Alvotech Reports First Half 2022 Financial Results and Business Update

August 31, 2022

- *Secured funding of approximately $185 million in gross proceeds through the merger with OACB (the "Business Combination") and private placement investment in public equity (PIPE) financing*
- *Debuted as publicly traded company on Nasdaq Stock Exchange in U.S. and on Nasdaq First North Market in Iceland; Board approved plan to move Iceland listing to Nasdaq Main Market*
- *Revenues for first half of 2022 increased to $40 million, driven by revenue from milestones related to pipeline progress and recent launches of AVT02 (adalimumab) in Canada and certain European markets*
- *Continued progress of the pipeline, including becoming the 2nd company to report positive topline results from a patient study for a proposed biosimilar to Stelara®*
- *Management to conduct a business update conference call and live webcast on Thursday, September 1, 2022, at 8:00 am ET (12:00 pm GMT)*

REYKJAVIK, Iceland, Aug. 31, 2022 (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 financial results for the first half of 2022 and provided a summary of recent corporate highlights. The company also filed the interim financial statements with the Icelandic stock exchange for the first six months of 2022, in accordance with the Nasdaq First North rulebook.

"We have achieved a number of pivotal milestones since we first announced our intention to enter the public markets; launching our first biosimilar in Europe and Canada, advancing multiple biosimilar candidates into clinical trials and transitioning from being a privately held company to being publicly listed both in the U.S. and Iceland," said founder and Executive Chairman of Alvotech, Robert Wessman. "We continue to deliver on our strategy and remain steadfast in our mission to improve people's lives by expanding access to affordable biologic medicines globally, through the promise of biosimilars."

Pipeline Highlights

Received approval for AVT02 in Canada: Health Canada granted marketing authorization for AVT02 paving way for marketing in Canada.

Exclusive global licensing agreement with BiosanaPharma: Entered into an exclusive global licensing agreement with BiosanaPharma to co-develop AVT23, a proposed biosimilar to Xolair® (omalizumab).

Expanded partnership for Japanese market: Granted Fuji Pharma exclusive commercial rights to an undisclosed biosimilar currently in early phase development by Alvotech. The agreement brings the total number of proposed biosimilars with respect to which the company is partnering to six.

FDA Accepted BLA for AVT02 including biosimilarity and interchangeability: Alvotech is the only known company that has a high-concentration biosimilar candidate to Humira® that has completed a switching study, to support a proposed interchangeable designation for the high concentration adalimumab; goal date in December 2022

Resolved U.S. Patent and Trade Secret Disputes with AbbVie: Alvotech executed a U.S. settlement agreement with AbbVie that grants Alvotech non-exclusive rights to market AVT02 (100mg/mL), its high-concentration, citrate-free biosimilar candidate for Humira® (adalimumab) in the United States. The settlement grants Alvotech a license entry date in the United States of July 1, 2023.

Announced positive results from a PK similarity study for AVT04: Results demonstrate bioequivalence of AVT04 (ustekinumab) to the reference product, Stelara®.

Announced positive results from a clinical patient study for AVT04: Results demonstrate therapeutic equivalence between AVT04 (ustekinumab) and the reference product, Stelara®. Alvotech is the 2nd company to report positive topline results from a patient study for a proposed biosimilar to Stelara®.

Launched AVT02 with JAMP Pharma in Canada: Exclusive Canadian partner JAMP Pharma launched AVT02 (adalimumab) under tradename Simlandi™.

Launched AVT02 with STADA in Europe: Exclusive European partner STADA launched AVT02 (adalimumab) under tradename Hukyndra® in European markets.

Initiated patient study for AVT06: Confirmatory clinical study in patients for AVT06 (aflibercept), a biosimilar candidate to Eylea®.

Initiated Pharmacokinetics study for AVT03: Pharmacokinetic, safety and tolerability study in healthy subjects for AVT03 (denosumab), a biosimilar

candidate to Prolia® and Xgeva®.

Initiated Patient Study for AVT03: Confirmatory clinical study in patients for AVT03 (denosumab), a biosimilar candidate for Prolia® and Xgeva®

Corporate Highlights

Completed merger with Oaktree Acquisition Corp. II (OACB): Transaction included a fully committed and upsized $175 million PIPE raised through top-tier investors at $10.00 per share.

