# ALVOTECH MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of Alvotech's financial condition and results of operations should be read in conjunction with Alvotech's unaudited condensed consolidated interim financial statements and related notes and other financial information that are included elsewhere in this filing, as well as our audited consolidated financial statements and the related notes for the year ended 31 December 2022 and other financial information included in the Company's annual report on the Form 20-F filed on 1 March 2023. The following discussion is based on Alvotech's financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Some of the information contained in this discussion and analysis, including information with respect to Alvotech's plans and strategy for its business and related financing, includes forward-looking statements that involve risks and uncertainties. Alvotech's actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Unless otherwise indicated or the context otherwise requires, all references to "Alvotech," the "Company," the "Group," "we," "our," "us" or similar terms refer to Alvotech and its consolidated subsidiaries.

All amounts discussed are in U.S. dollars, unless otherwise indicated.

### **Company Overview**

Alvotech is a highly 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 purposebuilt 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 eleven 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.

Alvotech's most advanced product is AVT02, the company's high-concentration biosimilar to Humira® (adalimumab), the world's top-selling non-COVID pharmaceutical product with approximately \$21.2 billion in global sales in 2022. Alvotech received approval for AVT02 for Europe in November 2021 and for Canada and the UK in January 2022. In April 2022, Alvotech's commercial partner, JAMP Pharma, launched AVT02 under the name SIMLANDI in Canada. In June 2022, Alvotech's commercial partner, STADA, launched AVT02 under the name Hukyndra in selected European countries, including France, Germany, Finland, and Sweden. AVT02 was approved in Australia in September 2022 and Saudi Arabia in January 2023. AVT02 is sold in 17 global markets with no negative safety signals or concerns and approved in 42 markets and currently planning for additional launches in additional markets during 2023 pending regulatory clarity.

In September 2020, Alvotech submitted its biologics license application, or BLA, for AVT02 to the FDA and in September 2021, the FDA notified Alvotech it had elected to defer the application. In February 2022, the FDA communicated that it had accepted Alvotech's BLA supporting interchangeability for review. 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.

In April 2023, Alvotech received from the FDA a complete response letter (CRL) for the Company's BLA. The CRL noted that certain deficiencies conveyed following the FDA's recent reinspection of the company's Reykjavik facility must be satisfactorily resolved before the application may be approved.

On 28 June 2023, the FDA issued a CRL for Alvotech's 2<sup>nd</sup> BLA, which contained data to support approval as a high-concentration biosimilar and additional information to support the interchangeability designation. The CRL noted that certain deficiencies, which were conveyed following the FDA's reinspection of the company's Reykjavik facility that concluded in March 2023, must be satisfactorily resolved before the application can be approved.

- Alvotech's next three most advanced product candidates, AVT06, AVT03, and AVT05, are proposed biosimilars to Eylea® (aflibercept), Prolia®/Xgeva® (denosumab) and Simponi®/Simponi Aria® (golimumab), respectively. Alvotech announced that the AVT04 filing was accepted in the U.S. in January 2023, and in Europe in February 2023.
- In March 2023, Alvotech provided BiosanaPharma ("Biosana") a notice of termination for the global licensing agreement between the two companies covering the co-development of AVT23, a proposed biosimilar to Xolair® (omalizumab).
- In May 2023, a confirmatory patient study was initiated for AVT05, a proposed biosimilar to Simponi® and Simponi Aria® (golimumab). The objective of the study is to demonstrate clinical similarity of AVT05 to Simponi® in terms of efficacy, safety, immunogenicity, and pharmacokinetics in adult patients with moderate to severe rheumatoid arthritis. In the twelve months up to April 2023, combined net revenues worldwide from sales of Simponi®, and Simponi Aria® were over U.S. \$2.1 billion according to quarterly filings by the manufacturer of the reference products. Currently Alvotech is aware of only one other company that has initiated a study to support a biosimilar candidate for Simponi® and Simponi Aria®.
- On 19 May 2023, Alvotech entered into termination agreements with STADA Arzneimittel AG ("STADA") to terminate the license and supply agreements between Alvotech and STADA pertaining to Alvotech's product candidates AVT03, a biosimilar candidate to Prolia® / Xgeva® (denosumab), AVT05, a biosimilar candidate to Simponi® and Simponi Aria® (golimumab) and AVT16, a proposed biosimilar to Entyvio® (vedolizumab). Pursuant to the terms of the termination agreements, Alvotech repaid the aggregate amount of \$18.9 million in July 2023 that Alvotech had previously received from STADA under the terminated agreements.
- On 22 May 2023, Alvotech entered into a master license and supply agreement with Mercury Pharma Group Limited (trading as Advanz Pharma Holdings) ("Advanz") and agreed on product schedules with respect to the supply and commercialization in Europe of AVT05, a biosimilar candidate to Simponi® and Simponi Aria® (golimumab), AVT16, a proposed biosimilar to Entyvio® (vedolizumab), and three additional early-stage, undisclosed biosimilar candidates (each, a "Product Schedule"). Under the terms of the agreements with Advanz, Alvotech will develop the product candidates and provide the dossier of data, information and know-how relating to the relevant product candidate to Advanz. Alvotech retains full ownership of all intellectual property rights in the product candidates and the dossiers. Advanz has an exclusive right to use the dossiers to apply for, and, subject to grant, maintain regulatory approvals for the products and to commercialize them in the European Economic Area, the United Kingdom and Switzerland. Advanz made upfront payments in the aggregate amount of \$61.0 million at signing of the Product Schedules and agreed to make additional payments for an aggregate amount of up to \$287.5 million upon the achievement of certain development and commercial milestones. Alvotech will manufacture, supply and deliver the product to Advanz and Advanz will exclusively buy the relevant biosimilar candidate from Alvotech at a royalty of approximately 40% of the estimated net selling price or an agreed-upon applicable floor price, whichever is

