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

August 30, 2023

- *Product revenue for the first six months of 2023 increased to $22.7 million, compared to $3.9 million for the same period in 2022*
- *Investors, including Teva Pharmaceuticals, subscribed to Alvotech's subordinated convertible bonds for an aggregate amount of $140 million in July 2023*
- *Expanded its existing commercialization partnerships with Teva Pharmaceuticals for the US and with Advanz Pharma for Europe*
- *Settlement reached with Johnson & Johnson securing a US license entry date for AVT04, Alvotech's biosimilar candidate to Stelara® (ustekinumab), no later than February 21, 2025*
- *Management will conduct a business update conference call and live webcast on Thursday August 31, 2023, at 8:00 am ET (12:00 pm GMT)*

REYKJAVIK, Iceland, Aug. 30, 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 six months of 2023 and provided a summary of recent corporate highlights.

"We continue to make significant investments in our manufacturing and quality processes and receiving US approval for AVT02, our interchangeable biosimilar candidate to high-concentration Humira®, remains of highest priority," said Robert Wessman, Chairman and CEO of Alvotech. "Meanwhile, we are expanding our global commercialization partnerships, based on extensive due diligence, which we believe demonstrates our partners' trust in Alvotech and the strength of our platform approach to biosimilars development and manufacture. We are pleased with the recently concluded financing round which we believe also showed the capital markets' confidence in our progress."

Recent Highlights

In May 2023, Alvotech and Advanz Pharma, expanded their partnership adding five biosimilar candidates which Advanz Pharma has agreed to commercialize in Europe. The agreement includes supply and commercialization of AVT05 (golimumab) and AVT16 (vedolizumab), candidate biosimilars to Simponi® and Entyvio®, respectively, and also includes three additional early-stage, undisclosed biosimilar candidates. Under the terms of the agreement, Advanz Pharma made upfront payments to Alvotech in the aggregate amount of $61 million 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. In conjunction with the corresponding termination of commercialization agreements for three of the biosimilar candidates previously licensed to STADA Arzneimittel ("STADA"), Alvotech repaid in early July $18.9 million to STADA.

In June 2023, Alvotech and Teva Pharmaceuticals Inc. ("Teva"), announced that the partners reached a settlement and license agreement with Johnson & Johnson concerning AVT04, Alvotech's proposed biosimilar to Stelara ® (ustekinumab). The settlement grants a license entry date for AVT04 in the US no later than February 21, 2025.

In June 2023, Alvotech received a complete response letter (CRL) from the US Food and Drug Administration (FDA) for the Company's second Biologics License Application (BLA) for AVT02, a high-concentration biosimilar candidate for Humira® (adalimumab), which contained data to support approval as a biosimilar and additional information supporting a potential interchangeability designation. 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.

In July 2023, Alvotech and Teva reached an agreement to expand their existing strategic partnership agreement, pertaining to exclusive commercialization rights in the US by Teva for two new biosimilar candidates developed by Alvotech, as well as line extensions of two current biosimilar candidates. The agreement includes milestone payments to Alvotech, the majority paid following product approvals and upon achieving significant sales milestones, as well as a share of profits from the commercialization of the biosimilars.

In July 2023, Alvotech announced the completion of a convertible private bond placement, in an overseas directed offering directed solely into Iceland to professional clients or eligible counterparties, for a total value of $100 million. Previously, Teva had also agreed to acquire convertible bonds from Alvotech for an additional $40 million, in a separate transaction.

Financial Results for First Six Months of 2023

Cash Position and Sources of Liquidity: As of June 30, 2023, the Company had cash and cash equivalents of $60.5 million, excluding $25.2 million of restricted cash. In addition, the Company had borrowings of $808.6 million, including $22.5 million of current portion of borrowings. Proceeds from the convertible bond placement, as mentioned above, were received subsequent to June 30, 2023.

Product Revenue: Product revenue was $22.7 million for the six months ended June 30, 2023, compared to $3.9 million for the same six months of 2022. Revenue for the six months ended June 30, 2023 consisted of product revenue from sales of AVT02 in select European countries and Canada.

License and Other Revenue: License and other revenue decreased by $38.6 million, which is primarily attributable to 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 principally due to the net impact of the licensing arrangements changed during the period.

Cost of product revenue: Cost of product revenue was $67.9 million for the six months ended June 30, 2023, as a result of the successful launch of AVT02 in select European countries and Canada.

