Press release

Interim Report for the period April – June 2022

FDA grants priority review for lecanemab marketing application

Events during the second quarter 2022

- Eisai completed the rolling submission of lecanemab for treatment of early Alzheimer's disease to the US Food and Drug Administration (FDA) under the accelerated approval pathway
- AbbVie took a strategic business decision to terminate its collaboration with BioArctic regarding its alpha-synuclein projects in Parkinson's disease. BioArctic is now working with AbbVie to bring back the projects with the intention of finding a new partner

Events after the second quarter

- The FDA accepted the Biologics License Application (BLA) and granted priority review of lecanemab for treatment of early Alzheimer's disease under the accelerated approval pathway, which entitles BioArctic to a milestone of MEUR 15 from Eisai

Financial summary April – June 2022

- Net revenues for the period amounted to MSEK 4.2 (7.3)
- Operating profit amounted to MSEK -45.7 (-33.8)
- Profit for the period amounted to MSEK -45.8 (-34.2) and earnings per share before and after dilution were SEK -0.52 (-0.39)
- Cash flow from operating activities amounted to MSEK -45.6 (-28.9)
- Cash and cash equivalents at the end of the period amounted to MSEK 752 (930)

Financial summary January – June 2022

- Net revenues for the period amounted to MSEK 8.0 (14.5)
- Operating profit amounted to MSEK -89.8 (-63.0)
- Profit for the period amounted to MSEK -90.1 (-63.3) and earnings per share before and after dilution were SEK -1.02 (-0.72)
- Cash flow from operating activities amounted to MSEK -85.4 (-66.4)
- Cash and cash equivalents at the end of the period amounted to MSEK 752 (930)

Comments from the CEO

"Every day the patients can remain in the early stages of Alzheimer's disease is highly valuable. "

BioArctic develops groundbreaking drugs for diseases which affect the brain, an area that today lacks effective treatments. Our treatment strategy with antibodies against pathogenic proteins has the potential to make a major difference. By being successful in what we do, we promote a sustainable society and sustainable health. In addition to

the value generated by our core operations, we constantly strive for a sustainable business, sustainable employeeship and the sustainable use of resources.

In early May, our partner Eisai submitted the final part of the rolling submission under the accelerated approval pathway of lecanemab for early Alzheimer's disease to the US Food and Drug Administration (FDA). The FDA recently notified Eisai that the Biologics License Application (BLA) for lecanemab under the accelerated approval pathway has been accepted for review, and granted priority review. We now know that a potential accelerated marketing approval of lecanemab in the US will be given at the latest by January 6, 2023. The FDA's acceptance of the application, entitles BioArctic to a milestone payment of MEUR 15 from Eisai.

In parallel with the ongoing regulatory processes for lecanemab, the major confirmatory Phase 3 study Clarity AD is under way with 1,795 patients with early Alzheimer's disease. The study is making good progress, with a low share of patients discontinuing the study and with most patients continuing into the open-label extension study, which will also evaluate the subcutaneous formulation of lecanemab. Results from Clarity AD are expected this autumn and if these are positive, Eisai will submit applications for full approval of lecanemab to regulatory authorities in the US, EU and Japan in the first quarter of 2023 at the latest. With this in mind, the ramp-up of the commercial organization continues.

The potential benefits for patients, their families and society when treated with lecanemab are significant. If patients reach the severe stages of the disease much later, fewer people will require resource-intensive elderly care. A recent published article in the scientific journal Neurology and Therapy presents the results of modeling based on clinical data generated thus far for lecanemab. The modeling showed that lecanemab could prolong the time patients remain in the early stages of the disease by at least 2.5 years. In the early stages of Alzheimer's disease, individuals often function well and can continue to live an active life together with friends and family. Every day, week and month the patients can remain in the early stages is therefore highly valuable. The modeling also indicates that treatment with lecanemab reduces the likelihood of patients needing institutional care in the later phases of the disease.

In Parkinson's disease, we are working actively with AbbVie to bring back BAN0805 and our other antibodies against alpha-synuclein from AbbVie, which during the quarter, for strategic reasons, chose to terminate our collaboration. We look forward to intensifying the discussions with new potential partners as soon as the projects have been transferred from AbbVie. During the quarter, a new drug substance patent for BAN0805 was granted in the US, which is valid until 2041, with a possible extension until 2046. Our preclinical data and results from the Phase 1 study are promising and we can already see interest in the project.

Our expanded in-house project portfolio is performing well and we are continuing to pursue these projects with full force. Our ALS project is progressing rapidly through the use of our unique technology platform and vast experience in developing antibodies and we have already begun humanization of some of our antibodies.

We are now looking forward to a number of exciting events during the remainder of the year, both for BioArctic and for the Alzheimer's disease research field. Further data for lecanemab will be presented at the end of July at the Alzheimer's Association International Conference in San Diego, in the US. During this autumn we will finally be seeing results from the large, confirmatory Phase 3 study of lecanemab in patients with early Alzheimer's disease.

I would like to end by wishing you all a great summer and I look forward to an exciting autumn together with you all!

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation
BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, July 12, 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-q2-2022

To participate in the conference, please call:
+46 8 505 583 56 (Sweden), pin code: 4533870
+44 333 300 08 04 (UK), pin code: 4533870
or +1 631 913 1422 (USA), pin code: 4533870

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

For more information, please contact
Gunilla Osswald, CEO, gunilla.osswald@bioarctic.se, phone +46 8 695 69 30
Jan Mattsson, CFO, jan.mattsson@bioarctic.se, phone + 46 70 352 27 72
Oskar Bosson, VP Communications & Investor Relations, oskar.bosson@bioarctic.se, phone +46 70 410 71 80

This information is information that BioArctic AB (publ) is obligated to make public pursuant to the Swedish Securities Market Act (Swe. VpmL). The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on July 12, 2022.

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.