higher, for the duration of the relevant Product Schedule.

- On 12 June 2023, Alvotech announced a settlement and license agreement with Johnson & Johnson concerning AVT04, Alvotech's proposed biosimilar to Stelara® (ustekinumab) in the United States. The settlement grants a license entry date for AVT04 in the United States no later than 21 February 2025.
- On 24 July 2023, Alvotech announced that Teva Pharmaceuticals, Inc. ("Teva") and Alvotech have agreed to expand their existing strategic partnership agreement. As part of the agreement, Teva will acquire subordinated convertible bond instruments, dated 20 December 2022, for \$40 million. The expansion to the existing strategic partnership agreement pertains to exclusive commercialization in the U.S. by Teva of two new biosimilar candidates (adding to the five products in the current partnership agreement, AVT02, AVT04, AVT05, AVT06 and AVT16) and line extensions of two current biosimilar candidates in the partnership, to be developed, and manufactured by Alvotech. The agreement includes milestone payments, the majority paid following product approvals and upon achieving significant sales milestones. Teva and Alvotech will share profit from the commercialization of the biosimilars. The agreement also includes increased involvement by Teva regarding manufacturing and quality at Alvotech's manufacturing facility. Teva is actively supporting Alvotech on-site in Iceland to be fully ready for an FDA inspection.
- 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.

Alvotech's net loss was \$86.9 million, and \$184.5 million for the six months ended 30 June 2023, and 2022, respectively. Alvotech's Adjusted EBITDA was \$(146.5) million, and \$(88.5) million for the six months ended 30 June 2023, and 2022, respectively. Alvotech expects to continue to incur expenses and operating losses for the foreseeable future, as it advances its product candidates 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 and the Icelandic stock exchange, director and officer liability insurance premiums, investor and public relations activities and other expenses associated with operating as a public company.

## **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 risks, see the "Risk Factors" sections of Alvotech's filings with the Securities and Exchange Commission. These factors include:

# 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.

## 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 15 June 2022 (the "Closing Date"), Alvotech consummated the business combination with Alvotech Holdings and OACB (the "Business Combination") pursuant to the business combination agreement dated 7 December 2021 and as amended by an amendment agreement dated 18 April 2022 and 7 June 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 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.

The closing of the Business Combination and the PIPE Financing provided the Group with gross proceeds of \$184.7 million that is expected to be used to finance the continuing development and commercialization of its biosimilar products. The Company also incurred \$26.6 million of transaction costs, which represent legal, financial advisory, and other professional fees in connection with the Business Combination and PIPE Financing, during the six months ended 30 June 2022. Of this amount, \$5.6 million represented equity issuance costs related to PIPE Financing.

