acquired by Alvotech and held
   by it and shares acquired by a person
   acting in his or her own name but on
   Alvotech's behalf, may not have the
   effect of reducing the net assets below the
   amount of the issued share capital plus
   the reserves (which may not be
   distributed by law or under the articles of
   association);
- the shares repurchased are fully paid-up;
   and
- the acquisition offer must be made on the same terms and conditions to all the shareholders who are in the same position, except for acquisitions which were

Delaware Luxembourg

unanimously decided by a general meeting at which all the shareholders were present or represented. In addition, listed companies may repurchase their own shares on the stock exchange without an acquisition offer having to be made to Alvotech's shareholders.

No prior authorization by shareholders is required (i) if the acquisition is made to prevent serious and imminent harm to Alvotech, provided that the board of directors informs the next general meeting of the reasons for and the purpose of the acquisitions made, the number and nominal values or the accounting value of the shares acquired, the proportion of the subscribed capital which they represent, and the consideration paid for them, and (ii) in the case of shares acquired by either Alvotech or by a person acting on its behalf with a view to redistributing the shares to its staff or staff of its controlled subsidiaries, provided that the distribution of such shares is made within 12 months from their acquisition.

Pursuant to Luxembourg law and in accordance with Alvotech's articles of association, Alvotech's Board of Directors must be composed of at least three directors. They are appointed by the general meeting of shareholders by a simple majority of the votes cast. Abstentions are not considered "votes." Directors may be reelected, but the term of their office may not exceed three years in accordance with Alvotech's articles of association.

NUMBER OF DIRECTORS

A typical certificate of incorporation and bylaws would provide that the number of directors on the board of directors will be fixed from time to time by a vote of the majority of the authorized directors.

## VACANCIES ON BOARD OF DIRECTORS

#### Delaware

#### Luxembourg

The DGCL provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (a) otherwise provided in the certificate of incorporation or by-laws of the corporation or (b) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Alvotech's articles of association provide that in case of a vacancy the remaining members of the board of directors may elect a director to fill the vacancy, on a temporary basis and for a period of time not exceeding the initial mandate of the replaced member of the board of directors, until the next general meeting of shareholders, which shall resolve on the permanent appointment in compliance with the applicable legal provisions and the articles of association.

# REMOVAL OF DIRECTORS; STAGGERED TERM OF DIRECTORS

Under Delaware law, a board of directors can be divided into classes. The board of directors is divided into three classes, with only one class of directors being elected in each year and each class serving a three-year term.

Under Luxembourg law, a director may be removed at any time by the general meeting of shareholders by a simple majority of the votes cast, with or without cause.

Alvotech's articles of association provides that the duration of the mandate of the directors will not exceed three (3) years. Directors of Alvotech may be reappointed for successive terms.

#### **CUMULATIVE VOTING**

Under the DGCL, a corporation may adopt in its certificate of incorporation that its directors shall be elected by cumulative voting. When directors are elected by cumulative voting, a stockholder has a number of votes equal to the number of shares held by such stockholder multiplied by the number of directors nominated for election. The stockholder may cast all of such votes for one director or among the directors in any proportion.

Not applicable.

# AMENDMENT OF GOVERNING DOCUMENTS

Under the DGCL, a certificate of incorporation may be amended if:

 the board of directors sets forth the proposed amendment in a resolution, declares the advisability of the amendment and directs that it be submitted Under Luxembourg law, amendments to Alvotech's articles of association require an extraordinary general meeting of shareholders held in front of a Luxembourg notary at which at least one half (50%) of the share capital is present or represented.

Delaware

to a vote at a meeting of stockholders; and

 the holders of at least a majority of shares of stock entitled to vote on the matter approve the amendment, unless the certificate of incorporation requires the vote of a greater number of shares.

In addition, under the DGCL, class voting rights exist with respect to amendments to the charter that adversely affect the terms of the shares of a class. Class voting rights do not exist as to other extraordinary matters, unless the charter provides otherwise. Under the DGCL, the board of directors may amend a corporation's bylaws if so authorized in the charter. The stockholders of a Delaware corporation also have the power to amend bylaws.

Luxembourg

The notice of the extraordinary general meeting shall set out the proposed amendments to the articles of association.

If the aforementioned quorum is not reached, a second meeting may be convened by means of a notice published in the Luxembourg official electronic gazette (RESA) and in a Luxembourg newspaper. The second meeting shall be validly constituted regardless of the proportion of the share capital present or represented.

At both meetings, resolutions will be adopted if approved by at least two-thirds of the votes cast by shareholders (unless otherwise required by Luxembourg law or the articles of association). Where different classes of shares exist and the resolution to be adopted by the general meeting of shareholders changes the respective rights attaching to such shares, the resolution will be adopted only if the conditions as to quorum and majority set out above are fulfilled with respect to each class of shares.

An increase of the commitments of the shareholders requires the unanimous consent of the shareholders.

Alvotech's articles of association and the Luxembourg Company Law provide that for any extraordinary resolutions to be considered at a general meeting, the quorum shall be at least one-half of Alvotech's issued share capital. If the said quorum is not present, a second meeting may be convened at which Luxembourg law does not prescribe a quorum. Any extraordinary resolution shall be adopted at a quorate general

Delaware Luxembourg

meeting (save as otherwise provided by mandatory law) by a two-thirds majority of the votes cast on such resolution by shareholders. Abstentions are not considered "votes."

In very limited circumstances, the board of directors may be authorized by the shareholders to amend the articles of association, albeit always within the limits set forth by the shareholders at a duly convened shareholders' meeting. This is the case in the context of Alvotech's authorized share capital within which the board of directors is authorized to issue further Ordinary Shares. The board of directors is then authorized to appear in front of a Luxembourg notary to record the capital increase and to amend the share capital set forth in the articles of association. The above also applies in case of the transfer of Alvotech's registered office outside the current municipality.

Luxembourg law permits Alvotech to keep directors indemnified against any expenses, judgments, fines and amounts paid in connection with liability of a director towards Alvotech or a third party for management errors i.e., for wrongful acts committed during the execution of the mandate (*mandat*) granted to the director by Alvotech, except in connection with willful misfeasance, bad faith, gross negligence or reckless disregard of the duties involved in the conduct of his or her office.

Under the articles of association of the company, the members of the board of directors, officers, employees and agents of Alvotech are not held personally liable for the indebtedness or other

INDEMNIFICATION OF DIRECTORS AND OFFICERS

The DGCL generally permits a corporation to indemnify its directors and officers against expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with a third-party action, other than a derivative action, and against expenses actually and reasonably incurred in the defense or settlement of a derivative action, provided that there is a determination made by the corporation that the individual acted in good faith and in a manner reasonably believed to be in or not opposed to the best interests of the corporation. Such determination shall be made, in the case of an individual who is a director or officer at the time of the determination:

Delaware

- Luxembourg
- by a majority of the disinterested directors, even though less than a quorum;
- by a committee of disinterested directors designated by a majority vote of disinterested, directors, even though less than a quorum;
- by independent legal counsel, regardless of whether a quorum of disinterested directors exists; or
- · by the stockholders

Without court approval, however, no indemnification may be made in respect of any derivative action in which an individual is adjudged liable to the corporation.

The DGCL requires indemnification of directors and officers for expenses relating to a successful defense on the merits or otherwise of a derivative or third-party action. The DGCL permits a corporation to advance expenses relating to the defense of any proceeding to directors and officers contingent upon those individuals' commitment to repay any advances, unless it is determined ultimately that those individuals are entitled to be indemnified.

obligations of Alvotech. As agents of Alvotech, they are responsible for the performance of their duties. Subject to the exceptions and limitations listed in the articles of association of Alvotech and mandatory provisions of law, every person who is, or has been, a member of the board of directors, officer (mandataire) or agent of Alvotech (and any other persons to which applicable law permits Alvotech to provide indemnification, including any person who is or was a director or officer of Alvotech, is or was serving at the request of Alvotech as a director, officer (mandataire), employee or agent of another company, partnership, joint venture, trust or other enterprise or employee benefit plan) (collectively, the "Covered Persons"), shall be indemnified by Alvotech to the fullest extent permitted by law against liability and against all expenses reasonably incurred or paid by them in connection with any claim, action, suit or proceeding which they become involved as a party or otherwise by virtue of his or her being or having been a Covered Person and against amounts paid or incurred by him or her in the settlement thereof. If applicable law is amended after approval of the current articles of association of Alvotech to authorize corporate action further eliminating or limiting the personal liability of Covered Persons, then the liability of a Covered Person to Alvotech shall be eliminated or limited to the fullest extent permitted by applicable law as so amended. The words "claim", "action", "suit" or "proceeding" shall apply to all claims, actions, suits or proceedings (civil, criminal or

Delaware Luxembourg

otherwise including appeals) actual or threatened and the words "liability" and "expenses" shall include without limitation attorneys' fees, costs, judgments, amounts paid in settlement and other liabilities.

Expenses (including attorneys' fees) incurred by a Covered Person in defending any claim (save for fraud, negligence or willful misconduct's claims) shall be paid by Alvotech in advance of the final disposition of such claim upon receipt of an undertaking by or on behalf of such Covered Person to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by Alvotech as authorized in Alvotech's articles of association. Such expenses (including attorneys' fees) incurred by former Covered Persons may be so paid upon such terms and conditions, if any, as Alvotech deems appropriate.

The indemnification and advancement of expenses provided by, or granted pursuant to, Alvotech's articles of association shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under this present articles of association, agreement, vote of shareholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office, it being the policy of Alvotech that indemnification of the persons specified in Alvotech's articles of association shall be made to the fullest extent permitted by law.

Delaware Luxembourg

No indemnification shall be provided to any Covered Person (i) against any liability by reason of willful misfeasance, bad faith, gross negligence or reckless disregard of the duties involved in the conduct of his or her office (ii) with respect to any matter as to which he or she shall have been finally adjudicated to have acted in bad faith and not in the interest of Alvotech or (iii) in the event of a settlement, unless the settlement has been approved by a court of competent jurisdiction or by the board of directors. The termination of any claim, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of Alvotech, and, with respect to any claim, had reasonable cause to believe that such person's conduct was unlawful. The right of indemnification set out above shall be severable, shall not affect any other rights to which any Covered Person may now or hereafter be entitled, shall continue as to a person who has ceased to be such Covered Person and shall inure to the benefit of the heirs, executors and administrators of such a person. Nothing contained herein shall affect or limit any rights to indemnification to which corporate personnel, including Covered Persons, may be entitled by contract or otherwise under law. Alvotech shall specifically be entitled to provide contractual indemnification to and may purchase and maintain insurance for any corporate personnel, including Covered Persons, as

Delaware Luxembourg

Alvotech may decide upon from time to time.

The obligations of Alvotech under Alvotech's articles of association only apply to Covered Persons in their capacity as Covered Persons.

Luxembourg law does not provide for an ex ante limitation of liability but it permits Alvotech to keep directors indemnified as set out above.

LIMITED LIABILITY OF DIRECTORS

ADVANCE NOTIFICATION REQUIREMENTS FOR PROPOSALS OF SHAREHOLDERS Delaware law permits limiting or eliminating the monetary liability of a director to a corporation or its stockholders, except with regard to breaches of duty of loyalty, intentional misconduct, unlawful repurchases or dividends, or improper personal benefit.

Delaware corporations typically have provisions in their bylaws that require a stockholder proposing a nominee for election to the board of directors or other proposals at an annual or special meeting of the stockholders to provide notice of any such proposals to the secretary of the corporation in advance of the meeting for any such proposal to be brought before the meeting of the stockholders. In addition, advance notice bylaws frequently require the stockholder nominating a person for election to the board of directors to provide information about the nominee, such as his or her age, address, employment and beneficial ownership of shares of the corporation's capital stock. The stockholder may also be required to disclose, among other things, his or her name, share ownership and agreement, arrangement or understanding with respect to such nomination.

For other proposals, the proposing stockholder is often required by the bylaws to provide a description of the proposal and any other information relating to such stockholder or beneficial owner, if any, on whose behalf that proposal is being made, required to be disclosed in a proxy statement or other filings required to

One or several shareholders holding at least 10% of the share capital may request the addition of one or several items on the agenda of a general meeting. Such request must be addressed to the registered office of Alvotech by registered mail.

If one or more shareholders representing at least 10% of the share capital request so in writing, with an indication of the agenda, the convening of a general meeting, the board of directors or the statutory auditor must convene a general meeting.

SHAREHOLDERS' SUITS

Delaware Luxembourg

be made in connection with solicitation of proxies for the proposal and pursuant to and in accordance with the Exchange Act and the rules and regulations promulgated thereunder.

Under Delaware law, a stockholder may bring a derivative action on a company's behalf to enforce the rights of a company. An individual also may commence a class action lawsuit on behalf of himself or herself and other similarly situated stockholders if the requirements for maintaining a class action lawsuit under Delaware law are met. An individual may institute and maintain a class action lawsuit only if such person was a stockholder at the time of the transaction that is the subject of the lawsuit or his or her shares thereafter devolved upon him or her by operation of law. In addition, the plaintiff must generally be a stockholder through the duration of the lawsuit.

Delaware law requires that a derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the lawsuit may be prosecuted, unless such demand would be futile.

Under Luxembourg law, the board of directors has sole authority to decide whether to initiate legal action to enforce a company's rights (other than, in certain circumstances, an action against board members).

Shareholders generally do not have the authority to initiate legal action on a company's behalf unless the company fails abusively to exercise its legal rights. However, a company's shareholders may vote at a general meeting to initiate legal action against directors on grounds that the directors have failed to perform their duties.

Luxembourg law does not provide for class action lawsuits.

However, it is possible for plaintiffs who have similar but separate claims against the same defendant(s) to bring an action on a "group" basis by way of a joint action. It is also possible to ask the court, under the Luxembourg New Civil Procedure Code, to join claims which are closely related and to rule on them together.

In addition, minority shareholders holding an aggregate of 10% of the voting rights and who voted against the discharge to a director at the annual general meeting of the company can initiate legal action against the director on behalf of the company.

#### CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

## Policies and Procedures for Related Person Transactions

The Board of Directors has adopted a written related person transaction policy that sets forth certain policies and procedures for the review and approval or ratification of transactions involving us in which a related person has or will have a direct or indirect material interest, as determined by the audit and risk committee of the Board. A "related person" for purposes of the policy means: (i) enterprises that directly or indirectly through one or more intermediaries, control or are controlled by, or are under common control with, us; (ii) Associates (defined as, unconsolidated enterprises in which we have a Significant Influence or which has Significant Influence over us); (iii) individuals owning, directly or indirectly, an interest in the voting power of us that gives them Significant Influence over us, and close members of any such individual's family; (iv) key management personnel (i.e., having authority and responsibility for planning, directing and controlling our activities), including Directors and close members of such individuals' families; and (v) enterprises in which a substantial interest in the voting power is owned, directly or indirectly, by any person described in (iii) or (iv) above or over which such a person is able to exercise Significant Influence, including enterprises owned by our Directors or major shareholders and enterprises that have a member of key management in common with us. "Significant Influence" for purposes of the policy means the power to participate in the financial and operating policy decisions of an enterprise but is less than control over those policies, provided that shareholders beneficially owning a 10% or more interest in the voting power of the enterprise concerned are presumed to have a significant influence on such enterprise.

Pursuant to the policy, each executive director, nominee for the position of executive director and executive officer shall promptly notify the designated contact of any transaction involving us and a related person. The designated contact will present any new related person transactions, and proposed transactions involving related persons, to the Audit and Risk Committee of the Board at its next occurring regular meeting. If the Audit and Risk Committee determines that the related person involved has a direct or indirect material interest in the transaction, and there therefore that the transaction is a related party transaction, the Audit and Risk Committee shall consider all relevant facts and circumstances, including the commercial reasonableness of the terms, the benefit and perceived benefit, or lack thereof, to the Company, opportunity costs of alternate transactions, the materiality and character of the Related Person's direct or indirect interest, and the actual or apparent conflict of interest of the Related Person. The Audit and Risk Committee will not approve or ratify a Related Person Transaction unless it shall have determined that, upon consideration of all relevant information, the Transaction is in, or not inconsistent with, our best interests. On an annual basis, the Audit and Risk Committee shall review previously approved related person transactions, under the standard described above, to determine whether such transaction should continue. If after the review described above, the Audit and Risk Committee determines not to approve or ratify a related person transaction (whether such transaction is being reviewed for the first time or has previously been approved and is being reviewed), the transaction will not be entered into or continued.

## Service Agreements with related parties

Service Agreement with Alvogen

On January 1, 2021, Alvotech entered into a shared service agreement with Alvogen, which was amended and restated on April 11, 2022, as agreed between Alvotech and OACB (the "Alvogen Services Agreement"), pursuant to which Alvotech, Alvogen and certain of their affiliates will perform certain support services for each other. Under the Alvogen Services Agreement, Alvotech and its affiliates (including its U.S. affiliate) are responsible for providing general finance, administrative, and legal services. Alvogen's affiliates are responsible for providing to Alvotech certain support services including marketing and IT services. Services provided by the parties are charged at a rate equal to each respective party's direct costs plus an 8% markup, provided that third party pass-through costs shall not include a mark-up. All proceeds from one party's work for the other party, such as any form of intellectual property, shall be the sole property of the party for which the services have been provided and no transfer of such rights is needed. The party providing the services transfers to the beneficiary of

the services the right to patent inventions resulting from such work. The amended and restated Alvogen Services Agreement will be for indefinite duration with a minimum term of 12 months, without termination rights (only termination for cause as set out below), after which it can be terminated by the party providing the services upon 12 months' notice and by the beneficiary of the services upon 30 days' notice. Notwithstanding the foregoing, either party may terminate the Alvogen Services Agreement upon (i) the liquidation, insolvency or bankruptcy of the other party; (ii) the other party ceasing or threatening to cease to carry on its business; or (iii) material breach by the other party following written notice of such breach and a thirty-day cure period.

Between January 1 and December 31, 2022, Alvotech has received an aggregate of \$0.5 million for services provided and has paid an aggregate of \$2.3 million for services received under the Alvogen Services Agreement.

# Service Agreement with Adalvo

On March 4, 2021, Alvotech entered into a shared service agreement with Alvogen Malta (Out-Licensing) Ltd. ("Adalvo"), which was amended and restated on April 21, 2022, as agreed between Alvotech and OACB (the "Adalvo Services Agreement"), pursuant to which Adalvo provides certain support services to Alvotech. Under the Adalvo Services Agreement, Adalvo is responsible for providing salary processing, supply chain management, portfolio and market intelligence research, regulatory, quality audit, publishing and legal services to Alvotech. Services provided by Adalvo are charged at a rate equal to Adalvo's direct costs plus an 8% mark-up, provided that third party pass-through costs shall not include a mark-up. All proceeds from one party's work for the other party, such as any form of intellectual property, shall be the sole property of the party for which the services have been provided and no transfer of such rights is needed. The party providing the services transfers to the beneficiary of the services the right to patent inventions resulting from such work. The amended and restated Adalvo Services Agreement will be for indefinite duration with a minimum term of 12 months, without termination rights (only termination for cause as set out below), after which it can be terminated by Adalvo with 9 months' notice and by Alvotech with 30 days' notice. Notwithstanding the foregoing, either party may terminate the Adalvo Services Agreement upon (i) the liquidation, insolvency or bankruptcy of the other party; (ii) the other party ceasing or threatening to cease to carry on its business; or (iii) material breach by the other party following written notice of such breach and a thirty-day cure period.

Between January 1 and December 31, 2022, Alvotech has received an aggregate of \$0 million for services provided and has paid an aggregate of \$1.1 million for services received under the Adalvo Services Agreement.

### Aztiq Services Agreement

On November 16, 2022, Alvotech entered into a transition services agreement with Aztiq Consulting ehf ("Aztiq Consulting") (the "Aztiq Services Agreement"), pursuant to which Aztiq Consulting will provide to Alvotech certain corporate administrative, legal, financial, and facility management services (the "Standard Services") and other ad hoc services as requested by Alvotech from time to time (the "Ad Hoc Services" and, together with the Standard Services, the "Services"). The Standard Services provided by Aztiq Consulting will be charged at a monthly rate of \$25,000 (the "Monthly Fee"), and Ad Hoc Services will be remunerated by means of a separate fee letter. At least once per year, the parties will review whether the Services are still required, whether the Services can be amended or terminated, and whether the Monthly Fee remains on an arm's length basis. Any form of intellectual property rights resulting from the Aztiq Services Agreement shall remain the sole property of Aztiq Consulting, except for any intellectual property rights that are specifically developed by Aztiq Consulting for Alvotech as a service deliverable. Unless terminated earlier, the Aztiq Services Agreement will be for a duration of three years. The Aztiq Services Agreement can be terminated (i) by Alvotech for any reason upon providing 60 days' notice, or (ii) by Aztiq Consulting (a) upon failure by Alvotech to pay any undisputed fees; (b) if Alvotech is in material breach of the Aztiq Services Agreement and that breach has not or cannot be remedied within 60 days of a notice from Aztiq Consulting; or (c) if Alvotech is subject to an Insolvency Event (as defined in the Aztiq Services Agreement).

Between January 1 and December 31, 2022, Alvotech has paid an aggregate of \$0.7 million for services received under the Aztiq Services Agreement.

# Supply and Distribution Agreements with Lotus Pharmaceuticals

On August 2, 2014, Alvotech entered into supply and distribution agreements with Lotus Pharmaceuticals Co., Ltd., an affiliate of Alvogen ("Lotus"), as amended on March 31, 2020, May 25, 2020 and November 20, 2020, respectively (together, the "Lotus Supply and Distribution Agreements") with respect to AVT02 in certain Thailand, Vietnam, Philippines and South Korea. Under the terms of the Lotus Supply and Distribution Agreements, Alvotech will develop AVT02 and provide the dossier of data, information and know-how relating to AVT02 to Lotus. Alvotech retains full ownership of all intellectual property rights in the product candidates and the dossiers. Lotus has the exclusive right and obligation to use the dossier to obtain and maintain regulatory approvals for that product and to market, sell and distribute the products in the respective countries. Lotus will own all right, title and interest in and with respect to the trademark for the product and Alvotech has the royalty-free right to use the trademark in the markets not covered by the Lotus Supply and Distribution Agreements during the term of the agreements. However, due to changes in the territorial scope of the Lotus Supply and Distribution Agreements as a result of the amendments, Lotus divested its distribution rights in several markets to Alvotech, for which Alvotech made an upfront payment to Lotus of \$3.1 million and will pay another \$7.44 million upon the launch of the product in China. Alvotech will manufacture, supply and deliver the product and Lotus will exclusively buy the relevant biosimilar candidate from Alvotech on a cost-plus basis. The parties do not owe royalties to each other. Invoices are payable within thirty days of the receipt of the product. The Lotus Supply and Distribution Agreements terminate 20 years after the first commercial sale of the product in the territories. The agreements can be terminated by either party (i) if the other party commits a material breach of the agreement; (ii) in case of insolvency, the appointment of a receiver with respect to the assets of the other party or the assignment for the benefit of creditors of assets of the other party; or (iii) if the other party or any of its affiliates, employees or agents become subject to an FDA investigation that could lead to them becoming debarred by the FDA.

As of December 31, 2022, Alvotech has paid an aggregate of \$3.1 million and is required to pay an additional \$7.4 million upon achieving certain milestones under the Lotus Supply and Distribution Agreements.

## **Product Rights Agreement with Alvogen**

On January 22, 2018, Alvotech entered into a product rights agreement with Alvogen, as amended on December 14, 2018 (the "Alvogen Product Rights Agreement"), pursuant to which Alvogen provides commercialization services with respect to Alvotech's product candidates. For Adalimumab, Aflibercept, Denosumab, Eculizumab, Golimumab, and Ustekinumab, Alvogen will provide commercialization services in the Alvogen Territories (as defined in the Alvogen Product Rights Agreement). Alvogen also has a "right of last look" with respect to the other territories and a "right of first refusal" with respect to new Alvotech products.

Alvogen will pay Alvotech, on a quarterly basis, a royalty equal to fifty percent (50%) of Alvogen's aggregate net sales on sales of Alvotech's products in the Alvogen Territories for the duration of the agreement. If, however, Alvotech sells any of its products to any distributor or other third party in any Alvogen Territory, then Alvotech shall be required to pay to Alvogen an amount equal to 50% of Alvotech's aggregate net sales to such third party in the Alvotech Territories. Alvogen also has a right to acquire rights to develop, license, distribute, market, commercialize or sell any Alvotech product by offering written terms to Alvotech that provide the same, or greater, aggregate financial value to Alvotech as the proposal of a third party for those rights (a "right of last look") in any territory that is not an Alvogen Territory. Alvogen is also entitled, for sales of adalimumab (AVT02) occurring in the United States, to a royalty equal to:

(i) if Adalimumab is not the first biosimilar to be interchangeable: (x) for a period of 60 months from the start of the first date on which the first U.S. commercial sale occurs, 10% of the Alvotech Royalty Payment (as defined in the Alvogen Product Rights Agreement) payable during each relevant quarterly period, and (y) for an additional 24 months, 7.5% of the Alvotech Royalty Payment payable during each relevant quarterly period; or

(ii) if Adalimumab is the first biosimilar to be interchangeable, for a period of 60 months from the start of the first date on which the first U.S. commercial sale occurs, 7.5% of the Alvotech Royalty Payment payable during each relevant quarterly period.

The contract expires, for each product, on the 20th anniversary of the first commercial sale of that product, provided that the Alvogen Product Rights Agreement shall automatically renew for an additional year unless Alvogen provides Alvotech with written notice of non-renewal. The agreement can be terminated by either party if (i) if the other party commits a material breach of the agreement; or (ii) in case of insolvency, the appointment of a receiver with respect to the assets of the other party, the assignment for the benefit of creditors of assets of the other party, the entry of an order of relief under Title 11 of the U.S. Code against the other party or the appointment of a liquidator, administrator or similar officer in respect of the other party (or analogous procedure in any jurisdiction).

As of December 31, 2022, Alvotech has not received or made any payments under the Alvogen Product Rights Agreement.

# Agreements with Fuji

On April 2, 2019, Alvotech and Fuji Pharma entered into a license agreement, as amended on June 23, 2020 to reflect a delay in the development process and therefore, among others, amended and restated the milestone payments, (the "Fuji Pharma AVT04 License Agreement") and a supply agreement (the "Fuji Pharma AVT04 Supply Agreement"). Under the Fuji Pharma AVT04 License Agreement, Alvotech will develop AVT04 and compile and provide a dossier of data, information and know-how relating to AVT04 to Fuji Pharma. Alvotech retains full ownership of all intellectual property rights in AVT04 and the AVT04 dossier. Fuji Pharma has the exclusive right to use the dossier to obtain and maintain regulatory approvals for AVT04 and to import, finish, market, promote, sell and distribute AVT04 in Japan. Fuji Pharma made a one-time payment on the signature date of \$4.6 million and will make an additional milestone payment to Alvotech upon the launch of the product, subject to certain conditions. If Fuji Pharma achieves annual sales in excess of certain target volumes, it will pay Alvotech an additional royalty on the net sales above the target. Under the Fuji Pharma AVT04 Supply Agreement, Alvotech will manufacture, supply and deliver the AVT04 product. Fuji Pharma will pay Alvotech a royalty or the applicable floor price, whichever is higher, for the duration of the agreement. All invoices are payable within thirty business days, in U.S. dollars and by wire transfer. The agreements terminate 20 years after the first commercial sale of AVT04 in Japan. They can be terminated by either party if the other party: (i) withholds any monies due to the other party for more than two months: (ii) commits or permits any substantial breach of any material term of the agreement; (iii) has a receiver or administrator appointed in respect of any of its assets or enters into any agreement with its creditors; or (iv) goes into liquidation. The agreements can be terminated by Fuji Pharma if (i) a competing product obtains reimbursement approval (Fuji Pharma AVT04 License Agreement) before AVT04 obtains reimbursement approval; (ii) AVT04 does not obtain reimbursement approval by November 30, 2023; or (iii) AVT04 obtains reimbursement approval at the same time two competing products obtain reimbursement approval.

On November 18, 2020, Alvotech and Fuji Pharma entered into four binding term sheets with respect to AVT06, two proposed AVT03 biosimilar products and AVT05. On February 10, 2022, Alvotech and Fuji Pharma expanded their strategic partnership and entered into an additional binding term sheet with respect to a new undisclosed biosimilar candidate currently in early phase development, and in January 2023 we announced the expansion with another undisclosed biosimilar candidate. Under the binding term sheets, Alvotech will develop the product candidates and provide a dossier of data, information and know-how relating to the relevant product to Fuji Pharma. Fuji Pharma has the exclusive right to use the dossier to obtain and maintain regulatory approvals and to import, finish, market, promote, sell and distribute the relevant product in Japan. As of December 31, 2021, Fuji Pharma made one-time payments on the signing dates of the binding term sheets of \$3.0 million and agreed to make additional payments upon achieving certain regulatory and development milestones. Alvotech and Fuji Pharma will enter into license and supply agreements for each product at a later

date, subject to fulfilling certain conditions related to the development of that product and the absence of commercial launch of competing products in Japan at that time. Fuji Pharma will exclusively buy the relevant biosimilar candidate from Alvotech at a royalty or the applicable floor price, whichever is higher, for the duration of the agreement. The license and supply agreements will terminate 20 years after the first commercial sale of the relevant product in Japan. They can be terminated by either party in case a party (i) withholds any monies due to the other party for more than two months; (ii) commits or permits any substantial breach of any material term of the agreement; (iii) has a receiver or administrator appointed in respect of any of its assets or enters into any agreement with its creditors; or (iv) goes into liquidation.

# Shareholder Loans and Financing

Aztiq Convertible Loans

On December 14, 2018, Alvotech, as borrower, entered into an amendment deed with Alvogen and Aztiq AB, as lenders, related to certain existing convertible loan agreements, including a convertible loan agreement for \$11.7 million dated December 22, 2017 with Aztiq AB as lender and convertible loan agreements dated December 22, 2017 for an aggregate of \$146.5 million with Alvogen as lender, each bearing interest at a rate of 15% per annum and with a maturity date set to December 31, 2022 (collectively the "Original 2017 Convertible Loan Agreements").

Each of the Original 2017 Convertible Loan Agreements provided that:

- indebtedness other than expressly agreed or acknowledged or the issuance of certain stocks by the borrower or any subsidiary is not permitted;
- the creation of lien and securities by the borrower or any of its subsidiaries is restricted;
- certain payments and redemptions by the borrower or any of its subsidiaries other than those expressly agreed are prohibited; and
- certain obligations and restrictions relating to real estate assets located at the head office in Iceland are applicable.

Pursuant to an agreement to the Original 2017 Convertible Loan Agreements dated May 10, 2019, Aztiq AB assigned and transferred its rights and obligations under the Original 2017 Convertible Loan Agreements to Aztiq. On May 14, 2019, Alvogen also assigned and transferred part of its rights and obligations under the Original 2017 Convertible Loan Agreements, for a principal amount of \$50 million, to Aztiq (the "Alvogen Transfer Debt"). Pursuant to the Alvotech SHA (See "—*Shareholder's Agreement*") Alvogen had the right to call the Alvogen Transfer Debt from Aztiq prior to certain exit events. With these assignments and transfers, Aztiq became a lender of Alvotech for an amount of \$61.7 million, as of May 14, 2019 (the "Original Aztiq Convertible Loan Agreement"). For Alvogen's remaining interest in the Original 2017 Convertible Loan Agreements that was not transferred to Aztiq, see "—*Alvogen Loan Agreement*."

On October 21, 2020, Aztiq assigned \$25 million of the principal amount outstanding under Alvogen Transfer Debt, which formed part of the Original Aztiq Convertible Loan Agreement, to fund tranche B of the 2020 Convertible Loan (see "—2020 Convertible Loan Agreement and investment agreements"). That same day, Alvotech and Aztiq entered into an amended and consolidated loan agreement with respect to the remaining outstanding amounts under the Original Aztiq Convertible Loan Agreement (the "Amended Aztiq Convertible Loan Agreement"), which included a right for Aztiq to convert the outstanding balance into Alvotech Holdings Class A Ordinary Shares under certain conditions set forth in an amended and restated conversion agreement of October 21, 2020 between Alvotech, Alvogen and Aztiq (the "Aztiq Conversion Agreement").

On June 30, 2021, the aggregate principal amount outstanding under the Amended Aztiq Convertible Loan Agreement amounted to \$36.7 million, which included the remaining \$25 million of principal under the Alvogen Transfer Debt. The interest rate on the principal amount of the loan was 15% per annum.

## Aztiq Loan Agreement

On May 14, 2019, as mentioned above, Alvotech, as borrower, entered into a loan agreement with Aztiq, as lender, for a principal amount of \$50 million (the "Original Aztiq Loan Agreement), bearing interest at a rate of 15% per annum and with a maturity date that falls 91 days after December 14, 2023.

On October 21, 2020, as mentioned above, Aztiq assigned and transferred \$25 million of the principal amount outstanding under the Alvogen Transfer Debt which formed part of the Original Aztiq Loan Agreement to fund tranche A of the 2020 Convertible Loan (see "—2020 Convertible Loan Agreement and investment agreements"). That same day, Alvotech and Aztiq entered into (i) an amended and consolidated loan agreement with respect to the remainder of the balance under the Original Aztiq Loan Agreement (the "Amended Aztiq Loan Agreement"), bearing interest at a rate of 15% per annum and with maturity date set to December 31, 2022, and (ii) an amended and restated warrant agreement (the "Aztiq Warrant Agreement") pursuant to which Aztiq was entitled to exercise a warrant to subscribe for Alvotech Holdings Class A Ordinary Shares.

# The Amended Aztiq Loan Agreement provided that:

- indebtedness other than expressly agreed or acknowledged or the issuance of certain stocks by the borrower or any subsidiary is not permitted;
- the creation of lien and securities by the borrower or any of its subsidiaries is restricted;
- · certain payments and redemptions by the borrower or any of its subsidiaries other than those expressly agreed are prohibited; and
- certain obligations and restrictions relating to real estate assets located at the head office in Iceland are applicable.

On June 30, 2021, the aggregate principal amount outstanding under the Amended Aztiq Loan Agreement amounted to \$25 million.

## 2020 Convertible Loan Agreement and investment agreements

On October 21, 2020, as part of a private placement transaction, Alvotech, as borrower, entered into a loan agreement with Aztiq, as lender, for an aggregate principal amount of \$50.0 million (the "2020 Convertible Loan Agreement") in two equal tranches, being the tranche A and tranche B, each bearing interest at a rate of 15% per annum and falling due on (a) (i) the date that is 91 calendar days after all of the convertible bonds issued by Alvotech are fully and irrevocably redeemed, in respect of the Tranche A, and (ii) December 31, 2022 in respect of the Tranche B; or (B) in case of a qualified initial public offering and conversion of all of the convertible bonds issued by Alvotech, December 31, 2022 with respect to Tranche A and Tranche B. Tranche A of the 2020 Convertible Loan Agreement was funded by a transfer of \$25.0 million from the Original Aztiq Convertible Loan Agreement was funded by a transfer of \$25.0 million from the Alvogen Transfer Debt, which formed part of the Original Aztiq Loan Agreement (see "—Aztiq Loan Agreement").

# The 2020 Convertible Loan Agreement provided that:

- indebtedness other than expressly agreed or acknowledged or the issuance of certain stocks by the borrower or any subsidiary is not permitted;
- the creation of lien and securities by the borrower or any of its subsidiaries is restricted;
- · certain payments and redemptions by the borrower or any of its subsidiaries other than those expressly agreed are prohibited; and

certain obligations and restrictions relating to real estate assets located at the head office in Iceland are applicable. Pursuant to a conversion
agreement of that same date (the "2020 Conversion Agreement"), Aztiq had the right to convert the outstanding balance of \$50.0 million
under the 2020 Convertible Loan Agreement into Alvotech Holdings Class A Ordinary Shares under certain conditions.

Further on October 21, 2020, Aztiq assigned and transferred in total \$23.125 million of the principal amount outstanding under the 2020 Convertible Loan to five investors, including Alvogen. The new lenders assumed the relevant obligations and rights of Aztiq under the 2020 Convertible Loan. In March 2021, Aztiq assigned and transferred another \$17.5 million of the principal amount outstanding under the 2020 Convertible Loan to five investors, including Aztiq AB.

On December 7, 2021, and as contemplated under the BCA Framework Agreement (as defined below), the outstanding principal amount under the 2020 Convertible Loan Agreement was converted into Alvotech Holdings Class A Ordinary Shares in accordance with the 2020 Conversion Agreement by all other creditors.

# Alvogen Loan Agreement

On December 14, 2018, Alvotech, as borrower, entered into an amendment deed to the Original 2017 Convertible Loan Agreements with Alvogen and Aztiq AB, as lenders, related to certain existing convertible loan agreements dated December 22, 2017 for an aggregate of \$146.5 million. On May 14, 2019, Alvogen assigned and transferred part of its rights and obligations under the Original 2017 Convertible Loan Agreements, for a principal amount of \$50.0 million, to Aztiq, known as the Alvogen Transfer Debt. See section "—Aztiq Convertible Loans" for the applicable covenants.

On April 16, 2020, Alvotech and Alvogen amended and consolidated the terms of the convertible loan agreements between them (the "Consolidated Alvogen Convertible Loan Agreement"), bearing interest at a rate of 15% per annum and with a maturity date set to December 31, 2022. The principal amount outstanding under the Consolidated Alvogen Convertible Loan Agreement amounted to \$21.5 million.

The Consolidated Alvogen Convertible Loan Agreement provided that:

- indebtedness other than expressly agreed or acknowledged or the issuance of certain stocks by the borrower or any subsidiary is not permitted;
- the creation of lien and securities by the borrower or any of its subsidiaries is restricted;
- · certain payments and redemptions by the borrower or any of its subsidiaries other than those expressly agreed are prohibited; and
- certain obligations and restrictions relating to real estate assets located at the head office in Iceland are applicable.

On October 21, 2020, Alvotech and Alvogen entered into an amended and consolidated loan agreement with respect to the remainder of the Consolidated Alvogen Convertible Loan Agreement (the "Amended Alvogen Convertible Loan Agreement"), bearing interest at a rate of 15% per annum and with a maturity date set to December 31, 2022. The principal amount outstanding under the Amended Alvogen Convertible Loan Agreement amounted to \$21.5 million on June 30, 2021. Alvogen had the right to convert this outstanding principal amount into Alvotech Holdings Class A Ordinary Shares under the conditions set forth in an amended and restated conversion agreement of October 21, 2020 between Alvotech, Aztiq and Alvogen (the "Alvogen Conversion Agreement").

The Amended Alvogen Convertible Loan Agreement provides that:

 indebtedness other than expressly agreed or acknowledged or the issuance of certain stocks by the borrower or any subsidiary is not permitted;

- the creation of lien and securities by the borrower or any of its subsidiaries is restricted;
- certain payments and redemptions by the borrower or any of its subsidiaries other than those expressly agreed are prohibited; and
- certain obligations and restrictions relating to real estate assets located at the head office in Iceland are applicable.

On December 7, 2021, Alvogen called the remaining Alvogen Transfer Debt in the amount of \$25 million thus increasing the principal amount under the Amended Alvogen Convertible Loan Agreement.

# Alvogen Bridge Financing

On June 30, 2020, Alvotech, as borrower, entered into a bridge loan financing agreement with Alvogen, as lender, for a principal amount of \$30.0 million (the "Alvogen Bridge Financing Agreement"), bearing interest at a rate of 15% per annum and with a maturity date that falls 91 days after December 14, 2023. Of such loan, Alvogen transferred a portion of the principal for an amount of \$5.625 million under the Alvogen Bridge Financing Agreement to Aztiq. The outstanding amounts due under the Alvogen Bridge Financing Agreement being (i) the Aztiq portion for an aggregate amount of \$5.625 million and (ii) Alvogen portion for an aggregate amount of \$24.375 million were used to offset Aztiq's and Alvogen's respective subscription price for the subscription of new Alvotech Holdings Class A Ordinary Shares issued by Alvotech in the context of the 2020 Alvotech private placement.

