Press release

Interim Report for the period April – June 2024

Lecanemab authorised in Great Britain and EU re-examination in progress

Events during the second quarter 2024

- BioArctic and Eisai entered into a research evaluation agreement regarding the drug candidate BAN2802
- Eisai received Fast Track designation and initiated a rolling Biologics License Application (BLA) to the FDA for subcutaneous maintenance dosing of Leqembi®
- Eisai published sales projection for Leqembi for fiscal year 2024 (April 2024 – March 2025) of JPY 56.5 billion
- The U.S. Food and Drug Administration (FDA) accepted Eisai's Supplemental Biologics License Application (sBLA) for less frequent monthly intravenous (IV) maintenance dosing for the treatment of Alzheimer's disease with Leqembi
- Leqembi was approved in South Korea and launched in China

Events after the end of the period

- Leqembi was approved for the treatment of Alzheimer's disease in Hong Kong, Israel, United Arab Emirates and Great Britain
- The European Medicines Agency (EMA) adopted a negative opinion on Marketing Authorization Approval for lecanemab as treatment for Alzheimer's disease. BioArctic's partner Eisai has requested a reexamination of the opinion
- Three-year data from the lecanemab extension study show continued increasing patient benefit with maintained safety profile
- Study results from phase 1 studies with exidavnemab published in The Journal of Clinical Pharmacology

Financial summary April – June 2024

- Net revenues for the period amounted to SEK 49.8 M (2.7), of which SEK 42.6 M (0.4) in royalties for Leqembi
- Operating profit amounted to SEK -75.8 M (-100.9)
- Profit for the period amounted to SEK -68.4 M (-102.3)
- Earnings per share before and after dilution was SEK -0.77 (-1.16)
- Cash flow from operating activities amounted to a negative SEK -94.3 M (-63.8)
- Cash and cash equivalents and short term investments at the end of the period amounted to SEK 890 M (1,042)

Financial summary January – June 2024

- Net revenues for the period amounted to SEK 79.5 M (396.1), of which SEK 63.9 M (0.4) in royalties for Leqembi
- Operating profit amounted to SEK -148.9 M (199.7)
- Profit for the period amounted to SEK -126.0 M (191.5)
- Earnings per share before dilution was SEK -1.43 (2.17) and after dilution -1.43 (2.16)
- Cash flow from operating activities amounted to a negative SEK -208.7 M (235.2)
- Cash and cash equivalents and short term investments at the end of the period amounted to SEK 890 M (1,042)

Comments from the CEO

"It is highly gratifying to see that we are helping more and more patients around the world. Sales in the US have started to take off and the launches in Japan and China are going better than expected."

It's time to summarize yet another eventful period that included the commercial launch of Leqembi in China, additional regulatory approvals, especially the UK, and two regulatory submissions to the US FDA regarding maintenance treatment with Leqembi, either via infusion or subcutaneously. The EMA's adoption of a negative opinion concerning the approval of lecanemab was a setback however. We were both surprised and very disappointed by the news, especially in light of approvals from other authorities. It is important to remember, though, that this is not the final decision in the EU. Our partner Eisai has already requested a re-examination, and we continue to work together to change the opinion for the final recommendation. We hope for a positive outcome before the end of the year. First and foremost, this opinion is unfortunate news for all Alzheimer patients in the EU who will now have to wait longer for a treatment that can change the course of this devastating disease. We draw strength from the firm support for lecanemab from both researchers and patient organizations from across Europe. Many of them are now getting involved to make their voices heard.

Regardless of the outcome, BioArctic's position is strong. Leqembi has already been approved in the US, Japan, China, South Korea, Hong Kong, Israel, the United Arab Emirates and now in Great Britain as well. According to figures presented by Eisai in March, these markets will account for more than 80% of total revenues by 2032. As a European biopharma company, it would be disheartening for us if our innovation could not help patients in the EU and the Nordics, but the outcome in the EU is not pivotal for the future of BioArctic.