### The Russia and Ukraine Conflict and Global Economic Conditions

Global economic and business activities continue to face widespread macroeconomic uncertainties, including health epidemics, labor shortages, bank failures, inflation and monetary supply shifts, recession risks and potential disruptions from the Russia-Ukraine conflict. The Company continues to actively monitor the impact of these macroeconomic factors on its financial condition, liquidity, operations, and workforce. We are unable to predict the effect that geopolitical events, including the conflict in Ukraine, global inflation, and rising interest rates, may have on our operations. To the extent that geopolitical events adversely affect our business prospects, financial condition, and results of operations, they may also have the effect of exacerbating many of the other risks described or referenced in the section titled "Risk Factors" of our Annual Report on Form 20-F for the year ended 31 December 2022, filed with the SEC on 1 March 2023.

As of 30 June 2023, the conflict in Ukraine 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

Starting during the six months ended 30 June 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. In June 2022, Alvotech's commercial partner, STADA, launched AVT02 under the name Hukyndra in selected European countries, including France, Germany, Finland, and Sweden. AVT02 was approved in Australia in September 2022 and Saudi Arabia in January 2023. 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 license and other revenue from milestone payments pursuant to long-term outlicense 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.

### Other income

Other income is generated from certain activities performed by Alvotech pursuant to an arrangement with Alvogen Lux Holdings S.à r.l. ("Alvogen"), a related party.

## 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. Cost of product revenue also includes depreciation expense for production equipment, changes to our excess and obsolete inventory reserves, certain direct costs such as shipping 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 and 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 does not capitalize such expenditures as intangible assets until marketing approval by a regulatory authority is obtained or is deemed highly probable. Therefore, Alvotech did not capitalize any research and development expenses as internally developed intangible assets during the six months ended 30 June 2023 and 2022.

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 and geopolitical conflicts;
- production shortages or other supply interruptions in clinical trial materials resulting from the COVID-19 pandemic and geopolitical conflicts;
- 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 or cost of product revenue. 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 Alvotech and CCHT Biopharmaceutical Co., Ltd. (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 the Joint Venture 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 consist of the translation of certain assets and liabilities that are denominated in foreign currency into U.S. dollars.

# 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.

# **Results of Operations**

# Comparison of the Six Months Ended 30 June 2023 and 2022

The following table sets forth Alvotech's results of operations for the six months ended 30 June:

USD in thousands	2023	2022
Product revenue	22,715	3,932
License and other revenue	(2,460)	36,186
Other income	45	142
Cost of product revenue	(67,909)	(17,813)
Research and development expenses	(99,582)	(86,884)
General and administrative expenses.	(41,910)	(139,147)
Operating loss.	(189,101)	(203,584)
Share of net loss of joint venture	(2,706)	(1,266)
Finance income	122,480	50,968
Finance costs	(64,300)	(52,406)
Exchange rate differences.	(3,081)	4,744
Non-operating profit / (loss)	52,393	2,040
Loss before taxes	(136,708)	(201,544)
Income tax benefit	49,854	17,073
Loss for the period	(86,854)	(184,471)

### Product revenue

			Change	
USD in thousands	Six Months I	Ended 30 June	2022 to 202	23
	2023	2022	\$	%
Product revenue	22,715	3,932	18,783	nm

nm = not meaningful, refer to explanation below

The Company successfully launched the AVT02 product in Canada and select European countries during the second quarter of 2022 and increased sales volume in these countries resulted in \$3.9 million and \$22.7 million of product revenue recognized during the six months ended 30 June 2022 and 2023, respectively.

### License and other revenue

			Change	
USD in thousands	Six Months 1	Ended 30 June	2022 to 2023	3
	2023	2022	\$	%
License and other revenue	(2,460)	36,186	(38,646)	nm

nm = not meaningful, refer to explanation below

License and other revenue decreased by \$38.6 million, from \$36.2 million for the six months ended 30 June 2022, to \$(2.5) million for the six months ended 30 June 2023. The decrease in license and other revenue was primarily driven by the recognition of \$34.7 million research and development milestone during the same period in the prior year, due to the completion of the AVT04 main clinical program. The remainder of the decrease is mainly due to the net impact of the changes in licensing arrangements during the six months ended 30 June 2023.

