



Alvotech Reports Financial Results for First three Months of 2023 and Provides Business Update

May 19, 2023

- Revenue for the first three months of 2023 increased to \$15.9 million, compared to \$0.8 million for the same period in 2022
- Confirmatory patient study for AVT05, a proposed biosimilar for Simponi[®] and Simponi Aria[®] (golimumab) initiated, marking the fifth internally developed portfolio candidate to be dosed in a patient study
- Satisfactory outcome of facility reinspection remains the key requirement for U.S. approval of Biologics License Applications (BLAs) for AVT02, a proposed high-concentration, interchangeable biosimilar to Humira[®] (adalimumab)
- Management will conduct a business update conference call and live webcast on Friday, May 19, 2023, at 8:00 am ET (12:00 pm GMT)

REYKJAVIK, Iceland, May 19, 2023 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO, or the "Company"), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today reported unaudited financial results for the first three months of 2023 and provided a summary of recent corporate highlights.

"It is with great pride that we have built a biosimilar-focused platform that now includes five biosimilar candidates that have reached in-patient studies, including AVT02 which is already marketed. I believe that we are well positioned to participate in the promise of global biosimilars for the long-term. And while we are a global company that has launched our first product in 17 markets around the world, we remain committed and focused to bringing AVT02, a proposed high-concentration, interchangeable biosimilar to Humira[®], to patients in the United States, after regulatory approval," said Robert Wessman, Chairman and CEO of Alvotech. "We continue to work collaboratively with the FDA regarding both Biologic License Applications for AVT02 and are preparing for all possible scenarios, including resubmission of the first AVT02 BLA and hosting a possible reinspection of our manufacturing facility, which we would anticipate in 2023, if needed."

Recent Highlights

In April 2023, Alvotech received from the US Food and Drug Administration (FDA) a complete response letter (CRL) for the Company's Biologics License Application (BLA) for AVT02, a high-concentration biosimilar candidate for Humira[®] (adalimumab). 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. Alvotech's second BLA for AVT02, which contains data to support approval as a biosimilar and additional information supporting a potential interchangeability designation, has a Biosimilar User Fee Amendment (BsUFA) goal date of June 28, 2023. Satisfactory outcome of the facility reinspection remains the key requirement for approval of both BLAs. Alvotech has requested a meeting with the FDA's Office of Pharmaceutical Manufacturing Assessment (OPMA) for clarification on the status of any potentially outstanding deficiencies noted in the recent inspection of the company's manufacturing facility.

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 2022, combined net revenues worldwide from sales of Simponi[®] and Simponi Aria[®] were nearly U.S. \$2.3 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[®].

In April 2023, Alvotech continued to strengthen the organization with the appointment of Sarah Tanksley to the Board of Directors of Alvotech hf., the operating entity for Alvotech's manufacturing site, and Sandra Casaca as the company's Chief Quality Officer, based on-site in Iceland. With over 25 years of experience, Sandra has held senior leadership positions in quality at leading companies including Bristol-Myers Squibb, Amgen, AbbVie and Atara.

In March 2023, Alvotech provided Biosana Pharma 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 March 2023, Alvotech provided an update on the company's Corporate Sustainability Framework that included new disclosures for 2022. The company has updated its Sustainability Portal, which provides data on the company's key environmental, social and governance indicators as well as other information related to sustainability. More information can be found at www.alvotech.com/corporate-sustainability.

Financial Results for First Three Months of 2023

Cash position and sources of liquidity

As of March 31, 2023, the Company had cash and cash equivalents of \$115.8 million, excluding \$25.2 million of restricted cash. In addition, the Company had borrowings of \$793.7 million, including \$23.0 million of current portion of borrowings, as of March 31, 2023.

Revenue

Revenue, including other income, was \$15.9 million for the three months ended March 31, 2023, compared to \$0.8 million for the same three months of 2022. Revenue for the three months ended March 31, 2023, consisted of product revenue from sales of AVT02 in certain European countries and

Canada.

Cost of product revenue

Cost of product revenue was \$39.1 million for the three months ended March 31, 2023. These costs were primarily a result of AVT02 product revenues in certain European countries and Canada. Cost of product revenue for the quarter 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 the 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 (R&D) expenses

R&D expenses were \$50.9 million for the three months ended March 31, 2023, compared to \$47.1 million for the same three months of 2022. The increase was 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 \$10.5 million increase in direct program expenses mainly from three biosimilar candidates, AVT03 and AVT06, that entered clinical development in 2022 and AVT05 that entered clinical development in 2023. These increases were partially offset by a decrease in spending of \$13.8 million primarily related to programs for which the clinical activities were winding down. In addition, there was a reclassification of pre-commercial manufacturing activities of \$12.4 million, that were previously recognized as R&D expense, which are now being recognized as cost of product revenue, in conjunction with the Company's commercial launch of AVT02.