Listed on Nasdaq Stock Market in U.S.: Ordinary shares and warrants began trading under ticker symbols “ALVO” and “ALVOW”, respectively. Largest debut by an Icelandic company on a U.S. stock exchange.

Listed on First North Market in Iceland: First dual-listed Icelandic company on both a United States and Icelandic stock market.

Expanded and diversified Board of Directors: Four new members enhance independence and diversity of Board of Directors.

Announced plan to list on Icelandic Main Market: Board of Directors approved a plan to move share listing in Iceland from the First North Growth Market to the Nasdaq Main Market.

Launched ESG reporting portal: Provides further transparency to stakeholders with reporting on Environmental, Social and Governance indicators.

Financial Results for First Half 2022

As of June 30, 2022, the Company had $128.4 million in cash and cash equivalents. In addition, the Company had borrowings of $559.0 million, including $120.8 million of current portion of borrowings, as of June 30, 2022.

Revenue: Revenue was $40.1 million for the six months ended June 30, 2022, compared to $2.0 million for the same six months of 2021. Revenue in the first six months ended June 30, 2022 consisted of $3.9 million of product revenue from the sales of AVT02 in select European countries and Canada, and $36.2 million of license and other revenue from the completion of the milestone related to the AVT04 main clinical program during the six months ended June 30, 2022.

Cost of Product Revenue: Cost of product revenue was $17.8 million for the six months ended June 30, 2022. These costs were a result of the successful launch of AVT02 in select European countries and Canada during the six months ended June 30, 2022.

Research and Development (R&D) Expenses: R&D expenses were $86.9 million for the six months ended June 30, 2022, compared to $90.4 million for the same six months of 2021. This decrease was primarily due to pre-commercial manufacturing costs that were previously recognized as research and development and are now recognized as cost of product revenue in conjunction with the Company’s first commercial launch.

General and Administrative (G&A) Expenses: G&A expenses were $139.1 million for the six months ended June 30, 2022, compared to $86.4 million for the same six months of 2021. This increase was primarily due to the $83.4 million non-cash share listing expense and $21.0 million of transaction costs recognized as a result of the Business Combination. These expenses were offset by a $55.7 million decrease in expenses related to the long-term incentive plan.

Net Loss: Net loss was $184.5 million, or ($1.02) per share on a basic and diluted basis, for the six months ended June 30, 2022 as compared to net loss of $273.7 million, or ($2.77) on a basic and diluted basis, for the same six months of 2021.

Business Update Conference Call

Alvotech will conduct a business update conference call and live webcast on Thursday, September 1, 2022, at 8:00 am ET (12:00 pm GMT).

In order to participate in the conference call, please register in advance following this link to obtain a local or toll-free phone number and your personal pin.

A live webcast of the call will be available on Alvotech’s website in the Investors Section of the Company’s website 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 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, Switzerland, and Canada. 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). AVT04 was developed using an Sp2/0 host cell line and is manufactured using a continuous perfusion process. The Sp2/0 host cell line allows for more efficient sialyation of the molecule as compared to Chinese hamster ovary (CHO) cells and is the same type of host cell line used to produce Stelara®. Ustekinumab binds to two cytokines, IL-12 and IL-23, that are involved in inflammatory and immune responses. Abnormal regulation of these cytokines has been associated with immune mediated diseases, such as psoriasis, psoriatic arthritis, Crohn’s disease, and ulcerative colitis.

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. Biosimiliarity 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). Aflibercept 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 has not been established by regulatory authorities and is not claimed.

About AVT23 (omalizumab)

AVT23 is a proposed biosimilar to Xolair (omalizumab). Omalizumab is an antibody that targets free IgE; it is used to improve the control of severe persistent allergic asthma, for chronic (long-term) spontaneous urticaria (itchy rash) in patients with elevated IgE who do not respond to treatment with antihistamines and to treat nasal polyps in people 18 years of age and older when medicines to treat nasal polyps called nasal corticosteroids have not worked well enough. Xolair, the only currently approved product containing omalizumab, was first approved in 2003. AVT23 is an investigational compound and has not received regulatory approval in any country. Biosimilarity has not been established by regulatory authorities and is not claimed.