#### Other income

			Change	
USD in thousands	Six Months 1	Ended 30 June	2022 to 20	23
	2023	2022	\$	%
Other income	45	142	(97)	(68.3)

Other income decreased by \$0.1 million, or 68.3%, from \$0.1 million for the six months ended 30 June 2022, to \$0.05 million for the six months ended June 30, 2023. The decrease in other income was driven by a decrease in services performed pursuant to Alvotech's support service arrangements with Alvogen, a related party, during the six months ended 30 June 2023, as compared to the six months ended 30 June 2022.

# Cost of product revenue

			Change	
USD in thousands	Six Months Ended 30 June		2022 to 202	23
	2023	2022	\$	%
Cost of product revenue	67,909	17,813	50,096	nm

nm = not meaningful, refer to explanation below

The Company successfully launched AVT02 in select European countries and Canada during the six months ended 30 June 2022. As a result, the Company recognized cost of product revenue in the amount of \$17.8 million and \$67.9 million during the six months ended 30 June 2022 and 2023, respectively. Cost of product revenue includes both variable and fixed manufacturing costs associated with commercial manufacturing. Cost of product revenue for the period is disproportionate relative to product revenue due to the timing of new launches and elevated production-related charges, resulting in higher costs than revenues recognized for the period. The Company expects this relationship to normalize with increased production from the scaling and expansion of new or recent launches. The Company estimates that the anticipated increase in sales volumes will result in a greater absorption of fixed manufacturing costs. Prior to the recognition of cost of product revenues, costs from pre-commercial manufacturing activities were reported as R&D expenses.

## Research and development expenses

			Change	
USD in thousands	Six Months Ended 30 June		2022 to 2023	
	2023	2022	\$	%
AVT02 development program expenses	2,310	5,558	(3,248)	(58.4)
AVT03 development program expenses	12,821	6,060	6,761	nm
AVT04 development program expenses	3,395	14,189	(10,794)	(76.1)
AVT05 development program expenses	13,851	4,933	8,918	nm
AVT06 development program expenses	15,872	8,058	7,814	97.0
Salary and other employee expenses	19,871	30,699	(10,828)	(35.3)
Depreciation and amortization	3,130	5,827	(2,697)	(46.3)
Other research and development expenses <sup>(1)</sup>	28,332	11,560	16,772	nm
Total research and development expenses	99,582	86,884	12,698	14.6

nm = not meaningful, refer to explanation below

(1) Other research and development expenses include manufacturing costs, facility costs and other operating expenses recognized as research and development expenses during the period.

Research and development expenses increased by \$12.7 million, or 14.6%, from \$86.9 million for the six months ended 30 June 2022, to \$99.6 million for the six months ended 30 June 2023. The increase was primarily driven by a one-time charge of \$18.5 million relating to the termination of the co-development agreement with Biosana for AVT23, and a \$24.6 million increase in direct program expenses mainly from three biosimilar candidates, AVT03, AVT05 and AVT06, that entered clinical development in 2022. These increases were partially offset by a decrease of \$21.0 million primarily related to programs which have completed clinical phase (i.e., AVT02 and AVT04 programs). In addition, upon the launch of AVT02 during the second quarter of 2022, the Company commenced recognizing precommercial manufacturing activities as cost of product revenue. As a result, research and development expenses during the six months ended 30 June 2022 included \$12.3 million of costs relating to AVT02 which have since been recognized as cost of product revenue.

## General and administrative expenses

			Change	
USD in thousands	Six Months Ended 30 June		2022 to 202	23
	2023	2022	\$	%
General and administrative	41,910	139,147	(97,237)	(69.9)
expenses				

General and administrative expenses decreased by \$97.2 million, or 69.9%, from \$139.1 million for the six months ended 30 June 2022, to \$41.9 million for the six months ended 30 June 2023. The decrease in general and administrative expenses was primarily attributable to a \$83.4 million non-cash share listing expense and \$21.0 million of transaction costs as a result of the Business Combination recognized as of 30 June 2022. See Note 1.1 of the unaudited condensed consolidated interim financial statements as of and for the six months ended 30 June 2023 for additional information. The Company also incurred \$10.6 million of IP-related legal expenses during the six months ended 30 June 2022, compared to \$1.3 million during the six months ended 30 June 2023. This decrease was partially offset by a \$7.7 million net increase in other general administrative expenses due to incremental costs from operating as a public company in both the U.S. and Iceland. Lastly, the Company recognized \$7.5 million of general and administrative expenses for share-based payments, resulting from the granting of RSUs during the six months ended 30 June 2023, against \$0.1 million during the six months ended 30 June 2022.

