Alvotech Reports Financial Results for First Quarter of 2024 and Provides a Business Update

May 21, 2024

- *Total revenues in Q1 2024 increased to $37 million compared to $16 million in the same period last year.*
- *Gross margin in Q1 2024 increased to $17 million, by $40 million compared to the same period last year.*
- *Alvotech signed new commercialization agreements for its high concentration interchangeable biosimilar to Humira® in the U.S. and for its proposed biosimilar to Prolia® and Xgeva® in the U.S. and Europe.*
- *Alvotech raises topline revenue guidance to $400-$500 million and tightens guidance for bottom line range for 2024 to $100-$150 million.*
- *Management will conduct a business update conference call and live webcast on Wednesday May 22, 2024, at 8:00 am ET (12:00 pm GMT).*

REYKJAVIK, Iceland, May 21, 2024 (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 2024 and provided a summary of recent corporate highlights.

"This year is turning out to be the busiest in Alvotech's history. We secured U.S. Food and Drug Administration (FDA) approval of AVT04, our biosimilar to Stelara® in the U.S., signed a key strategic partnership and commercialization agreement for our high concentration interchangeable biosimilar to Humira® in the U.S., under private label, as well as a new commercialization agreement in the U.S. and Europe for AVT03, our proposed biosimilar to Prolia® and Xgeva®. In addition to the U.S. private-label commercialization agreement, our partner Teva is making great progress on discussions positioning our Humira® biosimilar on formularies in the U.S.," said Robert Wessman, Chairman and CEO of Alvotech. "Pipeline development progressed briskly as well. On top of the recently announced results from our confirmatory patient study for AVT06, our biosimilar candidate to Eyela®, we've now announced positive top-line results from the confirmatory patient study for AVT05, our proposed biosimilar to Simponi® and are thus on track to file marketing applications for at least three biosimilar candidates in the second half of this year.

Joel Morales, Chief Financial Officer of Alvotech, added: "Based on rapid progress in commercialization and development, we raise our revenue guidance for 2024, to $400 - $500 million and tighten our guidance for EBIDTA to $100 - $150 million for the full year."

Recent Highlights

Alvotech and its commercialization partner in the U.S., Teva Pharmaceuticals ("Teva"), announced that the FDA approved AVT04 (ustekinumab-aekn) for marketing in the U.S. as a biosimilar to Stelara, under the tradename Selarsdi. The biosimilar has been launched in Canada, will be launched in Japan imminently in May, and is expected to be launched in Europe in Q3 2024 and in the U.S. in February next year.

Alvotech announced a U.S. strategic partnership agreement with Quallent Pharmaceuticals ("Quallent"), a subsidiary of Cigna group. Alvotech's high-concentration interchangeable biosimilar to Humira (adalimumab) will be distributed under Quallent's private label. As this is the first high-concentration, citrate-free biosimilar to Humira granted an interchangeability status by the FDA, Alvotech will have interchangeable exclusivity for the high-concentration presentation 40mg/0.4mL.

Alvotech signed a commercial partnership agreement with Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's"), for the commercialization of AVT03, Alvotech's biosimilar candidate to Prolia ® and Xgeva® (denosumab). The commercialization agreement includes an upfront payment to Alvotech with subsequent payments upon certain development and commercialization milestones as well as royalties on product sales. Dr. Reddy's commercialization rights are exclusive for the U.S. and semi-exclusive for Europe.

Alvotech announced positive top-line results from a confirmatory clinical study for AVT05, a proposed biosimilar to Simponi® and Simponi Aria® (golimumab). Alvotech is the first company to announce positive topline results of a clinical trial using a proposed biosimilar to Simponi and Simponi Aria and is one of only two companies known to have initiated such a patient study.

Financial Results for First Three Months of 2024

Cash position and sources of liquidity: As of March 31, 2024, the Company had cash and cash equivalents of $64.8 million, excluding $25.0 million of restricted cash. In addition, the Company had borrowings of $978.1 million, including $37.6 million of current portion of borrowings, as of March 31, 2024.