Research and Development (R&D) Expenses: R&D expenses were $99.6 million for the six months ended June 30, 2023, compared to $86.9 million for the same six months of 2022. 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 $32.3 million primarily related to programs that have completed clinical phase, and non-recurrence of pre-commercial manufacturing activities.

General and Administrative (G&A) Expenses: G&A expenses were $41.9 million for the six months ended June 30, 2023, compared to $139.1 million for the same six months of 2022. The decrease in G&A expenses was primarily attributable to a $83.4 million non-cash share listing expense, a $21.0 million of transaction costs recognized as a result of the Business Combination, and a $10.6 million of non-recurring IP-related legal expenses incurred during the six months ended June 30, 2022. 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. Lastly, the Company recognized $7.5 million of G&A expenses for share-based payments, resulting from the granting of Restricted Share Units (RSUs) during the six months ended June 30, 2023.

Loss for the Period: Loss for the period was $86.9 million, or ($0.39) per share on a basic and diluted basis, for the six months ended June 30, 2023, as compared to a loss of $184.5 million, or ($1.02) per share on a basic and diluted basis, for the same six months of 2022.

Business Update Conference Call

Alvotech will conduct a business update conference call and live webcast on Thursday, August 31 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 (https://investors.alvotech.com) under "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.

About AVT02 (adalimumab)

AVT02 is a monoclonal antibody and that has been approved as a biosimilar to Humira® (adalimumab) in several countries globally, including the 27 member states of the European Union, Norway, Lichtenstein, Iceland, the UK, Switzerland, Canada, Australia, Egypt and Saudi Arabia. It is currently marketed in multiple European countries and in Canada. Dossiers are also under review in multiple countries globally.

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 [1]. AVT03 is an investigational product and has not received regulatory approval in any country. Biosimiliarity has not been established by regulatory authorities and is not claimed.

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 [2]. AVT04 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and 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. Elevated TNF alpha levels have been implicated in several chronic inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis [3]. AVT05 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

About AVT06 (aflibercept)

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 [4]. AVT06 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

About AVT16 (vedolizumab)

AVT16 is a biosimilar candidate for Entyvio® (vedolizumab). Vedolizumab is an integrin receptor antagonist and is used for the treatment of moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease [5]. AVT16 is an investigational product and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

[1] https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Prolia/prolia_pi.pdf
[2] https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/STELARA-pi.pdf
[3] https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI-pi.pdf
[4] https://www.regeneron.com/downloads/eylea_fpi.pdf
[5] https://content.takeda.com/?contenttype=PI&product=ENTY&language=ENG&country=USA&documentnumber=1

Use of trademarks

Humira is a registered trademark of AbbVie Inc., Prolia and Xgeva are registered trademarks of Amgen Inc. Stelara, Simponi and Simponi Aria are registered trademarks of Johnson & Johnson Inc. Elyea is a registered trademark of Regeneron Pharmaceuticals Inc. Entyvio is a trademark of Millenium 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 operating performance of Alvotech and may include, for example, Alvotech's expectations regarding 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 submissions, review and interactions, including the resubmission of a BLA for AVT02 and a potential reinspection of Alvotech's manufacturing facility, the satisfactory responses to the FDA's inspection findings and resolution of other deficiencies conveyed following the inspection of Alvotech's manufacturing site, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, including for AVT04, and market launches, the estimated size of the total addressable market of Alvotech's pipeline products, the availability of financing options, including the size, timeline, securities, terms and conditions of, and use of proceeds from, a potential financing. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "expect", "intend", "will", "estimate", "anticipate", "believe", "predict", "potential", "aim" 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 standards; (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) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (9) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (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. 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CONTACTS

Alvotech Investor Relations and Global Communication
Benedikt Stefansson
alvotech.ir@alvotech.com

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

USD in thousands, except for per share amounts	**Six months ended 30 June 2023**	**Six months ended 30 June 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 difference	(3 081)	4 744
Non-operating profit	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)
Other comprehensive loss		
Item that will be reclassified to profit or loss in subsequent periods:		
Exchange rate differences on translation of foreign operations	(1 523)	(4 243)
Total comprehensive loss	(88 377)	(188 714)
Loss per share		
Basic and diluted loss for the period per share	(0,39)	(1,02)