## Share of net loss of joint venture

			Change	
USD in thousands	Six Months I	Ended 30 June	2022 to 2023	
	2023	2022	\$	%
Share of net loss of joint venture	2,706	1,266	1,440	nm

nm = not meaningful, refer to explanation below

Share of net loss of Joint Venture increased by \$1.4 million, from a loss of \$1.3 million for the six months ended 30 June 2022, to a loss of \$2.7 million for the six months ended 30 June 2023. The increase in the share of net loss of joint venture was due to losses incurred by the Joint Venture during the six months ended 30 June 2023, as compared to 30 June 2022, primarily driven by higher depreciation expenses due to an increase in fixed assets related to new office and production buildings incurred by the Joint Venture during the six months ended 30 June 2023.

## Finance income

			Change	
USD in thousands	USD in thousands Six Months Ended 30 J		2022 to 202	3
	2023	2022	\$	%
Finance income	122,480	50,968	71,512	nm

nm = not meaningful, refer to explanation below

Finance income during the six months ended 30 June 2023, relates to a \$99.5 million decrease in fair value of the Earn Out shares issued to holders of shares of Alvotech Holdings at the closing of the Business Combination, a \$14.7 million decrease in fair value of the conversion feature for the Tranche A convertible bonds, and a \$5.3 million decrease in the fair value of the senior bonds warrants. The decrease in fair value was predominantly a result of a decrease in the price of Alvotech's ordinary shares. See Note 22 of the unaudited condensed consolidated interim financial statements as of and for the six months ended 30 June 2023, for additional information.

#### Finance costs

			Change	
USD in thousands	Six Months l	Ended 30 June	2022 to 202	23
	2023	2022	\$	%
Finance costs	64,300	52,406	11,894	22.7

Finance costs increased by \$11.9 million, or 22.7%, from \$52.4 million for the six months ended 30 June 2022, to \$64.3 million for the six months ended 30 June 2023. The increase in finance costs is primarily related to a \$21.5 million increase in interest on debt and borrowings due to the additional financing obtained since 30 June 2022 and a \$5.9 million increase in fair value of derivative liabilities mainly driven by the OACB Warrants and the OACB Earn Out shares. This is partially offset by \$13.9 million in non-recurring charges related to the closing of the Business Combination.

See Note 16 of the unaudited condensed consolidated interim financial statements as of and for the six months ended 30 June 2023, for additional information.

## Exchange rate differences

			Change	
USD in thousands	Six Months I	Ended 30 June	2022 to 202	3
	2023	2022	\$	%
Exchange rate differences	(3,081)	4,744	(7,825)	nm

nm = not meaningful, refer to explanation below

Exchange rate differences decreased by \$7.8 million, from a gain of \$4.7 million for the six months ended 30 June 2022, to a loss of \$3.1 million for the six months ended 30 June 2023. The decrease was primarily driven by the movements in foreign currencies, predominantly Icelandic krona and euros.

### Income tax benefit

			Change	
USD in thousands	Six Months 1	Ended 30 June	2022 to 202	3
	2023	2022	\$	%
Income tax benefit	49,854	17,073	32,781	nm

The income tax benefit increased by \$32.8 million for the six months ended 30 June 2023, compared to the same period for 2022. This increase was driven by \$19.7 million deferred tax credit corresponding to an increase in operating losses and a \$13.8 million favorable foreign currency impact on the strengthening of the Icelandic krona against the US dollar, increasing the US dollar value of tax loss carry-forwards that Alvotech expects to fully utilize against future taxable profits. These increases were partly offset by a \$0.7 million increase in current tax charge.

# Reconciliation of non-IFRS financial measure

In addition to its operating results, as calculated in accordance with IFRS as issued by the IASB, 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 the operating performance and results of business activities performed. The adjusting items for the periods presented herein include the following:

- 1. Income tax benefit;
- 2. Total net finance costs (income);
- 3. Depreciation and amortization of property, plant, and equipment, right-of-use assets and intangible assets;
- 4. Impairment and loss on sale of fixed assets;
- 5. Receivable one-time charge;
- 6. Long-term incentive plan expense;
- 7. Share of net loss of joint venture;
- 8. Exchange rate differences;
- 9. Gain on extinguishment of SARs liability;
- 10. Share listing expense; and
- 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 operational 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 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 period.