Product Revenue: Product revenue was $12.4 million for the three months ended March 31, 2024, compared to $15.7 million for the same three months of 2023. Revenue for the three months ended March 31, 2024, consisted of product revenue from sales of AVT02 in select European countries and Canada, launch of AVT02 in the U.S and launch of AVT04 in Canada.

License and Other Revenue: License and other revenue was $24.4 million for the three months ended March 31, 2024. No license and other revenue were recognized during the first three months ended March 31, 2023. The license and other revenue of $24.4 million was primarily attributable to the recognition of a $6.5 million research and development milestone due to the approval of AVT04 in Europe and $16.8 million relative to research and development milestone due to the CTA submission for the AVT16 clinical program.

Cost of product revenue: Cost of product revenue was $20.0 million for the three months ended March 31, 2024, compared to $39.1 million for the same three months of 2023, as a result of sales in the period, including the launch of AVT04 in Canada, tempered by lower production-related charges and other costs associated with FDA inspection readiness. 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 continue normalizing 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.

Research and development (R&D) expenses: R&D expenses were $49.9 million for the three months ended March 31, 2024, compared to $50.9 million for the same three months of 2023. The slight decrease 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 recognized during the three months of 2023, and a $17.8 million increase in direct program expenses mainly from five biosimilar candidates, AVT03, AVT05, AVT06, AVT16 and AVT23 that are in clinical phase.

General and administrative (G&A) expenses: G&A expenses were $15.5 million for the three months ended March 31, 2024, compared to $22.2 million for the same three months of 2023. The decrease in G&A expenses was primarily attributable to $3.7 million in lower 3rd party services, lower insurance premiums and less headcount, coupled with a $1.9 million decrease in expenses for share-based payments.

Finance income: Finance income was $0.8 million for the three months ended March 31, 2024, compared to $1.2 million for the same three months of 2023. This was primarily attributable to interests received on bank accounts resulting from lower cash balances versus the same period in the prior year.

Finance costs: Finance costs were $184.1 million for the three months ended March 31, 2024, compared to $207.6 million for the same three months of 2023. The decrease was primarily attributable to lower fair value of derivative liabilities from $179.1 million for the three months ended March 31, 2023, to $140.9 million for the three months ended March 31, 2024, partially offset by an increase in interest charged on additional borrowings and convertible bonds issued during 2023.

Exchange rate differences: Exchange rate differences resulted in a gain of $6.5 million for the three months ended March 31, 2024, compared to a loss of $1.7 million for the same three months of 2023. The increase was primarily driven by the movements in the exchange rate of foreign currencies, predominantly Icelandic krona and euros.

Income tax benefit: Income tax benefit was $6.4 million for the three months ended March 31, 2024, compared to $29.4 million for the same three months of 2023. The decrease was mainly driven by a decrease in operating losses and an unfavorable foreign currency translation effect during the three months ended March 31, 2024 due to the weakening of the Icelandic krona against the U.S. dollar.

Loss for the Period: Reported net loss was $218.7 million, or ($0.89) per share on a basic and diluted basis, for the three months ended March 31, 2024, compared to a reported net loss of $276.2 million, or ($1.24) per share on a basic and diluted basis, for the same three months of 2023. As mentioned above, the net loss for the period is heavily impacted by the fair value costs associated with our derivative liabilities.

Business Update Conference Call

Alvotech will conduct a business update conference call and live webcast on Wednesday, May 22, 2024, at 8:00 am EDT (12:00 pm GMT). Registration for the conference call and access to the live webcast is found on https://investors.alvotech.com/events/event-details/q1-2024-earnings, 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 has been approved as a biosimilar to Humira® (adalimumab) in over 50 countries globally, including the U.S., Europe, Canada, Australia, Egypt, Saudi Arabia and South Africa. It is currently marketed in multiple European countries as HUKYNDRA and LIBMYRIS, in Canada as SIMLANDI and in Australia as ADALACIP. Dossiers are also under review in multiple countries globally.