The Alvogen Bridge Financing Agreement provided that:

- indebtedness other than expressly agreed or acknowledged or the issuance of certain stocks by the borrower or any subsidiary is not permitted;
- the creation of lien and securities by the borrower or any of its subsidiaries is restricted;
- certain payments and redemptions by the borrower or any of its subsidiaries other than those expressly agreed are prohibited; and
- certain obligations and restrictions relating to real estate assets located at the head office in Iceland are applicable.

# BCA Framework Agreement

On December 7, 2021, the Alvotech Holdings Shareholders entered into a BCA Framework Agreement with Alvotech Holdings, Alvotech and Floki Holdings S.à r.l. In the BCA Framework Agreement, all relevant consents under the shareholders agreement relating to Alvotech Holdings dated October 21, 2020 required for the Business Combination as well as a general cooperation covenant and certain waivers and voting undertakings in relation to the First Merger and the Second Merger were given.

Furthermore, the following transactions occurred pursuant to the BCA Framework Agreement:

- i. confirmation by Alvogen of its prior full exercise of its warrant right under the shareholders agreement relating to Alvotech Holdings dated October 21, 2020;
- ii. on December 14, 2021, Aztiq subscribed for a number of newly issued Alvotech Holdings Class A Ordinary Shares for an aggregate subscription price of \$50 million which has been set-off against (a) the principal amount of the Floki Loan in the amount of \$25 million and (b) an amount of accrued and unpaid interest due by Alvotech Holdings to Aztiq in the amount of \$25 million;
- iii. on December 14, 2021, Alvogen subscribed for a number of newly issued Alvotech Holdings Class A Ordinary Shares (a) for an aggregate subscription price of \$48.7 million which has been set-off against

the corresponding amount, consisting of accrued interest due by Alvotech Holdings to Alvogen, and (b) for an aggregate subscription price of \$46.5 million which has been paid through conversion of the outstanding principal amount of \$46.5 million under the Amended Alvogen Convertible Loan Agreement, including the Alvogen Transfer Debt, in accordance with the terms of the related conversion agreement;

- iv. on December 14, 2021, Aztiq exercised its right under the Aztiq Warrant Agreement by subscribing for Alvotech Holdings Class A Ordinary Shares, and set off the subscription price of such new Alvotech Holdings Class A Ordinary Shares against (a) the outstanding principal amount due by Alvotech Holdings to Aztiq under the Amended Aztiq Convertible Loan Agreement in the amount of \$11.7 million, and (b) the outstanding principal amount due by Alvotech Holdings to Aztiq under the 2020 Convertible Loan in the amount of \$9.4 million;
- v. on December 14, 2021, the outstanding principal amount under the 2020 Convertible Loan was converted into Alvotech Holdings Class A Ordinary Shares in accordance with the terms of the related conversion agreement in respect of all other holders thereof (except Aztiq as referred to under item (iv) above);
- vi. accrued and unpaid interest on the different loan agreements to which Alvotech Holdings was a borrower was used by the creditors thereof to pay for newly issued Alvotech Holdings Class A Shares of Alvotech at the valuation at which the PIPE Investors invest into Alvotech;
- vii. a compensatory share issue was agreed for holders of convertible bonds issued by Alvotech Holdings who/which had converted convertible bonds issued by Alvotech Holdings in June 2021 at a higher valuation than the valuation at which the PIPE Investors invest into Alvotech; and
- viii. the terms and conditions applicable to the Seller Earn Out Shares were agreed, i.e. (a) the holders of the Seller Earn Out Shares are entitled to the same voting and dividend rights generally granted to holders of Ordinary Shares and (b) vesting conditions and buyback provisions were set out.

Following the consummation of the aforementioned share capital increases of Alvotech Holdings in pursuance of the BCA Framework Agreement, all loan agreements referred to above, including any amendment or ancillary agreements thereto (including those not expressly mentioned), are terminated.

## Alvogen-Aztiq Loan Advances

In connection with an undertaking by shareholders of Alvotech Holdings to ensure that Alvotech was sufficiently funded through the closing of the Business Combination by providing at least \$50.0 million (but not to exceed \$100.0 million) for the operations of Alvotech, Alvotech entered into interest free loan advances with Alvogen and Aztiq (the "Alvogen-Aztiq Loan Advances"). The interest free loan advances provided for a facility of up to \$15.0 million from Alvogen, with the potential for up to \$10.0 million more in advances, and \$25.0 million from Aztiq, for a total of up to \$50.0 million. Repayment by Alvotech was due within 30 days of the Second Merger Effective Time.

On February 22, 2022, Alvotech, as borrower, withdrew \$15.0 million under the facility from Alvogen, as lender. On March 29, 2022, Alvotech withdrew an additional amount of \$10.0 million under the facility, bringing the total to \$25.0 million.

On March 11, 2022, Alvotech, as borrower, withdrew \$15.0 million under the facility from Aztiq, as lender. On March 31, 2022, Alvotech withdrew an additional amount of \$10.0 million under the facility, bringing the total to \$25.0 million.

On July 12, 2022, Alvotech, Aztiq and Alvogen agreed to settle the outstanding amounts under the Alvogen-Aztiq Loan Advances in Ordinary Shares rather than cash. Each of Aztiq and Alvogen entered into a

subscription and set-off agreement with Alvotech pursuant to which Alvogen and Aztiq subscribed to 2,500,000 Ordinary Shares each, for a subscription price of \$10.00 per share. The aggregate subscription price, \$25.0 million for each of Alvogen and Aztiq, was set off against the outstanding amounts under the Alvogen-Aztiq Loan Advances of \$25.0 million, for each of Alvogen and Aztiq. The subscription agreements provide customary registration rights for Alvogen and Aztiq.

# Alvogen Bridge Loans

On April 11, 2022, Alvotech, as borrower, entered into a loan agreement with Alvogen, as lender, for a loan of up to \$40.0 million bearing an interest rate of 10% per annum. The loan was drawable in two separate installments of \$20.0 million each. Each drawdown was subject to Alvogen approval. Repayment by Alvotech was due within 30 days of the Second Merger Effective Time. On April 12, 2022, Alvotech withdrew the first installment of \$20.0 million. On May 9, 2022, Alvotech withdrew the second installment of \$20.0 million.

On June 1, 2022, Alvotech, as borrower, entered into a second bridge loan agreement with Alvogen, as lender, for a loan of \$20.0 million bearing an interest rate of 10% per annum. Alvotech withdrew the entire loan amount of \$20.0 million on June 1, 2022.

The Alvogen Bridge Loans described in this section were rolled over into the Alvogen Facility, as described below.

# The Alvogen Facility

On November 16, 2022, Alvotech, as borrower, entered into a subordinated loan agreement with Alvogen, as lender, for a loan in an aggregate principal amount equal to \$113.3 million (the "Alvogen Facility"). The Alvogen Facility comprises (i) a cash facility for drawn by Alvotech in an aggregate principal amount of \$50 million, and (ii) a cashless rollover facility of the Alvogen Bridge Loans in an aggregate principal amount equal to \$63.3 million (as described above). The Alvogen Facility bears an interest rate of 17.5% per annum. The interest rate could be reduced to 15% per annum if Alvotech raised \$150.0 million in net proceeds from the issuance of new equity and received FDA approval for AVT02 by March 31, 2023. Interest is payable on June 30 and December 31 of each year and, on the interest payment date, shall be capitalized and added to the outstanding principal amount of the loan then outstanding and will accrue interest at the rate then applicable. Alvotech can draw on the cash facility in one or more installments but no amount repaid or prepaid may subsequently be re-borrowed.

The Alvogen Facility is subordinated to the Senior Bonds (described above in the section "Amendment to the Senior Bonds") and pari passu with the Aztiq Convertible Bond (as defined and described below). Subject to limitations resulting from the subordination, Alvotech may repay the Alvogen Facility, in whole or in part, at any time during the term of the loan. The outstanding amounts of the Alvogen Facility will become due and payable if the senior bonds have been repaid in full. The principal amount of the loan together with the accrued interest will be repaid by Alvotech on December 24, 2025, at the latest.

Under the terms of the Alvogen Facility, without the prior approval of Alvogen, Alvotech shall not be permitted to enter into any separate agreements that allow any outstanding indebtedness that (i) is secured on a basis junior to the Senior Bonds, (ii) is subordinated to the Senior Bonds, but senior to Alvotech Facility, (iii) is subordinated in the right of payment to the Alvotech Bonds and senior in right of payment to Alvotech Facility, or (iv) is pari passu with or senior to the Alvotech Facility.

Alvotech and Alvogen further agreed that the existing Alvogen Bridge Loans, dated April 11, 2022 and June 1, 2022, for an aggregate outstanding amount of \$63.3 million, are rolled over and are now subject to the terms of the Alvogen Facility. The rolled-over amount of the Alvogen bridge loans do not apply towards the \$50.0 million of the Alvogen Facility.

In connection with the Alvogen Facility, Alvotech and Alvogen also entered into the Alvogen Warrant Agreement on November 16, 2022, as described below.

On December 20, 2022, Alvotech used \$50.0 million of the proceeds from the December 2022 Convertible Bonds upsize to repay the upsize of the Alvogen Facility. As of December 31, 2022, the outstanding principal balance on the Alvogen Facility was \$64.6 million.

# The Alvogen Warrant Agreement

On November 16, 2022, in connection with the Alvogen Facility described above, Alvotech entered into a warrant agreement (the "Alvogen Warrant Agreement") with Alvogen, pursuant to which Alvogen will subscribe for warrants (the "Warrants"), allocated for no consideration. The Warrants would have been issued on the earlier of (i) December 15, 2022, if a Successful New Capital Increase (as defined in the Alvogen Warrant Agreement) had not occurred on or before that date, or (ii) December 20, 2022 if any amount remained outstanding pursuant to the Alvogen Facility on that date. Each Warrant would have entitled Alvogen, upon exercise, to receive from Alvotech one fully paid and non-assessable ordinary share of Alvotech, at the exercise price of one cent (\$0.01) per share, subject to certain adjustments stipulated in the Alvogen Warrant Agreement.

On December 16, 2022, Alvotech completed the private placement of \$59.1 million of subordinated convertible bonds. Those bonds qualified as a Successful New Capital Increase (as defined in the Alvogen Warrant Agreement) and Alvotech used the majority of the net proceeds to replace the Alvogen Facility. As a result, Alvotech did not issue any warrants to Alvogen under the Alvogen Warrant Agreement.

## **Aztiq Facility Contribution**

## Share Purchase Agreement

On November 16, 2022, Alvotech, as buyer, entered into a share purchase agreement (the "Share Purchase Agreement") relating to shares in Fasteignafélagið Sæmundur hf. ("Saemundur") with ATP Holdings ehf., an affiliate of Aztiq, as seller (the "Aztiq Facility Contribution"). Pursuant to the Share Purchase Agreement, Alvotech is purchasing 99.99% of the shares in Saemundur for a purchase price of \$115.0 million by issuing the Aztiq Convertible Bond, as defined and discussed below, and assuming the loans associated with the facility. Concurrently with the Share Purchase Agreement, Alvotech hf. entered into a share transfer agreement with Aztiq Pharma ehf. for the purchase of the one remaining share in Saemundur from Aztiq Pharma ehf. for an amount of ISK 10. At the time of closing, Saemundur's only asset was the property where Alvotech's Reykjavik manufacturing and research facility (the "Facility") are located.

As a condition precedent to the transaction, Saemundur entered into a loan facility with Landsbankinn hf., an Icelandic bank, secured with a first priority mortgage over the Facility (the "Saemundargata Loan"). The proceeds of the Saemundargata Loan are to be used to refinance Saemundur's previous indebtedness, release the previous mortgage, and to provide \$17.2 million in additional cash for the Alvotech group. In addition, on November 16, 2022, and as a condition precedent to the Share Purchase Agreement, Saemundur entered into a service agreement with Floki Invest ehf. ("Floki") (the "Saemundur Service Agreement") pursuant to which Floki will provide certain administrative and financial services to Saemundur for a service fee of ISK 4,500,000 per month. The Saemundur Service Agreement was entered into for an initial term expiring December 31, 2023, which will automatically extend for successive 12-month periods unless the agreement is terminated by either party with three months' prior notice.

Following the Aztiq Facility Contribution, on December 30, 2022, Alvotech, as seller, entered into a share purchase agreement relating to shares in Saemundur with its subsidiary Alvotech hf., as buyer, to sell all but one of its shares in Saemundur to Alvotech hf. on substantially the same terms as the Share Purchase Agreement. Following this agreement, Alvotech hf. holds 99.99% of the shares in Saemundur and Alvotech now owns one share in Saemundur.

## Aztiq Convertible Bond

On November 16, 2022, Alvotech entered into a subscription agreement and a convertible bond instrument with ATP Holdings ehf., an affiliate of Aztiq. Pursuant to the subscription agreement, Alvotech agreed to issue, and ATP Holdings ehf. agreed to subscribe for, convertible bonds in an aggregate principal amount equal to \$80.0 million (which can be increased to \$105.0 million (excluding any amount resulting from capitalization of PIK interest accrued) pursuant to the terms thereof) (the "Aztiq Convertible Bond"). The Aztiq Convertible Bond was entered into and issued on cashless basis as consideration for the Aztiq Facility Contribution, described above, and carries an interest of 12.5% per annum. Coupons are payable in six-monthly intervals and each coupon that is accrued shall be capitalized and added to the outstanding principal amount of the bonds then outstanding, will be treated as part of the principal amount of the bonds and will accrue interest. Each bond will cease to accrue interest when such bond is redeemed or repaid.

Bondholders have the right to convert their bonds into ordinary shares of Alvotech credited as fully paid on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date; provided that each exercise of the conversion right must be with respect to a principal amount of at least \$5.0 million, or if such exercise is with respect to all of the Bonds held by the relevant Bondholder and the principal amount of such Bonds is less than \$5.0 million, such lesser amount. The conversion price is \$10.00 per share, subject to certain adjustments stipulated in the convertible bond instrument.

The Aztiq Convertible Bond will be subordinated to the Senior Bonds (described above in the section "Amendment to the Senior Bonds") and payment obligations of Alvotech under the Aztiq Convertible Bond rank at least equally with all of Alvotech's other present and future direct, unsubordinated, unconditional and unsecured obligations (except for the Senior Bonds).

The Aztiq Convertible Bond matures on the later of the (i) 16 November 2025, or (ii) 91 days after the earlier of the full redemption or the final maturity date of the Senior Bonds.

# Lease Agreements

Leases of operational facilities

Alvotech entered into a lease agreement, as lessee, with Sæmundur, as lessor, on November 15, 2016 for a building where Alvotech's Reykjavik, Iceland, headquarters and the manufacturing facility are located (the "Sæmundur Lease Agreement"), the address being: Saemundargata 15-19, 102 Reykjavik, Iceland. Sæmundur is an affiliate of Aztiq. The Sæmundur Lease Agreement terminates on September 30, 2038, unless extended. The rental payments under the Sæmundur Lease Agreement amount to approximately \$7.7 million per annum. Following the transactions described above under "—Aztiq Facility Contribution", Alvotech owns the facility in Reykjavik.

Alvotech entered into a lease agreement, as lessee, with Fasteignafélagið Eyjólfur ehf. ("Eyjólfur"), as lessor, on October 22, 2021 for an extension to the main operational building at Saemundargata 15-19, 102 Reykjavik, Iceland for manufacturing, research, parking space and underground parking garage, located in Reykjavik, Iceland (the "Eyjólfur Lease Agreement"). Eyjólfur is an affiliate of Aztiq. The start of the building project was on December 30, 2020 and the site is expected to be operational in early 2024. The payments under this agreement are expected to commence on January 1, 2023. The Eyjólfur Lease Agreement terminates on September 30, 2038. The rental payments under the Eyjólfur Lease Agreement will amount to approximately \$4.1 million per annum, subject to certain cost adjustments and minimums.

Alvotech entered into a lease agreement, as lessee, with Lambhagavegur ehf. ("Lambhagavegur"), as lessor, on April 1, 2021 for a building located in Reykjavik, Iceland (the "Lambhagavegur Lease Agreement"). This site was taken into use as a warehouse facility and office space in November 2021. Lambhagavegur is an affiliate of Aztiq. The Lambhagavegur Lease Agreement terminates on September 30, 2030, unless extended. The rental payments under the Lambhagavegur Lease Agreement amount to approximately \$1.0 million per annum in 2021, subject to certain cost adjustments and minimums.

## Other Leases

Alvotech, as lessee, has entered into multiple lease agreements with HRJÁF ehf. ("HRJÁF"), as lessor, for numerous apartments in Reykjavík, Iceland, each dated as of December 15, 2015, August 27, 2019 (as amended on October 6, 2020), November 1, 2019 (as amended on October 6, 2020), January 1, 2020, August 10, 2020, June 25, 2021 and July 16, 2021, respectively (collectively, the "HRJÁF Lease Agreements"). HRJÁF is an affiliate of Aztiq. The HRJÁF Lease Agreements generally have a duration of 10 years, subject to certain early termination provisions. The total aggregate rental payments under the HRJÁF Lease Agreements amount to approximately \$1.4 million per annum in 2021. These apartments are leased in order to facilitate Alvotech's efforts to attract top international talent to its Reykjavík facility to be able to provide the team members with apartments for temporary use.

## Shareholder's Agreement

Alvotech and its then-existing shareholders entered into an amended and restated shareholders' agreement on October 21, 2020 (the "Alvotech SHA"). While the shareholders' agreement will terminate upon the consummation of this Business Combination, certain provisions of this agreement, including Alvotech's obligation to enter into a registration rights agreement with certain existing shareholders, will survive. Under the Alvotech SHA, Alvogen and Aztiq had certain warrant rights to subscribe for additional shares. Alvogen and Aztiq have exercised such rights on December 7, 2021, which terminated the right to exercise the warrants under the Alvotech SHA. The Alvotech SHA was terminated with effect as of June 15, 2022.

## Agreements with our Executive Officers and Directors

Phantom Share Settlement Agreement with Mr. McClellan

In connection with the settlement of Alvotech's pre-Business Combination Management Share Appreciation Rights Agreements, Alvotech entered into a settlement agreement with Mr. Joseph McClellan on June 15, 2022. Pursuant to that settlement agreement, Alvotech agreed to settle Mr. McClellan's outstanding claim under the Management Share Appreciation Rights Agreements for \$1.5 million in either shares or cash, at the option of Mr. McClellan, payable on June 16, 2023.

## Investor Rights and Lock-Up Agreement

In connection with the consummation of the Business Combination, Alvotech entered into an investor rights and lock-up agreement (the "IRA") with Oaktree Acquisition Holdings II, L.P., (the "Sponsor"), Aztiq, Alvogen and Mr. Richard Davies. Pursuant to the IRA, Ordinary Shares held by Sponsor, Aztiq, Alvogen and Mr. Davies may not be transferred (subject to certain exceptions) until: (i) with respect to Ordinary Shares held by the Sponsor after the Closing, 365 days after the Closing, subject to earlier release if Ordinary Shares trade at or above a volume weighted average price of \$12.00 for ten (10) trading days during any twenty (20) trading day period commencing at least 180 days following the Closing; (ii) with respect to Ordinary Shares held by Robert Wessman, the founder of Alvotech and Alvotech's chairman of the board of directors (the "Chairman Shares"), (x) 180 days following the Closing, with respect to one-third of the Chairman Shares (with earlier release if Ordinary Shares trade at or above a volume weighted average price of \$12.00 for ten (10) trading days during any twenty (20) trading day period commencing at least 180 days following the Closing), and (z) 545 days following the Closing, with respect to the remaining one-third of the Chairman Shares; and (iii) with respect to the Ordinary Shares held by Alvogen and Aztiq, 180 days after the Closing.

Additionally, pursuant to the IRA, the Warrants held by the Sponsor may not be transferred for a period of 30 days following the Closing. The transfer restrictions do not apply to shares acquired in the PIPE Financing or any other equity financing of Alvotech that have occurred prior to the Closing. The IRA also provides that Alvotech will file a registration statement to register the resale of Ordinary Shares held by the parties to the IRA within 30 days after the Closing.

The IRA also provides the parties with certain "demand" and "piggy-back" registration rights, subject to customary requirements and conditions.

# **Indemnification Agreements**

Our governing documents provide that we will indemnify our directors and officers to the fullest extent permitted by Luxembourg law.

In connection with the Business Combination, Alvotech entered into indemnification agreements with each of its directors and executive officers. These agreements provide that Alvotech will indemnify each of its directors and such officers to the fullest extent permitted by law and its articles of association.

# Sponsor Letter Agreement

On December 7, 2021, concurrent with the execution of the Business Combination Agreement, the Sponsor, OACB and TopCo entered into the Sponsor Letter Agreement. Pursuant to the Sponsor Letter Agreement, the Sponsor: (i) agreed to vote its OACB Ordinary Shares in favor of the Business Combination Agreement, the Business Combination, and any other matter reasonably necessary to consummate the transactions contemplated by the Business Combination Agreement, (ii) agreed not to transfer or pledge any of its OACB Ordinary Shares after the execution of the Business Combination Agreement and prior to the closing of the Business Combination, (iii) waived its rights of appraisal, any dissenters' rights and any similar rights relating to the transactions contemplated by the Business Combination Agreement that it may have by virtue of, or with respect to, any outstanding OACB ordinary shares owned thereby, and (iv) agreed to subject 1,250,000 of its OACB Ordinary Shares held as of immediately prior to the First Merger Effective Time, which will have been exchanged for TopCo Ordinary Shares, to certain transfer restrictions, vesting and buyback conditions

#### MAJOR SHAREHOLDERS

The following table sets forth information regarding the beneficial ownership of Ordinary Shares as of February 15, 2023 by:

- each person known by us to be the beneficial owner of more than 5% of Ordinary Shares;
- · each of our directors and executive officers; and
- all our directors and executive officers as a group.

Except as otherwise noted herein, the number and percentage of Ordinary Shares beneficially owned is determined in accordance with Rule 13d-3 of the Exchange Act, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rule, beneficial ownership includes any Ordinary Shares as to which the holder has sole or shared voting power or investment power and also any Ordinary Shares which the holder has the right to acquire within 60 days of February 15, 2023 through the exercise of any option, warrant or any other right.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

We have based percentage ownership on 262,500,781 Ordinary Shares outstanding as of February 15, 2023.

Name and Address of Beneficial Owners	Number of Shares	%
Directors and Executive Officers <sup>(1)</sup>		
Robert Wessman	_	_
Richard Davies <sup>(2)</sup>	1,133,131	*
Tomas Ekman	_	_
Ann Merchant	_	_
Arni Hardarson	_	
Lisa Graver	_	_
Linda McGoldrick	_	_
Tanya Zharov	_	_
Joseph E. McClellan	_	_
Joel Morales	_	_
Hafrun Fridriksdottir	_	_
All Directors and Executive Officers as a group (11 persons)	1,133,131	*
Five Percent Holders Post-Business Combination		
Alvogen Lux Holdings S.à r.l. <sup>(3)</sup>	91,014,964	34.67%
Aztiq Pharma Partners S.à r.l. <sup>(4)</sup>	101,165,374	38.54%
Entities affiliated with Oaktree Acquisition Holdings II, L.P. (5)	14,868,912	5.66%

<sup>\*</sup> Indicates beneficial ownership of less than 1% of the total ordinary shares outstanding.

<sup>(1)</sup> Unless otherwise noted, the business address of each of the directors and executive officers is 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg.

<sup>(2)</sup> Represents 1,133,131 Ordinary Shares held by Mr. Davies, including 195,761 Earn Out Shares.

<sup>(3)</sup> Represents shares held by Alvogen Lux Holdings S.a.r.l. ("Alvogen"). Through intermediary holding entities, Alvogen is a wholly-owned subsidiary of Celtic Holdings SCA ("Celtic Holdings"). Investment and voting decisions with respect to the shares held by Alvogen are made by the directors of Celtic Holdings

- Carmen Andre, Tomas Ekman, Arni Hardarson, Park Jung Ryun, Christoffer Sjøqvist and Robert Wessman are the directors of Celtic Holdings and may be deemed to have shared voting and dispositive power with respect to the shares held by Alvogen. Carmen Andre, Tomas Ekman, Arni Hardarson, Park Jung Ryun, Christoffer Sjøqvist and Robert Wessman each disclaim any beneficial ownership of any such shares, except to the extent of their pecuniary interest therein, if any. The address of Alvogen is 5, rue Heienhaff, L-1736 Senningerberg, Luxembourg, Grand-Duchy of Luxembourg and the address of Celtic Holdings is 20, avenue Monterey, L-2163 Luxembourg, Grand-Duchy of Luxembourg.
- (4) Represents shares held by Aztiq Pharma Partners S.a.r.l. ("APP"). APP is a wholly-owned subsidiary of Aztiq Fund I SCSp ("Aztiq Fund"). Investment and voting decisions at Aztiq Fund are made by its general partner, Floki GP S.à r.l. ("Aztiq GP"). Investment and voting decisions with respect to the shares held by APP are made by the members of the board of managers of Aztiq GP. Arni Hardarson, Johann Johannsson, Danny Major, Marc Levebvre and Robert Wessman are members of the board of managers of Aztiq GP and may be deemed to have shared voting and dispositive power with respect to the shares held by APP in Alvotech. Arni Hardarson, Johann Johannsson, Danny Major, Marc Levebvre and Robert Wessman each disclaim any beneficial ownership of any such shares, except to the extent of their pecuniary interest therein, if any. The address of APP is 5, rue Heienhaff, L-1736 Senningerberg, Grand-Duchy of Luxembourg and the address of Aztiq Fund and Aztiq GP is at 4 rue Robert Stumper, L-2557 Luxembourg, Grand-Duchy of Luxembourg.
- The information shown is based upon disclosures on a Schedule 13G filed with the SEC on February 14, 2023 by Oaktree Acquisition Holdings II, L.P. ("Acquisition Holdings"), Oaktree Acquisition Holdings II GP, Ltd. ("Acquisition Holdings GP"), Oaktree Capital Management, L.P. ("Capital Management"), Oaktree Capital Management GP, LLC ("Capital Management GP"), Oaktree Specialty Lending Corporation ("Specialty Lending"), Oaktree Fund Advisors, LLC ("Fund Advisors"), Oaktree Capital II, L.P. ("Capital II"), Oaktree Capital II GP LLC ("Capital II GP"), Atlas OCM Holdings, LLC ("Atlas"), Oaktree Capital Group Holdings GP, LLC ("OCGH LLC"), and Brookfield Asset Management, ULC ("Brookfield"). Acquisition Holdings directly holds 6,250,000 ordinary shares, inclusive of shares subject to certain restrictions and earnout terms and 4,666,667 Warrants. As the general partner of Acquisition Holdings, Acquisition Holdings GP may be deemed to beneficially own such ordinary shares and warrants. Specialty Lending directly hold 1,272,083 ordinary shares, inclusive of shares subject to certain earnout terms. Certain separately managed accounts managed by Capital Management ("SMAs") directly hold 2,680,162 ordinary shares, inclusive of shares subject to certain earnout, and Capital Management as the director of Acquisition Holdings GP may also be deemed to beneficially own the 6,250,000 ordinary shares and 4,666,667 Warrants held by Acquisition Holdings. As the general partner of Capital Management, Capital Management GP may be deemed to beneficially own the ordinary shares directly held by the SMAs and by Acquisition Holdings. Fund Advisors is the investment advisor to Specialty Lending and may be deemed to beneficially own the 1,272,083 ordinary shares directly held by Specialty Lending. Capital II, as the managing member of Fund Advisors, and Capital II GP, as the general partner of Capital II, may also be deemed to own such securities. Atlas is the sole managing member of Capital Management GP and the managing member of Capital II GP and may be deemed to beneficially own the 10,202,245 ordinary shares and 4,666,667 Warrants directly held by Acquisition Holdings, Specialty Lending, and the SMAs. Brookfield and OCGH LLC each, in its capacity as the indirect owner of Atlas has the ability to appoint and remove certain directors of Atlas and, as such, may indirectly control the decisions of Atlas regarding the vote and disposition of securities directly or indirectly held by Atlas. As such each of Brookfield and OCGH LLC may beneficially own the 10,202,245 ordinary shares and 4,666,667 Warrants beneficially owned by Atlas. The principal business office of each of Acquisition Holdings, Acquisition Holdings GP, Capital Management, Capital Management GP, Specialty Lending, Fund Advisors, Capital II, Capital II GP, Atlas, and OCGH LLC is 333 South Grand Avenue, 28th Floor, Los Angeles, CA 90071. The principal business office of Brookfield is Brookfield Place, Suite 100, 181 Bay Street, PO Box 762, Toronto, Ontario, Canada M5J 2T3.

## SELLING SECURITYHOLDERS

This prospectus relates to the resale by the Selling Securityholders from time to time of up to (i) 17,493,000 Ordinary Shares subscribed for by the Selling Securityholders, for a subscription price of \$10.00 per share, in the context of the PIPE Financing (as defined below), (ii) 6,250,000 Ordinary Shares issued to the Sponsor in exchange for the Founder Shares, 1,250,000 of which are subject to vesting or forfeiture, (iii) 4,666,667 Ordinary Shares issuable upon exercise of Private Placement Warrants, (iv) 186,206,553 Ordinary Shares issued to former shareholders of Alvotech Holdings in exchange for their Alvotech Holdings Ordinary Shares in connection with the Business Combination (subject to vesting and lockups), and (v) 4,666,667 Private Placement Warrants. When we refer to the "Selling Securityholders" in this prospectus, we mean the persons listed in the table below, and the pledgees, donees, transferees, assignees, successors, designees and others who later come to hold any of the Selling Securityholders' interest in the Ordinary Shares other than through a public sale.

The following table sets forth, as of the date of this prospectus, the names of the Selling Securityholders the aggregate number of Ordinary Shares beneficially owned by the Selling Securityholders, and the aggregate number of Ordinary Shares that the Selling Securityholders may offer pursuant to this prospectus. We have based percentage ownership on 243,649,505 Ordinary Shares outstanding as of June 15, 2022.

We have determined beneficial ownership in accordance with the rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Unless otherwise indicated below, to our knowledge, the persons and entities named in the tables have sole voting and sole investment power with respect to all securities that they beneficially own, subject to community property laws where applicable.

We cannot advise you as to whether the Selling Securityholders will in fact sell any or all of such Ordinary Shares. As such, we are unable to declare the number of Ordinary Shares that the Selling Securityholders will retain after any such sale. In addition, the Selling Securityholders may sell, transfer or otherwise dispose of, at any time and from time to time, the Ordinary Shares in transactions exempt from the registration requirements of the Securities Act after the date of this prospectus.

Selling Securityholder information for each new Selling Securityholder, if any, will be set forth by a prospectus supplement to the extent required prior to the time of any offer or sale of such Selling Securityholder's shares pursuant to this prospectus. Any prospectus supplement may add, update, substitute or change the information contained in this prospectus, including the identity of each Selling Securityholder and the number of Ordinary Shares registered on its behalf. A Selling Securityholder may sell or otherwise transfer all, some or none of such shares in this offering. See "Plan of Distribution."

					Warrants (1)			
	Ordinary Shares			to Purchase Ordinary Shares				
Name	Number Beneficially Owned Prior to Offering	Number Registered for Sale Hereby	Number Beneficially Owned After Offering	Percent Owned After Offering	Number Beneficially Owned Prior to Offering	Number Registered For Sale Hereby	Number Beneficially Owner After Offering	Percent Owner After Offering
Santo Holding (Deutschland) (2)	4,764,736	3,000,000	1,764,736	*				
Celtic Holdings II Limited (3)	1,636,236	1,636,236	_	_	_	_	_	_
Celtic Holdings III Limited (4)	910,871	910,871	_	_	_	_	_	_
YAS Holding LLC (5)	3,745,337	1,000,000	2,745,337	1.13%	_		_	_
Birchtree Fund Investments Private Limited (6)	1,000,000	1,000,000	_	_	_	_	_	_
Celtic Vatera Investments S.à r.l. (7)	345,893	345,893	_		_		_	_
Arctica Finance hf. (8)	2,700,000	2,700,000	_	_	_	_	_	_
Arion Bank hf. (9)	3,563,662	2,700,000	863,662		_		_	_
Landsbankinn hf. (10)	2,700,000	2,700,000	_	_	_	_	_	_
Averill Master Fund, Ltd. (11)	1,000,000	1,000,000	_	_	_	_	_	_
Nidema Funding, LLC (12)	500,000	500,000	_	_	_	_	_	_
Richard Davies (13)	1,118,131	1,118,131	_	_	_	_	_	_
Oaktree Acquisition Holdings II, L.P. (14)	10,916,667	10,916,667	_	_	4,666,667	4,666,667	_	_
Alvogen Lux Holdings S.à r.l. (15)	88,940,619	88,940,619	_	_	_	_	_	_
Aztiq Pharma Partners S.à r.l. (16)	101,147,803	101,147,803	_	_	_	_	_	_

Less than one percent of outstanding Ordinary Shares.

<sup>(1)</sup> Represents the Private Placement Warrants.

<sup>(2)</sup> Consists of (i) 3,000,000 Ordinary Shares subscribed to in connection with the PIPE Financing and (ii) 1,764,736 Ordinary Shares issued in exchange for Alvotech Holdings Ordinary Shares in connection with the Business Combination held by Santo Holding (Deutschland) GmbH. The common shares of Santo Holding (Deutschland) GmbH, are directly held by Santo Holding AG, Switzerland (89.60%) and ATHOS KG, Germany (10.40%). ATHOS KG holds indirectly via ATHOS Beteiligung GmbH, Germany 100% of the common shares of Santo Holding AG. Consequently ATHOS KG has directly/indirectly 100% ownership in Santo Holding (Deutschland) GmbH. Thomas Peter Maier is Managing Director of Santo Holding (Deutschland) GmbH. Thomas Peter Maier is authorized to represent the company alone. Thomas Maier is General Partner of ATHOS KG and authorized to represent ATHOS KG alone. ATHOS KG is owned by ten individual natural persons. The individuals above 10% ownership in ATHOS KG are Dr. Andreas Str ✓ ngmann, Dr. Thomas Str ✓ ngmann, Dr. Nicole Str ✓ ngmann-Butscheidt and Florian Str ✓ ngmann. Shareholder resolutions are generally passed with a simple majority of the votes cast. The mailing address for ATHOS KG and Santo Holding (Deutschland) GmbH is Bergfeldstraße 9, 83607 Holzkirchen—Germany.

<sup>(3)</sup> Consists of 1,636,236 Ordinary Shares subscribed to by Celtic Holdings II Limited ("Celtic II") in connection with the PIPE Financing. Investment and voting decisions at Celtic II are made by a majority of its board of directors, and

- therefore no individual director of Celtic II is the beneficial owner of the Ordinary Shares, except with respect to the Ordinary Shares in which such director holds a pecuniary interest. Each of Tomas Ekman, Carl Hansen and Brian Scholfield is a director of Celtic II entitled to participate in investment and voting decisions and therefore may be deemed to share voting and dispositive power with respect to the Ordinary Shares held by Celtic II. Each of Tomas Ekman, Carl Hansen and Brian Scholfield disclaim any beneficial ownership of any of such Ordinary Shares, except to the extent of his or her pecuniary interest therein. The address of Celtic II is 27 Esplanade St Helier, Isle of Jersey.
- (4) Consists of 910,871 Ordinary Shares subscribed to by Celtic Holdings III Limited ("Celtic III") in connection with the PIPE Financing. Investment and voting decisions at Celtic III are made by a majority of its board of directors, and therefore no individual director of Celtic III is the beneficial owner of the Ordinary Shares, except with respect to the Ordinary Shares in which such director holds a pecuniary interest. Each of Tomas Ekman, Carl Hansen and James Culshaw is a director of Celtic III entitled to participate in investment and voting decisions and therefore may be deemed to share voting and dispositive power with respect to the Ordinary Shares held by Celtic III. Each of Tomas Ekman, Carl Hansen and James Culshaw disclaim any beneficial ownership of any of such Ordinary Shares, except to the extent of his or her pecuniary interest therein. The address of Celtic III is 27 Esplanade St Helier, Isle of Jersey.
- (5) Consists of 3,745,447 Ordinary Shares, including (i) 1,000,000 shares subscribed to by YAS Holding LLC ("Yas Holding") in connection with the PIPE Financing, and (ii) 2,745,337 shares received in exchange for Alvotech Holdings Ordinary Shares. Mr. Sultan Al Shamsi owns 99% of all issued shares in YAS Holding and may be deemed to have voting and dispositive power with respect to the ordinary shares held by Yas Holding. Mr. Sultan Al Shamsi disclaims any beneficial ownership of any such ordinary shares, except to the extent of his pecuniary interest therein. Alvotech has formed a strategic commercial partnership with YAS Holding. In October 2019, Alvotech entered into license agreements with YAS Holding with respect to AVT02, AVT04 and AVT06, and in February 2022, Alvotech entered into a supply agreement with YAS Holding with respect to AVT02 (see "Business—Commercial Partnerships"). The address of YAS Holding is, Khalifa City A, Emirates Post Building Abu Dhabi, United Arab Emirates.
- (6) Consists of 1,000,000 Ordinary Shares subscribed to by Birchtree Fund Investments Private Limited in connection with the PIPE Financing. Birchtree Fund Investments Private Limited is a direct wholly-owned subsidiary of Fullerton Fund Investments Pte Ltd, which in turn is a direct wholly-owned subsidiary of Temasek Holdings (Private) Limited. Each of Fullerton Fund Investments Pte Ltd and Temasek Holdings (Private) Limited, through the ownership described herein, may be deemed to beneficially own the ordinary shares held directly by Birchtree Fund Investments Private Limited. The address for these entities is 60B Orchard Road, #06-18, Tower 2, The Atrium @ Orchard, Singapore 238891.
- (7) Consists of 345,893 Ordinary Shares subscribed to by Celtic Vatera Investments S.a.r.l. ("Celtic Vatera") in connection with the PIPE Financing. Investment and voting decisions at Celtic Vatera are made by a majority of its board of directors. Each of Michael Kim and Michael Allen is a director of Celtic Vatera entitled to participate in investment and voting decisions and therefore may be deemed to share voting and dispositive power with respect to the Ordinary Shares held by Celtic Vatera. Each of Messrs. Kim and Allen disclaim any beneficial ownership of any of such Ordinary Shares, except to the extent of his or her pecuniary interest therein. The address of Celtic Vatera is 15, rue Edward Steichen, Luxembourg.
- (8) Consists of 2,700,000 Ordinary Shares subscribed to by Arctica Finance hf. in connection with the PIPE Financing. Arctica Eignarhaldsfélag ehf. owns 50.0% of all issued shares in Arctica Finance hf., which represents 100% of all voting power in Arctica Finance hf. Mr. Bjarni Þórður Bjarnason owns 50.25% of all issued shares in Arctica Eignarhaldsfélag ehf. and Mr. Stefán Þór Bjarnason owns 33.50% of all issued shares in Arctica Eignarhaldsfélag ehf. The address of Arctica Finance hf. is Katrinartuni 2, 105 Reykjavik, Iceland. Mr. Bjarni Þórður Bjarnason and Mr. Stefán Þór Bjarnason each disclaim any beneficial ownership of the Ordinary Shares.
- (9) Consists of 3,563,662 Ordinary Shares, including 2,700,000 subscribed to by Arion Bank hf. in connection with the PIPE Financing. Investment decisions at Arion Bank hf. are made by the Arion Bank's Asset and Liability Committee (ALCO), and thus ALCO may be considered to be a control person of Arion Bank hf. with respect to the ordinary shares. The address of Arion Bank hf. is Borgartún 19, 105 Reykjavík. Arion Bank hf. is a lender of Alvotech (see "Management's discussion and analysis of financial condition and results of operations—Material Cash Requirements for Known Contractual Obligations and Commitments—Other borrowings").
- (10) Consists of 2,700,000 Ordinary Shares subscribed to by Landsbankinn hf. in connection with the PIPE Financing. The Iceland State Treasury owns 98% of Landsbankinn hf. The address of Landsbankinn hf. is Austurstræti 11, 155 Reykjavĺk. Landsbankinn hf. is a lender of Alvotech (see "Management's discussion and analysis of financial condition and results of operations—Material Cash Requirements for Known Contractual Obligations and Commitments—Alvotech Facility Loans and —Other borrowings"), acted as Alvotech's certified advisor for the listing of Ordinary Shares on Nasdaq First North and Nasdaq Iceland Main Market, and acts as a market maker for Ordinary Shares on Nasdaq Iceland Main Market.