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), 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 1955, 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 capitalization through equity or debt financing, future growth, results of operations, performance, future capital and other expenditures including the development of critical infrastructure for the global healthcare markets, 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, expected patient enrollment, the potential approval and commercial launch of its product candidates, the timing of the announcement of clinical study results, the commencement of patient studies, regulatory 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 maintain stock exchange listing standards or meet requirements for listing on the Nasdaq Main Market in Iceland; (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 enroll and retain patients in clinical studies; (9) the ability of Alvotech or its partners to gain approval from regulators for planned clinical studies, study plans or sites; (10) the ability of Alvotech's partners to conduct, supervise and monitor existing and potential future clinical studies, which may impact development timelines and plans; (11) 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; (12) the success of Alvotech's current and future collaborations, joint ventures, partnerships or licensing arrangements; (13) Alvotech's ability, and that of its commercial partners, to execute their commercialization strategy for approved products; (14) Alvotech's ability to manufacture sufficient commercial supply of its approved products; (15) the outcome of ongoing and future litigation regarding Alvotech's products and product candidates; (16) 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; and (17) 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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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 2022**	**Six months ended 30 June 2021**
Product revenue	3,932	-
License and other revenue	36,186	2,008
Other income	142	348
Cost of product revenue	(17,813)	-
Research and development expenses	(86,884)	(90,403)
General and administrative expenses	(139,147)	(86,360)
Operating loss	(203,584)	(174,407)
Share of net loss of joint venture	(1,266)	(837)
Finance income	50,968	4
Finance costs	(52,406)	(123,575)
Exchange rate differences	4,744	(3,611)
Gain on extinguishment of financial liabilities	-	2,561
Non-operating profit / (loss)	2,040	(125,458)
Loss before taxes	(201,544)	(299,865)
Income tax benefit	17,073	25,918
Loss for the period	(184,471)	(273,947)
Other comprehensive income / (loss)		
Item that will be reclassified to profit or loss in subsequent periods:		
Exchange rate differences on translation of foreign operations	(4,243)	243
Total comprehensive loss	(188,714)	(273,704)
Loss per share		
Basic and diluted loss for the period per share	(1.02)	(2.77)

Unaudited Condensed Consolidated Interim Statement of Financial Position

USD in thousands	**30 June 2022**	**31 December 2021**
Non-current assets		
Property, plant and equipment	87,411	78,530
Right-of-use assets	131,069	126,801
Goodwill	11,436	12,367
Other intangible assets	22,857	21,509
Contract assets	14,838	1,479
Investment in joint venture	51,334	55,307
Other long-term assets	3,915	1,663
Restricted cash	25,001	10,087
Deferred tax assets	187,976	170,418
Total non-current assets	535,837	478,161

Current assets		
Inventories	54,664	39,058
Trade receivables	5,304	29,396
Contract assets	24,998	17,959
Other current assets	23,758	14,736
Receivables from related parties	1,498	1,111
Cash and cash equivalents	128,438	17,556
Total current assets	238,660	119,816
Total assets	774,497	597,977

Unaudited Condensed Consolidated Interim Statement of Financial Position

USD in thousands	**30 June 2022**	**31 December 2021**
Equity		
Share capital	2,076	135
Share premium	1,026,282	1,000,118
Translation reserve	426	4,669
Accumulated deficit	(1,325,005)	(1,140,534)
Total equity	(296,221)	(135,612)
Non-current liabilities		
Borrowings	438,187	398,140
Derivative financial liabilities	197,470	-
Other long-term liability to related party	7,440	7,440
Lease liabilities	115,304	114,845
Long-term incentive plan	4,408	56,334
Contract liabilities	29,982	44,844
Deferred tax liability	141	150
Total non-current liabilities	792,932	621,753
Current liabilities		
Trade and other payables	44,726	28,587
Lease liabilities	7,282	7,295
Current maturities of borrowings	120,836	2,771
Liabilities to related parties	4,738	638
Contract liabilities	32,328	29,692
Taxes payable	1,047	841
Other current liabilities	66,829	42,012
Total current liabilities	277,786	111,836
Total liabilities	1,070,718	733,589
Total equity and liabilities	774,497	597,977

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