

### **Press release**

## Full Year Report January – December 2018

# BioArctic's partner Eisai will initiate BAN2401 confirmatory Phase 3-study in early Alzheimer's disease. AbbVie in-licensed the Parkinson portfolio

#### **October – December 2018**

- Net revenues for the period amounted to SEK 515.3 million (51.0)
- Operating profit amounted to SEK 430.3 million (14.7)
- Profit for the period amounted to SEK 335.2 million (11.8)
- Earnings per share were SEK 3.81 (0.16)
- Cash flow from operating activities amounted to SEK -89.3 million (-45.7)

#### January – December 2018

- Net revenues for the period amounted to SEK 714.0 million (140.7)
- Operating profit amounted to SEK 488.8 million (19.3)
- Profit for the period amounted to SEK 381.6 million (15.2)
- Earnings per share were SEK 4.33 (0.22)
- Cash flow from operating activities amounted to SEK -200.1 million (-135.3)

#### Key events during the period October – December 2018

- BioArctic's partner Eisai presented additional positive results from BAN2401 Phase 2b clinical study at Clinical Trials on Alzheimer's Disease 2018 (CTAD) conference on October 25. The results further support a potential disease modifying treatment for the broad studied population of early Alzheimer's disease patients
- In November AbbVie exercised its option to license BioArctic's portfolio of antibodies targeting alpha-synuclein for disease-modifying treatment for Parkinson's disease and other potential indications
- In December BioArctic and AbbVie received U.S. Federal Trade Commission (FTC) clearance to license BioArctic's alpha-synuclein antibody portfolio for Parkinson's disease and other potential indications to AbbVie. This triggered a milestone payment of USD 50 million which has led to an income of SEK 448.6 million
- BioArctic was granted a concept patent in Europe for the company's treatment strategy for disease-modifying treatment of Parkinson's disease
- BioArctic was granted European patent protection for a medical device for treatment of patients with Complete Spinal Cord Injury
- The Board of Directors proposes a dividend of SEK 1.50 per share for the fiscal year 2018

#### Key events after the period

• BioArctic announced that Eisai will initiate a single confirmatory Phase 3-study with BAN2401 in early Alzheimer's disease with start within the first quarter 2019

- U.S. Food and Drug Administration approved the Investigational New Drug Application for ABBV-0805, previously named BAN0805
- BioArctic's product candidate SC0806 for treatment of patients with complete spinal cord injury has progressed into the Phase 2 part of the Phase 1/2 study

Financial	summary
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	Oct-Dec	Oct-Dec	Jan-Dec	Jan-Dec
SEKm	2018	2017	2018	2017
Net revenues	515.3	51.0	714.0	140.7
Other operating income	0.7	10.4	16.3	19.0
Operating profit	430.3	14.7	488.8	19.3
Profit for the period	335.2	11.8	381.6	15.2
Operating margin, %	83.5%	28.9%	68.5%	13.7%
Earnings per share, SEK <sup>1, 2</sup>	3.81	0.16	4.33	0.22
Equity per share, SEK <sup>1</sup>	11.56	7.22	11.56	7.22
Cash flow from operating				
activities	-89.3	-45.7	-200.1	-135.3
Cash flow from operating				
activities per share, SEK <sup>1, 2</sup>	-1.01	-0.60	-2.27	-1.99
Equity/assets ratio, %	73.1%	55.8%	73.1%	55.8%
Return on equity, %	39.4%	3.4%	46.1%	4.3%
Share price end of the period	82.00	26.00	82.00	26.000
Number of shares	88,059,985	88,059,985	88,059,985	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** comments

#### A very successful year that created a good basis for the future

Looking back at the past year, I am amazed that so much can happen is such a short time. 2018 was an exciting and successful year, with three especially important events.

The first event was the positive 18 months results from the BAN2401 Phase 2b study with 856 patients with early Alzheimer's disease. This is the first study in late clinical phase that has demonstrated a disease modifying effect on clinical function as well as reduced aggregation of amyloid beta in the brain, and with good tolerability. The data support the positive effect of BAN2401 in all the subgroups of early Alzheimer patients.

BAN2401 is one of very few projects that have demonstrated reduction of amyloid in the brain and clinical effect. BAN2401 selectively binds to the toxic aggregated forms of amyloid-beta in the brain. The results with BAN2401 and other projects so far suggest that the antibody's binding profile is important.

Our partner Eisai is discussing the next stage in the development of BAN2401 with regulatory authorities and is preparing for initiation of a single Phase 3 confirmatory study within the first quarter 2019.

A second positive event was the out-licensing of BioArctic's portfolio of antibodies to alpha-synuclein for Parkinson's disease and other potential indications to our partner AbbVie. The licensing triggered a milestone payment of 50 MUSD. AbbVie will continue to develop BAN0805, now with the

designation ABBV-0805. FDA recently approved the IND-application for ABBV-0805. The first clinical study is planned to start in 2019.

The third event was that the inclusion of patients in the first of BioArctic's three panels in the ongoing Phase 1/2 study with SC0806 for the treatment of complete spinal cord injury was completed. In addition, we received approvals enabling inclusion of patients also from Estonia, Finland and Norway in the coming panels in the study. Recently, the Phase 2 part of the study has started and the first patient has received treatment with SC0806. An interim analysis of the first panel regarding efficacy and safety is planned no later than first half of 2020.

The company's early projects have progressed well during the year. BioArctic obtained exclusive rights to develop potential antibody treatments (AD1801), an entirely new target, for Alzheimer's disease from a research project jointly owned with Eisai.

During the year, BioArctic has extended research collaborations with universities concerning biomarkers and technologies for better passage of antibodies across the blood-brain barrier.

The recent accomplishments in the projects have created a very good basis for a bright future for BioArctic. I am pleased to lead this innovative company and with all co-workers continue our work to improve the quality of life for patients with central nervous system disorders. Finally, I would like to thank all who have contributed to a successful 2018.

Gunilla Osswald CEO, BioArctic AB

#### Contacts

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#### Presentation

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, February 14, at 09:30 – 10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson present BioArctic, comment on the Full Year Report 2018 and answer questions.

Webcast: https://tv.streamfabriken.com/bioarctic-q4-2018

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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 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 i.a. the antibody BAN0805. The total aggregated value of the agreement may amount to USD 755 million and, in addition, payments of royalty. VSD 80 million has been received and an additional USD 50 million was received in February 2019.

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. 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 February 14, 2019.