BIOARCTIC

Press release

Interim Report January – March 2019

BioArctic's partner Eisai initiated Phase 3-study with BAN2401 in Alzheimer's disease. Phase 1-study with ABBV-0805 in the Parkinson program started

Financial summary for the period January – March 2019

- Net revenues for the period amounted to MSEK 63.4 (52.3), which is an increase of MSEK 11.1
- Operating profit amounted to MSEK 17.3 (18.9), a decrease of MSEK 1.6. The operating margin was 27.3 percent (36.1)
- Profit for the period amounted to MSEK 13.6 (15.4) and earnings per share[1] were SEK 0.15 (0.18)
- Cash flow from operating activities amounted to MSEK 333.6 (-42.0)

Summary of key events for the period January – March 2019

- BioArctic's partner Eisai initiated a global, single confirmatory Phase 3 study with BAN2401 for early Alzheimer's disease to support a regulatory filing and informed about the design of the study and timelines
- The U.S. Food and Drug Administration approved the application to start a clinical study with ABBV-0805, previously named BAN0805, whereafter the clinical Phase 1-study with ABBV-0805 in the Parkinson program started
- BioArctic's product candidate SC0806 for treatment of patients with complete spinal cord injury progressed into the second part of the Phase 1/2 study after a positive safety evaluation of all patients in the first part of the study

Key events after the period

- There are no key events to report after the period

Financial summary

MSEK	Jan-Mar 2019	Jan-Mar 2018	Jan-Dec 2018
Net revenues	63.4	52.3	714.0
Other operating income	6.9	11.4	16.3
Operating profit	17.3	18.9	488.8
Operating margin, %	27.3	36.1	68.5
Profit for the period	13.6	15.4	381.6
Earnings per share, SEK [1]	0.15	0.18	4.33
Equity per share, SEK [1]	11.71	7.40	11.56
Cash flow from operating activities	333.6	-42.0	-200.1
Cash flow from operating activities per share, SEK [1]	3.79	-0.48	-2.27
Equity/assets ratio, %	78.5	58.8	73.1
Return on equity, %	1.3	2.4	46.1
Share price at the end of the period	78.00	21.40	82.00

[1] No share-based incentive program exists, thus there is no dilutive effect

CEO comments

A strong quarter for the projects in all therapy areas

We have made progress in all the company's therapy areas as the three clinical projects have moved to the next phase in their respective program. The confirmatory Phase 3 study with the drug candidate BAN2401, a potential disease modifying treatment for early Alzheimer's disease, has been initiated. In the Parkinson program, the Phase 1 study with the drug candidate ABBV-0805 has started. The product candidate SC0806 for complete spinal cord injury has advanced into the second part of the on-going Phase 1/2-study. All in all, this means that we have had a very successful first quarter. It is also gratifying to note that we have had another period with a positive net financial result.

In March, Eisai announced that they initiated the global, confirmatory Phase 3 study with BAN2401 (Clarity AD/Study 301) in patients with early Alzheimer's disease based on discussions with regulatory authorities. The study is expected to include 1,566 patients who will either be treated with BAN2401 or receive placebo. In the treatment group, BAN2401 will be administered at a dosage of 10 mg/kg twice a month. The primary endpoint is change from baseline in the cognition and function scale CDR-SB at 18 months of treatment. Changes in the clinical scales ADCOMS and ADAS-Cog will be key secondary endpoints together with brain amyloid levels as measured by amyloid PET. According to Eisai, the final readout of the primary endpoint is targeted as early as for 2022.

The confirmatory Phase 3 study, which supports the regulatory filing, is designed based on the positive results from the Phase 2b study with BAN2401 in 856 patients with early Alzheimer´s disease. The Phase 2b-study robustly demonstrated slowing of clinical decline, effects on biomarkers with good tolerability after 18 months treatment. BAN2401 is a unique antibody that binds selectively to the toxic soluble aggregated forms of amyloid beta in the brain, so called protofibrils, which are believed to be the harmful forms of amyloid beta. The Phase 2b-study with BAN2401 is the first study in late clinical phase to have demonstrated a potential disease modifying effect on clinical function as well as clearance of amyloid beta in the brain, and effects on neurodegenerative biomarkers. The results from the Phase 2b study strengthen BioArctic's belief that BAN2401's unique binding profile is important, which is supported also by the stopped trials with other companies' antibodies. It is very encouraging to note Eisai's strong commitment to the continued clinical development of BAN2401 in early Alzheimer's disease.