General and administrative (G&A) expenses

G&A expenses were \$22.2 million for the three months ended March 31, 2023, compared to \$24.2 million for the same three months of 2022. The decrease in G&A expense was primarily attributable to a decrease of approximately \$7.6 million in IP-related legal expenses and \$2.0 million in transaction costs, which were incurred in 2022 in preparation for the business combination with Oaktree Acquisition Corp. II. This was partially offset by an increase of \$4.4 million in services related to Alvotech's public listing in both the U.S. and Iceland and expenses associated with the company's long-term incentive plan.

Finance income

Finance income was \$1.2 million for the three months ended March 31, 2023, compared to \$4 thousand for the same three months of 2022. This was primarily attributable to interests received on bank accounts resulting from higher cash balances and favourable interest rate environment versus the same period in the prior year.

Finance costs

Finance costs were \$207.6 million for the three months ended March 31, 2023, compared to \$19.9 million for the same three months of 2022. The increase was primarily attributable to a \$179 million non-cash charge associated with the change in fair value of derivative instruments during the three months ended March 31, 2023.

Exchange rate differences

Exchange rate differences resulted in a gain of \$1.7 million for the three months ended March 31, 2023, compared to a gain of \$2.2 million for the same three months of 2022. The decrease was primarily driven by the impact of the exchange rate to financial assets and liabilities denominated in Icelandic Krona and Euros, along with the strengthening of the Icelandic Krona compared to the US Dollar over the current period.

Income tax benefit

Income tax benefit was \$29.4 million for the three months ended March 31, 2023, compared to \$18.2 million for the same three months of 2022. The increase was primarily driven by higher net operating losses, which Alvotech expects to fully utilize against future taxable profits, and a foreign currency benefit of \$6.3 million due to strengthening of the Icelandic Krona against the U.S. dollar, which increased the U.S. dollar value of tax loss carry-forwards expected to be utilized against future taxable profits.

Net Loss

Net loss was 276.2 million, or (\$1.24) per share on a basic and diluted basis, for the three months ended March 31, 2023, as compared to net loss of \$77.1 million, or (\$0.43) per share on a basic and diluted basis, for the same three months of 2022.

Business Update Conference Call

Alvotech will conduct a business update conference call and live webcast on Friday, May 19, at 8:00 am ET (12:00 noon GMT).

A live webcast of the call will be available on Alvotech's website in the Investors Section of the Company's website under <https://investors.alvotech.com> "News and Events – Events and Presentations", where you will also be able to find a replay of the webcast, following the call for 90 days.

In order to participate in the conference call, please register in advance using the link on Alvotech's Investor Relations website under News and Events – Events and Presentations, to obtain a local or toll-free phone number and your personal pin.

About AVT02 (adalimumab)

AVT02 is a monoclonal antibody that is being evaluated for biosimilarity and interchangeability to Humira[®] (adalimumab), which inhibits tumor necrosis factor (TNF). AVT02 has been approved in the EU, Norway, Iceland, Lichtenstein, the UK and Switzerland (Hukyndra[®]); Canada and Saudi Arabia (Simlandi[™]); and Australia (Ciptunec[™] and Aralicip[™]). AVT02 dossiers are under review in multiple countries, including in the United States.

About AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar candidate to Stelara[®] (ustekinumab). Ustekinumab binds to two cytokines, IL-12 and IL-23, that are involved in inflammatory and immune responses. AVT04 is an investigational product and has not received regulatory approval in any country. Biosimilarity is not claimed.

About AVT03 (denosumab)

AVT03 is a human monoclonal antibody and a biosimilar candidate to Prolia[®] and Xgeva[®] (denosumab). Denosumab targets and binds with high

affinity and specificity to the RANK ligand membrane protein, preventing the RANK ligand/RANK interaction from occurring, resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction. AVT03 is an investigational product and has not received regulatory approval in any country. Biosimilarity is not claimed.

About AVT05 (golimumab)

AVT05 is a biosimilar candidate for Simponi® and Simponi Aria® (golimumab). Golimumab is a monoclonal antibody that inhibits tumor necrosis factor alpha (TNF alpha), a cytokine protein in the body. Elevated TNF alpha levels have been implicated in several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. AVT05 is an investigational product and has not received regulatory approval in any country. Biosimilarity is not claimed.

