



Press release

Interim Report for the period January – December 2020

New data provides further support for BAN2401 (lecanemab)

Key events during the fourth quarter 2020

- BioArctic's drug candidate BAN2401 was assigned an international nonproprietary name (INN): lecanemab.
- Further data for drug candidate lecanemab (BAN2401) from the Phase 2b open-label extension study were presented at the Clinical Trials on Alzheimer's Disease (CTAD) conference.

Impact of COVID-19 on the company has been limited

- The spread and negative effects of the coronavirus during the year had a serious impact on society, the economy and the lives of private individuals. During the year, BioArctic successfully advanced its own projects without noticeable disruptions despite COVID-19. The company's revenue and costs for the year were only marginally impacted by the pandemic.
- Eisai increased the number of participants in Clarity AD study to ensure a robust dataset. Eisai still expects readout by September 2022.

Financial summary October – December 2020

- Net revenues for the period amounted to MSEK 8.4 (26.4)
- Operating profit amounted to MSEK -30.2 (-21.1)
- Profit for the period amounted to MSEK -13.2 (-17.1) and earnings per share were SEK -0.15 (-0.19)
- Cash flow from operating activities amounted to MSEK -25.3 (-54.2)
- Cash and cash equivalents at the end of the period amounted to MSEK 999.9 (1,112.8)

Financial summary January – December 2020

- Net revenues for the period amounted to MSEK 62.3 (281.8)
- Operating profit amounted to MSEK -85.0 (112.5)
- Profit for the period amounted to MSEK -68.5 (88.5) and earnings per share were SEK -0.78 (1.00)
- Cash flow from operating activities amounted to MSEK -90.9 (327.2)
- Cash and cash equivalents at the end of the period amounted to MSEK 999.9 (1,112.8)

Comments from the CEO

“New clinical data provide additional support for drug candidate lecanemab (BAN2401) in the treatment of Alzheimer’s disease.”

2020 was an eventful year, with positive momentum and advanced positions in our drug development projects. While the COVID-19 pandemic has entailed tremendous hardship for the world around us, we have done our utmost to keep the pandemic from impacting our operations. By changing our work procedures, BioArctic’s important efforts to improve the quality of life for patients with diseases of the central nervous system could be carried on according to plan. Our ambition remains: together with our partners, we intend to be one of the first companies to successfully develop disease-modifying treatments for Alzheimer’s and Parkinson’s diseases.

BioArctic’s drug candidate BAN2401, which was recently assigned the international nonproprietary name lecanemab by the World Health Organization, continues to show promising results. Baseline data for the patients participating in Clarity AD, the confirmatory Phase 3 study, were shown to be consistent with baseline in the Phase 2b study. The participants in the Clarity AD study are also representative of a population with early Alzheimer’s disease. BioArctic’s partner Eisai recently communicated that it had implemented a small expansion of the number of participants in the confirmatory Phase 3 study. The decision was taken proactively to ensure a robust dataset and to mitigate the potential impact of patients who temporarily missed doses due to the COVID-19 pandemic. Eisai also confirmed that time for data readout for Clarity AD remains unchanged and is still expected by September 2022.

We are also pleased with the findings from the open-label extension of the Phase 2b study with lecanemab, which demonstrated a rapid and continual decrease in amyloid levels in the brain after three, six and twelve months of treatment in the patients who previously received placebo. Another finding supporting the safety of lecanemab is that even though patients were treated with the highest dose of lecanemab right from the start, the frequency of the side effect ARIA-E, was at the same low level as in the Phase 2b study. This distinguishes lecanemab from other drug candidates in late-stage clinical development that demonstrate higher frequencies of these side effects. Lecanemab therefore can be administered at the intended dose already from the start, without titration.

During the year, Eisai initiated an additional global Phase 3 program: AHEAD 3–45, the purpose of which is to study and delay the development of the disease through treatment with lecanemab at the very earliest stages of the disease. Positive study results could be of great help for more individuals in slowing the disease at an early stage, and would entail additional market potential for lecanemab.

As regards Parkinson’s disease, our partner AbbVie is preparing a Phase 2 program with drug candidate ABBV-0805 based on the Phase 1 study.

BioArctic’s early-stage proprietary projects are also continuing to perform well. The preclinical data for our blood-brain barrier technology are extremely promising, and work is under way to obtain additional patent protection. Initially, the technology will be used in existing projects in our pipeline, but there are also business opportunities in offering the technology for antibodies from other companies.

In January, the European Patent Office approved our application for a patent on antibodies against truncated amyloid beta, which has a pronounced ability to form toxic aggregates that could cause Alzheimer’s disease. This approval further demonstrates the strength of the company’s research and its ability to find new and innovative ways to intervene in various stages of the course of Alzheimer’s disease. In the future, several alternatives and combinations of treatments may be needed to address different types of Alzheimer’s disease patients.

BioArctic’s research rests on a solid scientific foundation, and our value-driven leadership supports the work of developing the company further. I am extremely proud that our goal-oriented diversity initiatives are yielding results;

one proof of this is that we were awarded the Allbright Award for gender equality in 2020. I can conclude that, together with our partners, we have a fantastic opportunity to create the medicines of the future and to improve life for patients and their loved ones.

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation

BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, February 4, 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-q4-2020>

To participate in the conference, please call:

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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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The information was submitted for publication, though the agency of the named contact persons, at 08:00 a.m. CET on February 4, 2021.

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 Class B share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.