It is highly gratifying to see that we are helping more and more patients around the world. Sales in the US have started to take off and the launches in Japan and China are going better than expected. In Great Britain, a consultation process involving Eisai and other stakeholders will take place before Leqembi can become available for use in the national healthcare system. The reimbursement authority NICE's draft recommendation was that the cost effectiveness did not support routine use. The authority has requested additional information before its final decision. Sales for the second quarter grew fast, resulting in royalties of SEK 43 million to BioArctic. That is twice as much as the previous quarter, and we look forward to continued good growth for many quarters to come.

In late July/early August, we attended the world's largest annual Alzheimer's congress, AAIC, which was held in Philadelphia this year. Eisai presented three-year data from the phase 3 open label extension study with lecanemab that demostrated continued increasing patient benefit with a maintained safety profile as treatment continues. Moreover, results from the very earliest group of patients showed that over 50 percent of those treated not only reduced their clinical decline but continued to show improvement in cognition and function after 36 months. Although the latter is based on small patient numbers, it is inspiring to think about what this could mean as new diagnostic methods are becoming available. It also means that we are looking forward with confidence to the results of the ongoing AHEAD 3-45 study of lecanemab in people who have not yet developed symptoms of Alzheimer's disease, but have started to show changes in the biomarkers that measure disease progression. Participants in the study, which is expected to be fully enrolled within the next six months, will be treated for four years. Eisai also presented data showing that continuous treatment with lecanemab is important based on data showing that underlying biomarkers of disease progression return to harmful levels if treatment is stopped. Therefore, the regulatory applications that Eisai has initiated in the US regarding both intravenous and subcutaneous maintenance treatment, are very important. A regulatory response is expected in January 2025 for the intravenous version, and for the subcutaneous, for which the final part of the application is expected to be submitted in the fourth quarter, a response is anticipated later in 2025.

The research field is developing rapidly and our early product candidates in Alzheimer's, Parkinson's and ALS are at the forefront. Our most advanced project is exidavnemab in Parkinson's disease, in which we expect to start dosing in the phase 2a study in the fourth quarter. The entire early research portfolio is steadily progressing, and we estimate that several projects will be in clinical development within a few years, bringing with them the potential for new license agreements. The projects are based on our employees' scientific expertise and their tireless efforts to develop treatments for neurological disease where there are few options today. This gives me great comfort and I have good hopes that BioArctic will continue to be a leader in the research field for many years to come.

Finally, I note that we are experiencing increased interest in our sustainability agenda, and we are preparing for the upcoming legal reporting requirements under the CSRD. We have included a sustainability progress report section for the first time in this quarterly report. I can proudly say that we have an excellent platform to stand on. After an intense first half of the year, we look forward to continuing to pursue our promising projects and to being able to help more and more patients around the world. Our journey has only just begun.

Gunilla Osswald
CEO, BioArctic AB

Invitation to presentation
BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, August 29, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Anders Martin-Löf will present BioArctic, comment on the second quarter report and answer questions.

If you wish to participate via webcast, please use the link below. Via the webcast you are able to ask written questions.
Webcast: https://ir.financialhearings.com/bioarctic-q2-report-2024/register

If you wish to participate via teleconference, please register on the link below. After registration you will be provided phone numbers and a conference ID to access the conference. You can ask questions verbally via the teleconference.
https://conference.financialhearings.com/teleconference/?id=50047207

The webcast will afterwards also be available on demand at BioArctic's corporate website
https://www.bioarctic.se/sv/investerare/finansiella-rapporter-och-presentationer/

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The interim report is such information as BioArctic AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on August 29, 2024.

About BioArctic AB
BioArctic AB (publ) is a Swedish research-based biopharma company focusing on treatments that can delay or stop the progression of neurodegenerative diseases. The company invented Leqembi® (lecanemab) – the world's first drug proven to slow the progression of the disease and reduce cognitive impairment in early Alzheimer's disease. Leqembi has been developed together with BioArctic's partner Eisai, who are responsible for regulatory interactions and commercialization globally. In addition to Leqembi, BioArctic has a broad research portfolio with antibodies against Parkinson's disease and ALS as well as additional projects against Alzheimer's disease. Several of the projects utilize the company's proprietary BrainTransporter™ technology, which has the potential to actively transport antibodies across the blood-brain barrier to enhance the efficacy of the treatment. BioArctic's B share (BIOA B) is listed on Nasdaq Stockholm Large Cap. For further information, please visit www.bioarctic.se.