- (11) Consists of 1,000,000 Ordinary Shares subscribed to by Averill Master Fund, Ltd. in connection with the PIPE Financing. Suvretta Capital Management, LLC is the investment manager of Averill Master Fund, Ltd. Aaron Cowen is the control person of Suvretta Capital Management, LLC. The address of Averill Master Fund, Ltd. is 540 Madison Avenue, seventh floor, New York, New York 10022.
- (12) Consists of 500,000 Ordinary Shares subscribed to by Nidema Funding, LLC ("Nidema") in connection with the PIPE Financing. Farallon Capital Management, L.L.C. ("FCM"), as the manager of Nidema, may be deemed to beneficially own such ordinary shares held by Nidema. Each of Philip D. Dreyfuss, Michael B. Fisch, Richard B. Fried, Varun N. Gehani, Nicolas Giauque, David T. Kim, Michael G. Linn, Rajiv A. Patel, Thomas G. Roberts, Jr., William Seybold, Andrew J.M. Spokes, John R. Warren and Mark D. Wehrly (the "Managing Members"), as a senior managing member or managing member, as the case may be, of FCM, in each case with the power to exercise investment discretion, may be deemed to beneficially own such ordinary shares held by Nidema. Each of FCM and the Managing Members disclaims beneficial ownership of any such ordinary shares. The address of Nidema Funding, LLC is c/o Farallon Capital Management, L.L.C., One Maritime Plaza, Suite 2100, San Francisco, California 94111.
- (13) Consists of 1,118,131 Ordinary Shares held by Mr. Richard Davies. The business address of Mr. Davies is 9, Rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg. Mr. Davies serves as the director and the Deputy Chairman of Alvotech. On June 15, 2022, Mr. Davies entered into an investor rights and lock-up agreement, see "Certain Relationships and Related Party Transactions—Investor Rights and Lock-Up Agreement."
- Oaktree Acquisition Holdings II, L.P. ("Sponsor") is the record holder of the 6,250,000 Ordinary Shares, 1,250,000 of which are subject to vesting or forfeiture, and 4,666,667 Warrants reported herein. The Warrants became exercisable as of July 15, 2022. The general partner of Sponsor is Oaktree Acquisition Holdings II GP Ltd. ("Holdings GP"). The director of Holdings GP is Oaktree Capital Management, L.P. ("Oaktree"). The director of Oaktree is Oaktree Capital Management GP, LLC ("Management GP"). The sole managing member of Management GP is Atlas OCM Holdings, LLC ("Atlas"). Oaktree Capital Group Holdings GP, LLC ("OCGH GP") is the general partner of the owner of the class B units of Atlas. Brookfield Asset Management, Inc. ("BAM") is the indirect owner of the class A units of Atlas. BAM Trust Partners ("Partners") is the sole owner of Class B Limited Voting Shares of BAM. Each of Sponsor, Holdings GP, Oaktree, Management GP, Atlas, BAM, and Partners, disclaims beneficial ownership of the Ordinary Shares and Warrants reported herein except to the extent of their respective pecuniary interest therein. The principal business office of each of Sponsor, Holdings GP, Oaktree, Management GP, Atlas and OCGH GP is 333 South Grand Avenue, 28th Floor, Los Angeles, CA 90071. For material relationships between the Sponsor and Alvotech, see "Recent Developments—Business Combination," "Certain Relationships and Related Party Transactions—Sponsor Letter Agreement" and "—Investor Rights and Lock-Up Agreement."
- Consists of (i) 86,440,619 Ordinary Shares issued to Alvogen Lux Holdings S.à r.l. ("Alvogen") in exchange for Alvotech Holdings Ordinary Shares in connection with the Business Combination, 15,133,919 of which are subject to vesting or forfeiture over the five year period following the Closing and (ii) 2,500,000 Ordinary Shares subscribed to by Alvogen in connection with the Alvogen-Aztiq Loan Advance Conversion. Through intermediary holding entities, Alvogen is a wholly-owned subsidiary of Celtic Holdings SCA ("Celtic Holdings"). Investment and voting decisions at Celtic Holdings are made by a majority vote of its board of directors, subject to certain shareholders having consent rights over material actions and decisions of Celtic Holdings. Therefore, no individual director of Celtic Holdings is the beneficial owner of the securities, except with respect to the shares in which such director holds a pecuniary interest. The address of Alvogen is 5, Rue Heienhaff, L-1736 Senningerberg, Luxembourg, Grand-Duchy of Luxembourg and the address of Celtic Holdings is 20, Avenue Monterey, L-2163 Luxembourg, Grand-Duchy of Luxembourg. Each of Carmen Andre, Christoffer Sjøqvist, Tomas Ekman, Park Jung Ryun, Robert Wessman and Arni Hardarson is a director of Celtic Holdings entitled to participate in investment and voting decisions and therefore may be deemed to share voting and dispositive power with respect to the shares held by Celtic Holdings. Carmen Andre, Christoffer Sjøqvist, Tomas Ekman, Park Jung Ryun, Robert Wessman and Arni Hardarson each disclaim any beneficial ownership of any such shares, except to the extent of his or her pecuniary interest therein. For material relationships between Alvogen and Alvotech, see "Certain Relationships and Related Party Transactions."
- (16) Consists of (i) 98,647,803 Ordinary Shares held by Aztiq Pharma Partners S.à r.l. ("Aztiq") in exchange for Alvotech Holdings Ordinary Shares in connection with the Business Combination, 17,271,138 of which are subject to vesting or forfeiture over the five year period following the Closing and (ii) 2,500,000 Ordinary Shares subscribed to by Aztiq in connection with the Alvogen-Aztiq Loan Advance Conversion. Aztiq is a wholly-owned subsidiary of Aztiq Fund I SCSp ("Aztiq Fund"). Investment and voting decisions at Aztiq Fund are made by its general partner, Floki GP S.à r.l.

#### MATERIAL LUXEMBOURG INCOME TAX CONSIDERATIONS

The following information is of a general nature only and is based on the laws in force in Luxembourg as of the date of this prospectus and is subject to any change in law that may take effect after such date. It does not purport to be a comprehensive description of all tax considerations that might be relevant to an investment decision. It is not intended to be, nor should it be construed to be, legal or tax advice. It is a description of the essential material Luxembourg tax consequences with respect to the listing and may not include tax considerations that arise from rules of general application or that are generally assumed to be known to investors. Prospective holders of Ordinary Shares or Warrants should consult their professional advisors with respect to particular circumstances, the effects of state, local or foreign laws to which they may be subject, and as to their tax position.

Please be aware that the residence concept used under the respective headings applies for Luxembourg income tax assessment purposes only. Any reference in this section to a tax, duty, levy impost or other charge or withholding of a similar nature refers to Luxembourg tax law and/or concepts only. In addition, please note that a reference to Luxembourg income tax generally encompasses corporate income tax (impôt sur le revenu des collectivités), municipal business tax (impôt commercial communal), a solidarity surcharge (contribution au fonds pour l'emploi) as well as personal income tax (impôt sur le revenu). Corporate holders of Ordinary Shares or Warrants may further be subject to net worth tax (impôt sur la fortune) as well as other duties, levies or taxes. Corporate income tax, municipal business tax, the solidarity surcharge and net worth tax invariably apply to most corporate taxpayers resident in Luxembourg for tax purposes. Individual taxpayers are generally subject to personal income tax and the solidarity surcharge. Under certain circumstances, where an individual taxpayer acts in the course of the management of a professional or business undertaking, municipal business tax may apply as well.

## **Taxation of Alvotech**

#### Income Tax

From a Luxembourg tax perspective, Luxembourg companies are considered as being resident in Luxembourg provided that they have either their registered office or their central administration in Luxembourg.

Alvotech is a fully taxable Luxembourg company. The net taxable profit of Alvotech is subject to corporate income tax ("CIT") and municipal business tax ("MBT") at ordinary rates in Luxembourg.

The maximum aggregate CIT and MBT rate amounts to 24.94% (including the solidarity surcharge for the employment fund) for companies located in the municipality of Luxembourg-city. Liability to such corporation taxes extends to Alvotech's worldwide income (including capital gains), subject to the provisions of any relevant double taxation treaty. The taxable income of Alvotech is computed by application of all rules of the Luxembourg income tax law of December 4, 1967, as amended (*loi concernant l'impôt sur le revenu*), as commented and currently applied by the Luxembourg tax authorities ("LIR"). The taxable profit as determined for CIT purposes is applicable, with minor adjustments, for MBT purposes. Under the LIR, all income of Alvotech will be taxable in the fiscal period to which it economically relates and all deductible expenses of Alvotech will be deductible in the fiscal period to which they economically relate. Under certain conditions, dividends received by Alvotech from qualifying participations and capital gains realized by Alvotech on the sale of such participations, may be exempt from Luxembourg corporation taxes under the Luxembourg participation exemption regime. A tax credit is generally granted for withholding taxes levied at source within the limit of the tax payable in Luxembourg on such income, whereby any excess withholding tax is not refundable (but may be deductible under certain conditions).

Under the participation exemption regime (subject to the relevant anti-abuse rules), dividends derived from shares may be exempt from income tax if (i) the distributing company is a qualified subsidiary ("Qualified

Subsidiary") and (ii) at the time the dividend is put at Alvotech's disposal, the latter holds or commits itself to hold for an uninterrupted period of at least 12 months shares representing either (a) a direct participation of at least 10% in the share capital of the Qualified Subsidiary or (b) a direct participation in the Qualified Subsidiary of an acquisition price of at least €1.2 million ("Qualified Shareholding"). A Qualified Subsidiary means notably (a) a company covered by Article 2 of the Council Directive 2011/96/EU dated November 30, 2011 (the "Parent-Subsidiary Directive") or (b) a non-resident capital company (*société de capitaux*) liable to a tax corresponding to Luxembourg CIT. Liquidation proceeds are assimilated to a received dividend and may be exempt under the same conditions.

If the conditions of the participation exemption regime are not met, dividends derived by Alvotech from the Qualified Subsidiary may be exempt for 50 % of their gross amount.

Capital gains realized by Alvotech on shares are subject to CIT and MBT at ordinary rates, unless the conditions of the participation exemption regime, as described below, are satisfied. Under the participation exemption regime (subject to the relevant anti-abuse rules), capital gains realized on shares may be exempt from income tax at the level of Alvotech (subject to the recapture rules) if at the time the capital gain is realized, Alvotech holds or commits itself to hold for an uninterrupted period of at least 12 months shares representing a direct participation in the share capital of the Qualified Subsidiary (i) of at least 10% or of (ii) an acquisition price of at least €6 million. Taxable gains are determined as being the difference between the price for which shares have been disposed of and the lower of their cost or book value.

For the purposes of the participation exemption regime, shares held through a tax transparent entity are considered as being a direct participation proportionally to the percentage held in the net assets of the transparent entity.

## Net Worth Tax

Alvotech is as a rule subject to Luxembourg net worth tax ("NWT") on its net assets as determined for net worth tax purposes. NWT is levied at the rate of 0.5% on net assets not exceeding  $\epsilon$ 500 million and at the rate of 0.05% on the portion of the net assets exceeding  $\epsilon$ 500 million. Net worth is referred to as the unitary value (*valeur unitaire*), as determined on January 1 of each year. The unitary value is in principle calculated as the difference between (i) assets estimated at their fair market value (*valeur estimée de réalisation*), and (ii) liabilities.

Under the participation exemption regime, a Qualified Shareholding held by Alvotech in a Qualified Subsidiary is exempt for net worth tax purposes.

As from January 1, 2016, a minimum net worth tax ("MNWT") is levied on companies having their statutory seat or central administration in Luxembourg. For entities for which the sum of fixed financial assets, transferable securities and cash at bank exceeds 90% of their total gross assets and €350,000, the MNWT is set at €4,815. For all other companies having their statutory seat or central administration in Luxembourg which do not fall within the scope of the €4,815 MNWT, the MNWT ranges from €535 to €32,100, depending on their total balance sheet.

# Other Taxes

The incorporation of Alvotech through a contribution in cash to its share capital as well as further share capital increase or other amendment to the articles of incorporation of Alvotech are subject to a fixed registration duty of €75.

## Withholding Taxes

Dividends paid by Alvotech to holders of Ordinary Shares are generally subject to a 15% withholding tax in Luxembourg, unless a reduced treaty rate or the participation exemption applies. Under certain conditions, a

corresponding tax credit may be granted to the holders of Ordinary Shares. Responsibility for the withholding of the tax is assumed by Alvotech.

A withholding tax exemption applies under the participation exemption regime (subject to the relevant anti-abuse rules), if cumulatively (i) the holder of Ordinary Shares is an eligible parent ("Eligible Parent") and (ii) at the time the income is made available, the Eligible Parent holds or commits itself to hold for an uninterrupted period of at least 12 months a Qualified Shareholding in Alvotech. Holding a participation through a tax transparent entity is deemed to be a direct participation in the proportion of the net assets held in this entity. An Eligible Parent includes notably (a) a company covered by Article 2 of the Parent-Subsidiary Directive or a Luxembourg permanent establishment thereof, (b) a company resident in a State having a double tax treaty with Luxembourg and liable to a tax corresponding to Luxembourg CIT or a Luxembourg permanent establishment thereof, (c) a capital company (société de capitaux) or a cooperative company (société coopérative) resident in a member state of the EEA other than an EU member state and liable to a tax corresponding to Luxembourg CIT or a Luxembourg permanent establishment thereof or (d) a Swiss capital company (société de capitaux) which is subject to CIT in Switzerland without benefiting from an exemption.

No withholding tax is levied on capital gains and liquidation proceeds.

# Taxation of the Holders of Ordinary Shares / Warrants

## Tax Residency

A holder of Ordinary Shares or Warrants will not become resident, nor be deemed to be resident, in Luxembourg solely by virtue of holding and/or disposing of Ordinary Shares or Warrants or the execution, performance, delivery and/or enforcement of his or her rights thereunder.

## Income Tax

For the purposes of this section, a "disposal" may include a sale, an exchange, a contribution, a redemption and any other kind of alienation of Ordinary Shares or Warrants.

## Luxembourg Residents

Luxembourg Resident Individuals

Dividends and other payments derived from the Ordinary Shares held by resident individual holders, who act in the course of the management of either their private wealth or their professional/business activity, are subject to income tax at the ordinary progressive rates. Under current Luxembourg tax laws, 50% of the gross amount of dividends received by resident individuals from Alvotech may however be exempt from income tax.

Capital gains realized on the disposal of the Ordinary Shares or Warrants by resident individual shareholders, who act in the course of the management of their private wealth, are not subject to income tax, unless said capital gains qualify either as speculative gains or as gains on a substantial participation. Capital gains are deemed to be speculative if the Ordinary Shares or Warrants are disposed of within six months after their acquisition or if their disposal precedes their acquisition. Speculative gains are subject to income tax as miscellaneous income at ordinary rates. A participation is deemed to be substantial where a resident individual shareholder holds or has held, either alone or together with his/her spouse or partner and/or minor children, directly or indirectly at any time within the five years preceding the disposal, more than 10% of the share capital of the company whose shares are being disposed of (the "Substantial Participation"). A holder of Ordinary Shares is also deemed to alienate a Substantial Participation if he acquired free of charge, within the five years preceding the transfer, a participation that was constituting a Substantial Participation in the hands of the alienator (or the alienators in case of successive transfers free of charge within the same five-year period). Capital gains realized

on a Substantial Participation more than six months after the acquisition thereof are taxed according to the half-global rate method (i.e., the average rate applicable to the total income is calculated according to progressive income tax rates and half of the average rate is applied to the capital gains realized on the Substantial Participation).

Capital gains realized on the disposal of the Ordinary Shares or Warrants by resident individual holders, who act in the course of their professional/business activity, are subject to income tax at ordinary rates. Taxable gains are determined as being the difference between the price for which the Ordinary Shares or Warrants have been disposed of and the lower of their cost or book value.

# Luxembourg Resident Companies

Dividends and other payments derived from the Ordinary Shares held by Luxembourg resident fully taxable companies are subject to income taxes, unless the conditions of the participation exemption regime, as described below, are satisfied. A tax credit is generally granted for withholding taxes levied at source within the limit of the tax payable in Luxembourg on such income, whereby any excess withholding tax is not refundable (but may be deductible under certain conditions). If the conditions of the participation exemption regime are not met, 50% of the dividends distributed by Alvotech to a Luxembourg fully taxable resident company are nevertheless exempt from income tax.

Under the participation exemption regime (subject to the relevant anti-abuse rules), dividends derived from the Ordinary Shares may be exempt from CIT and MBT at the level of the holder if (i) the holder is an Eligible Parent and (ii) at the time the dividend is put at the holder's disposal, the latter holds or commits itself to hold for an uninterrupted period of at least 12 months a shareholding representing a direct participation of at least 10% in the share capital of Alvotech or a direct participation in Alvotech of an acquisition price of at least €1.2 million. Liquidation proceeds are assimilated to a received dividend and may be exempt under the same conditions. Capital gains realized by a Luxembourg fully-taxable resident company on the disposal of the Ordinary Shares are subject to income tax at ordinary rates, unless the conditions of the participation exemption regime, as described below, are satisfied.

Under the participation exemption regime (subject to the relevant anti-abuse rules), capital gains realized on the Ordinary Shares and Warrants may be exempt from CIT and MBT (save for the recapture rules) at the level of the holder if cumulatively (i) the holder is a Eligible Parent and (ii) at the time the capital gain is realized, the holder holds or commits itself to hold for an uninterrupted period of at least 12 months shares representing either (a) a direct participation of at least 10% in the share capital of Alvotech or (b) a direct participation in Alvotech of an acquisition price of at least €6 million. Taxable gains are determined as being the difference between the price for which the Ordinary Shares have been disposed of and the lower of their cost or book value. Under Luxembourg tax law it is debatable to what extent the warrants are eligible for the participation exemption regime although certain case law supports such argumentation in certain circumstances.

For the purposes of the participation exemption regime, Ordinary Shares held through a tax transparent entity are considered as being a direct participation proportionally to the percentage held in the net assets of the transparent entity.

For holders of Warrants, the exercise of the Warrants will not give rise to any immediate Luxembourg tax consequences.

Luxembourg Resident Companies Benefiting from a Special Tax Regime

A holder of Ordinary Shares or Warrants who is a Luxembourg resident company benefiting from a special tax regime, such as (i) a specialized investment fund governed by the amended law of February 13, 2007, (ii) a family wealth management company governed by the amended law of May 11, 2007 (iii) an undertaking for

collective investment governed by the amended law of December 17, 2010 or (iv) a reserved alternative investment fund treated as a specialized investment fund for Luxembourg tax purposes and governed by the amended law of July 23, 2016 is exempt from income tax in Luxembourg and profits derived from the shares or warrants are thus not subject to tax in Luxembourg.

# Luxembourg Non-Residents

Non-resident holders of Ordinary Shares or Warrants, who have neither a permanent establishment nor a permanent representative in Luxembourg to which or whom the Ordinary Shares or Warrants are attributable, are not liable to any Luxembourg income tax, whether they receive payments of dividends or realize capital gains on the disposal of the Ordinary Shares or Warrants, except with respect to capital gains realized on a substantial participation before the acquisition or within the first six months of the acquisition thereof, that are subject to income tax in Luxembourg at ordinary rates (subject to the provisions of any relevant double tax treaty) and except for the withholding tax mentioned above.

Non-resident holders of Ordinary Shares or Warrants having a permanent establishment or a permanent representative in Luxembourg to which or whom the Ordinary Shares or Warrants are attributable, must include any income received, as well as any gain realized on the disposal of the Ordinary Shares or Warrants, in their taxable income for Luxembourg tax assessment purposes, unless the conditions of the participation exemption regime, as described below, are satisfied. If the conditions of the participation exemption regime are not fulfilled, 50% of the gross amount of dividends received by a Luxembourg permanent establishment or permanent representative are however exempt from income tax. Taxable gains are determined as being the difference between the price for which the Ordinary Shares have been disposed of and the lower of their cost or book value.

Under the participation exemption regime (subject to the relevant anti-abuse rules), dividends derived from the Ordinary Shares may be exempt from income tax if cumulatively (i) the Ordinary Shares are attributable to a qualified permanent establishment ("Qualified Permanent Establishment") and (ii) at the time the dividend is put at the disposal of the Qualified Permanent Establishment, it holds or commits itself to hold a Qualified Shareholding in Alvotech. A Qualified Permanent Establishment means (a) a Luxembourg permanent establishment of a company covered by Article 2 of the Parent-Subsidiary Directive, (b) a Luxembourg permanent establishment of a capital company (société de capitaux) resident in a State having a double tax treaty with Luxembourg and (c) a Luxembourg permanent establishment of a capital company (société de capitaux) or a cooperative company (société coopérative) resident in a member state of the EEA other than an EU member state. Liquidation proceeds are assimilated to a received dividend and may be exempt under the same conditions. Ordinary Shares held through a tax transparent entity are considered as being a direct participation proportionally to the percentage held in the net assets of the transparent entity.

Under the participation exemption regime (subject to the relevant anti-abuse rules), capital gains realized on the Ordinary Shares or Warrants may be exempt from income tax (save for the recapture rules) if cumulatively (i) the Ordinary Shares or Warrants are attributable to a Qualified Permanent Establishment and (ii) at the time the capital gain is realized, the Qualified Permanent Establishment holds or commits itself to hold for an uninterrupted period of at least 12 months Ordinary Shares or Warrants representing either (a) a direct participation in the share capital of Alvotech of at least 10% or (b) a direct participation in of an acquisition price of at least €6 million.

Under Luxembourg tax laws currently in force (subject to the provisions of double taxation treaties), capital gains realized by a Luxembourg non-resident holder of Ordinary Shares or Warrants (not acting via a permanent establishment or a permanent representative in Luxembourg through which/whom the Ordinary Shares or Warrants are held) are not taxable in Luxembourg unless (a) the holder of Ordinary Shares or Warrants holds a Substantial Participation in Alvotech and the disposal of the Ordinary Shares or Warrants takes place less than six months after the Ordinary Shares or Warrants were acquired or (b) the holder of Ordinary Shares or Warrants has been a former Luxembourg resident for more than 15 years and has become a non-resident, at the time of transfer, less than five years ago.

#### Net Worth Tax

A Luxembourg resident as well as a non-resident who has a permanent establishment or a permanent representative in Luxembourg to which the Ordinary Shares or Warrants are attributable, are subject to Luxembourg NWT (subject to the application of the participation exemption regime) on such Ordinary Shares or Warrants, except if the holder of Ordinary Shares or Warrants is (i) a resident or non-resident individual taxpayer, (ii) a securitization company governed by the amended law of June 15, 2004 on venture capital vehicles, (iv) a professional pension institution governed by the amended law of July 13, 2005, (v) a specialized investment fund governed by the amended law of February 13, 2007, (vi) a family wealth management company governed by the law of May 11, 2007, (vii) an undertaking for collective investment governed by the amended law of December 17, 2010 or (viii) a reserved alternative investment fund governed by the amended law of July 23, 2016.

However, (i) a securitization company governed by the amended law of March 22, 2004 on securitization, (ii) a company governed by the amended law of June 15, 2004 on venture capital vehicles (iii) a professional pension institution governed by the amended law dated July 13, 2005 and (iv) an opaque reserved alternative investment fund treated as a venture capital vehicle for Luxembourg tax purposes and governed by the amended law of July 23, 2016 remain subject to the MNWT.

#### Other Taxes

Under current Luxembourg tax laws, no registration tax or similar tax is in principle payable by the holder of Ordinary Shares or Warrants upon the acquisition, holding or disposal of the Ordinary Shares or Warrants. However, a fixed or *ad valorem* registration duty may be due upon the registration of the Ordinary Shares or Warrants in Luxembourg in the case where the Ordinary Shares or Warrants are physically attached to a public deed or to any other document subject to mandatory registration, as well as in the case of a registration of the Ordinary Shares or Warrants on a voluntary basis.

No inheritance tax is levied on the transfer of the Ordinary Shares or Warrants upon death of a holder in cases where the deceased was not a resident of Luxembourg for inheritance tax purposes at the time of his death.

Gift tax may be due on a gift or donation of the Ordinary Shares or Warrants if the gift is recorded in a Luxembourg notarial deed or otherwise registered in Luxembourg.

#### MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a discussion of certain material U.S. federal income tax considerations generally applicable to (i) the acquisition, ownership, and disposition of Ordinary Shares (including Ordinary Shares issuable upon exercise of the Warrants) and (ii) the exercise, disposition, and lapse of the Private Placement Warrants, in each case, by a "U.S. Holder." For purposes of this discussion, Ordinary Shares (including Ordinary Shares issuable upon exercise of the Warrants) and the Private Placement Warrants are referred to collectively as "Securities." This discussion applies only to Securities that are held by a U.S. Holder as "capital assets" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not describe all U.S. federal income tax considerations that may be relevant to a U.S. Holder in light of such U.S. Holder's particular circumstances, nor does it address any state, local, or non-U.S. tax considerations, any non-income tax (such as gift or estate tax) considerations, the alternative minimum tax, the special tax accounting rules under Section 451(b) of the Code, the Medicare contribution tax on net investment income, or any tax consequences that may be relevant to U.S. Holders that are subject to special tax rules, including, without limitation:

- · banks or other financial institutions;
- insurance companies;
- mutual funds;
- pension or retirement plans;
- S corporations;
- broker or dealers in securities or currencies;
- traders in securities that elect mark-to-market treatment;
- regulated investment companies;
- real estate investment trusts;
- trusts or estates;
- tax-exempt organizations (including private foundations);
- persons that hold Securities as part of a "straddle," "hedge," "conversion," "synthetic security," "constructive sale," or other integrated transaction for U.S. federal income tax purposes;
- persons that have a functional currency other than the U.S. dollar;
- certain U.S. expatriates or former long-term residents of the United States;
- persons owning (directly, indirectly, or constructively) 5% (by vote or value) or more of our stock;
- persons that acquired Securities pursuant to an exercise of employee stock options or otherwise as compensation;
- partnerships or other entities or arrangements treated as pass-through entities for U.S. federal income tax purposes and investors in such entities;
- "controlled foreign corporations" within the meaning of Section 957(a) of the Code;
- · "passive foreign investment companies" within the meaning of Section 1297(a) of the Code; and
- corporations that accumulate earnings to avoid U.S. federal income tax.

If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds Securities, the tax treatment of a partner in such partnership generally will depend on the status of the partner and the activities of the partnership and the partner. Partnerships holding Securities should consult their tax advisors regarding the tax consequences in their particular circumstances.

This discussion is based on the Code, the U.S. Treasury regulations promulgated thereunder, administrative rulings, and judicial decisions, all as currently in effect and all of which are subject to change or differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences described herein. Furthermore, there can be no assurance that the Internal Revenue Service (the "IRS") will not challenge the tax considerations described herein and that a court will not sustain such challenge.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of Securities, that is, for U.S. federal income tax purposes:

- an individual who is a U.S. citizen or resident of the United States;
- a corporation (including an entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (i) if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more "United States persons" within the meaning of Section 7701(a)(30) of the Code have the authority to control all substantial decisions of the trust or (B) that has in effect a valid election under applicable U.S. Treasury regulations to be treated as a United States person.

THIS DISCUSSION IS FOR GENERAL INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES OF THE ACQUISTION, OWNERSHIP, AND DISPOSITION OF ORDINARY SHARES (INCLUDING ORDINARY SHARES ISSUABLE UPON EXERCISE OF THE WARRANTS) AND THE EXERCISE, DISPOSITION, AND LAPSE OF THE PRIVATE PLACEMENT WARRANTS IN THEIR PARTICULAR CIRCUMSTANCES.

## Distributions on the Ordinary Shares

Subject to the PFIC rules discussed below under "-Passive Foreign Investment Company Rules," distributions on Ordinary Shares (including constructive distributions as described below under "—Constructive Distributions on the Private Placement Warrants") generally will be taxable as a dividend for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Such distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the applicable U.S. Holder's adjusted tax basis in its Ordinary Shares. Any remaining excess will be treated as gain realized on the sale or other taxable disposition of Ordinary Shares and will be treated as described below under "—Sale or Other Taxable Disposition of the Securities." The amount of any such distributions will include any amounts required to be withheld by us (or another applicable withholding agent) in respect of any non-U.S. taxes. Any such amount treated as a dividend will be treated as foreign-source dividend income. Any such dividends received by a corporate U.S. Holder generally will not qualify for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. With respect to non-corporate U.S. Holders, any such dividends generally will be taxed at currently preferential long-term capital gains rates only if (i) Ordinary Shares are readily tradable on an established securities market in the United States or we are eligible for benefits under an applicable tax treaty with the United States, (ii) we are not treated as a PFIC with respect to the applicable U.S. Holder at the time the dividend was paid or in the preceding year, and (iii) certain holding period and other requirements are met. Any such dividends paid in a currency other than the U.S. dollar generally will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of actual or constructive receipt.

As noted above and subject to applicable limitations, taxing jurisdictions other than the United States may withhold taxes from distributions on Ordinary Shares, and a U.S. Holder may be eligible for a reduced rate of withholding to the extent there is an applicable tax treaty between the applicable taxing jurisdiction and the United States and/or may be eligible for a foreign tax credit against the U.S. Holder's U.S. federal income tax liability. Recently issued U.S. Treasury regulations, which apply to foreign taxes paid or accrued in taxable years beginning on or after December 28, 2021, may in some circumstances prohibit a U.S. Holder from claiming a foreign tax credit with respect to certain foreign taxes that are not creditable under applicable tax treaties. In lieu of claiming a foreign tax credit, a U.S. Holder may, at such U.S. Holder's election, deduct foreign taxes in computing such U.S. Holder's taxable income, subject to generally applicable limitations under U.S. tax law. An election to deduct foreign taxes in lieu of claiming a foreign tax credit applies to all foreign taxes paid or accrued in the taxable year in which such election is made. The foreign taxes, in their particular circumstances.

## Constructive Distributions on the Private Placement Warrants

Under Section 305 of the Code, an adjustment to (or a failure to adjust) the number of Ordinary Shares issuable upon exercise of the Private Placement Warrants, or an adjustment to (or a failure to adjust) the exercise price of the Private Placement Warrants, may be treated as a constructive distribution to a U.S. Holder to the extent such adjustment (or failure to adjust) has the effect of increasing such U.S. Holder's proportionate interest in our assets or earnings and profits, as determined under U.S. federal income tax principles, depending on the circumstances of such adjustment (or failure to adjust) (for example, if such adjustment is to compensate for a distribution of cash or other property to our stockholders). Any such constructive dividend will be treated as described above under "—Distributions on the Ordinary Shares," whether or not there is an actual distribution of cash or other property.

We are required to report the amount of any constructive distributions to the IRS or on our website and to certain U.S. Holders of the Private Placement Warrants that are not exempt from information reporting. The IRS has proposed U.S. Treasury regulations addressing the amount and timing of constructive distributions, obligations of withholding agents, and filing and notice obligations of issuers, effective for constructive distributions occurring on or after such U.S. Treasury regulations are adopted in final form. If adopted as proposed, such U.S. Treasury regulations generally would provide that (i) the amount of a constructive distribution is the excess of the fair market value of the right to acquire Ordinary Shares immediately after the conversion rate adjustment over the fair market value of the right to acquire Ordinary Shares without such adjustment, (ii) the constructive distribution occurs at the earlier of the date of such adjustment under the terms of the Private Placement Warrants and the date of the actual distribution of cash or other property that results in the constructive distribution, (iii) subject to certain limited exceptions, a withholding agent is required to impose any applicable withholding on the constructive distribution and, if there is no associated cash payment, may set off its withholding obligations against payments on our securities or sales proceeds received by, or other funds or assets of, the applicable U.S. Holder, and (iv) we will continue to be required to report the amount of any constructive distributions to the IRS or on our website and to all U.S. Holders (including U.S. Holders that would otherwise be exempt from information reporting). The final U.S. Treasury regulations will be effective for distributions occurring on or after the date of adoption, but U.S. Holders of the Private Placement Warrants and withholding agents may rely on them prior to that date under certain circumstances.

U.S. Holders should consult their tax advisors regarding the tax consequences of any constructive distributions on the Private Placement Warrants in their particular circumstances.

# Sale or Other Taxable Disposition of the Securities

Subject to the PFIC rules discussed below under "—*Passive Foreign Investment Company Rules*," upon any sale or other taxable disposition of Securities (other than by exercise of the Private Placement Warrants), a U.S.

Holder generally will recognize gain or loss in an amount equal to the difference, if any, between (i) the sum of (A) the amount of cash and (B) the fair market value of any other property received in such sale or disposition and (ii) the U.S. Holder's adjusted tax basis in the Securities. Any such gain or loss generally will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder's holding period for such Securities exceeds one year. Long-term capital gain recognized by non-corporate U.S. Holders generally will be taxed at currently preferential long-term capital gains rates. The deductibility of capital losses is subject to limitations. For foreign tax credit purposes, any such gain or loss generally will be treated as U.S. source gain or loss.

If the consideration received by a U.S. Holder upon a sale or other taxable disposition of Securities is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of such payment calculated by reference to the exchange rate in effect on the date of such sale or disposition. A U.S. Holder may have foreign currency gain or loss to the extent of the difference, if any, between (i) the U.S. dollar value of such payment on the date of such sale or disposition and (ii) the U.S. dollar value of such payment calculated by reference to the exchange rate in effect on the date of settlement.

U.S. Holders should consult their tax advisors regarding the tax consequences of a sale or other taxable disposition of Securities, including the creditability of foreign taxes imposed on such sale or disposition by a taxing jurisdiction other than the United States, in their particular circumstances.

# Exercise and Lapse of the Private Placement Warrants

A U.S. Holder generally will not recognize gain or loss upon exercise of the Private Placement Warrants and the related receipt of Ordinary Shares. The U.S. Holder generally will take a tax basis in the Ordinary Shares equal to the sum of (i) the U.S. Holder's tax basis in the Private Placement Warrants and (ii) the exercise price of the Private Placement Warrants. The U.S. Holder's holding period in the Ordinary Shares generally should begin on the day after the date of exercise.

In certain circumstances, the Private Placement Warrants may be exercised on a cashless basis. The U.S. federal income tax treatment of a cashless exercise of a warrant is not clear and may be different from the tax consequences described above. It is possible that a cashless exercise of a warrant could be a taxable event. U.S. Holders should consult their tax advisors regarding the tax consequences of a cashless exercise of the Private Placement Warrants, including their tax basis and holding period in the Ordinary Shares issuable upon such exercise, in their particular circumstances.

Upon the lapse or expiration of the Private Placement Warrants, a U.S. Holder generally will recognize a loss in an amount equal to the U.S. Holder's tax basis in the Private Placement Warrants. Any such loss generally will be a capital loss and will be long-term capital loss if the U.S. Holder has held the Private Placement Warrants for more than one year. As noted above, the deductibility of capital losses is subject to limitations.

## Passive Foreign Investment Company Rules

The U.S. federal income tax treatment of U.S. Holders could be materially different from that described above if we are treated as a PFIC for U.S. federal income tax purposes. A non-U.S. corporation generally will be treated as a PFIC for U.S. federal income tax purposes if either (i) at least 75% of its gross income in a taxable year, including its pro rata share of the gross income of any corporation in which it is considered to own at least 25% of the shares by value, is passive income or (ii) at least 50% of its assets in a taxable year (ordinarily determined based on fair market value and averaged quarterly over the year), including its pro rata share of the assets of any corporation in which it is considered to own at least 25% of the shares by value, are held for the production of, or produce, passive income. Passive income generally includes dividends, interest, rents and royalties (other than rents or royalties derived from the active conduct of a trade or business), and gains from the disposition of passive assets.

Based on our analysis of our income, assets, activities and market capitalization, we believe that we were not treated as a PFIC for our taxable year ended December 31, 2022. However, the determination of whether a non-U.S. corporation is a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, the total value of our assets for PFIC testing purposes may be determined in part by reference to our market capitalization from time to time, which may fluctuate considerably. As a result, there can be no assurance with respect to our status as a PFIC for any taxable year, and our U.S. counsel expresses no opinion with respect to our PFIC status for any taxable year.

Although PFIC status is generally determined annually, if we are determined to be a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U.S. Holder in its Securities and the U.S. Holder did not make either a mark-to-market election or a qualifying electing fund ("QEF") election, which are referred to collectively as the "PFIC Elections" for purposes of this discussion, for the first taxable year in which we are treated as a PFIC, and in which the U.S. Holder held (or was deemed to hold) Securities, or the U.S.

Holder does not otherwise make a purging election, as described below, the U.S. Holder generally will be subject to special and adverse rules with respect to (i) any gain recognized by the U.S. Holder on the sale or other taxable disposition of its Securities (other than by exercise of the Private Placement Warrants) and (ii) any "excess distribution" made to the U.S. Holder (generally, any distributions to the U.S. Holder during a taxable year of the U.S. Holder that are greater than 125% of the average annual distributions received by the U.S. Holder in respect of its Securities during the three preceding taxable years of the U.S. Holder or, if shorter, the U.S. Holder's holding period in its Securities).

#### Under these rules:

- the U.S. Holder's gain or excess distribution will be allocated ratably over the U.S. Holder's holding period in its Securities;
- the amount allocated to the U.S. Holder's taxable year in which the U.S. Holder recognized the gain or received the excess distribution, and to any period in the U.S. Holder's holding period before the first day of the first taxable year in which we are treated as a PFIC, will be taxed as ordinary income;
- the amount allocated to other taxable years (or portions thereof) of the U.S. Holder and included in the U.S. Holder's holding period will be taxed at the highest tax rate in effect for that year and applicable to the U.S. Holder; and
- an additional tax equal to the interest charge generally applicable to underpayments of tax will be imposed on the U.S. Holder with respect to the tax attributable to each such other taxable year of the U.S. Holder.

## PFIC Elections

If we are treated as a PFIC and Ordinary Shares constitute "marketable stock," a U.S. Holder may avoid the adverse PFIC tax consequences discussed above if such U.S. Holder makes a mark-to-market election with respect to its Ordinary Shares for the first taxable year in which the U.S. Holder holds (or is deemed to hold) Ordinary Shares and each subsequent taxable year. Such U.S. Holder generally will include for each of its taxable years as ordinary income the excess, if any, of the fair market value of its Ordinary Shares at the end of such year over its adjusted tax basis in its Ordinary Shares. The U.S. Holder also will recognize an ordinary loss in respect of the excess, if any, of its adjusted tax basis in its Ordinary Shares over the fair market value of its Ordinary Shares at the end of its taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). The U.S. Holder's adjusted tax basis in its Ordinary Shares will be adjusted to reflect any such income or loss amounts, and any further gain recognized on a sale or other taxable disposition of its Ordinary Shares will be treated as ordinary income. The mark-to-market election may not be made with respect to the Private Placement Warrants.

