



## **PRESS RELEASE**

### **Interim Report January – June 2018**

#### **Positive results of the BAN2401 Phase 2b study in early Alzheimer's disease**

##### **April – June 2018**

- Net revenues for the period amounted to SEK 52.3 million (32.0)
- Operating profit amounted to SEK 6.4 million (2.5)
- Profit for the period amounted to SEK 5.1 million (2.3)
- Earnings per share were SEK 0.06 (0.04)
- Cash flow from operating activities amounted to SEK -37.3 million (-27.6)

##### **January – June 2018**

- Net revenues for the period amounted to SEK 104.6 million (58.2)
- Operating profit amounted to SEK 25.3 million (3.9)
- Profit for the period amounted to SEK 20.5 million (3.4)
- Earnings per share were SEK 0.23 (0.05)
- Cash flow from operating activities amounted to SEK -79.3 million (-66.0)

##### **Key events during the period April – June 2018**

- The inclusion of patients with complete spinal cord injury in the first panel of three was completed in BioArctic's ongoing Phase 1/2 study with SC0806
- BioArctic extended the research collaboration with Uppsala University, Sweden, regarding new antibody technology for increased passage across the blood-brain barrier
- BioArctic announced changes in the Management Team effective September 1, 2018

##### **Key events after the period**

- Positive 18 months results in the Phase 2b study of BAN2401 in 856 early Alzheimer patients were announced on July 6
- BAN2401 Phase 2b detailed results at 18 months were presented at the 2018 Alzheimer's Association International Conference (AAIC) on July 25 in Chicago, in the U.S.
- BioArctic obtained exclusive rights to develop antibody treatments for Alzheimer's disease from a research project jointly owned with Eisai
- BioArctic received approvals from regulatory authorities in Finland for the clinical study of SC0806 in patients with Complete Spinal Cord Injury

## Financial summary

SEKm	Apr-Jun 2018	Apr-Jun 2017	Jan-Jun 2018	Jan-Jun 2017	Jan-Dec 2017
Net revenues	52.3	32.0	104.6	58.2	140.7
Other operating income	3.6	5.2	15.0	5.9	19.0
Operating profit	6.4	2.5	25.3	3.9	19.3
Profit for the period	5.1	2.3	20.5	3.4	15.2
Earnings per share, SEK <sup>1,2</sup>	0.06	0.04	0.23	0.05	0.22
Equity per share, SEK <sup>1,2</sup>	7.46	1.02	7.46	1.02	7.22
Cash flow from operating activities	-37.3	-27.6	-79.3	-66.0	-135.3
Cash flow from operating activities per share, SEK <sup>1,2</sup>	-0.42	-0.44	-0.90	-1.05	-1.99
Equity/assets ratio, %	61.7%	10.0%	61.7%	10.0%	55.8%
Return on equity, %	0.8%	3.7%	3.2%	5.5%	4.3%
Number of shares	88,059,985	4,203,999	88,059,985	4,203,999	88,059,985

<sup>1</sup> There are no potential shares, thus there is no dilutive effect

<sup>2</sup> The comparative figures have been recalculated as a result of the 15:1 split executed on August 1, 2017

## CEO statement

On July 25, the 18 month results from the Phase 2b study with BAN2401 in 856 patients with early Alzheimer's disease were presented by our partner Eisai at the Alzheimer's Association International Conference (AAIC) in Chicago. The detailed results of the study are very encouraging, showing consistent dose-dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints, as well as biomarkers including PET, combined with a good tolerability profile.

At the readout after 18 months of treatment an effect with dose-dependent slowing of cognitive decline from baseline on ADCOMS was demonstrated. The highest BAN2401 dose of 10 mg/kg twice a month demonstrated a significant slowing of clinical decline of 30% compared to placebo. A statistically significant slowing of decline on ADCOMS was observed as early as 6 months as well as at 12 months. Dose-dependent slowing of cognitive decline was also observed on the well-established cognition scale ADAS-Cog with 47% slower decline for the highest dose of BAN2401.