Unaudited Condensed Consolidated Interim Statements of Financial Position

USD in thousands	**30 June 2023**	**31 December 2022**
Non-current assets		
Property, plant and equipment	231,989	220,594
Right-of-use assets	101,402	47,501
Goodwill	11,886	11,643
Other intangible assets	14,007	25,652
Contract assets	8,312	3,286
Investment in joint venture	43,613	48,568
Other long-term assets	2,053	5,780
Restricted cash	25,187	25,187
Deferred tax assets	260,301	209,496
Total non-current assets	698,750	597,707
Current assets		
Inventories	79,366	71,470
Trade receivables	16,307	32,972
Contract assets	19,129	25,370
Other current assets	34,988	32,949
Receivables from related parties	1,656	1,548
Cash and cash equivalents	60,466	66,427
Total current assets	211,912	230,736
Total assets	910,662	828,443

Unaudited Condensed Consolidated Interim Statements of Financial Position

USD in thousands	**30 June 2023**	**31 December 2022**
Equity		
Share capital	2,271	2,126
Share premium	1,224,814	1,058,432
Other reserves	38,308	30,582
Translation reserve	(2,965)	(1,442)
Accumulated deficit	(1,740,968)	(1,654,114)
Total equity	(478,540)	(564,416)
Non-current liabilities		
Borrowings	786,175	744,654
Derivative financial liabilities	229,046	380,232
Other long-term liability to related party	7,440	7,440
Lease liabilities	87,416	35,369
Long-term incentive plan	-	544
Contract liabilities	57,387	57,017
Deferred tax liability	45	309
Total non-current liabilities	1,167,509	1,225,565
Current liabilities		
Trade and other payables	43,931	49,188
Lease liabilities	7,983	5,163
Current maturities of borrowings	22,463	19,916
Liabilities to related parties	1,137	1,131
Contract liabilities	58,978	36,915
Taxes payable	1,520	934
Other current liabilities	85,681	54,047
Total current liabilities	221,693	167,294
Total liabilities	1,389,202	1,392,859
Total equity and liabilities	910,662	828,443

Unaudited Condensed Consolidated Interim Statements of Cash Flows

USD in thousands	**Six months ended 30 June 2023**	**Six months ended 30 June 2022**
Cash flows from operating activities		
Loss for the period	(86 854)	(184 471)
Adjustments for non-cash items:		
Gain on extinguishment of SARs liability	-	(4 803)
Share listing expense	-	83 411
Share-based payment expense	11 911	5 555
Depreciation and amortization	10 934	9 977
Loss on disposal of property, plant and equipment	323	-
Change in allowance for receivables	18 500	-
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 difference	3 081	(4 744)
Income tax benefit	(49 854)	(17 073)
Operating cash flow before movement in working capital	(147 433)	(109 444)
(Increase) in inventories	(7 896)	(15 606)
Decrease in trade receivables	16 665	24 092
Increase / (decrease) in liabilities with related parties	(102)	2 825
(Increase) / decrease in contract assets	1 215	(20 398)
(Increase) / decrease in other assets	3 711	(11 384)
Increase / (decrease) in trade and other payables	(6 182)	17 408
Increase / (decrease) in contract liabilities	37 679	(12 226)
Increase / (decrease) in other liabilities	4 395	(6 963)
Cash used in operations	(97 948)	(131 696)
Interest received	25	8
Interest paid	(29 427)	(9 220)
Income tax paid	(652)	(248)
Net cash used in operating activities	(128 002)	(141 156)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(22 594)	(17 660)
Disposal of property, plant and equipment	133	379
Acquisition of intangible assets	(2 764)	(9 309)
Restricted cash in connection with the amended bond agreement	-	(14 914)
Net cash used in investing activities	(25 225)	(41 504)
Cash flows from financing activities		
Repayments of borrowings	(84 507)	(1 414)
Repayments of principal portion of lease liabilities	(3 700)	(5 033)
Proceeds from new borrowings	93 561	10 786
Gross proceeds from the private placement equity offering fee	136 877	-
Gross private placement equity offering fee paid	(4 141)	-
Proceeds from warrants	6 365	-
Gross proceeds from the PIPE Financing	-	174 930
Gross PIPE Financing fees paid	-	(5 561)
Proceeds from the Capital Reorganization	-	9 827
Proceeds from loans from related parties	-	110 000
Net cash generated from financing activities	144 455	293 535
(Decrease) increase in cash and cash equivalents	(8 772)	110 875
Cash and cash equivalents at the beginning of the period	66 427	17 556
Effect of movements in exchange rates on cash held	2 811	7
Cash and cash equivalents at the end of the period	60 466	128 438