The mark-to-market election is available only for "marketable stock," generally, stock that is regularly traded on a national securities exchange that is registered with the Securities and Exchange Commission, including the Nasdaq (on which Ordinary Shares are currently listed), or on a foreign exchange or market that the IRS determines has rules sufficient to ensure that the market price represents a legitimate and sound fair market value. As such, such election generally will not apply to any of our non-U.S. subsidiaries, unless the shares in such subsidiaries are themselves "marketable stock." As such, U.S. Holders may continue to be subject to the adverse PFIC tax consequences discussed above with respect to any lower-tier PFICs, as discussed below, notwithstanding their mark-to-market election with respect to Ordinary Shares.

If made, a mark-to-market election would be effective for the taxable year for which the election was made and for all subsequent taxable years unless Ordinary Shares cease to qualify as "marketable stock" for purposes of the PFIC rules or the IRS consents to the revocation of the election. U.S. Holders should consult their tax advisors regarding the availability and tax consequences of a mark-to-market election with respect to Ordinary Shares in their particular circumstances.

The tax consequences that would apply if we were a PFIC and a U.S. Holder of Ordinary Shares (but not the Private Placement Warrants) made a valid QEF election would also be different from the adverse PFIC tax consequences described above. In order to comply with the requirements of a QEF election, however, a U.S. Holder generally must receive a PFIC Annual Information Statement from us. If we are determined to be a PFIC for any taxable year, we do not currently intend to provide the information necessary for U.S. Holders to make or maintain a QEF election. As such, U.S. Holders should assume that a QEF election will not be available with respect to Securities.

If we are treated as a PFIC and a U.S. Holder failed or was unable to timely make a PFIC Election for prior periods, the U.S. Holder might seek to make a purging election to rid its Ordinary Shares of the PFIC taint. Under the purging election, the U.S. Holder will be deemed to have sold its Ordinary Shares at their fair market value and any gain recognized on such deemed sale will be treated as an excess distribution, as described above. As a result of the purging election, the U.S. Holder will have a new adjusted tax basis and holding period in Ordinary Shares solely for purposes of the PFIC rules.

#### Related PFIC Rules

If we are treated as a PFIC and, at any time, has a non-U.S. subsidiary that is treated as a PFIC, a U.S. Holder generally would be deemed to own a proportionate amount of the shares of such lower-tier PFIC, and generally could incur liability for the deferred tax and interest charge described above if we receive a distribution from, or sell or otherwise dispose of all or part of our interest in, such lower-tier PFIC, or the U.S. Holder otherwise was deemed to have sold or otherwise disposed of an interest in such lower-tier PFIC. U.S. Holders should consult their tax advisors regarding the application of the lower-tier PFIC rules in their particular circumstances.

Under proposed U.S. Treasury regulations, if a U.S. Holder has an option, warrant, or other right to acquire stock in a PFIC, such option, warrant, or right is treated as stock in a PFIC subject to the rules described above. In addition, the holding period of stock issuable upon exercise of such option, warrant, or right will include the period during which the U.S. Holder held such option, warrant, or right. Such holding period impacts the availability of the PFIC Elections with respect to such stock. Because of the complexity and uncertainty of the application of the PFIC rules to warrants, U.S. Holders of the Private Placement Warrants should consult their tax advisors regarding the application of the PFIC rules in their particular circumstances.

A U.S. Holder that owns (or is deemed to own) shares in a PFIC during any taxable year may have to file an IRS Form 8621 (whether or not a QEF election or a mark-to-market election is made) and to provide such other information as may be required by the U.S. Treasury Department. Failure to do so, if required, will extend the statute of limitations applicable to such U.S. Holder until such required information is furnished to the IRS and could result in penalties.

THE PFIC RULES ARE VERY COMPLEX AND THE APPLICATION OF THE PFIC RULES TO WARRANTS IS UNCLEAR. U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE APPLICATION OF SUCH RULES IN THEIR PARTICULAR CIRCUMSTANCES.

# Information Reporting and Backup Withholding

Payments of dividends (including constructive dividends) and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle the U.S. Holder to a refund, provided that the required information is timely furnished to the IRS.

U.S. Holders should consult their tax advisors regarding the information reporting requirements and the application of the backup withholding rules in their particular circumstances.

THIS DISCUSSION IS FOR GENERAL INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE U.S. FEDERAL, STATE, AND LOCAL AND NON-U.S. INCOME AND NON-INCOME TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF ORDINARY SHARES (INCLUDING ORDINARY SHARES ISSUABLE UPON EXERCISE OF THE WARRANTS) AND THE EXERCISE, DISPOSITION, AND LAPSE OF THE PRIVATE PLACEMENT WARRANTS, INCLUDING THE IMPACT OF ANY POTENTIAL CHANGE IN LAW, IN THEIR PARTICULAR CIRCUMSTANCES.

# PLAN OF DISTRIBUTION

We are registering the issuance by us of up to 10,916,647 Ordinary Shares that may be issued upon exercise of Warrants at an exercise price of \$11.50 per share.

We are also registering the resale by the Selling Securityholders, or their permitted transferees, from time to time of up to 219,616,200 Ordinary Shares, consisting of up to (i) 17,493,000 Ordinary Shares subscribed for by the Selling Securityholders, for a subscription price of \$10.00 per share, in the context of the PIPE Financing, (ii) 6,250,000 Ordinary Shares issued to the Sponsor in exchange for the Founder Shares, (iii) 4,666,667 Ordinary Shares issuable upon exercise of Private Placement Warrants, (iv) 186,206,553 Ordinary Shares issued to former shareholders of Alvotech Holdings in exchange for their Alvotech Holdings Ordinary Shares in connection with the Business Combination (subject to vesting and lockups), (v) 5,000,000 Ordinary Shares subscribed for by Alvogen and Aztiq, for a subscription price of \$10.00 per share, in the context of the Alvogen-Aztiq Loan Advance Conversion, and (vi) 4,666,667 Private Placement Warrants, which were purchased by the Sponsor at a price of \$1.50 per warrant.

We could potentially receive up to an aggregate of \$125.5 million if all the Warrants are exercised to the extent such Warrants are exercised for cash. We will not receive any of the proceeds from the sale of the securities by the Selling Securityholders. The aggregate proceeds to the Selling Securityholders will be the purchase price of the securities less any discounts and commissions borne by the Selling Securityholders.

# **Primary Offering**

Pursuant to the terms of the Warrants, the Ordinary Shares will be distributed to those holders who surrender the Warrants and provide payment of the exercise price to us. Upon receipt of proper notice by any of the holders of the Warrants issued that such holder desires to exercise a Warrant, we will, within the time allotted by the agreement governing the Warrants, issue instructions to our transfer agent to issue to the holder Ordinary Shares. If, at the time the Warrants are exercised, this Registration Statement is effective and the prospectus included herein is current, the Ordinary Shares issued upon the exercise of the Warrants will be issued free of a restrictive legend.

# Resale by Selling Securityholders

The Selling Securityholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Securityholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Securityholders in disposing of the securities. We will bear all other costs, fees and expenses incurred in effecting the registration of the securities covered by this prospectus, including, without limitation, all registration and filing fees, Nasdaq listing fees and fees and expenses of our counsel and our independent registered public accountants.

The securities beneficially owned by the Selling Securityholders covered by this prospectus may be offered and sold from time to time by the Selling Securityholders. The term "Selling Securityholders" includes donees, pledgees, transferees or other successors in interest selling securities received after the date of this prospectus from a Selling Securityholder as a gift, pledge, partnership distribution or other transfer. The Selling Securityholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. Each Selling Securityholder reserves the right to accept and, together with its respective agents, to reject, any proposed purchase of securities to be made directly or through agents. The Selling Securityholders and any of their permitted transferees may sell their securities offered by this prospectus on any stock exchange, market or trading facility on which the securities are traded or in private transactions. If underwriters are used in the sale, such underwriters will acquire the shares for their own account. These sales may be at a fixed price or

varying prices, which may be changed, or at market prices prevailing at the time of sale, at prices relating to prevailing market prices or at negotiated prices. The securities may be offered to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. The obligations of the underwriters to purchase the securities will be subject to certain conditions. The underwriters will be obligated to purchase all the securities offered if any of the securities are purchased.

Subject to the limitations set forth in any applicable registration rights agreement, the Selling Securityholders may use any one or more of the following methods when selling the securities offered by this prospectus:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an over-the-counter distribution in accordance with the rules of Nasdag;
- through trading plans entered into by a Selling Securityholder pursuant to Rule 10b5-1 under the Exchange Act that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
- through one or more underwritten offerings on a firm commitment or best efforts basis;
- settlement of short sales entered into after the date of this prospectus;
- agreements with broker-dealers to sell a specified number of the securities at a stipulated price per share;
- in "at the market" offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
- directly to purchasers, including through a specific bidding, auction or other process or in privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- through a combination of any of the above methods of sale; or
- any other method permitted pursuant to applicable law.

In addition, a Selling Securityholder that is an entity may elect to make an in-kind distribution of securities to its members, partners or stockholders pursuant to the registration statement of which this prospectus is a part by delivering a prospectus with a plan of distribution. To the extent a distributee is not an affiliate of ours, the distributee would thereby receive freely tradeable securities pursuant to the distribution through the registration statement. To the extent a distributee is an affiliate of ours (or to the extent otherwise required by law), we may file a prospectus supplement in order to permit the distributee to use the prospectus to resell the securities acquired in the distribution.

The Selling Securityholders also may transfer the securities in other circumstances, in which case the transferees, pledgees or other successors-in-interest will be the selling beneficial owners for purposes of this prospectus. Upon being notified by a Selling Securityholder that a donee, pledgee, transferee, other successor-in-interest intends to sell our securities, we will, to the extent required, promptly file a supplement to this prospectus to name specifically such person as a Selling Securityholder.

There can be no assurance that the Selling Securityholders will sell all or any of the securities offered by this prospectus. In addition, the Selling Securityholders may also sell securities under Rule 144 under the Securities Act, if available, or in other transactions exempt from registration, rather than under this prospectus. The Selling Securityholders have the sole and absolute discretion not to accept any purchase offer or make any sale of securities if they deem the purchase price to be unsatisfactory at any particular time.

With respect to a particular offering of the securities held by the Selling Securityholders, to the extent required, an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement of which this prospectus is part, will be prepared and will set forth the following information:

- the specific securities to be offered and sold;
- the names of the Selling Securityholders;
- the respective purchase prices and public offering prices, the proceeds to be received from the sale, if any, and other material terms of the
  offering;
- settlement of short sales entered into after the date of this prospectus;
- the names of any participating agents, broker-dealers or underwriters; and
- any applicable commissions, discounts, concessions and other items constituting compensation from the Selling Securityholders.

In connection with distributions of the securities or otherwise, the Selling Securityholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the securities in the course of hedging the positions they assume with Selling Securityholders. The Selling Securityholders may also sell the securities short and redeliver the securities to close out such short positions. The Selling Securityholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The Selling Securityholders may also pledge securities to a broker-dealer or other financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged securities pursuant to this prospectus (as supplemented or amended to reflect such transaction).

In order to facilitate the offering of the securities, any underwriters or agents, as the case may be, involved in the offering of such securities may engage in transactions that stabilize, maintain or otherwise affect the price of our securities. Specifically, the underwriters or agents, as the case may be, may overallot in connection with the offering, creating a short position in our securities for their own account. In addition, to cover overallotments or to stabilize the price of our securities, the underwriters or agents, as the case may be, may bid for, and purchase, such securities in the open market. Finally, in any offering of securities through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allotted to an underwriter or a broker-dealer for distributing such securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the securities above independent market levels. The underwriters or agents, as the case may be, are not required to engage in these activities, and may end any of these activities at any time.

The Selling Securityholders may solicit offers to purchase the securities directly from, and it may sell such securities directly to, institutional investors or others. In this case, no underwriters or agents would be involved. The terms of any of those sales, including the terms of any bidding or auction process, if utilized, will be described in the applicable prospectus supplement.

It is possible that one or more underwriters may make a market in our securities, but such underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for our securities. Our Ordinary Shares and Warrants are currently listed on the Nasdaq under the symbols "ALVO" and "ALVOW," respectively.

The Selling Securityholders may authorize underwriters, broker-dealers or agents to solicit offers by certain purchasers to purchase the securities at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we or the Selling Securityholders pay for solicitation of these contracts.

A Selling Securityholder may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by any Selling Securityholder or borrowed from any Selling Securityholder or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from any Selling Securityholder in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment). In addition, any Selling Securityholder may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

In effecting sales, broker-dealers or agents engaged by the Selling Securityholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the Selling Securityholders in amounts to be negotiated immediately prior to the sale.

In compliance with the guidelines of the Financial Industry Regulatory Authority ("FINRA"), the aggregate maximum discount, commission, fees or other items constituting underwriting compensation to be received by any FINRA member or independent broker-dealer will not exceed 8% of the gross proceeds of any offering pursuant to this prospectus and any applicable prospectus supplement.

If at the time of any offering made under this prospectus a member of FINRA participating in the offering has a "conflict of interest" as defined in FINRA Rule 5121 ("Rule 5121"), that offering will be conducted in accordance with the relevant provisions of Rule 5121.

To our knowledge, there are currently no plans, arrangements or understandings between the Selling Securityholders and any broker-dealer or agent regarding the sale of the securities by the Selling Securityholders. Upon our notification by a Selling Securityholder that any material arrangement has been entered into with an underwriter or broker-dealer for the sale of securities through a block trade, special offering, exchange distribution, secondary distribution or a purchase by an underwriter or broker-dealer, we will file, if required by applicable law or regulation, a supplement to this prospectus pursuant to Rule 424(b) under the Securities Act disclosing certain material information relating to such underwriter or broker-dealer and such offering.

Underwriters, broker-dealers or agents may facilitate the marketing of an offering online directly or through one of their affiliates. In those cases, prospective investors may view offering terms and a prospectus online and, depending upon the particular underwriter, broker-dealer or agent, place orders online or through their financial advisors.

In offering the securities covered by this prospectus, the Selling Securityholders and any underwriters, broker-dealers or agents who execute sales for the Selling Securityholders may be deemed to be "underwriters"

within the meaning of the Securities Act in connection with such sales. Any discounts, commissions, concessions or profit they earn on any resale of those securities may be underwriting discounts and commissions under the Securities Act.

The underwriters, broker-dealers and agents may engage in transactions with us or the Selling Securityholders, or perform services for us or the Selling Securityholders, in the ordinary course of business.

In order to comply with the securities laws of certain states, if applicable, the securities must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

The Selling Securityholders and any other persons participating in the sale or distribution of the securities will be subject to applicable provisions of the Securities Act and the Exchange Act, and the rules and regulations thereunder, including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of purchases and sales of any of the securities by, the Selling Securityholders or any other person, which limitations may affect the marketability of the shares of the securities.

We will make copies of this prospectus available to the Selling Securityholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Securityholders may indemnify any agent, broker-dealer or underwriter that participates in transactions involving the sale of the securities against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the Selling Securityholders against certain liabilities, including certain liabilities under the Securities Act, the Exchange Act or other federal or state law. Agents, broker-dealers and underwriters may be entitled to indemnification by us and the Selling Securityholders against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the agents, broker-dealers or underwriters may be required to make in respect thereof.

We have agreed with certain Selling Securityholders pursuant to the Subscription Agreements to use commercially reasonable efforts to keep the registration statement of which this prospectus constitutes a part effective until the earliest of (i) the third anniversary of the Closing, (ii) the date on which the Selling Securityholders cease to hold any Ordinary Shares issued pursuant to the Subscription Agreement, or (iii) on the first date on which the Selling Securityholder is able to sell all of its Ordinary Shares issued pursuant to the Subscription Agreements (or shares received in exchange therefor) under Rule 144 without the public information, volume or manner of sale limitations of such rule.

#### EXPENSES RELATED TO THE OFFERING

Set forth below is an itemization of the total expenses that are expected to be incurred by us in connection with the offer and sale of Ordinary Shares by the Selling Securityholders. With the exception of the SEC registration fee, all amounts are estimates.

	U.S. dollar
SEC Registration Fee	164,698
Legal Fees and Expenses	400,000
Accounting Fees and Expenses	150,000
Printing Expenses	187,500
Miscellaneous Expenses	57,802
Total	960,000

# SERVICE OF PROCESS AND ENFORCEMENT OF CIVIL LIABILITIES UNDER U.S. SECURITIES LAWS

Alvotech is incorporated in Luxembourg and conducts a majority of its operations through its subsidiary, Alvotech hf., located outside the United States. The majority of Alvotech's assets are located outside the United States. A majority of Alvotech's officers reside outside the United States and a substantial portion of the assets of those persons are located outside of the United States. As a result, it could be difficult or impossible for you to bring an action against Alvotech or against these individuals outside of the United States in the event that you believe that your rights have been infringed under the applicable securities laws or otherwise. Even if you are successful in bringing an action of this kind, the laws outside of the United States could render you unable to enforce a judgment against Alvotech's assets or the assets of Alvotech's officers.

# LEGAL MATTERS

The validity of our Ordinary Shares has been passed upon by Arendt & Medernach, Luxembourg counsel to Alvotech. We have been advised on U.S. securities matters by Cooley LLP.

# **EXPERTS**

The consolidated financial statements of Alvotech as of December 31, 2022 and 2021, and for each of the three years in the period ended December 31, 2022, included in this prospectus have been audited by Deloitte ehf. an independent registered public accounting firm, as stated in their report appearing herein. Such consolidated financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing. The offices of Deloitte ehf. are located at Smáratorgi 3, 201 Kópavogi, Iceland.

# WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act with respect to Ordinary Shares and Warrants offered in this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and our securities offered hereby, reference is made to the registration statement

and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

We are subject to the periodic reporting and other information requirements of the Exchange Act as applicable to a "foreign private issuer," and we will file annual reports and other information from time to time with the SEC in accordance with such requirements. Our SEC filings will be available to the public on the internet at a website maintained by the SEC located at *www.sec.gov*.

We also maintain an Internet website at *www.alvotech.com*. We will make available on our website, free of charge, the following documents as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC: our Annual Reports on Form 20-F; our reports on Form 6-K; amendments to these documents; and other information as may be required by the SEC. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

# INDEX TO FINANCIAL STATEMENTS

# Alvotech

Consolidated Financial Statements as of 31 December 2022 and 2021 and for the years ended 31 December 2022, 2021, and 2020

# Table of Contents

Report of Independent Registered Accounting Firm (PCAOB ID: 1490)	F-2
Consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss	F-3
Consolidated Statements of Financial Position	F-4 - F-5
Consolidated Statements of Cash Flows	F-6
Consolidated Statements of Changes in Equity	F-7
Notes to the Consolidated Financial Statements	F-8 - F-68

# Deloitte.

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Alvotech

# **Opinion on the Financial Statements**

We have audited the accompanying consolidated statements of financial position of Alvotech and subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of profit or loss and other comprehensive income or loss, changes in equity, and cash flows, for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

# **Going Concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1.5 to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1.5. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

# **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte ehf.

Kópavogur, Iceland

March 1, 2023

We have served as the Company's auditor since 2013.

Consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss for the years ended 31 December 2022, 2021, and 2020

USD in thousands, except for per share amounts	Notes	2022	2021	2020
Product revenue	5	24,836	_	_
License and other revenue	5	58,193	36,772	66,616
Other income		1,988	2,912	2,833
Cost of product revenue		(64,095)		—
Research and development expenses		(180,622)	(191,006)	(148,072)
General and administrative expenses		(186,742)	(84,134)	(58,914)
Operating loss		(346,442)	(235,456)	(137,537)
Share of net loss of joint venture	26	(2,590)	(2,418)	(1,505)
Finance income	7	2,549	51,568	5,608
Finance costs	7	(188,419)	(117,361)	(161,551)
Exchange rate differences		10,566	2,681	3,215
(Loss) / gain on extinguishment of financial liabilities	20	(27,311)	151,788	
Non-operating (loss) / profit		(205,205)	86,258	(154,233)
Loss before taxes		(551,647)	(149,198)	(291,770)
Income tax benefit	10	38,067	47,694	121,726
Loss for the year		(513,580)	(101,504)	(170,044)
Other comprehensive income / (loss)				
Item that will be reclassified to profit or loss in subsequent periods:				
Exchange rate differences on translation of foreign operations		(6,111)	(305)	5,954
Total comprehensive loss		(519,691)	(101,809)	(164,090)
Loss per share				
Basic and diluted loss for the year per share	11	(2.60)	(0.92)	(1.82)

The accompanying notes are an integral part of these Consolidated Financial Statements.

Consolidated Statements of Financial Position as of 31 December 2022 and 2021

# USD in thousands

Non-current assets	Notes	31 December 2022	31 December 2021
Property, plant and equipment	12	220,594	78,530
Right-of-use assets	13	47,501	126,801
Goodwill	14	11,643	12,367
Other intangible assets	15	25,652	21,509
Contract assets	5	3,286	1,479
Investment in joint venture	26	48,568	55,307
Other long-term assets		5,780	1,663
Restricted cash	16	25,187	10,087
Deferred tax assets	10	209,496	170,418
Total non-current assets		597,707	478,161
Current assets			
Inventories	17	71,470	39,058
Trade receivables	5	32,972	29,396
Contract assets	5	25,370	17,959
Other current assets	18	32,949	14,736
Receivables from related parties	24	1,548	1,111
Cash and cash equivalents	16	66,427	17,556
Total current assets		230,736	119,816
Total assets		828,443	597,977

 $\label{thm:companying} \textit{ notes are an integral part of these Consolidated Financial Statements.}$ 

Consolidated Statements of Financial Position as of 31 December 2022 and 2021

# USD in thousands

Equity	Notes	31 December 2022	31 December 2021
Share capital	19	2,126	135
Share premium	19	1,058,432	1,000,118
Other reserves	20, 22	30,582	_
Translation reserve		(1,442)	4,669
Accumulated deficit		(1,654,114)	(1,140,534)
Total equity		(564,416)	(135,612)
Non-current liabilities			
Borrowings	20	744,654	398,140
Derivative financial liabilities	27	380,232	_
Other long-term liability to related party	2	7,440	7,440
Lease liabilities	13	35,369	114,845
Long-term incentive plan	21	544	56,334
Contract liabilities	5	57,017	44,844
Deferred tax liability	10	309	150
Total non-current liabilities		1,225,565	621,753
Current liabilities			
Trade and other payables		49,188	28,587
Lease liabilities	13	5,163	7,295
Current maturities of borrowings	20	19,916	2,771
Liabilities to related parties	24	1,131	638
Contract liabilities	5	36,915	29,692
Taxes payable		934	841
Other current liabilities	25	54,047	42,012
Total current liabilities		167,294	111,836
Total liabilities		1,392,859	733,589
Total equity and liabilities		828,443	597,977

The accompanying notes are an integral part of these Consolidated Financial Statements.

Consolidated Statements of Cash Flows for the years ended 31 December 2022, 2021, and 2020

# USD in thousands

Cash flows from operating activities	Notes	2022	2021	2020
Loss for the year	110100	(513,580)	(101,504)	(170,044)
Adjustments for non-cash items:		(,)	( - ) )	( -,- ,
Gain on extinguishment of SARs liability	21	(4,803)	_	_
Share-listing expense	1.1	83,411	_	_
Long-term incentive plan expense	21	5,492	17,955	18,053
Depreciation and amortization	8	20,409	18,196	16,419
Impairment of property, plant and equipment	12	_	2,092	2,142
Impairment of other intangible assets	15	2,755	3,993	_
Share of net loss of joint venture	26	2,590	2,418	1,505
Finance income	7	(2,549)	(51,568)	(5,608)
Finance costs	7	188,419	117,361	161,551
Loss/(Gain) on extinguishment of financial liabilities	20	27,311	(151,788)	_
Share-based payments	22	10,317	_	_
Exchange rate difference		(10,566)	(2,681)	(3,215)
Income tax benefit	10	(38,067)	(47,694)	(121,726)
Operating cash flow before movement in working capital		(228,861)	(193,220)	(100,923)
Increase in inventories		(32,412)	(29,412)	(3,255)
(Increase) / decrease in trade receivables		(3,576)	(28,813)	21,771
Increase / (decrease) in liabilities with related parties		56	(453)	1,674
(Increase) / decrease in contract assets		(9,218)	15,286	(11,667)
Increase in other assets		(17,194)	(4,363)	(7,383)
Increase in trade and other payables		16,442	14,318	227
Increase in contract liabilities		19,396	21,470	24,019
(Decrease) / increase in other liabilities		(21,384)	5,160	7,134
Cash used in operations		(276,751)	(200,027)	(68,403)
Interest received		568	16	212
Interest paid		(35,372)	(28,004)	(5,664)
Income tax paid		(834)	(155)	(440)
-		(312,389)	(228,170)	
Net cash used in operating activities		(312,309)	(220,170)	(74,295)
Cash flows from investing activities	10	(27,000)	(20, 462)	(7.405)
Acquisition of property, plant and equipment	12	(37,880)	(20,462)	(7,485)
Disposal of property, plant and equipment	12	379	(20.171)	79
Acquisition of intangible assets	15	(11,122)	(20,171)	(4,497)
Restricted cash in connection with amended bond agreement	20	(14,914)		(5,000)
Net cash used in investing activities		(63,537)	(40,633)	(16,903)
Cash flows from financing activities				
Repayments of borrowings	20	(34,714)	(37,496)	(2,896)
Repayments of principal portion of lease liabilities	13	(11,147)	(7,350)	(6,087)
Proceeds from new borrowings	20	193,678	113,821	30,000
Proceeds on issue of equity shares	19	_	185,856	34,385
Transaction costs for amended borrowing agreements	20	(12,102)	_	_
Gross proceeds from the PIPE Financing	1.1	174,930	_	
Gross PIPE Financing fees paid	1.1	(5,562)	_	_
Proceeds from the Capital Reorganization	1.1	9,827	_	_
Proceeds from loans from related parties	20	160,000	_	_
Repayment of loans from related parties	20	(50,000)		
Net cash generated from financing activities		424,910	254,831	55,402
Increase / (decrease) in cash and cash equivalents		48,984	(13,972)	(35,796)
Cash and cash equivalents at the beginning of the year	16	17,556	31,689	67,403
Effect of movements in exchange rates on cash held		(113)	(161)	82
Cash and cash equivalents at the end of the year	16	66,427	17,556	31,689

Supplemental cash flow disclosures (Note 28)

 $\label{thm:companying} \textit{The accompanying notes are an integral part of these Consolidated Financial Statements.}$ 

 $Consolidated \ Statements \ of \ Changes \ in \ Equity \ for \ the \ years \ ended \ 31 \ December \ 2022, \ 2021, \ and \ 2020$ 

USD in thousands

	Share capital	Share premium	Other reserves	Translation reserve	Accumulated deficit	Total equity
At 1 January 2020	69	102,359	_	(980)	(868,986)	(767,538)
Loss for the year					(170,044)	(170,044)
Foreign currency translation differences				5,954		5,954
Total comprehensive loss		_	_	5,954	(170,044)	(164,090)
Increase in share capital	4	64,381	_	_	_	64,385
At 31 December 2020	73	166,740		4,974	(1,039,030)	(867,243)
Loss for the year			_	_	(101,504)	(101,504)
Foreign currency translation differences	_	_	_	(305)	_	(305)
Total comprehensive loss			_	(305)	(101,504)	(101,809)
Increase in share capital	62	833,378	_	_	_	833,440
At 31 December 2021	135	1,000,118		4,669	(1,140,534)	(135,612)
Loss for the year					(513,580)	(513,580)
Foreign currency translation differences	_	_	_	(6,111)	_	(6,111)
Total comprehensive loss				(6,111)	(513,580)	(519,691)
PIPE Financing	175	169,193	_	_	_	169,368
Settlement of SARs with shares	35	30,267	_	_	_	30,302
Capital Reorganization	1,731	(173,296)	_	_	_	(171,565)
Settlement of related party loans with Ordinary Shares	50	32,150	_		_	32,200
Recognition of share-based payments	_	_	14,548	_	_	14,548
Recognition of equity component of convertible bonds			16,034			16,034
At 31 December 2022	2,126	1,058,432	30,582	(1,442)	(1,654,114)	(564,416)

The accompanying notes are an integral part of these Consolidated Financial Statements.



#### 1. General information

Alvotech (the "Parent" or the "Company" or "Alvotech"), previously known as Alvotech Lux Holdings S.A.S., the surviving company after the Business Combination (as defined below) with, among other parties, Alvotech Holdings S.A. (the "Predecessor"), is a Luxembourg public limited company (société anonyme) incorporated and existing under the laws of the Grand Duchy of Luxembourg, having its registered office at 9, rue de Bitbourg, L-1273 Luxembourg, Grand Duchy of Luxembourg and is registered with the Luxembourg Trade and Companies' Register under number B 258884. The Company was incorporated on 23 August 2021. These consolidated financial statements were approved by the Group's Board of Directors, and authorized for issue, on 1 March 2023.

The Company and its subsidiaries (collectively referred to as the "Group") are a global biotech company specialized in the development and manufacture of biosimilar medicines for patients worldwide. The Group has commercialized a certain biosimilar product and has multiple biosimilar molecules.

# 1.1 Capital Reorganization

On 15 June 2022 (the "Closing Date"), the Company consummated the capital reorganization with Alvotech Holdings S.A. and OACB (the "Business Combination" or "Capital Reorganization") pursuant to the business combination agreement, dated as of 7 December 2021, as amended by an amendment agreement dated 18 April 2022 and 7 June 2022 (the "Business Combination Agreement"), by and among the Company, Oaktree Acquisition Corp. II ("OACB") and the Predecessor. The closing of the Business Combination resulted in the following transactions:

- OACB merged with and into the Company, whereby (i) all of the outstanding ordinary shares of OACB ("OACB Ordinary Shares") were exchanged for ordinary shares of Alvotech ("Ordinary Shares") on a one-for-one basis, pursuant to a share capital increase of Alvotech and (ii) all of the outstanding warrants of OACB ceased to represent a right to acquire OACB Ordinary Shares and now represent a right to be issued one Ordinary Share, with Alvotech as the surviving company in the merger. Prior to the merger OACB shares were redeemed, resulting in \$9.8 million of cash proceeds from the OACB trust account;
- Alvotech redeemed and canceled the initial shares held by the initial sole shareholder of Alvotech pursuant to a share capital reduction of Alvotech;
- The legal form of Alvotech changed from a simplified joint stock company (société par actions simplifiée) to a public limited liability company (société anonyme) under Luxembourg law; and
- The Predecessor merged with and into the Parent, whereby all outstanding ordinary shares of the Predecessor ("Predecessor Ordinary Shares") were exchanged for Ordinary Shares, pursuant to a share capital increase of Alvotech, with Alvotech as the surviving company in the merger.

Concurrently with the execution of the Business Combination Agreement, OACB and Alvotech entered into subscription agreements ("Subscription Agreements") with certain investors (the "PIPE Financing"). On 15 June 2022, immediately prior to the closing of the Business Combination, the PIPE Financing was closed, pursuant to the Subscription Agreements, in which subscribers collectively subscribed for 17,493,000 Ordinary Shares at \$10.00 per share for an aggregate subscription price equal to \$174.9 million.

As part of the Business Combination, Predecessor shareholders were granted a total of 38,330,000 Ordinary Shares subject to certain vesting conditions ("Predecessor Earn Out Shares"). Former OACB shareholders were granted a total of 1,250,000 Ordinary Shares subject to certain vesting conditions ("OACB Earn Out Shares"). Additionally, as part of the Business Combination the Company assumed the 10,916,647 outstanding warrants ("OACB Warrants"), on substantially the same contractual terms and conditions as were in effect immediately prior to the Business Combination. See Note 27 for further details.



The Business Combination was accounted for as a capital reorganization. Under this method of accounting, OACB was treated as the "acquired" company for financial reporting purposes, with Alvotech Holdings S.A. being the accounting acquirer and accounting predecessor. Accordingly, the capital reorganization was treated as the equivalent of Alvotech issuing shares at the closing of the Business Combination for the net assets of OACB as of the Closing Date, accompanied by a recapitalization. The capital reorganization, which was not within the scope of IFRS 3 since OACB did not meet the definition of a business in accordance with that guidance, was accounted for within the scope of IFRS 2. In accordance with IFRS 2, Alvotech recorded a one-time non-cash share listing expense of \$83.4 million, recognized as a general and administrative expense, based on the excess of the fair value of Alvotech shares issued, at the Closing Date, over the fair value of OACB's identifiable net assets acquired. The fair value of shares issued was estimated based on a market price of \$9.38 per share as of 15 June 2022.

	Shares	(in 000s)
OACB Shareholders		
Class A Shareholders	976,505	
Class B Shareholders	5,000,000	
OACB Earn Out Shares	1,250,000	
Total Alvotech Shares issued to OACB shareholders	7,226,505	
Fair value of Shares issued to OACB as of 15 June 2022	<del></del>	\$ 56,060
Fair value of OACB Earn Out Shares issued to OACB as of 15 June 2022		9,100
Estimated fair market value		65,160
Adjusted net liabilities of OACB as of 15 June 2022		(18,251)
Difference – being the share listing expense		83,411

In connection with the Business Combination and PIPE Financing, the Company incurred \$28.5 million of transaction costs, which represent legal, financial advisory, and other professional fees in connection with the Business Combination and PIPE Financing, during the year ended 31 December 2022. Of this amount, \$5.6 million represented equity issuance costs related to PIPE Financing that were capitalized in share premium. The remaining \$22.9 million was recognized as general and administrative expense.

# 1.2 Information about subsidiaries and joint ventures

Entity name	Principal activity	Issued and paid capital (presented in whole shares)	Place of establishment	Proportion of and voting por Alvot	wer held by
Alvotech hf	Biopharm.	3,885,102	Iceland	100.00%	100.00%
Alvotech Germany GmbH	Biopharm.	31,182	Germany	100.00%	100.00%
Alvotech Swiss AG	Biopharm.	153,930	Switzerland	100.00%	100.00%
Alvotech Hannover GmbH	Biopharm.	29,983	Germany	100.00%	100.00%
Alvotech Malta Ltd	Group Serv.	80,450	Malta	100.00%	100.00%
Alvotech USA Inc	Biopharm.	10	USA	100.00%	100.00%
Alvotech UK Ltd	Group Serv.	135	UK	100.00%	100.00%
Alvotech Manco ehf	Group Serv.	203,046	Iceland	100.00%	_
Alvotech Biosciences India Private Ltd	Biopharm	96,113	India	100.00%	_
Fasteignafelagið Sæmundur hf	Real estate	12,965,337	Iceland	100.00%	_
Alvotech & CCHN Biopharmaceutical Co. Ltd*	Biopharm,	110,000,021	China	50.00%	50.00%

<sup>\*</sup> Alvotech & CCHN Biopharmaceutical Co. Ltd. is an unconsolidated joint venture (see Note 26).

#### Notes to the Consolidated Financial Statements

#### 1.3 Information about shareholders

Significant shareholders of the Company are Aztiq Pharma Partners S.à r.l. (Aztiq) and Alvogen Lux Holdings S.à r.l. (Alvogen), with 40.7% and 35.8% ownership interest as of 31 December 2022, respectively. The remaining 23.5% ownership interest is held by various entities, with no single shareholder holding more than 2.4% ownership interest as of 31 December 2022.

Aztiq and Alvogen held 45.1% and 39.5% ownership interest as of 31 December 2021, respectively. The remaining 15.4% ownership interest was held by various entities, with no single shareholder holding more than 2.4% ownership interest as of 31 December 2021.

# 1.4 Impact of COVID-19, the Russia and Ukraine Conflict, and Economic Conditions

With the ongoing COVID-19 pandemic, the Group created a COVID-19 task force which implemented a business continuity plan to address and mitigate the impact of the pandemic on the Group's business and operations across sites. As a result, in the short-term, the pandemic has not had a material impact on the Group's financial condition, results of operations, the timelines for biosimilar product development, expansion efforts or the Group's operations as a whole. However, the extent to which the pandemic will impact the Group's business, biosimilar product development and expansion efforts, corporate development objectives and the value of and market for the Ordinary Shares will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate direction of the pandemic, emergence and spread of new variants of the disease, travel restrictions, quarantines, social distancing, business closure requirements and the effectiveness of other actions taken globally to contain and treat the disease. The global economic slowdown, the overall disruption of global supply chains and distribution systems, the effects of this on the work of appropriate regulatory authorities in different regions and the other risks and uncertainties associated with the pandemic could have a material adverse effect on the Group's business, financial condition, results of operations and growth prospects.

In February 2022, Russia began a military invasion of Ukraine. The global response to this invasion could have an adverse impact on the Group's business, including the effects of relocating clinical trials and the Group's ability to market and sell products in Europe, by creating disruptions in global supply chain, and potentially having an adverse impact on the global economy, European economy, financial markets, energy markets, currency rates, and otherwise. Currently, the conflict has not had a material impact on the Group's financial condition, results of operations, the timelines for biosimilar product development, expansion efforts or the Group's operations as a whole.

The Company believes that inflation will have a general impact on the business in line with overall price increases, increases in the cost of borrowing, and operating in an inflationary economy. We cannot predict the timing, strength, or duration of any inflationary period or economic slowdown or its ultimate impact on the Company. If the conditions in the general economy significantly deviate from present levels and continue to deteriorate it could have a material adverse effect on the Group's business, financial condition, results of operations and growth prospects.

# 1.5 Going concern

The Group has primarily funded its operations with proceeds from the issuance of ordinary shares and the issuance of loans and borrowings to both related parties and third parties. The Group has also incurred recurring losses since its inception, including net losses of \$513.6 million, \$101.5 million and \$170.0 million for the years ended 31 December 2022, 2021, and 2020, respectively, and had an accumulated deficit of \$1,654.1 million as of 31 December 2022. The Group has not generated positive operational cash flow, largely due to the continued focus on biosimilar product development and expansion efforts.

Notes to the Consolidated Financial Statements

As of 31 December 2022, the Group had cash and cash equivalents, excluding restricted cash, of \$66.4 million and current assets less current liabilities of \$63.4 million. In February and March 2022, Alvotech received \$25.0 million from each of Alvogen and Aztiq pursuant to interest free loan advances provided by both significant shareholders, who agreed to settle these outstanding amounts in Ordinary Shares rather than cash in July 2022. The closing of the Business Combination and the PIPE Financing provided the Group with net proceeds of \$131.9 million that is expected to be used to finance the continuing development and commercialization of its biosimilar products. Additionally, during the year ended 31 December 2022 the Company received \$110.0 million in loans from Alvogen, successfully amended and upsized the outstanding Senior Bonds resulting in \$57.9 million of net cash proceeds, along with net cash proceeds of \$73.4 million from the issuance of the Tranche A and Tranche B Convertible Bonds and Facility Loans, of which \$50.0 million was used to repay amounts drawn under the Alvogen Facility.

On 25 January 2023, the Company issued an additional \$10.0 million in Tranche B Convertible Bonds. Holders of the Tranche B Convertible Bonds may elect, at their sole discretion, to convert all or part of the principal amount and accrued interest into Alvotech Ordinary Shares at a conversion price of \$10.00 per share on December 31, 2023, or June 30, 2024. See Note 29 for further details.

On 10 February 2023, Alvotech completed a private placement, at the then-prevailing exchange rates, of its Ordinary Shares at a purchase price of \$11.57 per Ordinary Share, resulting in proceeds of \$137.0 million and transaction costs of \$4.8 million. See Note 29 for further details.