The following table reconciles loss for the period to Adjusted EBITDA for the six months ended 30 June 2023 and 2022:

USD in thousands	2023	2022
Loss for the period	(86,854)	(184,471)
Income tax benefit	(49,854)	(17,073)
Total net finance costs (income)	(58,180)	1,438
Depreciation and amortization	10,934	9,977
Impairment and loss on sale of fixed assets	323	-
Receivable one-time charge (5)	18,500	-
Long-term incentive plan expense (1)	11,911	5,555
Share of net loss of joint venture	2,706	1,266
Exchange rate differences	3,081	(4,744)
Gain on extinguishment of SARs liability (2)	-	(4,803)
Share listing expense (3)	-	83,411
Transaction costs (4)	918	20,956
Adjusted EBITDA	(146,515)	(88,488)

- (1) Represents expense related to the long-term incentive plans, reported within general and administrative expenses.
- (2) Represents the gain on extinguishment of the SARs liability, reported within general and administrative 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.
- (5) Represents a one-time charge in relation to the termination of the co-development agreement with Biosana for AVT23.

# Going Concern, Liquidity, and Capital Resources

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 \$86.9 million and \$184.5 million for the six months ended 30 June 2023 and 2022, respectively, and had an accumulated deficit of \$1,741.0 million as of 30 June 2023. As of 30 June 2023, Alvotech had cash and cash equivalents, excluding restricted cash, of \$60.5 million and current assets less current liabilities of \$(9.8) million.

On 25 January 2023, the Company issued an additional \$10.0 million in the December 2022 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.

On 10 February 2023, Alvotech completed a private placement for proceeds of \$137.0 million, and transaction costs of \$4.1 million, at the then-prevailing exchange rates, of its Ordinary Shares at a purchase price of \$11.57 per Ordinary Share.

In May 2023, the Company extended its strategic partnership with Advanz Pharma to commercialize five proposed biosilimars in Europe, yielding upfront payments from Advanz in the aggregate amount of \$61.0 million at signing of the Product Schedules and additional future payments for an aggregate amount of up to \$287.5 million upon the achievement of certain development and commercial milestones.

In July 2023, the Company expanded its existing strategic partnership agreement with Teva who will acquire subordinated convertible bonds in principal amount of \$40 million.

Also in July 2023, the Company secured a private placement of subordinated convertible bonds denominated in Icelandic krona and US dollar for a principal amount of \$100 million. ATP Holdings ehf., a subsidiary of Aztiq, the largest shareholder of Alvotech, committed to acquiring any of the bonds which had not been sold to other investors.

The Company expects to continue to source its cash flows during the development of its biosimilar product candidates from new and existing out-license contracts with commercial partners and financing through shareholder equity and related party and third-party debt financing.

However, even with the aforementioned cash received during 2023, management has determined that there is a material uncertainty that may cast significant doubt about Alvotech's ability to continue as a going concern.

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, if it is successful in these plans, management and the Board of Directors believe that Alvotech will have sufficient funds, and access to sufficient funds, to continue in operation for at least the next 12

months 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 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 30 June 2023, Alvotech had \$808.6 million in borrowings, 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 30 June 2023.

## **Borrowings**

Alvotech's debt consists of interest-bearing borrowings from financial institutions, third parties and related parties. The amount of the outstanding borrowings as of 30 June 2023, totaled \$808.6 million, including payment-in-kind interest and accrued interest. 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 16 of the unaudited condensed consolidated interim financial statements as of and for the six months ended 30 June 2023.

## Senior bonds

As of 30 June 2023, the carrying amount, including accrued interest, of the senior bonds was \$540.2 million. The Company has the option, at any time, to prepay all or any part of the outstanding bonds in exchange for the payment of the redemption premium pursuant to the terms of the agreement.

As a result of proceeds raised from the private placement offering executed in January 2023, 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.

## Convertible Bond

On 25 January 2023, the Company issued an additional \$10.0 million in Tranche B convertible bonds (the "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 US\$10 per share on 31 December 2023, or 30 June 2024.