About AVT04 (ustekinumab)

AVT04 is a monoclonal antibody and a biosimilar to Stelara® (ustekinumab). Ustekinumab binds to two cytokines, IL-12 and IL-23, that are involved in inflammatory and immune responses [1]. AVT04 has been launched in Canada as JAMTEKI and has received market authorization in Japan as USTEKINUMAB BS (F), in the EEA as UZPRUVO and in the U.S. as SELARSDI. 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 [2]. 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 AVT05 (golimumab)

AVT05 is a biosimilar candidate for Simponi® and Simponi Aria® (golimumab). Golimumab is a monoclonal antibody that inhibits tumor necrosis factor (TNF) 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.

Sources

[1] https://www.ema.europa.eu/en/documents/product-information/uzpruvo-epar-product-information_en.pdf
[2] https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/Prolia/prolia_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

Use of trademarks

Humira is a registered trademark of AbbVie Inc. Stelara is a registered trademark of Johnson & Johnson 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.

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.

Please visit our investor portal, and our website or follow us on social media on LinkedIn, Facebook, Instagram, X and YouTube.

Alvotech 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, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, and market launches. 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 ability to raise substantial additional funding, which may not be available on acceptable terms or at all; (2) the ability to maintain stock exchange listing standards; (3) changes in applicable laws or regulations; (4) the possibility that Alvotech may be adversely affected by other economic, business, and/or competitive factors; (5) Alvotech's estimates of expenses and profitability; (6) Alvotech's ability to develop, manufacture and commercialize the products and product candidates in its pipeline; (7) actions of regulatory authorities, which may affect the initiation, timing and progress of clinical studies or future regulatory approvals or marketing authorizations; (8) the ability of Alvotech or its partners to respond to inspection findings and resolve deficiencies to the satisfaction of the regulators; (9) the ability of Alvotech or its partners to enroll and retain patients in clinical studies; (10) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (11) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (12) 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; (13) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (14) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (15) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (16) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (17) the impact of worsening macroeconomic conditions, including rising inflation and interest rates and general market conditions, conflicts in Ukraine, the Middle East and other global geopolitical tension, on the Company's business, financial position, strategy and anticipated milestones; and (18) 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. 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ALVOTECH INVESTOR RELATIONS AND GLOBAL COMMUNICATIONS

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

USD in thousands, except for per share amounts	Three months ended March 31, 2024	Three months ended March 31, 2023
Product revenue	12,430	15,864
License and other revenue	24,422	-
Other income	42	19
Cost of product revenue	(19,957)	(39,095)
Research and development expenses	(49,868)	(50,864)
General and administrative expenses	(15,488)	(22,198)
Operating loss	(48,419)	(96,274)
Share of net loss of joint venture	-	(1,164)
Finance income	783	1,226
Finance costs	(184,063)	(207,600)
Exchange rate differences	6,532	(1,748)
Non-operating loss	(176,748)	(209,286)
Loss before taxes	(225,167)	(305,560)
Income tax benefit	6,438	29,380
Loss for the period	(218,729)	(276,180)
Other comprehensive loss		
Item that will be reclassified to profit or loss in subsequent periods:		
Exchange rate differences on translation of foreign operations	(820)	648
Total comprehensive loss	(219,549)	(275,532)
Loss per share		
Basic and diluted loss for the year per share	(0.89)	(1.24)

Unaudited Condensed Consolidated Interim Statement of Financial Position

USD in thousands	31 March 2024	31 December 2023
Non-current assets		
Property, plant and equipment	235,394	236,779
Right-of-use assets	127,440	119,802
Goodwill	11,779	12,058
Other intangible assets	19,370	19,076
Contract assets	10,356	10,856
Investment in joint venture	18,494	18,494
Other long-term assets	2,285	2,244
Restricted cash	25,000	26,132
Deferred tax assets	318,223	309,807
Total non-current assets	768,341	755,248
Current assets		
Inventories	92,236	74,433
Trade receivables	41,252	41,292
Contract assets	30,059	35,193