In late 2018, BioArctic out-licensed its portfolio of antibodies to alpha-synuclein for disease modifying treatment of Parkinson's disease and other potential indications to the company's strategic partner AbbVie. The licensing triggered a milestone payment to BioArctic of MUSD 50. BioArctic has developed the groundwork for the application to start clinical trials with ABBV-0805 in the U.S., a so-called IND application. In February 2019, the U.S, Food and Drug Administration, FDA, approved the application. Already in March, AbbVie started the Phase 1 study and they are responsible for financing and running the clinical program with ABBV-0805.

BioArctic's Alzheimer and Parkinson projects in research stages, as well as collaborative projects on biomarkers and technologies, have continued to develop well. In collaboration with Uppsala University, BioArctic develops technologies that facilitate the passage of antibodies across the blood-brain barrier with the aim to improve immunotherapy for Alzheimer's and Parkinson's diseases. The blood-brain barrier controls the exchange of substances between the blood and the brain and protects the brain from toxins and other pathogens, but it may also limit the delivery of therapeutic agents to the brain. Recently, BioArctic and Uppsala University received a non-dilutive grant of MSEK 10 from Sweden's Innovation Agency, Vinnova, for a collaboration project aimed at developing multi-specific antibodies with a transporter to facilitate passage across the blood brain barrier. This innovative technology could potentially be used to treat various diseases of the brain. The research work is at a very early stage but addresses an important challenge that can have revolutionary significance in the future.

BioArctic conducts a clinical study in patients with complete spinal cord injury with the product candidate SC0806 currently in Phase 1/2. The clinical development has, to a large extent, been financed by grants from EU's Horizon 2020. At the beginning of the year, a safety evaluation of all patients in the first panel was performed, supporting the start of the next panel. In February, the first patient in the second panel was treated with SC0806 and the second part of the Phase 1/2 study has thus started. An interim analysis of the first panel concerning efficacy and safety is planned for the first half of 2020, at the latest.

The forward momentum of the projects in all therapy areas during the past year and the first quarter of this year has created a very good basis for a continued progress for BioArctic. I look forward to developing our innovative projects further within our three disease areas, which all have high unmet medical needs. I am proud to lead this innovative company and our work to improve the quality of life for patients with central nervous system disorders.

Gunilla Osswald
CEO, BioArctic AB

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Presentation
BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, May 9, at 09:30 – 10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson present BioArctic, comment on the Interim Report and answer questions.

Webcast: https://tv.streamfabriken.com/bioarctic-q1-2019

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About BioArctic
BioArctic AB (publ) is a research-based biopharmaceutical company focusing on disease modifying treatments and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. The company also develops a treatment for complete spinal cord injury. The company focuses on new types of treatments in areas with high unmet medical needs. BioArctic was founded in 2003 based on innovative research from Uppsala University, Sweden.

The company has cutting-edge scientific competence and experience in developing drugs from idea to market. Collaborations with universities are of great importance to the company together with the strategically important global partners in the Alzheimer and Parkinson projects. BioArctic conducts its own clinical development in the field of complete spinal cord injury. Through long-term collaboration agreements with global pharmaceutical companies, BioArctic has demonstrated high skills and great ability to deliver innovative pharmaceutical projects.

In Alzheimer's disease, BioArctic has collaborated with Eisai since 2005. The company has entered into three research agreements and two license agreements relating to the antibodies BAN2401 and BAN2401 back-up. The total aggregated value of these agreements may amount to MEUR 218 and, in addition, payments of royalty. So far, MEUR 47 has been received. In Parkinson's disease, BioArctic has collaborated with AbbVie since 2016, when a research collaboration agreement was entered including i.a. the antibody BAN0805. The total aggregated value of the agreement may amount to MUSD 755 and, in addition, payments of royalty. So far, MUSD 130 has been received.

The project portfolio consists of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. For information about the projects, see the section Project portfolio.
BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B).

This information is information that BioArctic AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure through the agency of Christina Astrén, Director IR & Communications, at 08:00 a.m. CET on May 9, 2019.