About AVT06

AVT06 is a recombinant fusion protein and a biosimilar candidate to Eylea® (aflibercept), which binds vascular endothelial growth factors (VEGF), inhibiting the binding and activation of VEGF receptors, neovascularization, and vascular permeability. AVT06 is an investigational product and has not received regulatory approval in any country. Biosimilarity is not claimed.

About AVT23

AVT23 is a proposed biosimilar to Xolair® (omalizumab). Omalizumab is an antibody that targets free IgE and is used to treat patients with allergic asthma, chronic spontaneous urticaria (CSU) and nasal polyps. AVT23 is an investigational product and has not received regulatory approval in any country. Biosimilarity is not claimed.

Use of trademarks

Humira is a registered trademark of AbbVie Inc., Stelara, Simponi and Simponi Aria are registered trademarks of Janssen Biotech Inc., Xolair is a registered trademark of Novartis AG, Prolia and Xgeva are registered trademarks of Amgen Inc. Eylea is a registered trademark of Regeneron Pharmaceuticals, Inc.

About Alvotech

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Alvotech's current pipeline contains eight biosimilar candidates aimed at treating autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer. Alvotech has formed a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian countries and large parts of South America, Africa and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit www.alvotech.com. None of the information on the Alvotech website shall be deemed part of this press release.

Forward Looking Statements

Certain statements in this communication may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements generally relate to future events or the future financial or operating performance of Alvotech and may include, for example, Alvotech's expectations regarding future growth, results of operations, performance, future capital and other expenditures, competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, results, level of activities, performance, goals or achievements or other future events, regulatory review and interactions, the satisfactory responses to the FDA's inspection findings and resolution of other deficiencies conveyed following the re-inspection of Alvotech's manufacturing site, the potential approval, including for AVT02 and AVT04 by the FDA and other regulatory agencies and commercial launch of its product candidates, the timing of the announcement of clinical study results, the commencement of patient studies, regulatory applications, approvals and market launches, and the estimated size of the total addressable market of Alvotech's pipeline products. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential" or "continue", or the negatives of these terms or variations of them or similar terminology. Such forward looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to: (1) the outcome of any legal proceedings that may be instituted against Alvotech or others following the business combination between Alvotech Holdings S.A., Oaktree Acquisition Corp. II and Alvotech; (2) the ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (3) the ability to maintain stock exchange listing; (4) changes in applicable laws or regulations; (5) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (6) Alvotech's estimates of expenses and profitability; (7) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (10) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (11) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (12) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (13) Alvotech's ability to obtain and maintain regulatory approval or authorizations of its products, including the timing or likelihood of expansion into additional markets or geographies; (14) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (15) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (16) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (17) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (18) the potential impact of the ongoing COVID-19 pandemic on the FDA's review timelines, including its ability to complete timely inspection of manufacturing sites; (19) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market

conditions, war in Ukraine and global geopolitical tension, and the ongoing and evolving COVID-19 pandemic on the Company's business, financial position, strategy and anticipated milestones; and (20) other risks and uncertainties set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in documents that Alvotech may from time to time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. Nothing in this communication should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed. The recipient agrees that it shall not seek to sue or otherwise hold Alvotech or any of its directors, officers, employees, affiliates, agents, advisors, or representatives liable in any respect for the provision of this communication, the information contained in this communication, or the omission of any information from this communication.

CONTACTS

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Unaudited Condensed Consolidated Interim Statements of Profit or Loss and Other Comprehensive Income or Loss

	Three months ended 31 March 2023	Three months ended 31 March 2022
<i>USD in thousands, except for per share amounts</i>		
Product revenue	15,864	452
License and other revenue	-	-
Other income	19	341
Cost of product revenue	(39,095)	(1,748)
Research and development expenses	(50,864)	(47,138)
General and administrative expenses	(22,198)	(24,173)
Operating loss	<u>(96,274)</u>	<u>(72,266)</u>
Share of net loss of joint venture	(1,164)	(779)
Finance income	1,226	4
Finance costs	(207,600)	(19,938)
Exchange rate difference	(1,748)	(2,159)
Non-operating loss	<u>(209,286)</u>	<u>(22,872)</u>
Loss before taxes	<u>(305,560)</u>	<u>(95,138)</u>
Income tax benefit	29,380	18,159
Loss for the period	<u><u>(276,180)</u></u>	<u><u>(76,979)</u></u>
Other comprehensive income / (loss)		
<i>Item that will be reclassified to profit or loss in subsequent periods:</i>		
Exchange rate differences on translation of foreign operations	648	(84)
Total comprehensive loss	<u><u>(275,532)</u></u>	<u><u>(77,063)</u></u>
Loss per share		
Basic and diluted loss for the period per share	<u>(1.24)</u>	<u>(0.43)</u>