For disease-modifying treatments it is also important to show effect on biomarkers for example on amyloid. Highly statistically significant effects were observed for all BAN2401 dose groups in the study. At the highest dose, using standardized PET as measured with the Centiloid scale, the mean reduction in accumulated amyloid in the brain was approximately 70 units at 18 months. The observed baseline mean was 74.5 units, observed 18-month mean was 5.5 units. In amyloid PET image visual read BAN2401 demonstrated a dose-dependent improvement with 81% of patients converting from amyloid positive to amyloid negative status at 18 months at the highest dose.

A good tolerability profile was also reported for BAN2401 in the study. This is important since the treatment of the patients starts at an early stage of the disease. This is the first late stage clinical study demonstrating potential disease-modifying effects (on several different scales) on both cognition and biomarkers with a good tolerability profile. The study gives new hope for patients and their families. These positive results are

also important for BioArctic, Eisai and Biogen as well as for the Alzheimer field of research at large.

The long term and successful collaboration with Eisai has also led to the identification of a new biological target, for which BioArctic recently has obtained exclusive rights to develop antibody treatments for Alzheimer's disease.

The research collaboration with AbbVie in the Parkinson's disease program progresses well in line with the agreed project plan. According to the collaboration agreement, BioArctic has the primary responsibility for the preclinical research phase. The Parkinson's disease program has developed well and consists of three preclinical projects; BAN0805, PD1601 and PD1602, all antibodies targeting alpha-synuclein. During the fall, we will focus on delivering the preclinical activities with the drug candidate BAN0805 as efficiently as possible, preparing for clinical development and for start-up of clinical studies in the U.S. (IND). The goal is to start the first clinical study during 2019.

In April we announced that the inclusion of patients in the first of three panels in the company's ongoing Phase 1/2 study with the product candidate SC0806, for the treatment of complete spinal cord injury, had been completed. BioArctic has now also regulatory approvals to include Finnish patients. Patients from Sweden, Estonia, Norway and now also Finland can thus be recruited to the next two panels of the study.

In May BioArctic received the SwedenBIO Award 2018, a joyful event for all of us in the company.

BioArctic's most important task is to improve the quality of life for patients with diseases in the central nervous system. I am proud of the positive development of the project portfolio. In addition, we can again report a positive financial result. BioArctic is well positioned to advance the projects towards our goals and new potential collaborations in line with the company's strategy.

I am looking forward to continue to progress the company's innovative projects in our three treatment areas, which all have great medical needs, and to all our important activities in the fall. Finally, I would like to express my thanks to all who have contributed to the positive development of BioArctic.

*Gunilla Osswald*  
*President and CEO, BioArctic AB*

## **Contacts**

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## Presentation

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, August 23, at 09:30 – 10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson present BioArctic, comment on the Interim Report for the period January – June 2018 and answer questions.

Webcast: <https://tv.streamfabriken.com/bioarctic-q2-2018>

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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 great 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 collaboration agreements and two license agreements relating to the antibodies BAN2401 and BAN2401 back-up. The total aggregated value of these agreements may amount to EUR 218 million and, in addition, payments of royalty. So far, EUR 47 million has been received. In Parkinson's disease, BioArctic has collaborated with AbbVie since 2016, when a research collaboration agreement was entered including, among other things, the antibody BAN0805. AbbVie is entitled to acquire a license to develop and commercialize the antibodies. The total aggregated value of the agreement may amount to USD 755 million and, in addition, payments of royalty. So far, USD 80 million 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 (STO: BIOA B).



*This information is information that BioArctic AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation and the Swedish Securities Market Act (Swe. Vpml). The information was released for public disclosure through the agency of Christina Astrén, IR & Communications Director, at 08:00 a.m. CET on August 23, 2018.*

This report has been prepared in a Swedish original version and translated into English. In the event of any inconsistency between the two versions, the Swedish language version should have precedence.