Additionally, the Group expects to continue to source its financing during the development of its biosimilar products from new and existing out-license contracts with customers. In light of these conditions and events, along with those noted in Note 1.4, management evaluated whether there is substantial doubt about the Group's ability to continue as a going concern for at least one year after the date that the consolidated financial statements are issued. Based on the cash on hand, funding received, and projected future cash flows, management concluded that the Company has the ability to continue as a going concern for at least one year after the date that the consolidated financial statements are issued.

As such, the consolidated financial statements have been prepared on a going concern basis. However, although management continues to pursue these plans, there is no assurance that the Group will be successful in obtaining sufficient funding on terms acceptable to the Group to fund continuing operations, if at all. If financing is obtained, the terms of such financing may adversely affect the holdings or the rights of the Group's shareholders. The ability to obtain funding, therefore, is outside of management's control and is a material uncertainty that may cast significant doubt upon the Group's ability to continue as a going concern.

# 2. Summary of significant accounting policies

# 2.1 Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance and in compliance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), which comprise all standards and interpretations approved by the IASB.

All amendments to IFRSs issued by the IASB that are effective for annual periods that begin on or after 1 January 2022 have been adopted as further described within the footnotes to the consolidated financial statements. The Group has not adopted any standards or amendments to standards in issue that are available for early adoption.

The consolidated financial statements have been prepared on a historical cost basis, except for certain financial assets and financial liabilities which have been measured at fair value. Historical cost is generally based on the fair value of the consideration given in exchange for goods and services. The consolidated financial statements are presented in U.S. Dollar (USD) and all values are rounded to the nearest thousand unless otherwise indicated.

#### Notes to the Consolidated Financial Statements

#### 2.2 Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities controlled by the Company and its subsidiaries. Control is achieved when the Company:

- · has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

When the Company has less than a majority of the voting rights of an investee, it has power over the investee when the voting rights are sufficient to give it the practical ability to direct the relevant activities of the investee unilaterally. The Company considers all relevant facts and circumstances in assessing whether or not the Company's voting rights in an investee are sufficient to give it power, including:

- the size of the Company's holding of voting rights relative to the size and dispersion of holdings of the other vote holders;
- potential voting rights held by the Company, other vote holders or other parties;
- · rights arising from other contractual arrangements; and
- any additional facts and circumstances that indicate that the Company has, or does not have, the current ability to direct the relevant activities at the time that decisions need to be made, including voting patterns at previous shareholders' meetings.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statements of profit or loss and other comprehensive income or loss from the date the Company gains control until the date when the Company ceases to control the subsidiary. The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control.

All intra-group transactions, balances, income and expenses are eliminated in full in consolidation.

# 2.3 Investments in joint ventures

To the extent the Group concludes that it does not control, and thus consolidate, a joint venture, the Group accounts for its interest in joint ventures using the equity method of accounting. As such, investments in a joint venture are initially recognized at cost and the carrying amount is subsequently adjusted for the Group's share of the profit or loss of the joint venture, as well as any distributions received from the joint venture. The Group carries its ownership interest in a joint venture as "Investment in joint venture" on the consolidated statements of financial position. The Group's profit or loss includes its share of the profit or loss of the joint venture and, to the extent applicable, other comprehensive income or loss for the Group includes its share of other comprehensive income or loss of the joint venture. The Group's share of a joint venture's profit or loss in a particular year is presented as "Share of net loss of joint venture" in the consolidated statements of profit or loss and other comprehensive income or loss.

The carrying amount of equity-accounted investments is assessed for impairment as a single asset. Impairment losses are incurred only if there is objective evidence of impairment as a result of loss events that have an impact on estimated future cash flows and that can be reliably estimated. Losses expected as a result of future events are not recognized. The Group did not recognize any impairment losses related to its investment in the joint venture for the years ended 31 December 2022, 2021 or 2020.

Refer to Note 26 for additional information regarding the Group's joint venture as of 31 December 2022 and 2021 and for the years ended 31 December 2022, 2021 and 2020.

Notes to the Consolidated Financial Statements

# 2.4 Critical accounting judgments and key sources of estimation uncertainty

The preparation of the consolidated financial statements in conformity with IFRS requires Group management to make judgments, estimates and assumptions about the reported amounts of assets, liabilities, income and expenses that are not readily apparent from other sources.

The estimates and associated assumptions are based on information available when the consolidated financial statements are prepared, historical experience and other factors that are considered to be relevant. Judgments and assumptions involving key estimates are primarily made in relation to the measurement and recognition of revenue (as described in Note 2.6 and Note 5), the measurement and recognition of extinguishment of financial liabilities (as described in Note 2.18 and Note 20), the valuation of derivative financial liabilities (as described in Note 2.18 and Note 25), the valuation of management share appreciation rights (SARs) (as described in Note 2.18 and Note 21), and the valuation of deferred tax assets (as described in Note 2.14 and Note 10). Apart from those involving estimations, critical accounting judgments include the Group's evaluation as to whether it controls its joint venture in China (as described in Note 2.3 and 26) and material uncertainties with respect to the Group's going concern assessment (as described in Note 1.5).

Existing circumstances and assumptions may change due to events arising that are beyond the Group's control. Therefore, actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

# 2.5 Segment reporting

The Group operates and manages its business as one operating segment based on the manner in which the Chief Executive Officer, the Group's chief operating decision maker, assesses performance and allocates resources across the Group.

# 2.6 Revenue recognition

#### Product revenue

The Company recognizes revenue from the sale of its biosimilar product to commercial partners, identified as the customer, when control is transferred, and the performance obligations have been satisfied. This is when the title passes to the customer, which is upon shipment of the product. At that point, the commercial partner has full discretion over the channel and price to sell the products. Revenue is recognized based on the net selling price from the commercial partners, which is considered to be the transaction price and includes estimated rebates, returns and chargebacks, and other forms of variable consideration recognized by the Customer. Variable consideration is accounted for by the Company only to the extent that it is highly probable that a significant reversal in the revenue recognized will not occur. Variable consideration, which includes any adjustments to the net selling price, is estimated based on the most likely amount method on a contract-by-contract basis.

# Out-licensing revenue

The majority of the Group's revenue is generated from long-term out-license contracts which provide the customer with an exclusive right to market and sell products in a particular territory once such products are approved for commercialization. These contracts typically include the Group's promises to continue development of the underlying compound and to provide supply of the product to the customer upon



commercialization. The Group concludes that the license, development services and commercial supply are separate performance obligations. This is because customers generally have the capabilities to perform the necessary development, manufacturing and commercialization activities on their own or with readily available resources and have the requisite expertise in the industry and the territory for which the license has been granted. Further, the intellectual property is generally in a later phase of development at the time the license is granted such that any subsequent development activities performed by the Group are not expected to significantly modify or transform the intellectual property. The fact that the Group is contractually obligated to perform development activities for and provide commercial supply to the customer does not impact this conclusion. The Group's promise to provide commercial supply to its customers is contingent upon the achievement of regulatory approval in the particular territory for which the license has been granted.

The consideration to which the Group is entitled pursuant to these contracts generally includes upfront payments and payments based upon the achievement of development and regulatory milestones. All contracts include a potential refund obligation whereby the Group must refund the consideration paid by the customer in the event of a technical failure or the occurrence of certain other matters that result in partial or full cancellation of the contract. As such, the entire transaction price is comprised of variable consideration, which is estimated using the most likely amount method due to the binary nature of the outcomes under these contracts. Such variable consideration is included in the transaction price only when it is highly probable that doing so will not result in a significant reversal of cumulative revenue recognized when the underlying uncertainty associated with the variable consideration is subsequently resolved. The Group does not account for a significant financing component since a substantial amount of consideration promised by the customer is variable and the amount or timing of that consideration varies on the basis of a future event that is not substantially within the control of either party. Certain contracts also include commercialization milestones upon the first commercial sale of a product in a particular territory, as well as royalties. Commercialization milestones and royalties are accounted for as sales-based royalties; therefore, such amounts are not included in the transaction price and recognized as revenue until the underlying sale that triggers the milestone or royalty occurs.

Upfront payments, when applicable, are received in advance of transferring control of all goods and services. Therefore, a portion of upfront payments is recorded as a contract liability upon receipt. Due to the existence of refund provisions, upfront payments and certain development milestone payments are generally included in the transaction price upon submission of the first clinical trial application to the respective regulatory agency, since it is at this point in time that a significant reversal of cumulative revenue recognized related to such payments is no longer highly probable. Other development and regulatory milestones may not be included in the transaction price until such milestones are achieved due to the degree of uncertainty associated with achieving these milestones. Contract liabilities are presented on the consolidated statements of financial position as either current or non-current based upon forecasted performance. In certain contracts, the Group may transfer control of goods and services, and thus recognize revenue, prior to having the right to invoice the customer. In these circumstances, the Group recognizes contract assets for revenue recognized, and subsequently reclasses the contract asset to trade receivables upon issuing an invoice and the right to consideration is only conditional on the passage of time. Contract assets are presented on the consolidated statements of financial position as either current or non-current based upon the expected timing of settlement.

The standalone selling prices of the development services and the license to intellectual property are not directly observable and, therefore, are estimated. The standalone selling price of the development services is estimated based on the expected costs to be incurred during the development period, using various data points such as the underlying development budget, contractual milestones and performance completed at the time of entering into the contract with a customer. The standalone selling price of the license is estimated using the residual approach on the basis that the Group licenses intellectual property for a broad range of amounts and has not previously licensed intellectual property on a standalone basis. Therefore, the Group



first allocates the transaction price to the development services and subsequently allocates the remainder of the transaction price to the license. If product is still in early phase development and the constraint on variable consideration has not been resolved, all the transaction price is allocated to the development service.

The standalone selling price of the commercial supply is directly observable and the stated prices in the Group's supply contracts reflect the standalone selling price of such goods.

The licenses to intellectual property are right of use licenses on the basis that the ongoing development work performed by the Group does not significantly affect the intellectual property to which the customer has rights. Therefore, control of the license transfers to the customer at the point in time when the right to use the license is granted to the customer. The license is generally granted to the customer at the time the contract is executed with the customer.

The Group satisfies its performance obligation related to the development services over time as the Group's performance enhances the value of the licensed intellectual property controlled by the customer throughout the performance period. The Group recognizes revenue using a cost-based input measure since this measure best reflects the progress of the development services and, therefore, the pattern of transfer of control of the services to the customer. In certain instances, the Group may subcontract services to other parties for which the Group is ultimately responsible. Costs incurred for such subcontracted services are included in the Group's measure of progress for satisfying its performance obligation. Changes in the total estimated costs to be incurred in measuring the Group's progress toward satisfying its performance obligation may result in adjustments to cumulative revenue recognized at the time the change in estimate occurs.

Upon the achievement of regulatory approval and the commencement of commercial sale of its products, the Group will satisfy its performance obligation related to commercial supply at the point in time when control of the manufactured product is transferred to the customer. Transfer of control for such goods will occur in accordance with the stated shipping terms.

The Group does not incur incremental costs of obtaining a contract with a customer that would require capitalization. Costs to fulfill performance obligations are not incurred in advance of performance and, as such, are expensed when incurred.

# Other revenue

Other revenue primarily consists of clinical trial support services rendered by the Group for its customers, which is recognized as the service is provided. Revenue for such services is presented in the consolidated statements of profit or loss and other comprehensive income or loss net of any discounts.

# 2.7 Cost of product revenue

Cost of product revenue includes the cost of inventory sold, labor costs, manufacturing overhead expenses and reserves for expected scrap, as well as shipping and freight costs and royalty costs related to in-license agreements.

# 2.8 Research and development expenses

Research and development expenses primarily consist of personnel costs, material and other lab supply costs, facility costs and internal and external costs related to the execution of studies and other development program advancement initiatives. Such expenses also include costs incurred in preparation for commercial launch, such as designing and developing commercial-scale manufacturing capabilities and processes, quality control processes, production asset validation and other related activities. The costs also include amortization, depreciation and impairment losses related to software, property, plant and equipment, and right-of-use assets used in research and development activities and pre-commercial manufacturing and quality control activities.

# Notes to the Consolidated Financial Statements

An internally generated intangible asset arising from the Group's development is recognized only if the Group can demonstrate: the technical feasibility of completing the intangible asset so that it will be available for use or sale; the intent to complete the intangible asset and use or sell it; how the intangible asset will generate probable future economic benefits; the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible assets is the sum of the expenditures incurred from the date when the intangible asset first meets the aforementioned recognition criteria. If an internally-generated intangible asset cannot be recognized, the related development expenditure is charged to profit or loss in the period in which it is incurred.

Expenditures related to research and development activities are generally recognized as an expense in the period in which they are incurred. Due to significant regulatory uncertainties and other uncertainties inherent in the development of pharmaceutical products, the Group did not capitalize any research and development expenses as internally-developed intangible assets during the years ended 31 December 2022, 2021 and 2020.

# 2.9 General and administrative expenses

General and administration expenses primarily consist of personnel-related costs, including salaries and other related compensation expense, for corporate and other administrative and operational functions including finance, human resources, information technology and legal, as well as facility-related costs. These costs relate to the operation of the business and are not related to research and development initiatives.

Expenditures related to general and administration activities are recognized as an expense in the period in which they are incurred.

# 2.10 Finance income and finance cost

Finance income consists of changes in the fair value of derivative financial liabilities and interest income. Interest income from a financial asset is recognized when it is probable that the economic benefits will flow to the Group and the amount of income can be measured reliably. Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount on initial recognition.

Finance cost consists of changes in the fair value of derivative financial liabilities, interest expense related to lease liabilities and borrowings, accretion of borrowings and amortization of deferred debt issue costs.

# 2.11 Foreign currency translation

The consolidated financial statements are presented in U.S. Dollars, which is the Group's presentation currency. The Group maintains the financial statements of each entity within the Group in its respective functional currency. The majority of the Group's expenses are incurred in U.S. Dollar and Icelandic Krona, and the majority of the Company's cash and cash equivalents are held in a combination of U.S. Dollars and Euros. Transactions in currencies other than the Group's presentation currency (foreign currencies) are recognized at the rates of exchange prevailing at the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items carried at fair value that are denominated in foreign currencies are retranslated at the

#### Notes to the Consolidated Financial Statements

rates prevailing at the date when the fair value was determined. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated. Exchange differences on monetary items are recognized in profit or loss in the period in which they arise.

Exchange differences arising on translation of a foreign controlled subsidiary are recognized in other comprehensive income or loss and accumulated in a translation reserve within equity. The cumulative translation amount is reclassified to profit or loss if and when the net investment in the foreign controlled subsidiary is disposed.

#### 2.12 Fair value measurements

The Group measures certain financial liabilities at fair value through profit or loss (FVTPL) at each reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure the fair values of such financial liabilities, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

Fair values are categorized into different levels in a fair value hierarchy based on the inputs used in the valuation techniques, as follows:

- Level 1: quoted prices in active markets for identical assets and liabilities;
- Level 2: inputs other than quoted prices that are observable for the asset or liability, either directly (e.g., prices) or indirectly (e.g., derived from prices); and
- Level 3: inputs for the asset or liability that are unobservable.

The carrying amounts of cash and cash equivalents, restricted cash, trade receivables, other current assets, contract assets, trade and other payables and accrued and other liabilities in the Group's consolidated statements of financial position approximate their fair value because of the short maturities and nature of these instruments.

For liabilities that are measured at fair value on a recurring basis, the Group determines whether transfers have occurred between levels in the fair value hierarchy by reassessing the inputs used in determining fair value at the end of each reporting period.

# 2.13 Goodwill and other intangible assets

#### Goodwill

Acquisitions are first reviewed to determine whether a set of assets acquired constitute a business and should be accounted for as a business combination. If the assets acquired do not meet the definition of a business, the Group will account for the transaction as an asset acquisition. If the definition of a business combination is met, the Group will account for the transaction using the acquisition method of accounting. The consideration transferred in a business combination is measured at fair value, which is calculated as the sum of the acquisition-date fair values of the assets transferred by the Group, liabilities incurred by the Group to the former owners of the acquiree and the equity interests issued by the Group in exchange for control of the acquiree. Acquisition-related costs are recognized in the consolidated statements of profit or loss and other comprehensive income or loss as incurred.

Goodwill represents the excess of the purchase price of the business combination over the Group's interest in the net fair value of the identifiable assets, liabilities, contingent liabilities, the amount of any

# Notes to the Consolidated Financial Statements

noncontrolling interests in the acquiree and the fair value of the acquirer's previously held equity interest in the acquiree. Goodwill is reviewed for impairment at least annually, and whenever there is an indication that the asset may be impaired. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. The value in use calculation is performed using discounted expected future cash flows. The discount rate applied to these cash flows is based on the weighted average cost of capital and reflects current market assessments of the time value of money.

If the initial accounting for a business combination is incomplete by the end of the reporting period in which the business combination occurs, the Group reports provisional amounts for the items for which the accounting is incomplete. Those provisional amounts are adjusted during the measurement period, or as additional assets or liabilities are recognized, to reflect new information obtained about facts and circumstances that existed at the acquisition date that, if known, would have affected the amounts recognized at that date.

The Group did not complete any business combinations during the years ended 31 December 2021, and 2020. Refer to Note 1.1 for the Business Combination completed during the year ended 31 December 2022.

# Other intangible assets

Other intangible assets consist of software, customer relationships, and intellectual property rights licensed from Biosana (see Note 2.18). Intangible assets acquired in a business combination are identified and recognized separately from goodwill if they satisfy the definition of an intangible asset and their fair values can be reliably measured. The cost of intangible assets is their fair value at the acquisition date.

Intangible assets with finite useful lives are reported at cost less accumulated amortization and accumulated impairment losses. Amortization is recognized on a straight-line basis over an asset's estimated useful life. The estimated useful life and amortization method are reviewed at each balance sheet date, with the effect of any changes in estimate being accounted for on a prospective basis. Intangible assets that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The following useful lives are used in the calculation of amortization:

Software	3-5 years
Customer relationships	7 years

Intangible assets with indefinite useful lives are reviewed for impairment at least annually, and whenever there is an indication that the asset may be impaired. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. The value in use calculation is performed using discounted expected future cash flows. The discount rate applied to these cash flows is based on the weighted average cost of capital and reflects current market assessments of the time value of money.

# 2.14 Income tax

Income tax includes the current tax and deferred tax charge recorded in the consolidated statements of profit or loss and other comprehensive income or loss.



# Current tax

The current tax expense is based on taxable profit for the year. Taxable profit differs from 'profit before tax' as reported in the consolidated statements of profit or loss and other comprehensive income or loss because it excludes items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Group's current tax expense is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Accruals for tax contingencies are made when it is not probable that a tax authority will accept the tax position, based upon management's interpretation of applicable laws and regulations and the expectation of how the tax authority will resolve the matter. Accruals for tax contingencies are measured using either the most likely amount or the expected value amount depending on which method the entity expects to better predict the resolution of the uncertainty.

# Deferred tax

Deferred tax is provided in full for all temporary differences between the carrying amounts of assets and liabilities in the consolidated financial statements and the corresponding tax bases used in the computation of taxable profit, except to the extent the temporary difference arises from:

- The initial recognition of an asset or a liability in a transaction that is not a business combination and that affects neither the taxable profit nor accounting profit;
- The initial recognition of residual goodwill (for deferred tax liabilities only); or
- Investments in subsidiaries, branches, associates and joint ventures, where the Group is able to control the timing of the reversal of the temporary difference and it is not probable that it will reverse in the foreseeable future.

Deferred tax liabilities and assets are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset realized, based on tax rates and tax laws that have been enacted or substantively enacted by the end of the reporting period. The measurement of deferred tax liabilities and deferred tax assets reflects the tax consequences that would follow from the manner in which the Group expects, at the balance sheet date, to recover or settle the carrying amount of the assets and liabilities.

Deferred tax liabilities are generally recognized for all taxable temporary differences. Deferred tax assets are generally recognized for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax is charged or credited to the consolidated statements of profit or loss and other comprehensive income or loss, except when the tax arises from a business combination or it relates to items charged or credited directly to equity, in which case the deferred tax is also taken directly to equity.

Deferred tax assets and liabilities are offset when they relate to income taxes levied by the same taxation authority and the Group intends to settle its current tax assets and liabilities on a net basis in that taxation authority.

# 2.15 Property, plant and equipment

Property, plant and equipment is recognized as an asset when it is probable that future economic benefits associated with the asset will flow to the Group and the cost of the asset can be measured in a reliable manner. Property, plant and equipment which qualifies for recognition as an asset are initially measured at cost.

# Notes to the Consolidated Financial Statements

The cost of property, plant and equipment includes an asset's purchase price and any directly attributable costs of bringing the asset to working condition for its intended use.

Depreciation is calculated and recognized as an expense on a straight-line basis over an asset's estimated useful life. The estimated useful lives, residual values and depreciation method are reviewed at each balance sheet date, with the effect of any changes in estimate accounted for on a prospective basis. The following useful lives are used in the calculation of depreciation:

Facility	40 years
Facility equipment	5-20 years
Computer equipment	3 years
Leasehold improvements	3-15 years
Furniture and fixtures	5 years

Certain of the Group's property, plant and equipment assets have been pledged to secure borrowings as further described in Note 20. Significant disposals of pledged assets are subject to lender approval. Upon disposal or retirement of an asset, the difference between the sales proceeds, if applicable, and the carrying amount of the asset is recognized in the consolidated statements of profit or loss and other comprehensive income or loss at the time of disposal or retirement.

At the end of each reporting period, or sooner if events triggering an interim impairment assessment occur, the Group reviews the carrying amounts of its property, plant and equipment to determine whether there is any indication that the value of such assets are impaired. Triggering events that warrant an interim impairment assessment include, but are not limited to, the technical obsolescence of equipment or failure of such equipment to meet regulatory requirements. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss and the carrying amount of the asset is reduced to its recoverable amount, which is the higher of fair value less costs of disposal and value in use.

# 2.16 Inventories

Inventories, which consist of raw materials and supplies, work in progress and finished goods are stated at the lower of cost or net realizable value. Net realizable value is the expected sales price less completion costs and costs to be incurred in marketing, selling and distributing the inventory. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

Inventories include direct costs for raw materials and supplies and, as applicable, direct and indirect labor and overhead expenses that have been incurred to bring inventories to their present location and condition. See Note 17 for further details.

If the net realizable value is lower than the carrying amount, a write-down of inventory is recognized for the amount by which the carrying amount exceeds net realizable value. During the years ended 31 December 2022, 2021, and 2020, write-down of inventories amounted to \$2.1 million, \$1.2 million and \$1.3 million, respectively, due to product expiration. There were no reversals of inventory write-downs during the years ended 31 December 2022, 2021, and 2020. See Note 17 for further details.

The Group does not pledge inventories as collateral to secure its liabilities.



#### 2.17 Financial assets

# Recognition of financial assets

Financial assets are recognized when the Group becomes a party to the contractual provisions of the instrument. Financial assets are initially measured at fair value. Transaction costs that are directly attributable to the acquisition or issue of financial assets, other than financial assets measured at FVTPL, are added to or deducted from the fair value of the financial assets, as appropriate, on initial recognition. Transaction costs directly attributable to the acquisition of financial assets at FVTPL are recognized immediately in profit or loss. There were no transaction costs related to the acquisition of financials assets in 2022, 2021 or 2020. All of the Group's financial assets are measured at amortized cost as of 31 December 2022 and 2021.

# Financial assets measured at amortized cost

Financial assets measured at amortized cost are debt instruments that give rise to contractual cash flows that are solely payments of principal and interest on the principal amount outstanding. The Group's financial assets measured at amortized cost are trade receivables, certain other current assets, receivables from related parties, restricted cash and cash equivalents.

Interest income is recognized by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial.

# Impairment of financial assets

The Group recognizes a loss allowance for expected credit losses (ECL) on its trade receivables and other debt instruments that are measured at amortized cost. In addition, although contract assets are not financial assets, a loss allowance for ECL are also recognized for such assets. ECL is based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The amount of ECL is updated at each reporting date to reflect changes in credit risk since initial recognition of the respective financial instrument.

The Group always recognizes lifetime ECL for trade receivables and contract assets. The expected credit losses on these financial assets are estimated using a provision matrix based on the Group's historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current as well as the forecasted direction of conditions at the reporting date, including time value of money where appropriate.

The Group writes off a financial asset when there is no reasonable expectation of recovery, such as information indicating that the debtor is in severe financial difficulty and there is no realistic prospect of recovery. A trade receivable or contract asset that is considered uncollectible is written off against the allowance account. Subsequent recoveries of amounts previously written off are credited against the allowance account. Changes in the carrying amount of the allowance account are recognized in profit or loss. The Group did not write off any trade receivables or contract assets during the years ended 31 December 2022, 2021, and 2020.

The Group estimates impairment for related party receivables on an individual basis. No impairment is recognized for restricted cash or cash and cash equivalents as management has estimated that the effects of any calculated ECL would be immaterial.

#### Notes to the Consolidated Financial Statements

#### Derecognition of financial assets

The Group derecognizes a financial asset when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another party. If the Group neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Group recognizes its retained interest in the asset as well as an associated liability. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognizes a collateralized borrowing for the proceeds received.

On derecognition of a financial asset, the difference between the asset's carrying amount and the sum of the consideration received and receivable and the cumulative gain or loss that had been recognized in other comprehensive income or loss and accumulated in equity is recognized in profit or loss.

## 2.18 Financial liabilities

#### Financial liabilities

The Group's financial liabilities consist of trade and other payables, certain other current liabilities loans and borrowings, lease liabilities, derivative financial instruments, long-term incentive plans, share appreciation right plans and other long-term liability to a related party. All financial liabilities are initially measured at fair value. Loans and borrowings are recorded net of directly attributable transaction costs and less the value attributable to any embedded derivative financial instruments, if applicable.

The Group derecognizes financial liabilities when, and only when, the Group's obligations are discharged, cancelled, substantially modified or have expired. Additionally, management elected, as part of its accounting policy, to recognize the difference between the carrying amount of the financial liabilities and the fair value of the consideration paid for the extinguishment in the consolidated statement of profit or loss and other comprehensive income or loss.

#### Financial liabilities subsequently measured at amortized cost

After initial recognition, financial liabilities other than derivative financial instruments and awards issued pursuant to long-term incentive plans are subsequently measured at amortized cost using the effective interest method. The effective interest method is a method of calculating the amortized cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that discounts all estimated future cash payments through the expected life of the financial liability, or a shorter period if appropriate, to the amortized cost of a financial liability. The effective interest rate includes the effects of any discount or premium on acquisition of the financial liability, as well as any fees or costs incurred upon acquisition.

## Financial liabilities subsequently measured at FVTPL

## Derivative financial instruments

Certain rights and features pursuant to borrowing arrangements and other contracts may provide the counterparty with one or more financial instruments that need to be evaluated and potentially accounted for separately by the Group. These financial instruments are either embedded in a host instrument or are treated as a separate financial instrument if they are contractually transferable independent from the host instrument. Such rights and features pursuant to the Group's contracts with both third parties and related parties include earn out rights, conversion rights and warrant rights.



Equity conversion features within host debt instruments that meet the definition of a derivative and have economic and risk characteristics that are not closely related to the host instrument are embedded derivatives that are separated from the host instrument and accounted for separately. As part of the accounting for embedded derivatives or separate financial instruments, management considers the appropriate accounting classification under IAS 32. Embedded derivatives and separate financial instruments that meet the fixed-for-fixed criteria are classified as equity and initially measured at fair value. Warrant rights that provide the holder with an option to purchase ordinary shares at a specified price or pursuant to a specified formula are generally separate derivative financial instruments that are accounted for as derivative liabilities. Earn Out Shares grant the holder with a variable number of Ordinary Shares based on certain vesting conditions tied to the stock price and are accounted for as derivative liabilities. In the event that the fair value of any derivative liabilities, determined using unobservable inputs, exceeds the transaction price of a borrowing arrangement, the Group records a deferred loss at the inception of the borrowing arrangement for the difference between the fair value of the derivative liabilities and the transaction price of the borrowing arrangement. Such deferred losses are recognized over the term of the related borrowing arrangement using the straight-line method of amortization. The deferred loss is netted against derivative financial liabilities on the consolidated statements of financial position. Amortization of the deferred loss is recognized as a component of "Finance costs" in the consolidated statements of profit or loss and other comprehensive income or loss.

The Group recognized derivative liabilities related to the Predecessor Earn Out Shares, OACB Earn Out Shares and assumed OACB warrants. Additionally, the Group recognized an embedded derivative for the conversion feature associated with the Tranche A Convertible Bonds, as further described in Note 20. These features are liability-classified, rather than equity-classified, because the Group is obligated to issue a variable number of ordinary shares to the holder upon conversion or exercise of the feature. Therefore, these derivative liabilities were initially recorded at fair value and remeasured to fair value at each reporting period with gains and losses arising from changes in the fair value recognized in finance income or finance costs, as appropriate.

The fair values of the derivative liabilities were determined using a valuation approach that incorporated a range of inputs that are both observable and unobservable in nature. The inputs used in the initial and subsequent fair value measurements predominantly relate to (i) the price of the Group's Ordinary Shares (ii) the volatility of the Group's Ordinary Shares, (ii) a risky discount rate corresponding to the credit risk associated with the repayment of the host debt instruments, and (iii) the probabilities of each derivative being exercised by the holder and the timing of such exercises. The probabilities are determined based on all relevant internal and external information available and are reviewed and reassessed at each reporting date.

The Group will derecognize any derivative liabilities if and when the rights are exercised by the holders or the time period during which the rights can be exercised expires.

## Other long-term liability to related party

The Group's other long-term liability to a related party arose from its acquisition of rights for the commercialization of the Group's biosimilar Adalimumab product in certain territories in Asia from Lotus Pharmaceutical Co. Ltd., a related party, during the year ended 31 December 2020. Pursuant to the terms of the asset acquisition, the Group made an upfront payment of \$1.9 million and is required to pay \$7.4 million upon the commercial launch of Adalimumab in China. The Group concluded that the event triggering future payment is probable and, as such, recorded the full amount of the liability as a non-current liability in the consolidated statements of financial position as of 31 December 2022 and 2021. The upfront payment and contingent payment amounts were charged to "Research and development expense" in the consolidated statements of profit or loss and other comprehensive income or loss.

## Other current liabilities

In December 2021, Alvotech entered into an exclusive global licensing agreement with BiosanaPharma (Biosana) for the co-development of AVT23. Under the terms of the agreement, Biosana granted Alvotech an exclusive global right for AVT23, which will be produced using Biosana's proprietary process

#### Notes to the Consolidated Financial Statements

technology. In exchange, Alvotech made an upfront payment of \$7.5 million upon the signing of the agreement (the "upfront payment"), with an additional \$7.5 million due at the earlier of the closing of the Business Combination (see Note 27) or 30 April 2022 (the "deferred upfront payment"). In addition, Alvotech may be obligated to pay Biosana up to an aggregate of \$13.5 million, payable upon the achievement of various development and regulatory milestones, as well as certain tiered royalty payments based on commercial sales of AVT23. The agreement terminates 15 years after the launch of AVT23 and is subject to certain customary termination rights.

The Group concluded that the deferred upfront payment is probable and, as such, recorded the full amount of the liability in "Other current liabilities" on the consolidated statement of financial position as of 31 December 2021. The upfront payment and the deferred upfront payment amounts were capitalized as other intangible assets in the consolidated statement of financial position and will be amortized over the useful life of 15 years. The Group will accrue the additional contingent payments if and when the related milestones and other contingencies are deemed probable of being achieved.

## Long-term incentive plans

## Share appreciation rights

The Group issued to certain current and former employees share appreciation rights (SARs) that require settlement in connection with the occurrence of specified, future triggering events. Grants occurred from 2015 through 2020. The awards include a combination of vesting conditions, such as service and performance conditions, as well as non-vesting conditions depending on the particular award. The individuals retain their vested awards upon termination of employment with the Group. Settlement amounts are determined by the change in the Group's market value from the grant date of the SAR until the triggering events occur. The SARs do not expire at a specific date.

Pursuant to the terms of the SAR agreements, management determined that the Group cannot avoid paying cash to settle the awards and, therefore, SARs are liability-classified in the consolidated statements of financial position. Accordingly, SARs were recorded at fair value and were subsequently remeasured each reporting period with the change in fair value reflected as a gain or loss in the consolidated statements of profit or loss and other comprehensive income or loss, as appropriate. The fair value of the SARs was determined using the Black-Scholes-Merton pricing model. In connection with the closing of the Business Combination, the Company reached a settlement agreement for share appreciation rights previously awarded to certain current and former employees. The remaining share appreciation rights were settled through the issuance of fully vested RSUs under the Management Incentive Plan on 1 December 2022. See Note 21 for further details.

### Employee incentive plan

The Group also sponsors an employee incentive plan for certain qualifying employees. Under the plans, such employees are entitled to cash payments upon achievement of key milestones, such as a research and development milestone or the occurrence of an exit event. The awards include a combination of vesting conditions, such as service and performance conditions, as well as non-vesting conditions depending on the particular award. Since the Group cannot avoid paying cash to settle the awards, the employee incentive plan is liability-classified in the consolidated statements of financial position. Accordingly, awards issued pursuant to the employee incentive plan are recorded at fair value and are subsequently remeasured each reporting period with the change in fair value reflected as a gain or loss in the consolidated statements of profit or loss and other comprehensive income or loss, as appropriate. Employee incentive plan liabilities are presented as either current or non-current on the consolidated statements of financial position based on the anticipated timing of settlement.



The fair value of the employee incentive plan awards is determined by estimating the probability of success in reaching the specified milestones and other levers, such as the anticipated timing of potential milestone achievement. See Note 21 for further details.

## Management Incentive Plan

The Group can issue share options, restricted share units ("RSUs"), and other share-based awards under the Company's new incentive plan (the "Management Incentive Plan") which was approved by the Board in June 2022. Awards issued under the Management Incentive Plan are accounted for in accordance with IFRS 2. Share-based payments are classified as equity-settled share-based payments as the Company intends to settle the awards with equity and has the commercial substance to do so. Share-based payments are measured at the grant date fair value of the instruments issued and recognized over the expected vesting periods. The number of shares expected to vest are reviewed and adjusted at the end of each reporting period such that the amount of expense recognized shall be based on the number of equity instruments that will eventually vest. See Note 22 for further details.

#### 2.19 Litigation and other contingencies

The Group may, from time to time, become involved in legal proceedings arising out of the normal course of its operations. For instance, as a developer and manufacturer of biosimilars, the Group may be subject to lawsuits alleging patent infringement or other similar claims filed by the reference product sponsor. Similarly, the Group may utilize patent challenge procedures to challenge the validity, enforceability or infringement of the reference product sponsor's patents. Other parties may also file patent infringement claims against the Group alleging that the Group's products or manufacturing process techniques infringe their patents.

The Group establishes reserves for specific legal matters when it determines that the likelihood of an unfavorable outcome is probable and the loss is reasonably estimable. When such conditions are not met for a specific legal matter, no reserve is established. Although management currently believes that resolving claims against the Group, including claims where an unfavorable outcome is reasonably possible, will not have a material impact on the liquidity, results of operations, or financial condition of the Group, these matters are subject to inherent uncertainties and management's view of these matters may change in the future. It is possible that an unfavorable outcome of a lawsuit or other contingency could have a material impact on the liquidity, results of operations, or financial condition of the Group.

Significant judgment is required in both the determination of probability of loss and the determination as to whether the amount of loss can be reasonably estimated. Accruals are based only on information available at the time of the assessment, due to the uncertain nature of such matters. As additional information becomes available, management reassesses potential liabilities related to pending claims and litigation and may revise its previous estimates, which could materially affect the Group's results of operations in a given period.

The Group maintains liability insurance coverages for various claims and exposures. The Group's insurance coverage limits its maximum exposure on claims; however, the Group is responsible for any uninsured portion of losses. Management believes that present insurance coverage is sufficient to cover potential exposures.

## 2.20 Leases

The Group assesses whether a contract is or contains a lease at inception of the contract. The Group recognizes a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for those with a lease term of twelve months or less and leases of low value assets. For these leases, the Group recognizes the lease payments as an operating expense on a straight-line



basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed. The Group's leased assets consist of various real estate, fleet and equipment leases.

Right-of-use assets reflect the initial measurement of the lease liability, lease payments made at or before the lease commencement date and any initial direct costs less lease incentives that may have been received by the Group. These assets are subsequently measured at cost less accumulated depreciation, impairment losses and remeasurements of the underlying lease liability. Right-of-use assets are depreciated over the shorter of the lease term and the useful life of the underlying asset. If a lease transfers ownership of the underlying asset to the Group or the lease includes a purchase option that the Group is reasonably certain to exercise, the related right-of-use asset is depreciated over the useful life of the underlying asset. Depreciation starts at the commencement date of the lease.

Lease liabilities are initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the Group uses its incremental borrowing rate, which is the rate of interest that the Group would need to pay to borrow, on a collateralized basis, an amount equal to the lease payments over a similar term in a similar economic environment based on information available at the commencement date of the lease. The lease payments included in the measurement of the lease liability comprise fixed payments (including in-substance fixed payments) less any incentives, variable lease payments that depend on an index or rate, expected residual guarantees and the exercise price of purchase options reasonably certain to be exercised by the Group.

The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability, using the effective interest method, and by reducing the carrying amount to reflect payments made during the lease term. The Group remeasures the lease liability if the lease term has changed, when lease payments based on an index or rate change or when a lease contract is modified and the modification is not accounted for as a separate lease.

Variable payments that do not depend on an index or rate are not included in the measurement of the lease liability and the right-of-use asset. The related payments are recognized as an expense in the period in which the event or condition that triggers those payments occurs.

As a practical expedient, lessees are not required to separate non-lease components from lease components, and instead account for any lease and associated non-lease components as a single lease component. The Group has used this practical expedient.

### 2.21 Loss per share

Holders of the Predecessor Earn Out Shares and OACB Earn Out Shares have equal dividend and participation rights to the ordinary shareholders. However, these participating securities are classified as liabilities and as such, the shares held are not included in the weighted average number of ordinary shares outstanding in the basic loss per share calculation.

The calculation of basic loss per share is based on the loss for the year attributable to ordinary shareholders of the Group and the weighted average number of ordinary shares outstanding during the period.

Diluted loss per share is computed by dividing the loss for the year attributable to ordinary shareholders of the Group by the weighted average number of ordinary shares outstanding in the basic loss per share calculation, both of which are adjusted for the effects of all dilutive potential ordinary shares. Antidilutive effects of potential ordinary shares, which result in an increase in earnings per share or a reduction in loss per share, are not recognized in the computation of diluted loss per share.

#### Notes to the Consolidated Financial Statements

#### 3. New accounting standards

## New standards and interpretations adopted and effective during the periods

The following new IFRS standards have been adopted by the Group effective 1 January 2022:

## IAS 16 (Amendments) - Property, Plant and Equipment - Proceeds before Intended Use

The IASB issued amendments to IAS 16, which prohibit deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced before that asset is available for use; that is, proceeds from items being sold while bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Consequently, an entity recognizes such sales proceeds and related costs in profit or loss. The entity measures the cost of those items in accordance with IAS 2 Inventories. The amendments also clarified the meaning of 'testing whether an asset is functioning properly'. IAS 16 now specifies this as assessing whether the technical and physical performance of the asset is such that it is capable of being used in the production or supply of goods or services, for rental to others, or for administrative purposes. The adoption of the amendments did not have a material impact on the consolidated financial statements of the Group.

#### IAS 37 (Amendment) – Onerous Contracts – Cost of Fulfilling a Contract

The IASB issued amendments to IAS 37 to specify that the 'cost of fulfilling' a contract comprises the 'costs that relate directly to the contract'. Costs that relate directly to a contract consist of both the incremental costs of fulfilling that contract (examples would be direct labor or materials) and an allocation of other costs that relate directly to fulfilling contracts (an example would be the allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract). The amendments apply to contracts for which the entity has not yet fulfilled all its obligations at the beginning of the annual reporting period in which the entity first applies the amendments. Comparatives are not restated. Instead, the entity shall recognize the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings or other component of equity, as appropriate, at the date of initial application. The adoption of the amendments did not have a material impact on the consolidated financial statements of the Group.

