



Press release

Interim Report for the period January – September 2020

An additional Phase 3 study in Alzheimer's disease

Key events during the third quarter 2020

- BioArctic's partner Eisai has started an additional global clinical Phase 3 program (AHEAD 3-45) to evaluate the effect of BAN2401 in individuals who have not yet developed symptoms of Alzheimer's disease but have intermediate or elevated amyloid levels in the brain.
- Eisai presented new data regarding BAN2401 from the open-label extension study at the Alzheimer's Association International Conference® (AAIC). The data indicated a rapid and continual reduction in amyloid levels in the brain in connection with BAN2401 treatment in patients who received placebo in the earlier study. The study continued to show a good safety profile.
- BioArctic's partner AbbVie decided to stop recruitment into the second part of the Phase 1 study of ABBV-0805 in Parkinson's disease patients. A detailed plan to accelerate ABBV-0805 into a Phase 2 Proof of Concept study in Parkinson's disease patients is currently being prepared by AbbVie.

Financial summary July – September 2020

- Net revenues for the period amounted to MSEK 10.5 (20.6)
- Operating profit amounted to MSEK -20.7 (-10.5)
- Profit for the period amounted to MSEK -20.7 (-8.3) and earnings per share were SEK -0.23 (-0.09)
- Cash flow from operating activities amounted to MSEK -9.4 (-49.4)
- Cash and cash equivalents at the end of the period amounted to MSEK 1,036 (1,170)

Financial summary January – September 2020

- Net revenues for the period amounted to MSEK 54.0 (255.4)
- Operating profit amounted to MSEK -54.9 (133.6)
- Profit for the period amounted to MSEK -55.3 (105.6) and earnings per share were SEK -0.63 (1.20)
- Cash flow from operating activities amounted to MSEK -65.6 (381.4)
- Cash and cash equivalents at the end of the period amounted to MSEK 1,036 (1,170)

Comments from the CEO

"Our ambition is to develop the medicines of the future with the aim of improving life for people with disorders of the central nervous system."

Almost exactly three years ago, on October 12, 2017, BioArctic initiated its public offering at Nasdaq Stockholm. Since then, our drug projects against Alzheimer's disease and Parkinson's disease have made significant advances, new projects have been added and the company's market value has more than tripled. We are proud and pleased to have developed the company into one of the foremost in the world today in the development of disease-modifying treatments for neurodegenerative disorders such as Alzheimer's disease and Parkinson's disease. These diseases cause a great deal of suffering, limit the quality of life for millions of people, and give rise to enormous costs to society.

BioArctic continued its positive performance this quarter as well. Eisai, our partner in Alzheimer's disease, initiated an additional broad Phase 3 program with BAN2401 together with the Alzheimer's Clinical Trials Consortium (ACTC). The intent of the program is to study the benefit of treatment in the very earliest stages of Alzheimer's disease, before the emergence of symptoms. The new and extremely ambitious program, which is expected to encompass 1,400 persons, emphasizes Eisai's strong commitment to BAN2401 and, if successful, could enable more people in the future to have access to a treatment with the potential to slow the progress of the disease.

At the same time, the Clarity-AD Phase 3 study is continuing with BAN2041, the purpose of which is to confirm the positive results of the Phase 2b study. Eisai expects the study to be fully enrolled by the end of the year, and the results of the study to be available in 2022. This past summer, new data, from the open-label extension of the previously concluded Phase 2b study with BAN2401, was presented that was consistent with the previously shown biomarker effect and safety profile. The patients who received placebo in the earlier study and are now being treated with BAN2401 have shown a rapid and continual decrease in amyloid levels after three and additionally after six months and twelve months. The occurrence of the ARIA-E side effect remains low: less than 10 per cent of the patients studied. Results from the effect on clinical outcomes are expected to be presented in the future.

BioArctic has a project portfolio with several promising proprietary preclinical projects with the aim to develop next generation medicines. Today, more than 30 million people suffer from Alzheimer's disease, a number that unfortunately is expected to rise dramatically over the next few decades as populations age. We recently informed that one of our preclinical projects, AD1801, is linked to ApoE, which is the most common genetic risk factor for the disease. This new approach creates additional opportunities to develop alternative treatments for Alzheimer's disease.

Our collaboration with AbbVie to develop a new type of treatment against Parkinson's disease continues to progress well. A comprehensive Phase 1 study with ABBV-0805 is in progress, and AbbVie recently decided to halt recruitment for the second part of the Phase 1 study to instead develop a detailed plan for advancing the drug candidate to a Phase 2 study. ABBV-0805 has the potential to become one of the first disease-modifying treatments for Parkinson's disease, which could improve quality of life for patients.

With committed, highly specialized and experienced employees, dedicated academic and global industrial partners as well as approximately SEK 1 billion in cash, we will continue our work to bring new effective medicines to patients. In the portfolio of early projects, the focus is on our efforts in the blood-brain barrier technology and on our own drug projects oriented to disorders of the central nervous system. As a consequence of the COVID-19 pandemic, we have adjusted our work processes, and it is gratifying to see that the company's own projects continue to develop as planned. After three successful years as a listed company, we are continuing our work to be able to offer disease-modifying treatments for patients with neurodegenerative disorders, all based on high-quality research resting on a solid scientific basis.

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media on October 14, at 09:30 CET, where Gunilla Osswald, CEO, and Oskar Bosson, VP Communications & Investor Relations, will present BioArctic and comment on the Interim Report for the period January – September 2020 followed by a Q&A-session.

Webcast: <https://tv.streamfabriken.com/bioarctic-q3-2020>

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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 and reliable biomarkers and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. 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 partners in the Alzheimer (Eisai) and Parkinson (AbbVie) projects. 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 B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.