The conversion feature associated with the Tranche B Convertible Bonds was determined to be an embedded derivative as the economic characteristics and risks are not closely related to the debt host. The Tranche B conversion

feature was classified as equity due to the conversion price having preservation and passage of time adjustments that meet the fixed-for-fixed criteria.

As of 30 June 2023, the carrying amount, including accrued interest, of the Tranche A and Tranche B Convertible Bond was \$41.3 million and \$9.9 million, respectively.

# Aztiq Convertible Bonds and Other Bonds

In April 2023, ATP Holdings ehf., an affiliate of Aztiq, a related party, sold a portion of the Aztiq Convertible Bond to Mitsui & Co., Ltd. ("Mitsui"), a global trading and investment company headquarter in Japan, and Shinhan Healthcare fund 5 ("Shinhan"), a fund established under the laws of the Republic of Korea.

As of 30 June 2023, the carrying amount, including accrued interest, of the Aztiq Convertible Bonds, the Mitsui Convertible Bonds and the Shinhan Convertible Bonds was \$13.8 million, \$54.1 million and \$5.0 million, respectively.

## Alvogen Facility

In connection with the 16 November 2022 Senior Bond amendment, Alvotech entered into a subordinated loan agreement with Alvogen (the "Alvogen Facility").

As of 30 June 2023, the carrying amount, including accrued interest, of the Alvogen Facility was \$70.3 million.

### Other borrowings

In December 2022 the Group refinanced its manufacturing facility in Reykjavik with two Landsbankinn hf loans. Those two Landsbankinn loans were denominated in Icelandic krona and included a conversion clause to convert them into US dollar. The conversion of these two loans took place in March 2023.

Under the terms of the loan agreements after conversion, the first loan is a bullet loan with a final maturity in December 2029 and includes a variable interest rate of USD SOFR plus a margin of 4.75%. The second loan includes annuity payments that are due monthly with a final maturity in December 2027 and a variable interest rate of USD SOFR plus a margin of 3.75%.

The Group determined that conversion to US dollars of the two loans was a substantial modification to loan agreements and accounted for the transaction as an extinguishment. No gain or loss was recognized as part of the extinguishment.

As of 30 June 2023, the outstanding balance on the two loans was \$17.8 million and \$32.7 million, respectively.

## Leases

In April 2023 the Group started to lease a new building in Reykjavik from Fasteignafélagið Eyjólfur ehf., a related party. At the commencement of the lease the carrying value of the asset was \$51.7 million.

Alvotech's future undiscounted payments pursuant to lease agreements totaled \$123.0 million as of 30 June 2023. The timing of these future payments can be found in Note 10 of the unaudited condensed consolidated interim financial statements as of and for the six months ended 30 June 2023.

# Other long-term liability to a related party

Alvotech's other long-term liability to a related party arose from the acquisition of product rights for commercialization of AVT02 in China from Lotus Pharmaceutical Co. Ltd., a related party, during the year ended 31 December 2020. Pursuant to the terms of the asset acquisition, Alvotech is required to pay \$7.4 million upon the commercial launch of AVT02 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 condensed consolidated statements of financial position as of 30 June 2023.

## Purchase obligations

For the six months ended 30 June 2023 and 2022, 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 Six Months Ended 30 June 2023 and 2022

			Change	
USD in thousands	Six Months Ended 30 June		2022 to 2023	
	2023	2022	<b>\$</b>	%
Cash used in operating activities	(128,002)	(141,156)	(13,154)	(9.3)
Cash used in investing activities	(25,225)	(41,504)	(16,279)	(39.2)
Cash generated from financing activities	144,455	293,535	(149,080)	(50.8)

# Operating activities

Net cash used in operating activities decreased by \$13.2 million, or 9.3%, from \$141.2 million for the six months ended 30 June 2022, to \$128.0 million for the six months ended 30 June 2023. The decrease reflected the \$97.6 million decrease in loss for the period, a \$20.2 million increase in interest paid, a \$38.0 million increase in non-cash operating costs and a \$33.7 million decrease in cash used in working capital.

The increase in non-cash operating costs was primarily driven by a \$71.5 million increase in total net finance income and a \$32.8 million increase in income tax benefit and by the \$83.4 million in share listing expense recognized as a result of the Business Combination in the prior period. These were partially offset by a \$18.5 million increase in allowance charges for receivables.