## Annual Improvements to IFRS Standards 2018-2020 Cycle

### IFRS 9 Financial Instruments

The IASB issues amendments on IFRS 9, which clarifies that in applying the '10 percent' test to assess whether to derecognize a financial liability, an entity includes only fees paid or received between the entity (the borrower) and the lender, including fees paid or received by either the entity or the lender on the other's behalf. The amendment is applied prospectively to modifications and exchanges that occur on or after the date the entity first applies the amendment. The adoption of the amendments did not have a material impact on the consolidated financial statements of the Group.

### New and revised IFRS standards in issue but not yet effective

The following new standards are not yet adopted by or effective for the Group and have not been applied in preparing these consolidated financial statements.



IFRS 10 and IAS 28 (Amendments) - Sale or Contribution of Assets between Investor and its Associate or Joint Venture:

The IASB issues amendments to IFRS 10 and IAS 28, which relate to situations where there is a sale or contribution of assets between an investor and its associate or joint venture. The amendments state that gains or losses resulting from the loss of control of a subsidiary that does not contain a business in a transaction with an associate or a joint venture that is accounted for using the equity method, are recognized in the parent's profit or loss only to the extent of the unrelated investors' interests in that associate or joint venture. Similarly, gains and losses resulting from the remeasurement of investments retained in any former subsidiary (that has become an associate or a joint venture that is accounted for using the equity method) to fair value are recognized in the former parent's profit or loss only to the extent of the unrelated investors' interests in the new associate or joint venture. The effective date of the amendments has yet to be set by the Board; however, earlier application of the amendments is permitted. The Group anticipates that the application of these amendments may have an impact on the consolidated financial statements in future periods should such transactions arise.

## IAS 1 (Amendments) - Classification of Liabilities as Current or Non-Current

The IASB issues amendments to IAS 1, which affect the presentation of liabilities as current or non-current in the statement of financial position. The amendment does not impact the amount or timing of recognition of any asset, liability, income or expenses, or the information disclosed about those items. The amendments clarify that the classification of liabilities as current or non-current is based on rights that are in existence at the end of the reporting period, specify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability, explain that rights are in existence if covenants are complied with at the end of the reporting period, and introduce a definition of 'settlement' to make clear that settlement refers to the transfer to the counterparty of cash, equity instruments, other assets or services. The amendments are applied retrospectively for annual periods beginning on or after 1 January 2023, with early application permitted. The Group anticipates that the application of these amendments may have an impact on the consolidated financial statements in future periods.

Annual Improvements to IFRS Standards 2018-2020 Cycle

The Annual Improvements include amendments to the following Standards that are relevant to the Group:

#### IFRS 16 Leases

The IASB issues amendments on IFRS 16, which removes the illustration of the reimbursement of leasehold improvements. As the amendment to IFRS 16 only regards an illustrative example, no effective date is stated.

#### IAS 1 Presentation of Financial Statements, Practice statement 2 and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors

The aim to improve accounting policy disclosures and to help users of the financial statements to distinguish between changes in accounting estimates and changes in accounting policies. The amendment is effective for annual periods beginning on or after 1 January 2023.

## IAS 12 Income Taxes

These require companies to recognize deferred tax on transactions that, on initial recognition give rise to equal amounts of taxable and deductible temporary differences. The amendment is effective for annual periods beginning on or after 1 January 2023.



The Group anticipates that the application of these amendments will not have a material impact on the consolidated financial statements.

## 4. Segment reporting

As disclosed in Note 2, the Group operates and manages its business as one operating segment.

The majority of the Group's revenue is generated from long-term out-license contracts which provide the customer with exclusive rights to a particular territory, which generally span multiple countries or a particular continent, as well as the Group's promises to continue development of the underlying compound and to provide supply of the product to the customer upon commercialization. Therefore, based on the nature of the customer agreements, revenue information is not currently available on a country-by-country basis.

Revenue from customers based on the geographic market in which the revenue is earned, which predominantly aligns with the rights conveyed to the Group's customers pursuant to its out-license contracts, is as follows (in thousands):

	2022	2021	2020
North America	30,780	11,660	37,928
Europe	39,433	20,509	19,710
Asia	6,798	1,323	4,107
Other	6,018	3,280	4,871
	83,029	36,772	66,616

Non-current assets, excluding financial instruments and deferred tax assets, based on the location of the asset is as follows (in thousands):

	2022	2021
North America	240	439
Europe	334,837	249,803
Asia and Other	3,715	2,194
	338,792	252,436

Revenue from transactions with individual customers that exceed ten percent or more of the Group's total revenue is as follows (in thousands, except for percentages):

	202	2022		2022 2021		2020	
	Revenue	% Total	Revenue	% Total	Revenue	% Total	
Customer A	17,940	21.6%	10,070	27.4%	36,270	54.4%	
Customer B	38,376	46.2%	18,369	50.0%	18,572	27.9%	



#### Revenue and other income

## Revenue from contracts with customers

## Disaggregated revenue

The following table summarizes the Groups' revenue from contracts with customers, disaggregated by the type of good or service and timing of transfer of control of such goods and services to customers (in thousands):

	2022	2021	2020
Product revenue (point in time revenue recognition)	24,836	_	_
License revenue (point in time revenue recognition)	424	1,453	24,067
Research and development and other service revenue (over time revenue recognition)	57,769	35,319	42,549
	83,029	36,772	66,616

## Reassessment of variable consideration

Subsequent changes to the estimate of the transaction price are generally recorded as adjustments to revenue in the period of change. The Group updates variable consideration estimates on a quarterly basis. The quarterly changes in estimates did not result in material adjustments to the Group's previously reported revenue or trade receivables during the years ended 31 December 2022, 2021, and 2020.

## Contract assets and liabilities

A reconciliation of the beginning and ending balances of contract assets and contract liabilities is shown in the table below (in thousands):

	Contract Assets	Contract Liabilities
31 December 2020	34,724	53,066
Contract asset additions	21,525	_
Amounts transferred to trade receivables	(36,811)	_
Customer prepayments	_	34,577
Revenue recognized		(13,107)
31 December 2021	19,438	74,536
Contract asset additions	29,823	_
Amounts transferred to trade receivables	(19,690)	_
Customer prepayments	_	46,127
Revenue recognized	_	(26,782)
Foreign currency adjustment	(915)	51
31 December 2022	28,656	93,932

The net increase in contract assets as of 31 December 2022 is primarily due revenue recognized when the performance obligation has been met which is offset by the transfer of such amounts to trade receivables on the basis that the Group's right to that consideration is no longer contingent on its performance. The net increase in contract liabilities as of 31 December 2022 is due to customer prepayments in advance of the Group's performance. As of 31 December 2022, \$3.3 million and \$25.4 million are recorded as non-current contract assets and current contract assets, respectively. Non-current contract assets will materialize over the



next 2 to 3 years. As of 31 December 2022, \$57.0 million and \$36.9 million are recorded as non-current contract liabilities and current contract liabilities, respectively. Non-current contract liabilities will be recognized as revenue over the next 2 to 5 years as either services are rendered or contractual milestones are achieved, depending on the performance obligation to which the payment relates.

## Remaining performance obligations

Due to the long-term nature of the Group's out-license contracts, the Group's obligations pursuant to such contracts represent partially unsatisfied performance obligations at year-end. The revenues under existing out-license contracts with original expected durations of more than one year are estimated to be \$283.0 million. The Group expects to recognize the majority of this revenue over the next 3 years.

## Out-license agreements

## Teva Pharmaceutical Industries Ltd. (Teva)

In August 2020, the Group entered into an exclusive strategic agreement with Teva for the commercialization in the United States of five of the Group's biosimilar product candidates. The initial pipeline contains biosimilar candidates addressing multiple therapeutic areas. Under this agreement, the Group will be responsible for the development, registration and supply of the biosimilars, while Teva will be exclusively commercializing the products in the United States pursuant to an intellectual property license granted by the Group to Teva.

In connection with the agreement, Teva made an upfront payment of \$40.0 million. The Group also received \$35.0 million in development milestones and is entitled to receive up to an additional \$50.0 million in development milestones, \$175.0 million in regulatory milestones and milestones due upon the first commercial sale of the biosimilar product candidates and \$200.0 million in contingent payments based upon the achievement of cumulative net sales amounts. Subject to some limitations, as consideration for supply of product the Group will receive 40% of the value of Teva's net sales of the products.

On 27 February 2023, the Group and Teva signed an amendment to licence & development agreement. As part of that amendment, the Group agreed to provide future financial consideration to Teva to assist with the cost of launching and marketing the licensed biosimilar products.

## STADA Arzneimittel AG (STADA)

In November 2019, the Group entered into an exclusive strategic agreement with STADA for the commercialization of seven biosimilars in all key European markets and selected markets outside Europe. The initial pipeline contains biosimilar candidates aimed at treating autoimmunity, oncology, ophthalmology and inflammatory conditions. Under this agreement, the Group will be responsible for the development, registration and supply of the biosimilars, while STADA will be exclusively commercializing the products in the relevant territories pursuant to an intellectual property license granted by the Group to STADA.

In connection with the agreement, STADA made an upfront payment of \$5.9 million. The Group has received \$78.6 million in development milestones through the year ended 31 December 2022. The Group is also entitled to receive up to an aggregate of \$130.9 million in additional development milestones, \$60.1 million in regulatory milestones and milestones due upon the first commercial sale of the biosimilar product candidates and \$11.8 million in contingent payments based upon the achievement of cumulative net sales amounts. The Group is also expected to receive a royalty of approximately 40% of the estimated net selling price from STADA's and its affiliates' commercialization of the contracted biosimilars.

#### Notes to the Consolidated Financial Statements

## 6. Salaries and other employee expenses

The average number of individuals employed by the Group during the years ended 31 December 2022, 2021, and 2020 was 858, 645, and 488, respectively. The aggregate salary and other employee expenses incurred by the Group for these employees were as follows (in thousands):

	2022	2021	2020
Salary expense	92,082	67,433	45,904
Defined contribution plan expense (1)	10,052	7,694	5,234
Long-term incentive plan expense	5,481	17,955	18,053
Share-based payments (see Note 22)	10,317	_	_
Other employee expense	11,670	10,274	10,186
Temporary labor	5,838	6,164	3,441
	135,440	109,520	82,818

(1) Defined contribution plan expense consists of costs incurred by the Group for employees of certain subsidiaries that are required by local laws to participate in pension schemes. These pension schemes are not sponsored or administered by the Group. Pursuant to the requirements of the schemes, the Group is required to contribute a certain percentage of its payroll costs to the pension schemes. Such contributions are charged to the consolidated statements of profit or loss and other comprehensive income or loss as they become payable in accordance with the rules of the pension schemes.

Salaries and other employee expense is included within the consolidated statements of profit or loss and other comprehensive income or loss as follows (in thousands):

	2022	2021	2020
Cost of product revenue	42,501		
Research and development expenses	52,962	71,588	49,043
General and administrative expenses	39,977	37,932	33,775
Total salary and other employee expenses	135,440	109,520	82,818

#### 7. Finance income and finance cost

Finance income earned during the years ended 31 December 2022, 2021 and 2020 is as follows (in thousands):

		2021	2020
Changes in the fair value of derivatives (see Note 27)	1,637	51,549	5,393
Interest income from cash and cash equivalents	556	18	166
Other interest income	356	1	49
	2,549	51,568	5,608



Finance cost incurred during the years ended 31 December 2022, 2021, and 2020 is as follows (in thousands):

	2022	2021	2020
Changes in the fair value of derivatives (see Note 27)	96,981	2,804	60,823
Interest on debt and borrowings	71,452	106,548	91,985
Consenting fee (see Note 20)	7,430	_	_
Loss on remeasurement of bonds (see Note 20)	6,511	_	_
Interest on lease liabilities (see Note 13)	6,022	6,423	5,481
Amortization of deferred debt issue costs	23	1,586	3,262
	188,419	117,361	161,551

## 8. Depreciation, amortization and impairment

Depreciation, amortization and impairment expenses incurred during the years ended 31 December 2022, 2021 and 2020 are as follows (in thousands):

	2022	2021	2020
Depreciation and impairment of property, plant and equipment (see Note 12)	9,807	10,666	10,363
Depreciation of right of use assets (see Note 13)	9,869	8,699	7,188
Amortization and impairment of intangible assets (see Note 15)	3,488	4,916	1,010
	23,164	24,281	18,561

Depreciation, amortization and impairment expense is included within the consolidated statements of profit or loss and other comprehensive income or loss as follows (in thousands):

	2022	2021	2020
Cost of product revenue	10,053		_
Research and development expenses	9,757	21,764	16,358
General and administrative expenses	3,354	2,517	2,203
Total depreciation, amortization and impairment expense	23,164	24,281	18,561

## 9. Audit fees

	2022	2021	2020
Financial Statement audit fees	2,615	5,502	382
Other fees, including tax services	676	136	607
Total fees	3,291	5,638	989

Audit fees for 2021 include fees for the audit of the PCAOB uplift of the consolidated financial statements for 2019 and 2020. Other fees for 2022 include review services for the F-4 and other SEC filings.

Notes to the Consolidated Financial Statements

#### 10. Income tax

Taxation recognized in the consolidated statements of profit or loss and other comprehensive income or loss during the years ended 31 December 2022, 2021 and 2020 is as follows (in thousands):

Current tax			
	2022	2021	2020
Direct taxes - current	1,015	706	248
Direct taxes – prior year	(115)	491	
Total current tax	900	1,197	248
Deferred tax			
Current	(54,236)	(48,414)	(121,974)
Prior year	15,269	(477)	_
Total deferred tax	(38,967)	(48,891)	(121,974)
Total income tax benefit	(38,067)	(47,694)	(121,726)

The prior year deferred tax impact of \$15.3 million mainly relates to foreign currency impact on losses denominated in Icelandic krona.

The factors affecting the tax benefit during the years ended 31 December 2022 and 2021 relate to the recognition of a deferred tax asset on accumulated tax losses, as management assessed that it was probable that the accumulated tax losses would be fully utilized in the coming years, as further described below.

There were no accruals for tax contingencies during the years ended 31 December 2022, 2021, and 2020.

The effective tax rate for the year of 6.9% (2021: 32.0%, 2020: 41.7%) is lower than the applicable Luxembourgish statutory rate of corporation tax. The reconciling items between the statutory rate and the effective tax rate are as follows:

	2022	2021	2020
Tax rate	24.9%	24.9%	24.9%
Effect of tax rate in foreign jurisdictions	(2.4%)	(8.2%)	(4.9%)
Recognition of tax losses	_	_	27.9%
Permanent differences	(8.9%)	30.4%	_
Non-recognition of tax losses	(3.8%)	(15.0%)	(6.2%)
Other items	(2.9%)	(0.1%)	
Effective tax rate	6.9%	32.0%	41.7%
Other items	(3.8%) (2.9%)	(0.1%)	(6.2%) — 41.7%

The movement in net deferred taxes during the years ended 31 December 2022 and 2021 is as follows (in thousands):

	2022	2021
Balance at 1 January	170,268	121,647
Deferred tax credited to profit or loss	38,919	48,621
Balance at 31 December	209,187	170,268
Deferred tax assets	209,496	170,418
Deferred tax liabilities	(309)	(150)

Where there is a right of offset of deferred tax balances within the same tax jurisdiction, IAS 12 requires these to be presented after such offset in the consolidated statements of financial position. The closing deferred tax balances included above are after offset; however, the disclosure of deferred tax assets by category below are presented before such offset.

#### Notes to the Consolidated Financial Statements

The amount of deferred tax recognized in the consolidated statements of financial position as of 31 December 2022 and 2021 is as follows (in thousands):

	2022	2021
Deferred tax assets attributable to temporary differences in respect of tax losses	205,290	158,330
Deferred tax assets attributable to other temporary differences	6,832	12,088
Deferred tax liabilities attributable to other temporary differences	(2,935)	(150)
Net deferred tax assets	209,187	170,268

A deferred tax liability of \$2.9 million and \$0.2 million has been recognized in relation to the difference in measurement basis of customer relationships and other ordinary timing differences as of 31 December 2022 and 2021, respectively.

A deferred tax asset has been recognized in relation to ordinary timing differences arising from various provisions, reserves, employee benefits and tax losses carried forward in the group. The recognition of the deferred tax asset on the Icelandic tax losses, since 2020, is backed by the Group's latest ten-year forecast whereby profit associated with product and milestone revenue is significant and provides considerable headroom over and above the level needed to support full recognition of such losses. A deferred tax asset of \$209.5 million and \$170.4 million is recognized as of 31 December 2022 and 2021, respectively.

These tax losses expire as follows (in thousands):

2023-2025	35,751
2026-2028	210,224
Later	836,536
	1,082,511

## 11. Loss per share

Basic loss per share is computed by dividing loss for the year by the weighted average number of ordinary shares outstanding during the period.

Diluted loss per share is computed by adjusting the calculation of basic loss per share for the effects of dilutive potential ordinary shares from financial instruments that may be converted or exercised into ordinary shares of the Group. For the year ended 31 December 2022, 148,857,998 potential ordinary shares pursuant to the RSUs, Senior Bond Warrants, Aztiq Convertible Bond, December Convertible Bonds, OACB Warrants, Predecessor Earn Out Shares, and OACB Earn Out Shares were excluded in the calculation of diluted loss per share, since the effect of doing so would result in a reduction of loss per share and thus be antidilutive. For the year ended 31 December 2021, there were no potential ordinary shares pursuant to such agreements as all conversion, warrant and funding rights associated with these agreements had been exercised or otherwise expired (refer to Note 21 for further details). Therefore, the calculation of diluted loss per share did not differ from the calculation of basic loss per share. For the year ended 31 December 2020 there were 57,084,128 potential ordinary shares pursuant to convertible shareholder loan agreements, convertible bond agreements and warrant agreements, respectively, were not included in the calculation of diluted loss per share, since the effect of doing so would result in a reduction of loss per share and thus be antidilutive.



The calculation of basic and diluted loss per share for the years ended 31 December 2022, 2021, and 2020 is as follows (in thousands, except for share and per share amounts):

	2022	2021	2020
Earnings			
Loss for the year	(513,580)	(101,504)	(170,044)
Number of shares			
Weighted average number of ordinary shares outstanding	197,721,710	110,673,309	93,648,813
Basic and diluted loss per share	(2.60)	(0.92)	(1.82)

# 12. Property, plant and equipment

Property, plant and equipment consists of facility and computer equipment, furniture, fixtures and leasehold improvements. Movements within property, plant and equipment during the years ended 31 December 2022 and 2021 are as follows (in thousands):

	Facility	Facility Equipment	Furniture, fixtures and leasehold improvements	Computer equipment	Total
Cost					
Balance at 1 January 2022	_	88,510	32,395	1,551	122,456
Reclassification of assets	_	25,486	(25,486)	—	_
Additions	115,000	35,156	2,706	357	153,219
Disposals	_	(2,959)	_	_	(2,959)
Translation difference		(1,043)	(17)	51	(1,009)
Balance at 31 December 2022	115,000	145,150	9,598	1,959	271,707
Depreciation					
Balance at 1 January 2022	_	33,853	8,614	1,459	43,926
Reclassification of assets	_	5,985	(5,985)	_	_
Depreciation	359	8,752	621	75	9,807
Disposals	_	(2,597)	_	_	(2,597)
Translation difference		9	(17)	(15)	(23)
Balance at 31 December 2022	359	46,002	3,233	1,519	51,113
Net carrying amount					
Balance at 31 December 2022	114,641	99,148	6,365	440	220,594
		Facility equipment	Furniture, fixtures and leasehold improvements	Computer equipment	Total
Cost					
Balance at 1 January 2021		70,308	27,600	1,513	99,421
Additions		19,345	4,845	69	24,259
Translation difference		(1,143)	(50)	(31)	(1,224)
Balance at 31 December 2021		88,510	32,395	1,551	122,456
Depreciation					
Balance at 1 January 2021		25,540	7,016	1,419	33,975
Depreciation		6,870	1,637	67	8,574

Notes to the Consolidated Financial Statements

	Facility equipment	Furniture, fixtures and leasehold improvements	Computer equipment	Total
Impairment	2,092			2,092
Translation difference	(649)	(39)	(27)	(715)
Balance at 31 December 2021	33,853	8,614	1,459	43,926
Net carrying amount				
Balance at 31 December 2021	54,657	23,781	92	78,530

On 16 November 2022 the Group entered into a share purchase agreement (the "Share Purchase Agreement") relating to shares in Fasteignafélagið Sæmundur hf. ("Saemundur") with ATP Holdings ehf., an affiliate of Aztiq. Pursuant to the Share Purchase Agreement, Alvotech is purchased 99.99% of the shares in Saemundur through the issuance the Aztiq Convertible Bond, as defined and discussed in Note 20, and the assumption of debt. At the time of closing, Saemundur's only asset was the property where Alvotech's Reykjavik manufacturing and research facility (the "Facility") are located. See Note 20 for further details.

The Share Purchase Agreement was accounted for as an asset acquisition under IFRS 3 as all of the fair value of the gross assets acquired from Saemundur were concentrated in the Alvotech Facility. As a result, the purchase price was determined to be \$115.0 million, which consists of \$80.0 million related to the fair value of the Aztiq Convertible Bond, \$30.0 million in loans assumed by the Company, and \$5.0 million associated with the settlement of the pre-existing relationship with Saemundur. The entire purchase price was allocated to the Facility as it was the only asset acquired. Additionally, the Company recognized a \$3.9 million loss on the extinguishment of the lease liability related to the Facility. See Note 20 for further details.

At 31 December 2021, the Group performed a review of its property, plant and equipment and determined certain laboratory equipment was no longer in use. In assessing recoverable amount, the Group determined the market for resale was non-existent due to the unique nature of the equipment. Management therefore determined to fully impair the assets, resulting in an impairment of \$2.1 million during each of the year ended 31 December 2021. See Note 8 for where impairment charges have been recognized as an expense within in the consolidated statements of profit or loss and other comprehensive income or loss.

The Group pledged \$122.4 million and \$6.8 million of property, plant and equipment as collateral to secure bank loans with third parties as of 31 December 2022 and 2021, respectively.

#### 13. Leases

The Group's leased assets consist of facilities, fleet and equipment pursuant to both arrangements with third parties and related parties. The carrying amounts of the Group's right-of-use assets and the movements during the years ended 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Right-of-use assets		
Balance at 1 January	126,801	111,519
Adjustments for indexed leases	10,201	5,358
New or renewed leases	9,583	18,871
Derecognition due to acquisition of Alvotech Facility (see Note 12)	(88,941)	_
Depreciation	(9,869)	(8,699)
Translation difference	(274)	(248)
Balance at 31 December	47,501	126,801

# Notes to the Consolidated Financial Statements

The Group's right-of-use assets as of 31 December 2022 and 2021 are comprised of the following (in thousands):

	2022	2021
Right-of-use assets		
Facilities	41,702	122,927
Fleet	339	159
Equipment	5,460	3,715
	47,501	126,801

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The Group's lease liabilities and the movements during the years ended 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Lease liabilities		
Balance at 1 January	122,140	108,947
Adjustments for indexed leases	10,247	5,358
New or renewed leases	7,458	18,116
Installment payments	(7,655)	(6,595)
Derecognition due to acquisition of Alvotech Facility (see Note 12)	(80,075)	_
Foreign currency adjustment	(11,682)	(3,744)
Translation difference	99	58
Balance at 31 December	40,532	122,140
Current liabilities	(5,163)	(7,295)
Non-current liabilities	35,369	114,845

The amounts recognized in the consolidated statements of profit or loss and other comprehensive income or loss during the years ended 31 December 2022, 2021 and 2020 in relation to the Group's lease arrangements are as follows (in thousands):

2022	2021	2020
(9,423)	(8,228)	(6,955)
(119)	(38)	(7)
(327)	(433)	(226)
(9,869)	(8,699)	(7,188)
(6,022)	(6,423)	(5,481)
11,682	3,744	3,248
(3,859)		(241)
(8,068)	(11,378)	(9,662)
	(9,423) (119) (327) (9,869) (6,022) 11,682 (3,859)	(9,423) (8,228) (119) (38) (327) (433) (9,869) (8,699) (6,022) (6,423) 11,682 3,744 (3,859) —

The maturity analysis of undiscounted lease payments as of 31 December 2022 and 2021 is as follows (in thousands):

	2022	2021
Less than one year	6,000	13,164
One to five years	20,160	49,379
Thereafter	22,274	117,511
	48,434	180,054

The Group's lease liabilities as of 31 December 2022 and 2021 do not include \$0.1 million of costs for short-term leases and low value leases.



#### 14. Goodwill

The Group's goodwill balances as of 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Balance as of 1 January	12,367	13,427
Translation difference	(724)	(1,060)
Balance as of 31 December	11,643	12,367

Goodwill is recognized at the Group level, which is determined to be the smallest cash-generating unit. The recoverable amount of the cash-generating unit is determined based on a value in use calculation which uses cash flow projections based on the financial forecast for the period 2023-2030 that has been approved by management and the Board of Directors. The Group's operations are currently in a development phase, and the ten-year forecast includes the initial revenue generating phase when products currently in development will be available for market. The Group determined that the terminal growth rate and the discount rate are the key assumptions used in determining the current estimate of value in use.

Cash flows beyond 2030 have been extrapolated using a negative 5.0% terminal rate in both the 2022 and 2021 value in use calculations respectively. A discount rate of 27.6% (2021: 21.5%) per annum was used in determining the current estimate of value in use. Since the recoverable amount of the cash-generating unit was substantially in excess of its carrying amount as of 31 December 2022 and 2021, management believes that any reasonably possible change in the key assumptions on which the recoverable amount of the cash-generating unit is based would not cause the carrying amount of the cash-generating unit to exceed its recoverable amount.

There were no goodwill impairment charges recognized in the consolidated statements of profit or loss and other comprehensive income or loss in any prior periods.

## 15. Intangible assets

Intangible assets consist of software, customer relationships and licensed intellectual property rights. Movements in intangible assets during the years ended 31 December 2022 and 2021 are as follows (in thousands):

	Software	Customer relationships	Intellectual property rights	Total
Cost				
Balance at 1 January 2022	8,777	2,329	15,000	26,106
Additions	7,682	_	_	7,682
Impairment	(2,755)	_	_	(2,755)
Translation difference	(20)	(148)	_	(168)
Balance at 31 December 2022	13,684	2,181	15,000	30,865
Amortization				
Balance at 1 January 2022	2,933	1,664	_	4,597
Amortization	423	310	_	733
Translation difference	(13)	(104)		(117)
Balance at 31 December 2022	3,343	1,870		5,213
Net carrying amount	<del></del>			<u></u>
Balance at 31 December 2022	10,341	311	15,000	25,652



	Software	Customer relationships	Intellectual property rights	Total
Cost				
Balance at 1 January 2021	7,603	2,528	_	10,131
Additions	5,186	_	15,000	20,186
Impairment	(3,993)	_	_	(3,993)
Translation difference	(19)	(199)	_	(218)
Balance at 31 December 2021	8,777	2,329	15,000	26,106
Amortization				
Balance at 1 January 2021	2,351	1,445	_	3,796
Amortization	591	332	_	923
Translation difference	(9)	(113)	_	(122)
Balance at 31 December 2021	2,933	1,664		4,597
Net carrying amount				
Balance at 31 December 2021	5,844	665	15,000	21,509

Additions during the year ended 31 December 2021 were primarily comprised of licensed intellectual property rights from Biosana. Refer to Note 2.18 for further details.

Expense for amortization of the Group's intangible assets is included within the consolidated statements of profit or loss and other comprehensive income or loss as follows (in thousands):

	2022	2021	2020
Cost of product revenue	471	_	
Research and development expenses	_	324	357
General and administrative expenses	262	599	653
	733	923	1,010

At 31 December, 2022 and 2021, the Group performed a review of its intangible assets and determined certain software development had been abandoned. In assessing recoverable amount, the Group determined the market for resale was non-existent. Management therefore determined to fully impair the assets, resulting in an impairment charge of \$2.8 million and \$4.0 million during the year ended 31 December 2022 and 2021, respectively. The impairment charge was recognized as an expense as follows: \$2.1 million in "Cost of product revenue" and \$0.7 million in "General and administrative expenses." For the year ended 31 December 2021 the impairment was recognized as an expense within "Research and development expenses" in the consolidated statements of profit or loss and other comprehensive income or loss.

At 31 December 2022 the Group performed an impairment analysis on the intellectual property rights indefinite lived intangible asset. No impairment loss was recognized as the asset's recoverable amount exceeded the carrying amount.

## 16. Cash and cash equivalents

## Cash and cash equivalents

Cash and cash equivalents include both cash in banks and on hand. Cash and cash equivalents as shown in the consolidated statements of cash flows as of 31 December 2022 and 2021 is as follows (in thousands):

	2022	2021
Cash and cash equivalents denominated in US dollars	10,377	15,798
Cash and cash equivalents denominated in other currencies	56,050	1,758
	66,427	17,556



### Restricted cash

Restricted cash as shown on the consolidated statements of financial position relates to cash that may only be used pursuant to certain of the Group's borrowing arrangements. Therefore, these deposits are not available for general use by the Group. Movements in restricted cash balances during the years ended 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Balance at 1 January	10,087	10,087
Additions during the year	14,914	
Interest income	186	_
Balance at 31 December	25,187	10,087

The Group's restricted cash is available for use after one year or later.

#### 17. Inventories

The Group's inventory balances as of 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Raw materials and supplies	41,961	26,590
Work in progress	29,450	13,730
Finished goods	2,121	_
Inventory reserves	(2,062)	(1,262)
Balance at 31 December	71,470	39,058

The increase in inventory from 31 December 2021 to 31 December 2022 is due to the commercial launch of certain of the Group's biosimilar product candidates.

The Company recognized \$8.5 million of inventories in cost of product revenue during the year ended 31 December 2022.

### 18. Other current assets

The composition of other current assets as of 31 December 2022 and 2021 is as follows (in thousands):

	2022	2021
Value-added tax	6,468	4,725
Prepaid expenses	20,601	9,320
Proceeds receivable from Convertible Bonds (see Note 20)	3,520	_
Derivative asset	851	_
Other short-term receivables	1,509	691
	32,949	14,736

## 19. Share capital

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all liabilities. Equity instruments issued by a Group entity are recognized in the amount of the proceeds received, net of direct issue costs.

#### Notes to the Consolidated Financial Statements

Prior to the Capital Reorganization the Group's equity consisted of Class A and Class B ordinary shares (together the "Predecessor Ordinary Shares"). The Group's authorized share capital was \$99.7 million, consisting of the equivalent of 99,961,829 Class A or Class B ordinary shares with a par value of \$0.01 per share. All share capital issued as of 31 December 2021 and 2020 was fully paid.

The Capital Reorganization resulted in the following share capital activity:

- All of the outstanding Predecessor Ordinary Shares were exchanged for 180,600,000 Ordinary Shares and 38,330,000 Predecessor Earn Out Shares;
- 976,505 of Class A OACB Ordinary Shares were exchanged for Ordinary Shares;
- 6,250,000 of Class B OACB Ordinary Shares were exchanged for 5,000,000 Ordinary Shares and 1,250,000 OACB Earn Out Shares; and
- 17,493,000 Ordinary Shares were issued in the PIPE Financing.

No dividends were paid or declared during the years ended 31 December 2022, 2021, and 2020.

Share capital and share premium of the Group's Ordinary Shares issued as of 31 December 2022 and 2021 is as follows (in thousands, except for share amounts):

	2022		2021	
	Share			Share
		capital and		capital and
	C1	share	61	share
	Shares	premium	Shares	premium
Class A ordinary shares	_	_	13,386,098	997,824
Class B ordinary shares	_	_	95,701	2,429
Ordinary Shares	252,160,087	1,060,558	_	_
Total share capital and share premium	252,160,087	1,060,558	13,481,799	1,000,253

Movements in the Group's Class A and Class B ordinary shares, share capital and share premium during the years ended 31 December 2022, 2021 and 2020 are as follows (in thousands, except for share amounts):

	Ordinary Shares	Predecessor Ordinary Shares	Share capital	Share premium	Total
Balance at 1 January 2020		6,937,062	69	102,359	102,428
Share issue	_	322,077	4	64,997	65,001
Transaction costs arising on share issue				(616)	(616)
Balance at 31 December 2020		7,259,139	73	166,740	166,813
Share issue	_	6,222,660	62	833,378	833,440
Balance at 31 December 2021.		13,481,799	135	1,000,118	1,000,253
Elimination of Predecessor Ordinary Shares (Note 1.1)	_	(13,481,799)	(135)	135	_
Issuance of Ordinary Shares (Note 1.1)	186,576,505	_	1,866	63,169	65,035
PIPE Financing (Note 1.1)	17,493,000	_	175	174,755	174,930
Transaction costs arising on share issue	_	_	_	(5,562)	(5,562)
Predecessor Earn Out Shares (Note 22)	38,330,000	_	_	(227,500)	(227,500)
OACB Earn Out Shares (Note 22)	1,250,000	_		(9,100)	(9,100)
SARs Settlement (Note 21)	3,510,582	_	35	30,267	30,302
Settlement of related party loans with Ordinary Shares	5,000,000		50	32,150	32,200
Balance at 31 December 2022.	252,160,087		2,126	1,058,432	1,060,558

#### Notes to the Consolidated Financial Statements

Alvotech Manco ehf., a subsidiary of Alvotech hf., owns 27,072,167 Ordinary Shares in Alvotech. Such shares are intended for the future issuance of Ordinary Shares under the Management Incentive Plan and other equity offerings.

## 20. Borrowings

The Group's debt consists of interest-bearing borrowings from financial institutions, related parties and third parties. Outstanding borrowings, net of transaction costs, presented on the consolidated statements of financial position as current and non-current as of 31 December 2022 and 2021 is as follows (in thousands):

	2022	2021
Senior Bonds	530,506	_
Bonds	_	394,129
Aztiq Convertible Bond	65,793	_
Alvogen Facility	64,588	_
Convertible Bonds	32,441	_
Other borrowings	71,242	6,782
Total outstanding borrowings, net of debt issue costs	764,570	400,911
Less: current portion of borrowings	(19,916)	(2,771)
Total non-current borrowings	744,654	398,140

#### Convertible shareholder loans

In connection with the Business Combination Agreement (see Note 1.1), on 7 December 2021, the Group's shareholders entered into the BCA Framework Agreement resulting in the exercise of the conversion, warrant, and funding rights associated with the convertible shareholder loans. As a result, the following issuances of Class A ordinary shares occurred:

- 1,522,103 shares from the exercise of warrant and funding rights in exchange for \$101.3 million of cash;
- 1,137,248 shares from the exercise of warrant rights in exchange for the settlement of \$73.7 million of accrued payment-in-kind interest; and
- 2,306,555 shares resulting from the conversion of \$166.8 million of outstanding principal and accrued payment-in-kind interest.

In connection with these exercises, for the year ended 31 December 2021, the Group recognized finance income of \$48.7 million resulting from the remeasurement of the derivative liabilities at the date of extinguishment and a \$149.2 million gain on extinguishment of financial liabilities, which primarily reflects the difference between the carrying amount of the pre-transaction convertible shareholder loans and the related derivative financial liabilities and the fair value of the ordinary shares issued. In addition, the gain on extinguishment of financial liabilities includes transaction costs incurred as part of the extinguishment, the acceleration of previously deferred debt issue costs incurred in connection with the issuance of the convertible shareholder loans and the acceleration of previously unamortized accretion of the convertible shareholder loans.

## Convertible bonds, Bonds and Senior Bonds

#### Convertible bonds

On 14 December 2018, the Group issued \$300.0 million of convertible bonds to multiple third parties. The offering included \$125.0 million of Tranche A bonds that included a guarantee from Alvogen and a 10%

#### Notes to the Consolidated Financial Statements

bonus if the bondholders converted at the time of an IPO. In addition, \$175.0 million of Tranche B bonds were issued that do not have a guarantee but include a 25% bonus if the bondholders elect to convert at the time of an IPO. The bonds offered a 15% payment-in-kind interest rate and a put option to sell the bond back to the Group if an IPO had not occurred within three years from the original date of issuance.

The Group recorded \$5.4 million, recorded as a component of finance income in the consolidated statements of profit or loss and other comprehensive income or loss for the year ended 31 December 2020. Fair value measurements of the derivative financial liabilities are set out in Note 27.

#### **Bonds**

On 24 June 2021, holders of the Group's convertible bonds converted \$100.7 million of principal and accrued interest and \$4.8 million of additional premium offered by the Group to the bondholders into 455,687 Class A ordinary shares. Following the conversion, certain bondholders elected to redeem their remaining bonds for cash, resulting in the payment of \$55.3 million in outstanding principal and accrued interest plus an additional \$6.1 million of premium that the bondholders elected to be paid in cash.

The remaining unconverted and unredeemed bonds were replaced with new bonds with an extended maturity of June 2025 and the elimination of conversion rights, among other amendments to the terms and conditions. The Group offered the holders of the replaced bonds an extension premium of \$8.1 million for their agreement to extend the maturity of the replaced bonds to June 2025, as well as an additional premium of \$2.6 million, both of which were granted to the bondholders in the form of additional bonds. The Group also issued an additional \$113.8 million of bonds to one previous bondholder and one new bondholder. On the date of issuance, the fair value and the nominal value of the bonds was \$358.8 million and \$397.4 million, respectively. The difference between the nominal value and fair value was recognized as a discount that will be amortized over the term of the bonds.

The Group determined that the 24 June 2021 transaction was a substantial modification to its convertible bonds and the associated derivative financial liability and accounted for the transaction as an extinguishment. As a result, the Group recognized a gain on extinguishment of financial liabilities of \$2.6 million during the year ended 31 December 2021, primarily driven by the difference between the fair value of the post-transaction bonds and the carrying amount of the pre-transaction bonds. The gain on extinguishment of financial liabilities also includes the following:

- Transaction costs and fees incurred as part of the extinguishment;
- · The acceleration of previously deferred debt issue costs incurred in connection with the issuance of the pre-transaction bonds; and
- The acceleration of previously unamortized accretion of the pre-transaction bonds.

Prior to the extinguishment of the convertible bonds and as noted above, the bondholders had the option to convert the bonds into Class A ordinary shares up to fourteen days prior to maturity. This conversion right was separately accounted for as a derivative financial liability. During the period from 1 January 2021 to 24 June 2021, there was no change in fair value of the derivative financial liability.

As of 31 December 2021, the carrying amount of the bonds was \$363.1 million. Accrued interest on the bonds as of 31 December 2021 is \$31.0 million. The Group has the option, at any time, to prepay all or any part of the outstanding bonds. If the Group elects to prepay the bonds within the first three years of the bond agreement, the bondholders are entitled to be paid an additional premium of at least 2.0% of the outstanding principal at the time of such prepayment.

# Notes to the Consolidated Financial Statements

In January and June of 2022, the Group amended the terms of the outstanding bonds. The amendments resulted in the following:

- Following the close of the Business Combination, the interest rate will range from 7.5% to 10.0% depending on the amount of aggregate net proceeds, as defined by the terms of the amended bond agreement;
- A \$7.4 million consent fee, recognized as finance costs, paid to the bondholders who did not vote against the Business Combination Agreement;
- The requirement for Alvotech to maintain a minimum of \$25.0 million of restricted cash in a separate liquidity account; and
- A decrease in the interest rate to 7.5%, following the closing of the Business Combination, if the Company issues additional shares
  within six months of the Closing Date, resulting in the Company exceeding the amount of aggregate net proceeds, as defined in the
  bond agreement.

