Press release

Interim Report for the period July – September 2022

Groundbreaking results for lecanemab in Phase 3 study in early Alzheimer's disease

Events during the third quarter 2022

- Lecanemab showed positive results in the pivotal Phase 3 study, Clarity AD, in early Alzheimer's disease, and both primary and all key secondary endpoints were met with high statistical significance
- New lecanemab data were presented by Eisai at the Alzheimer's Association International Conference (AAIC), including data on a subcutaneous formulation of lecanemab
- The FDA accepted the Biologics License Application (BLA) and granted priority review for lecanemab for treatment of early Alzheimer's disease under the accelerated approval pathway, which resulted in a milestone of MEUR 15 from Eisai in the quarter

Financial summary July – September 2022

- Net revenues for the period amounted to MSEK 218.2 (4.0)
- Operating profit amounted to MSEK 133.0 (-37.4)
- Profit for the period amounted to MSEK 136.8 (-37.6)
- Earnings per share before dilution were SEK 1.55 (-0.43) and earnings per share after dilution were SEK 1.54 (-0.43)
- Cash flow from operating activities amounted to MSEK 111.9 (-34.8)
- Cash and cash equivalents at the end of the period amounted to MSEK 863 (892)

Financial summary January – September 2022

- Net revenues for the period amounted to MSEK 226.2 (18.4)
- Operating profit amounted to MSEK 43.2 (-100.4)
- Profit for the period amounted to MSEK 46.7 (-100.8)
- Earnings per share before and after dilution were SEK 0.53 (-1.15)
- Cash flow from operating activities amounted to MSEK 26.6 (-101.2)
- Cash and cash equivalents at the end of the period amounted to MSEK 863 (892)

Comments from the CEO

"The results of the Phase 3 study met all our expectations, and more."

On September 28, the results from the Clarity AD Phase 3 study of lecanemab in patients with early Alzheimer's disease were communicated and we were pleased to note that both the primary and all key secondary endpoints were met with high statistical significance. Moreover, the side effect profile was within expectations based on observations from previous studies – which underscores the favorable risk/benefit profile for lecanemab.

The results of the Phase 3 study met all our expectations, and more. The robust and consistent results are a big step on the path toward fundamentally improving the treatment of this severely vulnerable patient population. Among patients who were treated with lecanemab, the clinical decline was slowed by 27 percent compared with placebo after 18 months of treatment – and this effect increased over time. According to a publication by Eisai earlier this year modelling long-term effects of lecanemab based on the Phase 2b results, a change of this kind could mean delaying the progress of the disease by several years; naturally, this is very valuable not only for patients but also for their families and society.

In July, the U.S. Food and Drug Administration (FDA) accepted Eisai's Biologics License Application (BLA) for lecanemab under the Accelerated Approval Pathway and granted Priority Review, announcing that a decision on a potential approval would come January 6, 2023 at the latest.

This decision will be followed by further applications. Our partner, Eisai, aims to file for full approval in the US as well as submitting marketing authorization applications in Japan and the EU by the end of the first quarter of 2023 at the latest. The treatment could thereby be made available to patients across large parts of the globe already in 2023 or 2024, depending on geography. Subject to approvals, Eisai has the marketing rights to lecanemab worldwide. BioArctic has the right to market lecanemab in the Nordics and preparations for this are ongoing together with Eisai. At the same time BioArctic's work to build a commercial organization is being intensified.

Additionally, Eisai is developing a subcutaneous formulation of lecanemab to make the treatment as convenient as possible. In the ongoing AHEAD 3-45 Phase 3 study for persons with pre-symptomatic Alzheimer's disease, the potential effects of lecanemab in slowing the progress of the disease in even earlier phases of the disease are being investigated.

I would like to extend my warmest thanks to the patients and their relatives, physicians and other hospital staff who have been involved in the Clarity AD study, as well as our partner Eisai and our fantastic employees, all our long-term shareholders, and our other partners. Without you, it would not have been possible for BioArctic to contribute to a better treatment for Alzheimer's disease. At the same time, I would like to emphasize that the company is at the start of a long journey, with the goal of generating innovative medicines that improve the lives of patients with disorders of the central nervous system. The convincing Phase 3 results for lecanemab has increased the possibility of success in our other drug projects, which are also built on our knowledge of misfolded proteins in neurodegenerative diseases. Currently, we are pursuing another five in-house projects in Alzheimer's disease, and the Phase 1 results for our drug candidate BAN0805 against Parkinson's disease have already proven to be promising. BioArctic is also having two projects against ALS, a severe disease that impacts the body's ability to control muscular activity and for which there is currently no effective treatment. In parallel with this, our project to increase the ability of antibodies to enter the brain – which we call Brain Transporter – continues to progress well.

The positive Phase 3 results for lecanemab validate both Professor Lars Lannfelt's original hypothesis on the role of soluble misfolded proteins (protofibrils) in the progress of the disease, and increase the likelihood that several of BioArctic's other projects can succeed. Through professional, dedicated and persistent effort, we now stand before a potential breakthrough in the treatment of Alzheimer's disease. Next year marks 20 years since the founding of BioArctic by Lars Lannfelt and Pär Gellerfors, and a few days ago we celebrated the fifth anniversary of the company's listing. This is still only the beginning of our efforts to develop new drugs for neurodegenerative diseases, and I look forward to hopefully soon being able to help patients to a better life.

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation
BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, October 20, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson will present BioArctic, comment on the interim report and answer questions.

Webcast: https://tv.streamfabriken.com/bioarctic-q3-2022

To participate in the conference, please call:
+46 8 519 993 83 (Sweden)
+44 333 300 0804 (UK), pin code: 87560307#
+1 631 913 1422 (USA), pin code: 87560307#

The webcast will afterwards also be available on demand at BioArctic's corporate website **https://www.bioarctic.se/en/section/investors/presentations/**

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About BioArctic AB
BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments for neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and ALS. BioArctic focuses on innovative treatments in areas with high unmet medical needs. The company was founded in 2003 based on innovative research from Uppsala University, Sweden. Collaborations with universities are of great importance to the company together with its strategically important global partner Eisai in Alzheimer disease. The project portfolio is a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. BioArctic's Class B share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.