Other current assets	62,900	31,871
Receivables from related parties	1,038	896
Cash and cash equivalents	64,811	11,157
Total current assets	292,296	194,842
Total assets	1,060,637	950,090

Unaudited Condensed Consolidated Interim Statement of Financial Position

USD in thousands	**31 March 2024**	**31 December 2023**
Equity		
Share capital	2,604	2,279
Share premium	1,726,610	1,229,690
Other reserves	38,883	42,911
Translation reserve	(2,348)	(1,528)
Accumulated deficit	(2,424,574)	(2,205,845)
Total equity	(658,825)	(932,493)
Non-current liabilities		
Borrowings	940,593	922,134
Derivative financial liabilities	330,976	520,553
Lease liabilities	110,585	105,632
Contract liabilities	88,913	73,261
Deferred tax liability	1,610	53
Total non-current liabilities	1,472,677	1,621,633
Current liabilities		
Trade and other payables	50,175	80,563
Lease liabilities	11,161	9,683
Current maturities of borrowings	37,550	38,025
Liabilities to related parties	24,532	9,851
Contract liabilities	46,258	59,183
Taxes payable	1,096	925
Other current liabilities	76,013	62,720
Total current liabilities	246,785	260,950
Total liabilities	1,719,462	1,882,583
Total equity and liabilities	1,060,637	950,090

Unaudited Condensed Consolidated Interim Statements of Cash Flows

USD in thousands	**Three months ended March 31, 2024**	**Three months ended March 31, 2023**
Cash flows from operating activities		
Loss for the year	(218,729)	(276,180)
Adjustments for non-cash items:		
Long-term incentive plan expense	-	6,449
Depreciation and amortization	7,190	4,841
Change in allowance for receivables	-	18,500
Change in inventory reserves	(5,379)	-
Share of net loss of joint venture	-	1,164

Finance income	(783)	(1,226)
Finance costs	184,063	207,600
Share-based payments	2,828	-
Exchange rate difference	(6,532)	1,748
Income tax benefit	(6,438)	(29,380)
Operating cash flow before movement in working capital	(43,780)	(66,484)
Increase in inventories	(12,424)	(3,766)
Increase in trade receivables	40	2,952
Increase / (decrease) in liabilities with related parties	14,539	(573)
(Increase) / decrease in contract assets	5,634	895
Increase in other assets	(2,959)	5,246
Increase in trade and other payables	(28,927)	(18,600)
Increase in contract liabilities	4,176	616
(Decrease) / increase in other liabilities	(7,139)	(4,477)
Cash used in operations	(70,840)	(84,191)
Interest received	26	21
Interest paid	(4,403)	(1,845)
Income tax paid	(186)	(116)
Net cash used in operating activities	(75,403)	(86,131)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(4,069)	(11,327)
Acquisition of intangible assets	(543)	(2,548)
Restricted cash in connection with amended bond agreement	1,132	-
Net cash used in investing activities	(3,480)	(13,875)
Cash flows from financing activities		
Repayments of borrowings	(1,629)	(50,812)
Repayments of principal portion of lease liabilities	(2,338)	(1,525)
Proceeds from new borrowings	-	60,421
Gross proceeds from equity offering	138,049	136,879
Fees from equity offering	(5,743)	(4,141)
Proceeds from warrants	4,841	6,365
Net cash generated from financing activities	133,180	147,187
Decrease in cash and cash equivalents	54,297	47,181
Cash and cash equivalents at the beginning of the period	11,157	66,427
Effect of movements in exchange rates on cash held	(643)	2,236
Cash and cash equivalents at the end of the period	64,811	115,844