As a result of the closing of the Business Combination, there was a change in future cash flows on the bonds related to the increase in interest rate from 7.5% to 10.0%. The Company remeasured the carrying value in accordance with IFRS 9 to the present value of the revised cash flows and recognized a \$6.5 million loss on the remeasurement of the bonds.

#### Senior Bonds

On 16 November 2022, the Group amended and upsized the outstanding bonds by \$70.0 million. The amended bond agreement (the "Senior Bonds") resulted in the following:

- An increase in principal from \$455.7 million at the time of the amendment, to \$525.7 million;
- An increase in the interest rate, resulting in a range from 10.75% to 12.0% depending on the occurrence of certain events, as defined by the terms of the agreement. The Group accounted for this interest rate feature (the "Senior Bond Interest Rate Feature") as an embedded derivative, classified as an other current asset in the consolidated statement of financial position as of 31 December 2022;
- Amended the terms of the related party loans from Alvogen, setting forth subordination conditions;
- Contingently issuable penny warrants (exercise price of \$0.01) to the bondholders (the "Senior Bond Warrants") if certain events occur, issuable in two tranches representing 1.5% and 1.0% of the fully diluted ordinary share capital, as defined in the Senior Bonds agreement (see Note 27).

The Group determined that the 16 November 2022 transaction was a substantial modification to its bonds and accounted for the transaction as an extinguishment. As a result, the Group recognized a loss on extinguishment of financial liabilities of \$40.9 million, including \$12.1 million of transaction costs, during the year ended 31 December 2022, primarily driven by the difference between the fair value of the post-transaction Senior Bonds and the Senior Bond Warrants and the carrying amount of the pre-transaction bonds. The loss on extinguishment of financial liabilities includes the following:

- Extinguishment of bonds with a carrying value of \$440.1 million, including \$4.8 million of accrued interest;
- Net cash proceeds of \$57.9 million, including transaction costs paid of \$12.1 million;
- Recognition of a \$4.6 million derivative asset for the Senior Bond Interest Rate Feature;
- Recognition of \$528.2 million and \$15.4 million representing the fair value of the new Senior Bonds and Senior Bond Warrants (see Note 27), respectively.

## Notes to the Consolidated Financial Statements

As of 31 December 2022, the carrying amount of the Senior Bonds is \$530.5 million. Accrued interest on the Senior Bonds as of 31 December 2022 is \$2.6 million. The Group has the option, at any time, to prepay all or any part of the outstanding bonds.

The Group has pledged its intellectual property as collateral for the Senior Bonds.

## Aztiq Convertible Bond

On 16 November 2022 the Group issued a convertible bond (the "Aztiq Convertible Bond") to ATP Holdings ehf. for the Share Purchase Agreement and the acquisition of the Alvotech Facility (See Note 12). The Aztiq Convertible Bond has a principal amount of \$80.0 million and carries an interest rate of 12.50% per annum. Interest is payable in six-month intervals and is capitalized and added to the outstanding principal amount of the bonds. The maturity date of the convertible bond is the later of the (i) 16 November 2025 or (ii) 91 days after the earlier of the full redemption or the final maturity date of the Senior Bonds. Bondholders have the right to convert their outstanding bonds into ordinary shares of Alvotech on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date, for a conversion price is \$10.00 per share.

The conversion feature (the "Aztiq Conversion Feature") was determined to be an embedded derivative as the economic characteristics and risks are not closely related to the debt host. The Group classified the Aztiq Conversion Feature as equity due to the conversion price having preservation and passage of time adjustments that meet fixed-for-fixed criteria. As a result, the Group recognized the following related to the Aztiq Convertible Bond:

- \$64.0 million related to the debt host;
- \$16.0 million related to the Aztiq Conversion Feature;
- \$30.0 million related to the loans (the "Facility Loans") on the building, which were assumed by the Group as part of the asset acquisition.

As of 31 December 2022, the carrying amount of the Aztiq Convertible Bond is \$65.8 million. Accrued interest on the Aztiq Convertible Bond as of 31 December 2022 is \$0.5 million.

## Facility Loans

As noted above, the Group assumed the Facility Loans as part of the asset acquisition for the Facility. On 9 December 2022, the Group extinguished the assumed loans from Arion banki hf., with an outstanding balance of \$30.9 million, with new loans from Landsbankinn hf. for \$48.8 million, and carries variable interest rate, currently 8.3% and 9.3% per annum. The refinancing resulted in net cash proceeds of \$17.2 million after transaction costs paid.

As of 31 December 2022, the carrying amount of the Facility Loans is \$48.8 million. Accrued interest on the Facility Loans as of 31 December 2022 is \$0.3 million.

## Related party loans and Alvogen Facility

In connection with an undertaking by Alvotech shareholders to ensure that Alvotech was sufficiently funded through the closing of the Business Combination by providing at least \$50.0 million for the operations of the Group, Alvogen and Aztiq provided interest free loan advances to Alvotech. On 22 February 2022, Alvotech borrowed \$15.0 million under the facility from Alvogen, as lender. On 29 March 2022, Alvotech withdrew an additional amount of \$10.0 million under the facility, for aggregate indebtedness of \$25.0 million. On 11 March 2022, Alvotech borrowed \$15.0 million under the facility from Aztiq, as lender. On 31 March 2022, Alvotech withdrew an additional amount of \$10.0 million under the facility, for aggregate indebtedness of \$25.0 million.

#### Notes to the Consolidated Financial Statements

On 12 July 22, the Company entered into settlement agreements with both Aztiq and Alvogen for the \$25.0 million in related party loans provided by each party. As a result of the settlement agreements, Aztiq and Alvogen each received 2,500,000 Ordinary Shares. The settlement was accounted for as an extinguishment of financial liabilities. In accordance with IFRS 9, the difference between the fair value of the consideration paid for the settlement, which was determined to be \$32.2 million, and the extinguished financial liabilities of \$50.0 million was recognized as a gain on the extinguishment of financial liabilities in the consolidated statement of profit or loss and other comprehensive income or loss.

On 11 April 2022, Alvotech entered into a loan agreement with Alvogen, as lender, for a loan of up to \$40.0 million bearing an interest rate of 10% per annum. The loan was drawable in two separate installments of \$20.0 million each. On 12 April 2022, Alvotech withdrew the first installment of \$20.0 million. Alvotech withdrew a second installment of \$20.0 million on 9 May 2022 for aggregate indebtedness of \$40.0 million.

On 1 June 2022, Alvotech also entered into a loan agreement with Alvogen, as lender, for a loan of \$20.0 million bearing an interest rate of 10% per annum. Alvotech withdrew the entire loan amount of \$20.0 million on 1 June 2022.

In connection with the 16 November 2022 bond amendment, Alvotech entered into a subordinated loan agreement with Alvogen (the "Alvogen Facility"). As part of the subordinated loan agreement, the Group agreed to the following:

- Rollover the \$63.3 million outstanding, which includes \$3.3 million of accrued interest, under the Alvogen loans, into the new subordinated loan agreement, and withdraw an additional \$50.0 million in loans;
- The interest rate was increased from 10% per annum to 17.5% per annum on the outstanding amounts under the loan facility;
- A repayment date of 91 days after the full redemption or the final maturity date of the Senior Bonds;
- Contingently issuable penny warrants to the bondholders (the "Alvogen Facility Warrants") if certain events occur, representing 4.0% of the fully diluted ordinary share capital, as defined in the Alvogen Facility agreement.

The Group determined that the 16 November 2022 transaction was a substantial modification to its related party loans and accounted for the transaction as an extinguishment. As a result, the Group recognized the following:

- Extinguishment of bonds with a carrying value of \$63.2 million, including \$3.2 million of accrued interest;
- Net cash proceeds of \$50.0 million;
- Recognition of \$113.2 million and \$1.3 million representing the fair value of the new Alvogen Facility and Alvogen Facility Warrants, respectively.

On 20 December 2022, the Company repaid \$50.0 million under the Alvogen Facility, with proceeds from the Convertible Bonds. As a result, Alvotech extinguished the liability to issue the Alvogen Facility Warrants.

As of 31 December 2022, the carrying amount of the loans is \$64.6 million.

## Convertible Bonds

On 20 December 2022 the Group issued two tranches of convertible bonds (the "Convertible Bonds"). Tranche A is ISK denominated with a principal balance of \$59.1 million, of which \$3.5 million in cash

#### Notes to the Consolidated Financial Statements

proceeds were received subsequent to 31 December 2022 (see Note 18), and carries an annual payment-in-kind interest rate of 15% per year, while Tranche B is USD denominated with a principal balance of \$0.6 million and carries an annual payment-in-kind interest rate of 12.5% per year. The maturity date of the Convertible Bonds is the later of the (i) 20 December 2025 or (ii) 91 days after the earlier of the full redemption or the final maturity date of the Senior Bonds. Holders of both the Tranche A and Tranche B Convertible Bonds, may elect, at their sole discretion, to convert all or part of the principal amount and accrued interest into Alvotech Ordinary Shares at a conversion price of \$10.00 per share on December 31, 2023, or June 30, 2024.

The conversion features (the "Tranche A Conversion Feature" and "Tranche B Conversion Feature") for both the Tranche A and Tranche B Convertible Bonds were determined to be embedded derivatives as the economic characteristics and risks are not closely related to the debt host. The Group classified the Tranche A Conversion Feature as a liability due to the variability created by conversion rates resulting from the tranche being denominated in ISK and was determined to have a fair value of \$24.9 million at issuance date (see Note 27 for further details). The Group classified the Tranche B Conversion Feature as equity due to the conversion price having preservation and passage of time adjustments that meet the fixed-for-fixed criteria.

As of 31 December 2022, the carrying amount of the Tranche A and Tranche B Convertible Bond is \$31.9 million and \$0.5 million, respectively.

## Other borrowings

In 2015 and 2016, the Group entered into several term loan agreements with a financial institution for a total principal amount of \$25.9 million. The loan agreements set forth terms and conditions between the Group and the financial institution, inclusive of certain representations and non-financial covenants. Per the terms of the loan agreements, the loans mature throughout late 2023 and into the second half of 2024, depending on the issuance date of each loan. Interest on the loans is variable interest rate of USD SOFR plus a margin of 4.95%, payable on a monthly basis. Interest accrued and unpaid at the end of each interest period increases the principal obligations owed by the Group to the financial institution. As of 31 December 2022 and 2021, the outstanding balance on the loans, including accrued interest, is \$3.2 million and \$5.7 million, respectively. The Group is in compliance with all representations and non-financial covenants required by these agreements. In addition, the Group has pledged property, plant and equipment as collateral to secure these borrowings, as further described in Note 12.

In 2021, the Group entered into two loan agreements with two separate lenders, Origo hf. and Arion banki hf. The outstanding balance on the borrowings held with Origo hf. and Arion banki hf., including accrued interest, was \$0.2 million and \$0.3 million as of 31 December 2022 and 31 December 2021, respectively. The loans mature in late 2023 and 2024.

On 22 February 2022, the Group entered into a credit facility agreement with Landsbankinn hf. with the ability to draw down an amount up to \$18.3 million. The credit facility is in place to help finance equipment purchases in the future. Per the terms of the credit facility, any borrowings are required to be paid by 1 August 2023 and have a variable interest rate of USD SOFR plus a margin of 4.95%. As of 31 December 2022, the outstanding balance on the credit facility was \$14.0 million, including accrued interest.

On 22 February 2022, the Group entered into a loan agreement with Landsbankinn hf. for a principal amount of \$3.2 million. The loan is in place to help finance equipment purchases. Per the terms of the loan agreement, annuity payments are due monthly with a final maturity in February 2029. The loan has a variable interest rate of USD SOFR plus a margin of 4.25%. As of 31 December 2022, the outstanding balance on the loan was \$2.9 million, including accrued interest.



On 8 August 2022, the Group entered into a loan agreement with Landsbankinn hf. for a principal amount of \$1.8 million. The loan is in place to help finance equipment purchases. Per the terms of the loan agreement, annuity payments are due monthly with a final maturity in August 2029. The loan has a variable interest rate of USD SOFR plus a margin of 4.25%. As of 31 December 2022, the outstanding balance on the loan was \$1.8 million, including accrued interest.

Movements in the Group's outstanding borrowings during the years ended 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Borrowings, net at 1 January	400,911	567,899
Borrowings converted to equity	_	(105,501)
Redemption of borrowings	_	(34,899)
Paid payment-in-kind interest	_	(19,200)
Premium on redeemed and unredeemed bonds	_	15,472
Change in fair value upon extinguishment of convertible shareholder loans	_	32,114
Recognition of deferred debt issue costs	(2,889)	_
Accretion/derecognition of borrowings discount	35,065	5,506
Recognition of new borrowings discount	(43,241)	(34,302)
Proceeds from new borrowings	467,196	114,282
Loans from related party converted to equity	(50,000)	(240,542)
Repayments of borrowings	(83,951)	(2,597)
Accrued interest	40,424	89,958
Amortization of deferred debt issue costs	23	12,754
Foreign currency exchange difference	1,032	(33)
Borrowings, net at 31 December	764,570	400,911

The weighted-average interest rates of outstanding borrowings for the years ended 31 December 2022, 2021, and 2020 are 12.41%, 14.83% and 14.85%, respectively.

Contractual maturities of principal amounts on the Group's outstanding borrowings as of 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Within one year	19,916	2,771
Within two years	3,804	2,920
Within three years	696,646	622
Within four years	3,374	394,222
Thereafter	40,830	376
	764,570	400,911

## 21. Long-term incentive plans

# Share appreciation rights

Prior to 2019, the Group granted SARs to three former employees. During the year ended 31 December 2020 and 2019, the Group granted SARs to one and two current employees, respectively. There were no new granted SARS in the years ended 31 December 2022 and 2021.



## Settlement of SARs

In connection with the closing of the Business Combination, the Company reached a settlement agreement for share appreciation rights previously awarded to certain current and former employees. The rights were settled as follows:

- two former employees will each receive 1,755,291 Ordinary Shares to be issued one year after the Closing Date. In accordance with IFRS 2, the settlements were accounted for as a modification of a share-based payment transaction that changes the awards classification from cash-settled to equity-settled;
- one former employee will receive a \$1.5 million cash payment in July 2022; and
- one current employee can elect to receive a cash payment of \$1.5 million or 150,000 Ordinary Shares to be issued one year after the Closing Date. The Company recognized the cash settlement option as a liability with a fair value of \$0.8 million and the share settlement option as equity with a fair value of \$0.7 million.

The settlement agreements resulted in a net \$36.8 million decrease in the SARs liability, a \$31.0 million increase in equity equal to the fair value of the Ordinary Shares issued to the two former employees and potentially issued to one current employee, a \$1.5 million increase in other current liabilities and income of \$4.3 million in general and administrative expense recognized for the difference between the extinguished liabilities and the fair value of consideration paid to the current and former employees. As of 31 December 2022, the Company recognized \$0.7 million as an other current liability related to the remaining SARs liability.

Significant assumptions used in the Finnerty model to determine the fair value of the Ordinary Shares to be issued for the settlement as of 15 June 2022 are as follows:

	<u>15 J</u>	June 2022
Asset price	\$	9.38
Term (years)		1 year
Volatility rate		35.0%
Dividend yield		0.0%
Indicated put option value	\$	0.75
Discount for lack of marketability		8.0%

The asset price is based on the public trading price of Ordinary Shares at the time of the settlement. The term is based on when the holder's will no longer be restricted from trading the Ordinary Shares. The volatility rate is based on historical data from a peer group of public companies with an enterprise value between \$500 million and \$5 billion. The dividend yield is based on the expected dividends to be paid out by the Company. The discount for lack of marketability reflects the timing of when the shares will be issued and can be traded by the holders.

On 1 December 2022, the Company issued Ordinary Shares to settle the remaining outstanding SARs. The vested portion of the Group's SARs liability as of the settlement date was \$3.8 million. The Ordinary Shares granted for the settlement will be delivered in June 2023. As a result, management recognized a gain of \$0.3 million on the extinguishment of the SARs liability resulting from the difference in the carrying value of the liability and fair value of the Ordinary Shares issued.

## Historical SARs Accounting

The Group's SAR liability as of 31 December 2021 totaled \$41.4 million. Expense recognized for the Group's SAR liability for the years ended 31 December 2021 and 2020 totaled \$11.3 million and \$7.8 million, respectively. The vested portion of the Group's SAR liability as of 31 December 2021 is \$36.6 million.



Significant assumptions used in the Black-Scholes-Merton pricing model as of 31 December 2021 and 2020 are as follows:

	2021	2020
Risk-free interest rate	0.1%	0.1%
Volatility rate	42.0%	42.0%
Expected dividend yield	0.0%	0.0%
Expected life	0.4 - 1.0  years	1.0 - 1.2 years
Share price at valuation	\$ 1,806	\$ 1,465
Strike price	\$ 925 - \$1,695	\$ 904 - \$1,296

The risk-free interest rate is the continuously compounded risk-free rate for a one-year US government zero-yield bond. Expected volatility is based on historical data from a peer group of public companies. The expected life is based on when the Group expects each holder's award will be fully vested and settled by the Group, which is dependent on management's expectation of when specified triggering events requiring settlement will occur. The share price at valuation is based on the Group's equity valuation at the time of various equity-related transactions that occurred during 2021 and 2020. The strike price represents actual and anticipated increases in equity between the SAR agreement date and the anticipated dates of settlement triggering events. The strike price is used to determine the difference between the equity value at the time of the settlement triggering event and the original equity value of the Group.

## Employee incentive plan

Movements in the Group's employee incentive plan liabilities during the years ended 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Balance at 1 January	14,935	10,501
Additions	5,075	6,648
Payments	(7,693)	(2,214)
Balance at 31 December prior to reclassification	12,317	14,935
Reclassified to other current liabilities	(11,773)	_
Balance at 31 December	544	14,935

## 22. Share-based payments

On 1 December 2022, the Renumeration Committee authorized and the Group granted restricted stock units ("RSUs") to employees, executives, and directors granting rights to Ordinary Shares once vesting conditions are met. Compensation expense for RSUs is determined based upon the market price of the Ordinary Shares underlying the awards on the date of grant and expensed over the vesting period, which is generally a one to four-year period, with a 1-year cliff vesting period and subsequent monthly vesting, resulting from participates completing a service condition. Movements in RSUs during the year ended 31 December 2022 are as follows:

		Weighted Average
	RSUs	Fair Value
Granted	7,659,049	\$ 6.68
Vested	(679,563)	\$ 6.30
Outstanding at 31 December	6,979,486	\$ 6.72



The Group recognized \$10.3 million of share-based payment expense during the year ended 31 December 2022 (in thousands):

	2022
Cost of product revenue	1,522
Research and development expenses	2,994
General and administrative expenses	5,801
	10,317

## 23. Litigation

In 2022, prior to the issuance date of these consolidated financial statements, the Group was involved in four litigations (all now dismissed) in the United States adverse to AbbVie arising out of the development of Alvotech's AVT02 product, and the filing of a biologics license application with the U.S. Food and Drug Administration seeking regulatory approval (the "AbbVie Litigations").

On 19 March 2021, AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively, "AbbVie") filed an action against Alvotech hf. in the United States District Court for the Northern District of Illinois alleging trade secret misappropriation under the Defend Trade Secrets Act and under the Illinois Trade Secrets Act. The complaint pleaded, among other things, that Alvotech hired a certain former AbbVie employee in order to acquire and access trade secrets belonging to AbbVie. In October 2021, the Court granted Alvotech's motion to dismiss the action, and AbbVie later appealed that ruling to U.S. Court of Appeals for the Seventh Circuit.

On 17 December 2021, AbbVie Inc., AbbVie Biotechnology Ltd, and AbbVie Operations Singapore Pte. Ltd. filed a complaint with the U.S. International Trade Commission against Alvotech hf., Alvotech Germany GmbH, Alvotech Swiss AG, Alvotech USA Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc., and Ivers-Lee AG (Certain Adalimumab, Processes for Manufacturing or Relating to Same, and Products Containing Same, Investigation No. 337-TA-1296). The complaint raised trade secret misappropriation allegations similar to those raised in the trade secret litigation that AbbVie previously filed in the Northern District of Illinois.

On 27 April 2021, AbbVie filed an action against Alvotech hf. in the United States District Court for the Northern District of Illinois alleging infringement of four patents, under the patent laws of the United States. On 28 May 2021, AbbVie filed another action against Alvotech hf. in the United States District Court for the Northern District of Illinois alleging infringement of 58 patents, under the patent laws of the United States, the BPCIA, and the Declaratory Judgment Act, and later added two more patents.

As of 31 December 2022, the AbbVie Litigations were dismissed. On 8 March 2022, Alvotech entered into the AbbVie U.S. Agreement with AbbVie Inc. and AbbVie Biotechnology Ltd with respect to AVT02 for the U.S. market. Pursuant to the settlement component of the AbbVie U.S. Agreement, the parties agreed to stipulate to the dismissal of all claims, counterclaims and potential claims in the four U.S. litigations, with each party to bear its own fees and costs. The parties further agreed to release each other from certain claims and demands. Under the licensing component of the AbbVie U.S. Agreement, AbbVie granted Alvotech a license effective 1 July 2023 to make, import, use, distribute, sell and offer for sale AVT02 in the U.S. and a license to manufacture, import and store a reasonable amount of AVT02 in anticipation of the commercial launch of AVT02 in the U.S. Under the agreement, Alvotech may sublicense certain rights to Teva, as a commercialization partner, and may also sublicense to other parties subject to certain conditions. In return, Alvotech is obligated to pay a royalty to AbbVie in the single digits of the net sales of AVT02 in the U.S. The agreement does not provide for upfront or milestone payments. The obligation of Alvotech to pay



royalties shall terminate on the earlier of (i) 11 February 2025; or (ii) a determination that licensed patents are invalid or unenforceable, at which time the license granted will be deemed fully paid up and irrevocable. Each party has the right to terminate the agreement upon breach of certain terms of the agreement that remains uncured for a certain period of time. Additionally, AbbVie may terminate the agreement if Alvotech takes certain actions concerning the patentability, validity or enforceability of AbbVie's patents in the U.S. with respect to AVT02.

The Group incurred approximately \$8.7 million, \$13.5 million and \$7.9 million in legal expenses during the years ended 31 December 2022, 2021, and 2020, respectively, in preparation for, and/or in relation to, these litigations. Aside from these matters, the Group is not currently a party to any material litigations or similar matters.

## 24. Related parties

Related parties are those parties which have considerable influence over the Group, directly or indirectly, including a parent company, owners or their families, large investors, key management personnel and their families and parties that are controlled by or dependent on the Group, such as affiliates and joint ventures. Key management personnel include the Group's executive officers and directors, since these individuals have the authority and responsibility for planning, directing and controlling the activities of the Group. Interests in subsidiaries are set out in Note 1.

## Transactions with related parties

A related party transaction is a transfer of resources, services or obligations between the Group and a related party, regardless of whether a price is charged. The Group engages with related parties for both purchased and sold services, loans and other borrowings and other activities.

The Group entered into two lease agreements with Fasteignafélagið Sæmundur hf. in January 2019 and October 2020 for facilities in Iceland, both with remaining lease terms of approximately 17 years as of 31 December 2021. The Group also entered into ten separate lease agreements with HRJAF ehf. throughout 2019 and 2020 for a group of apartment buildings in Iceland used for temporary housing of employees and third party contractors. Two of the leases were terminated during the year ended 31 December 2020. The group extinguished the lease agreements with Sæmundur hf. as a result of the Share Purchase Agreement (see Note 12). The remaining lease terms for the other eight leases approximate 8 years, on average, as of 31 December 2022.

The Group provides and receives certain support services through arrangements with Aztiq, Alvogen and Alvogen Malta (Outlicensing) Ltd. (Adalvo). Services provided to Alvogen consist of finance, administrative, legal and human resource services. Services received from Alvogen primarily consist of marketing, salary processing and information technology support services. Services received from Adalvo primarily consist of legal, regulatory, supply chain management and portfolio and market intelligence services.

Purchased service includes rental fees and service expenses, as described above. Rental fees and service expenses with related parties are presented as "General and administrative expenses" or "Research and development expenses" in the consolidated statements of profit or loss and other comprehensive income or loss, depending on the nature of the service performed and expense incurred by the Group. Rental liabilities from lease arrangements with related parties are presented as a component of "Lease liabilities" on the consolidated statements of financial position. Service payables are presented as "Liabilities to related parties" on the consolidated statements of financial position.

Interest includes interest expense on borrowings. Interest expenses on loans from related parties are presented as "Finance costs" in the consolidated statements of profit or loss and other comprehensive



income or loss. Borrowings are presented as "Borrowings" and "Current maturities of borrowings" on the consolidated statements of financial position. See Note 20 for further details on the Borrowing arrangements with related parties.

Sold service includes services provided to related parties, as described above. Income from related parties for such services are presented as "Other income" in the consolidated statements of profit or loss and other comprehensive income or loss. Amounts receivable for such activities are presented as "Receivables from related parties" on the consolidated statements of financial position. The Group has not recorded bad debt provisions for its receivables from related parties.

Related party transactions as of and for the year ended 31 December 2022 are as follows (in thousands):

	Purchased service / interest	Sold service	Receivables	Payables/ loans
Alvogen Lux Holdings S.à r.l. – Sister company (a)	5,415			64,588
Aztiq Fjárfestingar ehf. (a)	216	_	_	20
Aztiq Consulting ehf.	442	_	_	25
ATP Holdings ehf. (e)	1,254	_	765	81,254
Fasteignafélagið Sæmundur hf Sister company (e)	7,189	_	_	
Fasteignafélagið Eyjólfur hf Sister company	_	196	—	
Alvogen Iceland ehf Sister company	465	174	_	484
Alvogen ehf Sister company	_	68	1	
Lotus Pharmaceuticals Co. Ltd Sister company (b)	_	3	2	7,440
Lotus International Pte. Ltd Sister company	_	4	3	
Alvogen Emerging Markets - Sister company	98	_	_	
Alvogen Korea co. Ltd - Sister company	_	1	_	
Alvogen Inc Sister company	585	266	12	222
Alvotech & CCHN Biopharmaceutical Co., Ltd. (c)	_		758	
Adalvo Limited – Sister company	1,218	106	_	349
Alvogen Malta Sh. Services - Sister company	603	_	7	
Alvogen Spain SL - Sister Company	117	_	_	
Norwich Clinical Services Ltd - Sister Company	301		_	31
Alvogen Pharma Pvt Ltd - Sister Company	1,159	_	_	
Flóki Fasteignir ehf. (HRJÁF ehf.) - Sister company	1,516		_	8,876
L41 ehf.	26	_	_	
Lambahagavegur 7 ehf. (d)	537			
	21,141	818	1,548	163,289

- (a) The full amount of purchased service relates to interest expenses from long-term liabilities and the full amount of payables / loans are interest-bearing long-term liabilities (see Note 20).
- (b) Payables to Lotus Pharmaceuticals Co. Ltd. consists of the long-term liability as further described in Note 2. This long-term liability is presented as "Other long-term liability to related party" on the consolidated statements of financial position.
- (c) The amount receivable from Alvotech & CCHN Biopharmaceutical Co., Ltd. relates to amounts due for reference drugs used in research and development studies and certain consulting fees incurred by the Group.
- (d) Lambahagavegur is no longer a related party as it was sold during the year ended 31 December 2022.
- (e) Fasteignafélagið Sæmundur hf. was acquired as part of the Share Purchase Agreement, with ATP Holdings ehf., on 16 November 2022. The related party transactions reflect activity until the acquisition date. See Note 12 and Note 20 for further details.

# Notes to the Consolidated Financial Statements

Related party transactions as of and for the year ended 31 December 2021 are as follows (in thousands):

	Purchased service / interest	Sold service	Receivables	Payables/ loans
Alvogen Lux Holdings S.à r.l. – Sister company (a)	9,383			
Aztiq Pharma Partners S.à r.l. – Sister company (a)	16,048	_	_	_
Alvogen Aztiq AB – Sister company (a)	297	_	_	43
Aztiq Fjárfestingar ehf. (a)	120	_		
Aztiq Investment Advisory AB (a)	_	_	2	_
Fasteignafélagið Sæmundur hf. – Sister company	7,762	_	_	83,770
Alvogen Iceland ehf. – Sister company	454	2,308	109	14
Alvogen ehf. – Sister company	6	2	2	
Alvogen UK – Sister company	299	_	17	_
Lotus Pharmaceuticals Co. Ltd. – Sister company (b)	_	312	295	7,440
Alvogen Emerging Markets – Sister company	238	_	_	16
Alvogen Korea co. Ltd – Sister company	_	9	_	
Alvogen Inc. – Sister company	89	654	301	_
Alvotech & CCHN Biopharmaceutical Co., Ltd. (c)	_	_	320	
Alvogen Malta Sh. Services – Sister company	1,216	151	_	283
Alvogen Malta (Outlicensing) Ltd – Sister company	1,045	279	65	229
Alvogen Spain SL – Sister Company	294	_	_	23
Norwich Clinical Services Ltd – Sister Company	41	_	_	17
Alvogen Pharma Pvt Ltd – Sister Company	491	_	_	13
HRJAF ehf – Sister company	1,415	_	_	9,794
L41 ehf.	29	_	_	_
Lambahagavegur 7 ehf.	713			12,661
	39,940	3,715	1,111	114,303

<sup>(</sup>a) The full amount of purchased service relates to interest expenses from long-term liabilities and the full amount of payables / loans are interest-bearing long-term liabilities (see Note 20).

<sup>(</sup>b) Payables to Lotus Pharmaceuticals Co. Ltd. consists of the long-term liability as further described in Note 2. This long-term liability is presented as "Other long-term liability to related party" on the consolidated statements of financial position.

<sup>(</sup>c) The amount receivable from Alvotech & CCHN Biopharmaceutical Co., Ltd. relates to amounts due for reference drugs used in research and development studies and certain consulting fees incurred by the Group.

Notes to the Consolidated Financial Statements

Relatedparty transactions for the year ended 31 December 2020 are as follows (in thousands):

	,134
Alvogen Lux Holdings S.à r.l. – Sister company (a) 9,452 1	
Aztiq Pharma Partners S.à r.l. – Sister company (a) 19,471	_
Fasteignafélagið Sæmundur hf. – Sister company 8,111	_
Alvogen Iceland ehf. – Sister company 2,268 1	,310
Alvogen ehf. – Sister company 40	_
Alvogen UK – Sister company 1,153	_
Lotus Pharmaceuticals Co. Ltd. – Sister company (b) 3,060	—
Alvogen Emerging Markets – Sister company 68	_
Alvogen Inc. – Sister company 67	—
Alvogen PB R&D LLC —	7
Alvogen Malta Operations Ltd – Sister company 239	_
Alvogen Malta Group Services – Sister company 478	_
Alvogen Malta Sh. Services – Sister company 101	—
Alvogen Malta LTD – Sister company —	4
Alvogen Malta (Outlicensing) Ltd – Sister company 142	185
Alvogen Spain SL – Sister Company 132	_
Norwich Clinical Services Ltd – Sister Company 92	—
Alvogen Pharma Pvt Ltd – Sister Company 218	_
HRJAF ehf – Sister company 1,083	
46,175	2,640

- (a) The full amount of purchased service relates to interest expenses from long-term liabilities and the full amount of payables / loans are interest-bearing long-term liabilities (see Note 20).
- (b) Payables to Lotus Pharmaceuticals Co. Ltd. consists of the long-term liability as further described in Note 2. This long-term liability is presented as "Other long-term liability to related party" on the consolidated statements of financial position.

## Commitments and guarantees

The Group does not have any contractual commitments with its related parties other than the receivables, loans and payables previously disclosed.

# Key management personnel

At 31 December 2022 and 2021 there are no loans to the members of the Board of Directors and the CEO. In addition, there were no transactions carried out (except those in Note 24) between the Group and members of the Board of Directors nor the CEO in the year ended 31 December 2022 and 2021. The Board of Directors' remuneration is shown in the table below.

# Notes to the Consolidated Financial Statements

Board of Directors' fee for the year and shares at year end (board			
fees in thousands and shares in whole amounts).		2022	
		Pension	Shares at
	Board fees	<u>contribution</u>	year-end**
Robert Wessman, Chairman of the board	740	_	_
Richard Davies, Vice-Chairman	68		1,133,131
Ann Merchant, Board Member (from 16.6.2022)	43	_	
Árni Harðarson, Board Member (from 16.6.2022)*	_	_	_
Faysal Kalmoua, Board Member*	_	_	_
Linda McGoldrick, Board Member (from 16.6.2022)	38	_	
Lisa Graver, Board Member (from 16.6.2022)	38	_	_
Tomas Ekman, Board Member*	_	_	_
Hirofumi Imai, Board member (until 16.6.2022)	_	_	_
	927		1,133,131

- \* Waived their board compensation (both cash and equity).
- \*\* Direct share ownership

	Salaries and	Pension	Termination	Other long-
Key employees	benefits	contribution	benefits	term benefits
Mark Levick CEO	892	162	1,157	
Other Executive Team Members (9)	5,400	446	820	5,015
	6,292	608	1,977	5,015

Board of Directors' fee for the year and shares at year end			
(board fees in thousands and shares in whole amounts).		2021	
	Board	Pension	Shares at
	fees	contribution	year-end**
Robert Wessman, Chairman of the board	_		
Richard Davies, Vice-Chairman	_	_	893,060
Faysal Kalmoua, Board Member*	_	_	_
Tomas Ekman, Board Member*	_	_	_
Hirofumi Imai, Board member	_	_	_
Tanya Zharov (from 23.8.2021)*	_	_	
	_		893,060

- \* Waived their board compensation (both cash and equity).
- \*\* Direct share ownership

			2021	
	Salaries and	Pension	Termination	Other long-
Key employees	benefits	contribution	benefits	term benefits
Mark Levick CEO	877	159		
Other Executive Team Members (9)	4,531	333		985
	5,408	492		985

Notes to the Consolidated Financial Statements

## 25. Other current liabilities

The composition of other current liabilities as of 31 December 2022 and 2021 is as follows (in thousands):

2022	2021
15,620	10,235
2,249	7,547
_	7,500
5,025	4,626
12,433	_
18,720	12,104
54,047	42,012
	15,620 2,249 — 5,025 12,433 18,720

## 26. Interests in joint ventures

In September 2018, Alvotech hf., a subsidiary of the Group, entered into a joint venture agreement with Changchun High & New Technology Industries (Group) Inc. (the "joint venture partner") to form a newly created joint venture entity, Alvotech & CCHN Biopharmaceutical Co., Ltd. (the "joint venture" or "JVCO"). The purpose of the JVCO is to develop, manufacture and sell biosimilar products in the Chinese market. The JVCO's place of business is also the country of incorporation.

	Place of	Ownership interest		Carrying Amount		
Name of entity	business	2022	2021	2022	2021	
Alvotech & CCHN Biopharmaceutical Co., Ltd.	China	50%	50%	48,568	55,307	

The proportion of ownership interest is the same as the proportion of voting rights held by the Group. Management evaluated whether the Group's voting rights are sufficient for providing a practical ability to direct the relevant activities and strategic objectives of JVCO unilaterally. As the Group does not hold a majority of the voting rights, the Group does not control JVCO. As a result, the Group's investment in JVCO is accounted for using the equity method.

The following table provides the change in the Group's investment in a joint venture during the years ended 31 December 2022 and 2021 (in thousands):

	2022	2021
Balance at 1 January	55,307	56,679
Share in losses	(2,590)	(2,418)
Translation difference	(4,149)	1,046
Balance at 31 December	48,568	55,307



The tables below provide summarized financial information for the JVCO. The information disclosed reflects the amounts presented in the financial statements of the JVCO and not the Group's share of those amounts. They have been amended to reflect adjustments made by the Group when using the equity method, including fair value adjustments and modifications for differences in accounting policy.

Summarized Statements of Financial Position (in thousands)	2022	2021	
Current assets			
Cash and bank balances	17,203	29,659	
Trade receivables	<u> </u>	15	
Inventories	250	18	
Other current assets	1,539	1,372	
Total current assets	18,992	31,064	
Total non-current assets	107,487	94,525	,
Current liabilities			
Financial liabilities	145	_	
Other current liabilities	14,129	12,156	j
Total current liabilities	14,274	12,156	i
Total non-current liabilities	15,069	2,820	,
Net assets	97,136	110,613	_
The disself			•
Reconciliation to carrying amounts (in thousands):	2022	2021	
Opening net assets at 1 January	110,613	113,061	
Loss for the year	(5,180)	(4,836)	
Other comprehensive income	<u> </u>	_	
Cash contributions of owners	_	_	
Receivable from owners	_	_	
Dividends paid	_	_	
Other, net	(8,297)	2,388	
Closing net assets at 31 December	97,136	110,613	
Group's share in %	50%	50%	ò
Group's share in USD	48,568	55,307	
Carrying amount	48,568	55,307	
marized Statements of Profit or Loss & Other Comprehensive Income			
nousands)	2022	2021 2	2020
renue			
rest income	433	· ·	2,5
reciation and Amortization	829	210	2
rest expense	151	_	_
ome tax expense	<del></del>		4.0
er expenses	4,633		4,84
hange rate differences	<u> </u>	1 (4.026)	65
s for the year	(5,180)	(4,836)	3,0
er comprehensive income		_	
al comprehensive loss	(5,180)	(4,836) (	3,0
idends received from joint venture entity	_	_	_

## Notes to the Consolidated Financial Statements

The Group did not receive any dividends from JVCO during the years ended 31 December 2022, 2021, and 2020. The Group had a \$5.0 million commitment to provide a cash contribution to JVCO as of 31 December 2019, which was paid during the year ended 31 December 2020. Similarly, the joint venture partner had a \$50.0 million commitment to provide a cash contribution to JVCO as of 31 December 2019, which was also paid during the year ended 31 December 2020. The Group does not have any remaining commitments to JVCO as of 31 December 2022 and 2021. Furthermore, the Group does not have any contingent liabilities relating to its interests in JVCO as of 31 December 2022 or 2021. While there are no significant restrictions resulting from contractual arrangements with JVCO, entities in China are subject to local exchange control regulations. These regulations provide for restrictions on exporting capital from those countries, other than dividends.

## 27. Financial instruments

## Accounting classification and carrying amounts

Financial assets as of 31 December 2022 and 2021, all of which are measured at amortized cost, are as follows (in thousands):

	2022	2021
Cash and cash equivalents	66,427	17,556
Restricted cash	25,187	10,087
Trade receivables	32,972	29,396
Other current assets	5,880	14,518
Receivables from related parties	1,548	1,111
Other long-term assets	4,484	_
	136,498	72,668

Financial liabilities as of 31 December 2022 and 2021 are as follows (in thousands):

	2022	2021
Borrowings (measured at amortized cost)	764,570	400,911
Derivative financial liabilities (measured at FVTPL)	380,232	_
Other long-term liability to related party (measured at amortized cost)	7,440	7,440
Long-term incentive plan (measured at FVTPL)	544	56,334
Trade and other payables (measured at amortized cost)	49,188	28,587
Lease liabilities (measured at amortized cost)	40,532	122,140
Liabilities to related parties (measured at amortized cost)	1,131	638
Other current liabilities	53,664	42,012
	1,297,301	658,062

It is management's estimate that the carrying amounts of financial assets and financial liabilities carried at amortized cost approximate their fair value, with the exception of the Senior Bonds, since any applicable interest receivable or payable is either close to current market rates or the instruments are short-term in nature. Material differences between the fair values and carrying amounts of these borrowings are identified as follows (in thousands):

	At 31 Deci	ember 2022
	Carrying Amount	Fair Value
Senior Bonds	530,506	535,167

Notes to the Consolidated Financial Statements

	At 31 Dec	ember 2021
	Carrying Amount	Fair Value
Bonds	363,100	368,476

## Fair value measurements

The following tables illustrate the fair value measurement hierarchy of the Group's financial instruments measured to fair value on a recurring basis as of 31 December 2022 (in thousands):

		2022		
	Level 1	Level 2	Level 3	Total
Senior Bond Warrants		_	45,325	45,325
Tranche A Conversion Feature	_	_	38,055	38,055
Senior Bond Interest Rate Feature (included in other current assets)	_	_	851	851
Predecessor Earn Out Shares	_	276,200	_	276,200
OACB Earn Out Shares	_	10,500	_	10,500
OACB Warrants	10,152			10,152
	10,152	286,700	84,231	381,083

The Group did not recognize any transfers of assets or liabilities between levels of the fair value hierarchy during the years ended 31 December 2022, 2021, and 2020.