Unaudited Condensed Consolidated Interim Statements of Financial Position

USD in thousands

	31 March 2023	31 December 2022
Non-current assets		-
Property, plant and equipment	224,533	220,594
Right-of-use assets	47,788	47,501
Goodwill	11,911	11,643
Other intangible assets	14,527	25,652
Contract assets	13,070	3,286
Investment in joint venture	47,586	48,568
Other long-term assets	2,012	5,780
Restricted cash	25,187	25,187
Deferred tax assets	239,710	209,496
Total non-current assets	626,324	597,707
Current assets		
Inventories	75,236	71,470
Trade receivables	30,020	32,972
Contract assets	14,691	25,370
Other current assets	31,799	32,949
Receivables from related parties	1,551	1,548
Cash and cash equivalents	115,844	66,427
Total current assets	269,141	230,736
Total assets	895,465	828,443

Unaudited Condensed Consolidated Interim Statements of Financial Position

USD in thousands

	31 March 2023	31 December 2022
Equity		
Share capital	2,281	2,126
Share premium	1,235,274	1,058,432
Other reserves	37,766	30,582
Translation reserve	(794)	(1,442)
Accumulated deficit	(1,930,294)	(1,654,114)
Total equity	(655,767)	(564,416)
Non-current liabilities		
Borrowings	770,656	744,654
Derivative financial liabilities	520,576	380,232
Other long-term liability to related party	7,440	7,440
Lease liabilities	36,865	35,369
Long-term incentive plan	544	544
Contract liabilities	54,651	57,017
Deferred tax liability	166	309
Total non-current liabilities	1,390,898	1,225,565
Current liabilities		
Trade and other payables	29,766	49,188
Lease liabilities	5,222	5,163
Current maturities of borrowings	23,048	19,916
Liabilities to related parties	561	1,131
Contract liabilities	24,847	36,915
Taxes payable	1,790	934

Other current liabilities	75,100	54,047
Total current liabilities	160,334	167,294
Total liabilities	1,551,232	1,392,859
Total equity and liabilities	895,465	828,443

Unaudited Condensed Consolidated Interim Statements of Cash Flows

<i>USD in thousands</i>	Three months ended 31 March 2023	Three months ended 31 March 2022
Cash flows from operating activities		
Loss for the period	(276,180)	(76,979)
Adjustments for non-cash items:		
Long-term incentive plan expense	6,449	1,822
Depreciation and amortization	4,841	4,691
Impairment of property, plant and equipment	-	362
Change in allowance for receivables	18,500	-
Share of net loss of joint venture	1,164	779
Finance income	(1,226)	(4)
Finance costs	207,600	19,938
Exchange rate difference	1,748	2,159
Income tax benefit	(29,380)	(18,159)
Operating cash flow before movement in working capital	(66,484)	(65,391)
(Increase) in inventories	(3,766)	(10,694)
(Increase) / decrease in trade receivables	2,952	27,890
Increase / (decrease) in liabilities with related parties	(573)	1,687
Decrease in contract assets	895	-
(Increase) / decrease in other assets	5,246	(1,914)
Increase / (decrease) in trade and other payables	(18,600)	8,534
Increase / (decrease) in contract liabilities	616	2,400
Increase in other liabilities	(4,477)	1,628
Cash used in operations	(84,191)	(35,860)
Interest received	21	4
Interest paid	(1,845)	(1,616)
Income tax paid	(116)	(110)
Net cash used in operating activities	(86,131)	(37,582)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(11,327)	(12,846)
Acquisition of intangible assets	(2,548)	(348)
Net cash used in investing activities	(13,875)	(13,194)
Cash flows from financing activities		
Repayments of borrowings	(50,812)	(656)
Repayments of principal portion of lease liabilities	(1,525)	(1,750)
Proceeds from new borrowings	60,421	6,770
Gross proceeds from the private placement equity offering	136,879	-
Gross private placement financing fees paid	(4,141)	-
Proceeds from warrants	6,365	-
Proceeds from loans from related parties	-	50,000
Net cash generated from financing activities	147,187	54,364

Increase in cash and cash equivalents	47,181	3,588
Cash and cash equivalents at the beginning of the year	66,427	17,556
Effect of movements in exchange rates on cash held	2,236	(15)
Cash and cash equivalents at the end of the period	<u>115,844</u>	<u>21,129</u>