

#### Press release

# **Interim Report January – September 2018**

# BioArctic reports strong BAN2401 Phase 2b results for Alzheimer patients. AbbVie exercises its option to a license for Parkinson's projects

## July - September 2018

- Net revenues for the period amounted to SEK 94.0 million (31.5)
- Operating profit amounted to SEK 33.1 million (0.6)
- Profit for the period amounted to SEK 25.9 million (-0.1)
- Earnings per share were SEK 0.29 (0.00)
- Cash flow from operating activities amounted to SEK -31.5 million (-23.6)

## January - September 2018

- Net revenues for the period amounted to SEK 198.6 million (89.7)
- Operating profit amounted to SEK 58.5 million (4.6)
- Profit for the period amounted to SEK 46.4 million (3.3)
- Earnings per share were SEK 0.53 (0.05)
- Cash flow from operating activities amounted to SEK -110.8 million (-89.6)

### Key events during the period July – September 2018

- BioArctic signed a research agreement with Brain Biomarker Solutions in Gothenburg AB to develop new diagnostics for Alzheimer's disease
- BioArctic received approvals from regulatory authorities in Finland for the clinical study of SC0806 in patients with Complete Spinal Cord Injury
- 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 expanded the research collaboration with Uppsala University concerning antibody-based diagnostic imaging of the brain in Alzheimer patients

## Key events after the period

- 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 treatment for the broad studied population of early Alzheimer's disease patients
- AbbVie exercised its option to license BioArctic's portfolio of antibodies targeting alpha-synuclein for Parkinson's disease. Pending clearance under the U.S. antitrust legislation, a milestone payment of USD 50 million will be received
- BioArctic was granted a concept patent in Europe for the company's strategy for disease-modifying treatment of Parkinson's disease



 BioArctic received European patent protection for a medical device for treatment of patients with Complete Spinal Cord Injury

# **Financial summary**

	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
SEKm	2018	2017	2018	2017	2017
Net revenues	94.0	31.5	198.6	89.7	140.7
Other operating income	0.6	2.8	15.6	8.7	19.0
Operating profit	33.1	0.6	58.5	4.6	19.3
Profit for the period	25.9	-0.1	46.4	3.3	15.2
Operating margin, %	35.2%	2.0%	29.4%	5.1%	13.7%
Earnings per share, SEK 1, 2	0.29	0.00	0.53	0.05	0.22
Equity per share, SEK 1, 2	7.75	1.02	7.75	1.02	7.22
Cash flow from operating					
activities	-31.5	-23.6	-110.8	-89.6	-135.3
Cash flow from operating					
activities per share, SEK 1, 2	-0.36	-0.37	-1.26	-1.42	-1.99
Equity/assets ratio, %	66.1%	10.5%	66.1%	10.5%	55.8%
Return on equity, %	3.9%	-0.2%	7.0%	5.3%	4.3%
Share price end of the period <sup>3</sup>	118.90	-	118.90	-	26.00
Number of shares	88,059,985	63,059,985	88,059,985	63,059,985	88,059,985

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

#### CEO comments

In early July BioArctic reported positive topline 18 months results of the BAN2401 Phase 2b study in 856 early Alzheimer's disease patients. More detailed results were presented later in July by our partner Eisai. BAN2401 demonstrated a dose-dependent effect on clinical and biomarker endpoints. The highest BAN2401 dose showed clinically meaningful effect compared to placebo. All doses of BAN2401 strongly reduced amyloid in the brain as measured by PET techniques. 81% of patients, in the highest BAN2401 dose group, converted from Alzheimer positive to Alzheimer negative status. That is, an improvement in which the former disease-related degree of amyloid has disappeared. BAN2401 was well tolerated across the dose-range.

In October, Eisai presented additional results that further support the positive effects of BAN2401 in all sub-groups of early Alzheimer patients. A correlation was shown between the dose-dependent amyloid reduction in the brain and the clinical effects of BAN2401, and the clinical effects were shown to increase over time. The positive clinical results were further supported by consistent biomarker data indicating that BAN2401 reduces neurodegenerative processes in Alzheimer's disease.

Eisai is currently discussing the next steps for BAN2401 with regulatory authorities and preparing for further clinical studies. The patients who participated in the Phase 2b study are offered continued

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

<sup>&</sup>lt;sup>3</sup> The company was listed in October 2017, so no observable share price exists before the listing



treatment with BAN2401. The results mark an important advancement in the future treatment of Alzheimer's disease and give new hope for the patients and their families.

I am also very pleased with how well BioArctic's research collaboration with AbbVie has developed. During the period, the work

has been intense delivering the projects and preparing for an IND-application to start the first clinical study with BAN0805 in the US next year. It is; therefore, very exciting that AbbVie earlier than expected announced that they exercise their option to license our alpha-synuclein antibody portfolio, pending clearance under the U.S. antitrust legislation.

In the project for treatment of complete spinal cord injury, the inclusion of patients in the first of three panels in the company's ongoing Phase 1/2 study has been completed. BioArctic has regulatory approvals to include patients from Sweden, Estonia, Norway and Finland. The first patients from Estonia are currently in screening phase. An interim analysis of the first panel is planned for Q4 2019/Q1 2020.

BioArctic's ambition is to improve the quality of life for patients with disorders in the central nervous system. Our project portfolio is progressing well, and I am pleased to notice yet another period with a positive financial result. The company 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 our innovative projects in our three disease areas each with high unmet medical need.

Gunilla Osswald CEO, BioArctic AB

#### **Contacts**

For further information, please contact:

Gunilla Osswald, CEO, gunilla.osswald@bioarctic.se, telephone + 46 (0)8 695 69 30 Jan Mattsson, CFO, jan.mattsson@bioarctic.se, telephone + 46 (0)703 52 27 72

#### Presentation

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, November 8, 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 – September 2018 and answer questions.

Webcast: <a href="https://tv.streamfabriken.com/bioarctic-q3-2018">https://tv.streamfabriken.com/bioarctic-q3-2018</a>

Sweden: + 46 850 639 549 Denmark: + 45 354 455 75 Germany: + 49 692 222 290 46 The Netherlands: + 31 207 168 416



Switzerland: + 41 225 675 548

UK: + 44 203 008 9815 US: + 1 855 831 5947

#### **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. 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 (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 November 8, 2018.