The Group recognized derivative financial liabilities related to the equity conversion rights in the convertible bonds as well as the equity conversion rights, warrant rights and funding rights in the convertible shareholder loans as of 31 December 2020. These derivative financial liabilities were extinguished during the year ended 31 December 2021. Refer to Note 20 for additional details on the extinguishment.

## Tranche A Conversion Feature

As noted in Note 20, in connection with the Convertible Bonds the Group classified the Tranche A Conversion Feature as an embedded derivative liability due to the variability created by conversion rates resulting from the tranche being denominated in ISK. The conversion feature had a fair value of \$24.9 million and \$38.1 million as of 20 December 2022 and 31 December 2022, respectively. The change in fair resulted in \$13.2 million of finance costs for the year ended 31 December 2022.

The fair value of the Tranche A Conversion Feature was determined using a lattice model that incorporated inputs and assumptions as further described below. The inputs and assumptions associated with the valuation of the instruments are determined based on all relevant internal and external information available and are reviewed and reassessed at each reporting date. The following table presents the assumptions and inputs that were used for the model in valuing the Tranche A Conversion Feature:

	31 December 2022		20 1	20 December 2022	
Stock price	\$	10.00	\$	8.00	
Conversion price	\$	10.00	\$	10.00	
Volatility rate		45.0%		45.0%	
Risk-free interest rate		4.2%		4.0%	
Dividend yield		0.0%		0.0%	
Risky yield		19.3%		18.6%	

Notes to the Consolidated Financial Statements

## Senior Bond Warrants

As part of the Senior Bonds agreement (see Note 20), the Group agreed to issue penny warrants to the Bondholders that are issuable if certain events occur. The contingently issuable Senior Bond Warrants include two tranches:

- One tranche representing 1.5% of the fully diluted ordinary share capital if the aggregate amount of the net proceeds of all new
  equity issuances received by the Company on or before 15 December 2022 is less than \$75.0 million, as defined in the Senior Bonds
  agreement.
- One tranche representing 1.0% of the fully diluted ordinary share capital if the aggregate amount of the net Proceeds of all new
  equity issuances received by the Company on or before 31 March 2023 is less than \$150.0 million, as defined in the Senior Bonds
  agreement.

The Senior Bond Warrants are accounted for as derivative financial liabilities in accordance with IFRS 9 and IAS 32 and will be subject to ongoing mark-to-market adjustments through the consolidated statement of profit or loss and other comprehensive income or loss. The Senior Bond Warrants had a fair value of \$15.4 million on 16 November 2022. The fair value was determined using the Finnerty model along with the publicly quoted trading price of Ordinary Shares and probability of the contingent events occurring at the valuation date. Probabilities associated with the instruments are determined based on all relevant internal and external information available and are reviewed and reassessed at each reporting date.

On 31 December 2022, the Company issued 4,198,807 warrants, with an exercise price of \$0.01, representing the first tranche of Senior Bond Warrants. The issued warrants, along with the remaining tranche of contingently issuable warrants had a fair value of \$45.3 million as of 31 December 2022. The Group recognized \$29.9 million in finance costs resulting from the change in fair value of the Senior Bond Warrants.

## Predecessor Earn Out Shares

As part of the Business Combination, Predecessor shareholders were granted a total of 38,330,000 Ordinary Shares subject to certain vesting conditions ("Predecessor Earn Out Shares"). One half of the Predecessor Earn Out Shares will vest if, at any time during the five years following the closing of the Business Combination, the Alvotech ordinary share price is at or above a volume weighted average price ("VWAP") of \$15.00 per share for any ten trading days within any twenty-trading day period, with the other half vesting at a VWAP of \$20.00 per share for any ten trading days within any twenty-trading day period. The Predecessor Earn Out Shares are accounted for as derivative financial liabilities in accordance with IAS 32 and will be subject to ongoing mark-to-market adjustments through the consolidated statement of profit or loss and other comprehensive income or loss. The Predecessor Earn Out Shares had a fair value of \$227.5 million at the Closing Date and \$276.2 million as of 31 December 2022, resulting in \$48.7 million of finance costs during the year ended 31 December 2022.

The fair value of the Predecessor Earn Out Shares was determined using Monte Carlo analysis that incorporated inputs and assumptions as further described below. The inputs and assumptions associated with the valuation of the instruments are determined based on all relevant internal and external information available and are reviewed and reassessed at each reporting date. The following table presents the assumptions and inputs that were used for the model in valuing the Predecessor Earn Out Shares:

	31 December 2022	15 June 2022
Share price	\$ 10.00	\$ 9.38
Volatility rate	45.0%	37.5%
Risk-free rate	4.1%	3.4%

Notes to the Consolidated Financial Statements

#### OACB Earn Out Shares

Former OACB shareholders were granted a total of 1,250,000 Ordinary Shares subject to certain vesting conditions ("OACB Earn Out Shares"). One half of the OACB Earn Out Shares will vest if, at any time during the five years following the closing of the Business Combination, the Alvotech ordinary share price is at or above a VWAP of \$12.50 per share for any ten trading days within any twenty-trading day period, with the other half vesting at a VWAP of \$15.00 per share. The OACB Earn Out Shares are accounted for as derivative financial liabilities in accordance with IAS 32 and will be subject to ongoing mark-to-market adjustments through the consolidated statement of profit or loss and other comprehensive income or loss. The OACB Earn Out Shares had a fair value of \$9.1 million at the Closing Date and \$10.5 million as of 31 December 2022, resulting in \$1.4 million of finance costs during the year ended 31 December 2022.

The fair value of the OACB Earn Out Shares was determined using a Monte Carlo analysis that incorporated inputs and assumptions as further described below. Assumptions and inputs associated with the valuation of the instruments are determined based on all relevant internal and external information available and are reviewed and reassessed at each reporting date. The following table presents the assumptions and inputs that were used for the model in valuing the OACB Earn Out Shares:

	31 December	15 June
	2022	2022
Share price	\$ 10.00	\$ 9.38
Volatility rate	45.0%	37.5%
Risk-free rate	4.1%	3.4%

## **OACB Warrants**

Additionally, as part of the Business Combination the Company assumed the 10,916,647 outstanding OACB Warrants, on substantially the same contractual terms and conditions as were in effect immediately prior to the Business Combination, including an exercise price of \$11.50. Each warrant entitles the holder to purchase one Alvotech ordinary share. The OACB warrants are accounted for as derivative financial liabilities in accordance with IAS 32 and will be subject to ongoing mark-to-market adjustments through the consolidated statement of profit or loss and other comprehensive income or loss. The OACB warrants had a fair value of \$11.8 million at the Closing Date and \$10.2 million as of 31 December 2022. The fair value of the warrants was derived from the publicly quoted trading price at the valuation date. The change in fair value of the OACB Warrants resulted in \$1.6 million of finance income for the year ended 31 December 2022.

## Convertible shareholder loans

The fair value of the derivatives associated with the convertible shareholder loans was \$485.9 million and \$534.7 million at 7 December 2021, the date of extinguishment (refer to Note 20 for additional details) and 31 December 2020. Changes in the fair value of the financial instruments during the period are recognized in the consolidated statements of profit or loss and other comprehensive income or loss.

The fair value of the derivatives associated with the convertible shareholder loans on 7 December 2021 was determined based on the number of shares to be issued at the closing of the Business Combination Agreement multiplied by OACB stock price (\$9.86).

In aggregate, the fair value of the derivative liabilities associated with the convertible shareholder loans and convertible bonds at 31 December 2019 was \$479.3 million. In 2020, the fair value of the derivative liabilities increased by \$55.4 million, resulting in derivative liabilities of \$534.7 million at 31 December 2020. In 2021, the fair value of the financial instruments decreased by \$48.8 million, resulting in derivative liabilities of \$485.9 million at 7 December 2021, the date of extinguishment. Included in the changes in fair

## Notes to the Consolidated Financial Statements

value of the derivative liabilities is the amortization of a deferred loss associated with the recognition of funding rights at the inception of the convertible shareholder loan with Aztiq. Specifically, at inception, the fair value of the funding rights, determined using unobservable inputs, exceeded the transaction price by \$15.0 million. The deferred loss was recognized over the 5-year term of the convertible shareholder loan using the straight-line method of amortization. The unamortized deferred loss, which is netted against derivative financial liabilities on the consolidated statements of financial position, was \$3.1 million as of 7 December 2021, the date of extinguishment.

## Capital management

The capital structure of the Group consists of equity, debt and cash. For the foreseeable future, the Board of Directors will maintain a capital structure that supports the Group's strategic objectives through managing the budgeting process, maintaining strong investor relations and managing the financial risks of the Group, as further described below. No changes were made in the objectives, policies or processes for managing capital during the years ended 31 December 2022, 2021 and 2020.

# Financial risk management

The Group's corporate treasury function provides services across the organization, coordinates access to domestic and international financial markets, monitors and manages the financial risks relating to the Group's operations through internal risk reports which analyze exposures by degree and magnitude of risks. These risks include market risk (including currency risk and interest rate risk), credit risk and liquidity risk.

## Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Group's exposure to the risk of fluctuations in market interest rates primarily relates to the cash in bank that is subject to floating interest rates.

The following table provides an interest rate sensitivity analysis for the effect on loss before tax (in thousands):

	2022	2021
Variable-rate financial liabilities +100	(186)	(65)
Variable-rate financial liabilities -100	186	65

## Foreign currency risk

Foreign currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Group's exposure to currency risk arises from financial assets and financial liabilities denominated in other currencies than the presentation currency of the Group.

Below are the foreign currencies that have the most significant impact on the Group's operations.

	Closin	Closing rate		Average rate	
	2022	2021	2022	2021	Change
EUR	1.061	1.133	1.052	1.183	(6.4%)
GBP	1.204	1.350	1.233	1.376	(10.8%)
ISK	0.007	0.008	0.007	0.008	(8.3%)
CHF	1.071	1.094	1.047	1.094	(2.1%)
INR	0.012	0.013	0.013	0.014	(10.1%)

## Notes to the Consolidated Financial Statements

The Group's assets and liabilities that are denominated in foreign currencies as of 31 December 2022 are as follows (in thousands):

	_		Net
	Assets	Liabilities	assets
EUR	36,420	26,514	9,906
GBP	111	1,538	(1,427)
ISK	49,484	109,507	(60,023)
CHF	69	7,305	(7,236)
INR	11	517	(506)

The Group's assets and liabilities that are denominated in foreign currencies as of 31 December 2021 are as follows (in thousands):

	Assets	Liabilities	Net assets
EUR	31,718	15,720	15,998
GBP	180	673	(493)
ISK	5,421	148,747	(143,326)
CHF	715	7,305	(6,590)

A reasonable possible strengthening or weakening of the Group's significant foreign currencies against the USD would affect the measurement of financial instruments denominated in a foreign currency and affect equity by the amount shown in the sensitivity analysis table below. The analysis assumes that all other variables, such as interest rates, remain constant.

	EUR	GBP	ISK	CHF	INR
Year ended 31 December 2022					
-10% weakening	(991)	(143)	(6,002)	(724)	(51)
+10% strengthening	991	143	6,002	724	51
Year ended 31 December 2021					
-10% weakening	(1,600)	(49)	(14,333)	(659)	N/A
+10% strengthening	1,600	49	14,333	659	N/A

## Credit risk

Credit risk it the risk that a counterparty will not fulfill its contractual obligations under a financial instrument contract, leading to a financial loss for the Group. The maximum credit risk exposure for the Group's financial assets as of 31 December 2022 and 2021 is as follows (in thousands):

	2022	2021
Cash and cash equivalents	66,427	17,556
Restricted cash	25,187	10,087
Other assets	44,884	66,344
	136,498	93,987

The Group's cash and cash equivalents and restricted cash are deposited with high-quality financial institutions. Management believes these financial institutions are financially sound and, accordingly, that minimal credit risk exists. The Group has not experienced any losses on its deposits of cash and cash equivalents and restricted cash yet monitors the credit rating of these financial institutions on a periodic basis.

## Notes to the Consolidated Financial Statements

Other assets primarily consist of other current assets, as described in Note 18, and trade receivables and contract assets recognized in connection with the Group's performance pursuant to its contracts with customers, all of which are large multinational pharmaceutical companies. There are no significant amounts past due as of 31 December 2022 and 2021 and the Group concludes that any expected credit losses with respect to these assets is immaterial.

# Liquidity risk

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities that are settled by delivering cash or another financial asset.

Contractual maturities of financial assets and liabilities as of 31 December 2022 are as follows (in thousands):

	Within one year	One to two years	Thereafter	Total
Financial assets				
Non-interest bearing	40,400	_	_	40,400
Variable-interest bearing	66,427	_	29,671	96,098
Total financial assets	106,827		29,671	136,498
Financial liabilities				
Non-interest bearing	104,366	_	7,984	112,350
Fixed-interest bearing - Borrowings	45,757	66,308	896,921	1,008,986
Derivative liabilities		_	380,232	380,232
Variable-interest bearing - Borrowings	25,259	8,036	59,109	92,404
Total financial liabilities	175,382	74,344	1,344,246	1,593,972

Contractual maturities of financial assets and liabilities as of 31 December 2021 are as follows (in thousands):

	Within one year	One to two years	Thereafter	Total
Financial assets			<u> </u>	
Non-interest bearing	29,396	_	_	29,396
Variable-interest bearing	17,556	_	10,087	27,643
Total financial assets	46,952		10,087	57,039
Financial liabilities				
Non-interest bearing	71,237	_	63,774	135,011
Fixed-interest bearing - Borrowings	16,663	33,235	500,675	550,573
Variable-interest bearing - Borrowings	3,041	3,035	1,117	7,193
Total financial liabilities	90,941	36,270	565,566	692,777

Refer to Note 13 for the maturity analysis of the Group's undiscounted lease payments.

Notes to the Consolidated Financial Statements

## 28. Supplemental cash flow information

Supplement cash flow information for the year ended 31 December 2022, 2021 and 2020 is included below (in thousands).

Non-cash investing and financing activities	2022	2021	2020
Acquisition of property, plant and equipment in trade payables	4,131	3,812	
Acquisition of intangibles in trade payables and other current liabilities	4,075	_	_
Right-of-use assets obtained through new operating leases	9,583	18,871	15,204
Addition of the Facility through Aztiq Convertible Bond	115,005	_	_
Non-cash issuance of Aztiq Convertible Bond	80,000	_	_
Equity issued through conversion of borrowings	32,200	346,043	30,000
Acquisition of other intangible assets through financing agreements	_	461	_

## 29. Subsequent events

The Group evaluated subsequent events through 1 March 2023, the date the consolidated financial statements were available to be issued.

On 25 January 2023, the Company issued an additional \$10.0 million in Tranche B Convertible Bonds. Holders of the Tranche B Convertible Bonds may elect, at their sole discretion, to convert all or part of the principal amount and accrued interest into Alvotech Ordinary Shares at a conversion price of \$10.00 per share on 31 December 2023, or 30 June 2024. The conversion feature will be accounted for as an embedded derivative and classified as equity.

On 10 February 2023, the Company completed a private placement equity offering of \$137.0 million, at current ISK exchange rates, of its Ordinary Shares, par value \$0.01 per share, at a purchase price of \$11.57 per share. The Shares are expected be delivered from previously issued ordinary shares held by Alvotech's subsidiary, Alvotech Manco ehf. As a result of proceeds raised from the private placement offering, the Company extinguished the liability related to the Senior Bond Warrants resulting in the potential issuance of penny warrants representing 1.0% of the fully diluted ordinary share capital (see Note 20). This will be accounted for as an extinguishment of a financial liability in the consolidated statement of profit or loss and other comprehensive income or loss.

On 17 February 2023, the first tranche of OACB Earn Out Shares vested resulting in the issuance of 625,000 Ordinary Shares. The issuance of Ordinary Shares for the first tranche will be accounted for as an extinguishment of a financial liability in the consolidated statement of profit or loss and other comprehensive income or loss.

On 27 February 2023, the Group and Teva signed an amendment to the license and development agreement. As part of that amendment, the Group agreed to provide future financial consideration to Teva to assist with the cost of launching and marketing the licensed biosimilar products.

Subsequent to 31 December 2022, Senior Bond Warrant holders elected to exercise their warrants. As a result, 3,014,189 Ordinary Shares were issued in exchange for the exercising of the penny warrants. The Company received an immaterial amount of cash and will recognize the transaction as an extinguishment of the derivative financial liabilities. The difference between the equity issued and carrying value of the

Notes to the Consolidated Financial Statements

derivative financial liabilities will be recognized in the consolidated statement of profit or loss and other comprehensive income or loss.

Subsequent to 31 December 2022, holders of the OACB Warrants exercised their warrant rights for an exercise price of \$11.50 for the rights to one Ordinary Share per warrant. The exercises result in the issuance of 271,150 Ordinary Shares and cash proceeds of \$3.1 million. The Company will recognize the transaction as an extinguishment of the derivative financial liabilities. The difference between the equity issued and carrying value of the derivative financial liabilities will be recognized in the consolidated statement of profit or loss and other comprehensive income or loss.

## PART II. INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 6. Indemnification of Directors and Officers.

Article 441-8 of the Luxembourg Company Law provides that the directors shall not incur any personal obligation by reason of the commitments of the company. Article 441-9 of the Luxembourg Company Law provides that the directors, the members of the management committee and the managing executive officer shall be liable to the company in accordance with general law for the execution of the management to them and for any misconduct in the management of the company's affairs. The directors and members of the management committee shall be jointly and severally liable towards either the company or any third parties for damages resulting from this violation of the Luxembourg Company Law or the company's articles of association. The directors and members of the management committee shall be discharged from such liability in the case of a violation to which they were not a party provided no misconduct is attributable to them and they have reported such violation, as regards members of the board of directors, to the first general meeting and, as regards members of the management committee, during the first meeting of the board of directors after they had acquired knowledge thereof.

Alvotech's articles of association provide that directors of Alvotech are not held personally liable for the indebtedness or other obligations of Alvotech. As agents of Alvotech, they are responsible for the performance of their duties. Subject to the exceptions and limitations listed in Alvotech's articles of association and mandatory provisions of law, every person who is, or has been, a director or officer of Alvotech shall be indemnified by Alvotech to the fullest extent permitted by law against liability and against all expenses reasonably incurred or paid by such person in connection with any claim, action, suit or proceeding which he becomes involved as a party or otherwise by virtue of his or her being or having been a director or officer of Alvotech, or, at the request of Alvotech, of any other company of which Alvotech is a shareholder or creditor and by which he is not entitled to be indemnified, and against amounts paid or incurred by him or her in the settlement thereof. The words "claim", "action", "suit" or "proceeding" shall apply to all claims, actions, suits or proceedings (civil, criminal or otherwise including appeals) actual or threatened and the words "liability" and "expenses" shall include without limitation attorneys' fees, costs, judgments, amounts paid in settlement and other liabilities. However, no indemnification shall be provided to any director or officer of Alvotech (i) against any liability by reason of willful misfeasance, bad faith, gross negligence or reckless disregard of the duties involved in the conduct of his or her office (ii) with respect to any matter as to which he or she shall have been finally adjudicated to have acted in bad faith and not in the interest of Alvotech or (iii) in the event of a settlement, unless the settlement has been approved by a court of competent jurisdiction or by the board of directors of Alvotech.

Alvotech's articles of association provide that the right of indemnification provided by such articles of association shall be severable, shall not affect any other rights to which any director or officer may now or hereafter be entitled, shall continue as to a person who has ceased to be such director or officer and shall inure to the benefit of the heirs, executors and administrators of such a person. Nothing contained in such articles of association shall affect or limit any rights to indemnification to which corporate personnel, including directors and officers, may be entitled by contract or otherwise under law. Alvotech shall specifically be entitled to provide contractual indemnification to and may purchase and maintain insurance for any corporate personnel, including directors and officers of Alvotech, as Alvotech may decide upon from time to time.

In connection with the Business Combination, Alvotech entered into indemnification agreements with each of its directors and executive officers. These agreements provide that Alvotech will indemnify each of its directors and such officers to the fullest extent permitted by law and its articles of association.

Alvotech will also maintain a general liability insurance policy, which will cover certain liabilities of directors and officers of Alvotech arising out of claims based on acts or omissions in their capacities as directors or officers.

## Item 7. Recent Sales of Unregistered Securities

The following list sets forth information as to all of Alvotech's securities sold in the last three years which were not registered under the Securities Act. The descriptions of these issuances are historical and have not been adjusted to give effect to the Business Combination.

In connection with Alvotech's initial formation on August 23, 2021, Alvotech issued 4,000,000 initial shares with a nominal value of \$0.01 per share to Floki Holdings S.à r.l., an affiliate of Alvotech.

In connection with the Business Combination, Alvotech issued 17,493,000 Ordinary Shares to the Subscribers in the PIPE at a price of \$10.00 per share, for an aggregate offering price of \$174,930,000.

On July 12, 2022, Alvotech issued 5,000,000 Ordinary Shares to Aztiq and Alvogen pursuant to the Alvogen-Aztiq Loan Advance Conversion. The shares were issued at a price of \$10.00 per share and set-off against repayment of an aggregate of \$50.0 million of outstanding loans.

On November 16, 2022, Alvotech amended and restated certain terms and conditions of the existing senior bonds and issued new senior bonds in the aggregate principal amount equal to \$70.0 million. Pursuant to the terms of the amended Senior Bonds, Alvotech was required to use commercially reasonable efforts to raise new funding through the issuance of additional Ordinary Shares and/or unsecured convertible bond(s), for net proceeds of at least \$75.0 million by December 15, 2022, and \$150.0 million by March 31, 2023.

Since Alvotech had not raised \$75.0 million by December 15, 2022, Alvotech issued 4,198,807 warrants to the bondholders on December 31, 2022. Each new warrant entitles the bondholders, upon exercise, to receive from Alvotech one Ordinary Share, at the exercise price of one cent (\$0.01) per share. Following the issuance of the December 2022 Convertible Bonds (as described below) and the closing of the private placement of Ordinary Shares for gross proceeds of \$137.0 million on February 10, 2023 (as described below), Alvotech is not obligated to issue the additional 1.0% warrants to the bondholders. Further, if Alvotech fail to raise at least \$150.0 million by March 31, 2023, Alvotech are required to grant penny warrants representing 1.0% of the ordinary share capital to the bondholders.

On November 16, 2022, Alvotech issued the Aztiq Convertible Bond to ATP Holdings ehf. for the acquisition of the Alvotech manufacturing facility. The Aztiq Convertible Bond has a principal amount of \$80.0 million and carries an interest rate of 12.5% per annum. Interest payable in sixmonth intervals and is capitalized and added to the outstanding principal amount of the bonds. The maturity date of the convertible bond is the later of the (i) November 16, 2025, or (ii) 91 days after the earlier of the full redemption or the final maturity date of the Senior Bonds. Bondholders have the right to convert their outstanding bonds into ordinary shares of Alvotech on December 31, 2023, June 30, 2024, or when the bond has been called or put up for redemption, including on the maturity date, for a conversion price of \$10.00 per share.

On December 20, 2022, Alvotech issued two tranches of the December 2022 Convertible Bonds. Tranche A is ISK denominated with a principal balance of \$59.1 million, of which \$3.5 million in cash proceeds were received subsequent to December 31, 2022, and carries an annual payment-in-kind interest rate of 15% per year. Tranche B is USD denominated with a principal balance of \$0.6 million and carries an annual payment-in-kind interest rate of 12.5% per year. Holders of both the Tranche A and Tranche B convertible bonds, may elect, at their sole discretion, to convert all or part of the principal amount and accrued interest into Ordinary Shares at a conversion price of \$10.00 per share on December 31, 2023, or June 30, 2024. On January 25, 2023, we issued an additional \$10.0 million in the Tranche B December 2022 Convertible Bonds.

On February 10, 2023, we closed a private placement of 11,834,061 Ordinary Shares at a purchase price of \$11.57 per Ordinary Share for proceeds of \$137.0 million and transaction costs of \$4.8 million. The offer or sale of Ordinary Shares was made in an overseas directed offering directed solely into Iceland and in accordance with local laws and customary practices and documentation.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The Registrant believes these transactions were exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D or Regulation S promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about the Registrant.

# Item 8. Exhibits.

# (a) Exhibits

The exhibits filed as part of this registration statement are listed in the index to exhibits immediately following the signature page to this registration statement, which index to exhibits is incorporated herein by reference.

Exhibit Number	Description
2.1†	Business Combination Agreement, dated as of December 7, 2021, by and among Oaktree Acquisition Corp. II, Alvotech Lux Holdings S.A.S., and Alvotech Holdings SA (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by OACB on December 7, 2021).
2.2†	First Amendment to the Business Combination Agreement, dated as of December 7, 2021, by and among Oaktree Acquisition Corp. II, Alvotech Lux Holdings S.A.S., and Alvotech Holdings SA, dated April 18, 2022 (incorporated by reference to Exhibit 2.2 to the Registration Statement on Form F-4/A filed on May 2, 2022).
2.3†	Second Amendment to the Business Combination Agreement, dated as of December 7, 2021, by and among Oaktree Acquisition Corp. II, Alvotech Lux Holdings S.A.S., and Alvotech Holdings SA, dated June 7, 2022 (incorporated by reference to Exhibit 2.1 to the Current Report filed on Form 8-K filed by OACB on June 7, 2022).
3.1	Amended and Restated Articles of Association of Alvotech (incorporated by reference to Exhibit 1.1 to the Annual Report on Form 20-F filed on March 1, 2023).
4.1	<u>Specimen Unit Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed by OACB on August 31, 2020).</u>
4.2	<u>Specimen Ordinary Share Certificate (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 filed by OACB on August 31, 2020).</u>
4.3	<u>Specimen Warrant Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1/A filed by OACB on September 14, 2020).</u>
4.4	Warrant Agreement, dated as of September 21, 2020, between Continental Stock Transfer & Trust Company and OACB (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by OACB on September 22, 2020).
4.5	Amended and restated Convertible Bond Instrument (Tranche A), dated November 16, 2022 (incorporated by reference to Exhibit 99.4 to the Current Report on Form 6-K filed on November 17, 2022).
4.6	Amended and restated Convertible Bond Instrument (Tranche B), dated November 16, 2022 (incorporated by reference to Exhibit 99.5 to the Current Report on Form 6-K filed on November 17, 2022).

Exhibit Number	Description	
4.7	Warrant Assignment, Assumption and Amendment Agreement by and between OACB, Alvotech, Continental Stock Transfer & Trust Company, Computershare Inc. and Computershare Trust Company, dated June 15, 2022 (incorporated by reference to Exhibit 2.7 to the Shell Company Report filed on Form 20-F filed on June 22, 2022).	
4.8	Convertible Bond Instrument by and between Alvotech and the Bondholders named therein, dated November 16, 2022 (incorporated by reference to Exhibit 99.9 to the Current Report on Form 6-K filed on November 17, 2022).	
4.9	December 2022 Convertible Bond Instrument (Tranche A) by and between Alvotech and the Bondholders named therein, dated December 20, 2022 (incorporated by reference to Exhibit 2.9 to the Annual Report on Form 20-F filed on March 1, 2023).	
4.10	December 2022 Convertible Bond Instrument (Tranche B) by and between Alvotech and the Bondholders named therein, dated December 20, 2022 (incorporated by reference to Exhibit 2.10 to the Annual Report on Form 20-F filed on March 1, 2023).	
5.1**	Opinion of Arendt & Medernach, as to the validity of Alvotech ordinary shares.	
5.2**	Opinion of Cooley LLP, as to the validity of the Warrants.	
10.1††	<u>License and supply agreement between Alvotech hf. and STADA for AVT02 (Adalimumab), dated August 30, 2019 (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.2††	First Amendment to the license and supply agreement between Alvotech hf. and STADA for AVT02 (Adalimumab) dated August 30, 2019, dated March 13, 2020 (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.3††	Second Amendment to the license and supply agreement between Alvotech hf. and STADA for AVT02 (Adalimumab) dated August 30, 2019, dated May 3, 2021 (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.4††	<u>License and supply agreement between Alvotech hf. and STADA for AVT03 (Denosumab), dated November 6, 2019 (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.5††	First Amendment to the license and supply agreement between Alvotech hf. and STADA for AVT03 (Denosumab) dated November 6, 2019, dated March 13, 2020 (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.6††	<u>License and supply agreement between Alvotech hf. and STADA for AVT04 (Ustekinumab), dated November 6, 2019 (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.7††	First Amendment to the license and supply agreement between Alvotech hf. and STADA for AVT04 (Ustekinumab) dated November 6, 2019, dated March 13, 2020 (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.8††	<u>License and supply agreement between Alvotech hf. and STADA for AVT05 (Golimumab), dated November 6, 2019 (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.9††	First Amendment to the license and supply agreement between Alvotech hf. and STADA for AVT05 (Golimumab) dated November 6, 2019, dated March 13, 2020 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form F-4 filed on December 20, 2021).	

Exhibit Number	Description	
10.10††	<u>License and supply agreement between Alvotech hf. and STADA for AVT06 (Aflibercept), dated November 6, 2019 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.11††	First Amendment to the license and supply agreement between Alvotech hf. and STADA for AVT06 (Aflibercept), dated March 13, 2020 (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.12††	<u>License and supply agreement between Alvotech hf. and STADA for AVT16, dated November 6, 2019 (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.13††	First Amendment to the license and supply agreement between Alvotech hf. and STADA for AVT16, dated November 6, 2019, dated March 13, 2020 (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.14††	<u>Product Supply Agreement between Alvotech hf. and Teva, dated August 5, 2020 (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.15††	<u>License and Development Agreement between Alvotech hf. and Teva, dated August 5, 2020 (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form F-4 filed on December 20, 2021).</u>	
10.16††	Settlement Agreement, Release and Amendment to the License and Development Agreement between Alvotech hf. and Teva dated August 5, 2020, dated June 28, 2021 (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.17††	Amended and Restated Services Agreement between Alvogen and Alvotech, dated April 11, 2022 (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form F-4/A filed on April 19, 2022).	
10.18+	BCA Framework Agreement between Alvotech Holdings S.A., Alvotech Lux Holdings S.A.S., Floki Holdings S.à r.l, and certain other shareholders dated December 7, 2021 (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form F-4 filed on December 20, 2021).	
10.19	Sponsor Letter Agreement, dated as of December 7, 2021, by and among OACB, Sponsor and Alvotech (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by OACB on December 7, 2021).	
10.20	Form of Support Agreement, each dated as of December 7, 2021, by and among, OACB, Alvotech, Alvotech Holdings and certain Alvotech Holdings Shareholders (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by OACB on December 7, 2021).	
10.21	Form of U.S. Subscription Agreement (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by OACB on December 7, 2021).	
10.22	Form of Foreign Subscription Agreement (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by OACB on December 7, 2021).	
10.23	<u>Product Rights Agreement between Alvotech hf. and Alvogen, dated January 22, 2018 (incorporated by reference to Exhibit 10.25 to the Registration Statement on Form F-4/A filed on February 7, 2022).</u>	
10.24††	First Amendment to the Product Rights Agreement between Alvotech hf. and Alvogen dated January 22, 2018, dated December 14, 2018 (incorporated by reference to Exhibit 10.26 to the Registration Statement on Form F-4/A filed on February 7, 2022).	
10.25	<u>Loan Advance between Alvotech Holdings S.A. and Alvogen, dated March 21, 2022 (incorporated by reference to Exhibit 10.27 to the Registration Statement on Form F-4/A filed on April 4, 2022).</u>	

Exhibit Number	Description
10.26	Loan Advance between Alvotech Holdings S.A. and Aztiq, dated March 8, 2022 (incorporated by reference to Exhibit 10.28 to the Registration Statement on Form F-4/A filed on March 14, 2022).
10.27††	Settlement and License Agreement between Alvotech hf. and AbbVie, dated March 8, 2022 (incorporated by reference to Exhibit 10.29 to the Registration Statement on Form F-4/A filed on March 14, 2022).
10.28	Loan Advance between Alvotech Holdings S.A. and Alvogen, dated March 28, 2022 (incorporated by reference to Exhibit 10.30 to the Registration Statement on Form F-4/A filed on April 4, 2022).
10.29††	Settlement and License Agreement between Alvotech hf. and AbbVie, dated April 4, 2022 (incorporated by reference to Exhibit 10.31 to the Registration Statement on Form F-4/A filed on April 19, 2022).
10.30	Loan agreement between Alvotech Holdings S.A. and Alvogen, dated April 11, 2022 (incorporated by reference to Exhibit 10.32 to the Registration Statement on Form F-4/A filed on April 19, 2022).
10.31††	Standby Equity Purchase Agreement between Alvotech and YA II PN, LTD., dated April 18, 2022 (incorporated by reference to Exhibit 10.34 to the Registration Statement on Form F-4/A filed on May 2, 2022).
10.32	Loan agreement between Alvotech Holdings S.A. and Alvogen Lux Holdings S.à r.l., dated June 1, 2022 (incorporated by reference to Exhibit 4.38 to the Shell Company Report filed on Form 20-F filed on June 22, 2022)
10.33	Management Incentive Plan (incorporated by reference to Exhibit 4.39 to the Shell Company Report filed on Form 20-F filed June 22, 2022).
10.34	<u>Investor Rights and Lock-Up Agreement between Alvotech and certain Investors, dated June 15, 2022 (incorporated by reference to Exhibit 10.37 to the Registration Statement on Form F-1 filed on July 14, 2022).</u>
10.35	Subscription and Set-off Agreement between Alvotech and Aztiq, dated July 12, 2022 (incorporated by reference to Exhibit 10.38 to the Registration Statement on Form F-1 filed on July 14, 2022).
10.36	Subscription and Set-off Agreement between Alvotech and Alvogen, dated July 12, 2022 (incorporated by reference to Exhibit 10.39 to the Registration Statement on Form F-1 filed on July 14, 2022).
10.37	Subordinated Loan Agreement by and between Alvotech and Alvogen Lux Holdings S.à r.l., dated November 16, 2022 (incorporated by reference to Exhibit 99.6 to the Current Report on Form 6-K filed on November 17, 2022).
10.38	Warrant Agreement by and between Alvotech and Alvogen Lux Holdings S.à r.l., dated November 16, 2022 (incorporated by reference to Exhibit 99.7 to the Current Report on Form 6-K filed on November 17, 2022).
10.39	Share Purchase Agreement by and between Alvotech and ATP Holdings ehf., dated November 16, 2022 (incorporated by reference to Exhibit 99.8 to the Current Report on Form 6-K filed on November 17, 2022).
10.40	Share Purchase Agreement by and between Alvotech and Alvotech hf., dated December 30, 2022 (incorporated by reference to Exhibit 4.42 to the Annual Report on Form 20-F filed on March 1, 2023).
10.41	<u>Transition Services Agreement between Alvotech and Aztiq Consulting ehf., dated November 16, 2022 (incorporated by reference to Exhibit 99.10 to the Current Report on Form 6-K filed on November 17, 2022).</u>

Exhibit Number	Description		
10.42	Form of Purchase Agreement relating to shares in Alvotech (incorporated by reference to Exhibit 4.44 to the Annual Report on Form 20-F filed on March 1, 2023).		
10.43	Form of Indemnification Agreement between Alvotech and Executive Officers and Directors (incorporated by reference to Exhibit 4.45 to the Annual Report on Form 20-F filed on March 1, 2023).		
10.44	Form of Indemnification Agreement between Alvotech and Non-Executive Directors (incorporated by reference to Exhibit 4.46 to the Annual Report on Form 20-F filed on March 1, 2023).		
10.45	Second amendment to the License and Development Agreement between Alvotech hf. and Teva dated August 5, 2020, dated February 27, 2023 (incorporated by reference to Exhibit 4.47 to the Annual Report on Form 20-F filed on March 1, 2023).		
21.1	List of subsidiaries of Alvotech (incorporated by reference to Exhibit 8.1 to the Annual Report on Form 20-F filed on March 1, 2023).		
23.1*	Consent of Deloitte ehf., independent registered accounting firm for Alvotech.		
23.2**	Consent of Arendt & Medernach (included as part of Exhibit 5.1).		
23.3**	Consent of Cooley LLP (included as part of Exhibit 5.2).		
24.1**	Power of Attorney (included on signature page to the initial filing of the Registration Statement).		
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)		
101.SCH	Inline XBRL Taxonomy Extension Schema Document		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document		
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document		
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)		

<sup>\*</sup> Filed herewith.

# (b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

# (d) Filing Fee Table.

The Filing Fee Table and related disclosure is filed herewith as Exhibit 107.

<sup>\*\*</sup> Previously filed.

<sup>†</sup> Certain schedules and exhibits to this Exhibit have been omitted pursuant to Regulation S-K Item 601(b)(2). The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

<sup>††</sup> Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

<sup>+</sup> Certain schedules and exhibits to this Exhibit have been omitted pursuant to Regulation S-K Item 601(a)(5). The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

## Item 9. Undertakings.

- (a) The undersigned hereby undertakes:
- (1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act;
- (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) that, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
- (iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
- (2) that for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;
- (3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;
- (4) to file a post-effective amendment to the registration statement to include any financial statements required by "Item 8.A. of Form 20-F" at the start of any delayed offering or throughout a continuous offering. Financial statements and information otherwise required by Section 10(a)(3) of the Securities Act need not be furnished; provided, that the registrant includes in the prospectus, by means of a post-effective amendment, financial statements required pursuant to this paragraph and other information necessary to ensure that all other information in the prospectus is at least as current as the date of those financial statements; and
  - (5) that, for the purpose of determining liability under the Securities Act to any purchaser:
    - (i) if the registrant is relying on Rule 430B:
- (A) each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
- (B) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is

part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

- (ii) if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- (b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
  - (c) The undersigned hereby undertakes:
- (1) that for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and
- (2) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

## **SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Grand Duchy of Luxembourg on March 13, 2023.

# ALVOTECH

By: /s/ Robert Wessman
Name: Robert Wessman
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Capacity	Date
/s/ Robert Wessman Robert Wessman	Chief Executive Officer and Executive Chairman of the Board (principal executive officer)	March 13, 2023
/s/ Joel Morales Joel Morales	Chief Financial Officer (principal financial and accounting officer)	March 13, 2023
* Richard Davies	Deputy Chairman of the Board	March 13, 2023
* Tomas Ekman	Director	March 13, 2023
* Faysal Kalmoua	Director	March 13, 2023
* Ann Merchant	Director	March 13, 2023
* Arni Hardarson	Director	March 13, 2023
* Lisa Graver	Director	March 13, 2023
* Linda McGoldrick	Director	March 13, 2023
* By: /s/ Joel Morales  Joel Morales, Attorney-in-fact		

# AUTHORIZED REPRESENTATIVE

Pursuant to the requirements of the Securities Act, this registration statement on Form F-1 has been signed on behalf of the registrant by the undersigned, solely in his capacity as the duly authorized representative of the registrant in the United States, on March 13, 2023.

# ALVOTECH USA INC.

By: /s/ Joel Morales

Name: Joel Morales

# CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement No. 333-266136 on Form F-1 of our report dated March 1, 2023, relating to the financial statements of Alvotech. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Deloitte ehf.

Kópavogur, Iceland

March 10, 2023