The decrease in cash used in working capital was primarily driven by a \$21.6 million decrease in contract assets, a \$49.9 million increase in contract liabilities, partially offset by a \$23.6 million decrease in other payables. The increase in contract assets and decrease in contract liabilities were driven by the timing of cash collections from Alvotech's partners pursuant to out-license contracts. The decrease in trade receivables is due to the payments received from customers for the achievement of milestones pursuant to out-license contracts.

## Investing activities

Net cash used in investing activities decreased by \$16.3 million, or 39.2%, from \$41.5 million for the six months ended 30 June 2022, to \$25.2 million for the six months ended June 30, 2023. The decrease was primarily driven by a \$6.5 million decrease in cash outflow for intangible assets and a decrease of a \$14.9 million in the restricted cash in connection with the amended bond agreement. This is partially offset by the increase of \$4.9 million in acquisition of property, plant and equipment during the six months ended 30 June 2023.

### Financing activities

Net cash generated from financing activities decreased by \$149.1 million, or 50.8%, from \$293.5 million for the six months ended 30 June 2022, to \$144.5 million for the six months ended 30 June 2023. The decrease was primarily 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 in the prior period. These decreases were offset by a \$226.3 million increase in net proceeds from new borrowings for the six months ended 30 June 2023.

### **Quantitative and Qualitative Disclosures about Market Risk**

Alvotech is 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 Alvotech conducts business. As of 30 June 2023, Alvotech had cash and cash equivalents of \$60.5 million, excluding restricted cash. Alvotech's cash and cash equivalent include both cash in banks and cash on hand.

## Foreign currency exchange risk

Alvotech is subject to foreign exchange risk in its operations, as a majority of its financial assets and financial liabilities are denominated in currencies other than Alvotech's functional currency. Any strengthening or weakening of Alvotech's significant foreign currencies against the USD could impact the measurement of financial instruments in a foreign currency and affect equity. Alvotech's significant assets and liabilities denominated in foreign currencies as of 30 June 2023, are denominated in EUR, GBP, ISK, and CHF.

### Interest rate risk

Alvotech's interest-bearing investments and borrowings are subject to interest rate risk. Alvotech's exposure to the risk of fluctuations in market interest rates primarily relates to the cash in bank that is denominated with floating interest rates. Alvotech analyzes at the end of each year the sensitivity to interest rate changes. Specifically, Alvotech has 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 30 June 2023. Through this analysis, Alvotech notes that the impacts of the interest rate sensitivity did not have a significant effect on loss before tax.

# **Critical Accounting Policies and 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. For a summary of our significant accounting policies, see Note 2 of the audited consolidated financial statements as of and for the years ended 31 December 2022 and 2021.

# **Recent Accounting Pronouncements**

For information on the standards applied for the first time as of 1 January 2023, please refer to Note 4 of the unaudited condensed consolidated interim financial statements as of and for the six months ended 30 June 2023.

## **Emerging Growth Company Status**

Section 102(b)(1) of the Jumpstart our Business Startups Act of 2012 ("JOBS Act") exempts emerging growth companies from certain SEC disclosure requirements and standards. Alvotech intends to take advantage of some of the reduced regulatory and reporting requirements of emerging growth companies pursuant to the JOBS Act so long as Alvotech qualifies as an emerging growth company, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act.

### Material Weaknesses in Internal Control Over Financial Reporting

In connection with the preparation of its audited consolidated financial statements as of 31 December 2022, Alvotech identified material weaknesses in the design and operating effectiveness of its internal control over financial reporting

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 Alvotech 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 Alvotech 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. Upon identifying the material weaknesses, Alvotech began taking steps intended to address the underlying causes of the control deficiencies in order to remediate the material weaknesses, which included the implementation of new tools and controls, engagement of outside consultants to develop remediation plans, provide training to control owners and plans to implement a new enterprise resource planning system and automated controls. Alvotech will continue its remediation efforts, including:

- implementing a compliance tool to provide workflow and electronic approval capabilities as well as to maintain control evidence;
- engaging outside consultants to assist in evaluating the internal controls and developing a remediation plan to address the control deficiencies;
- implementing entity level and business process-level controls to mitigate the key risks identified;
- implementing a new ERP system; and
- hiring more accounting resources.