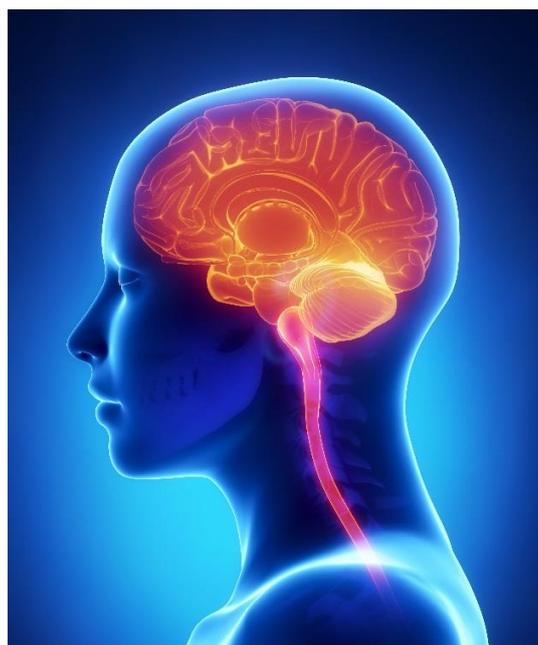


## Full Year Report January – December 2018



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### Financial Calendar

Annual Report 2018, week commencing April 15, 2019
Interim Report Jan – Mar, May 9, 2019
Annual General Meeting, May 9, 2019
Interim Report Jan – Jun, Jul 11, 2019
Interim Report Jan – Sep, Oct 24, 2019

Unless otherwise stated in this report, all data refers to the Group. Figures in parentheses relate to the corresponding period in 2017.

## 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

SEKm	Oct-Dec 2018	Oct-Dec 2017	Jan-Dec 2018	Jan-Dec 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

## 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. Previously, USD 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. For information about the projects, see the section Project portfolio.

BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B).

## 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 in 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.

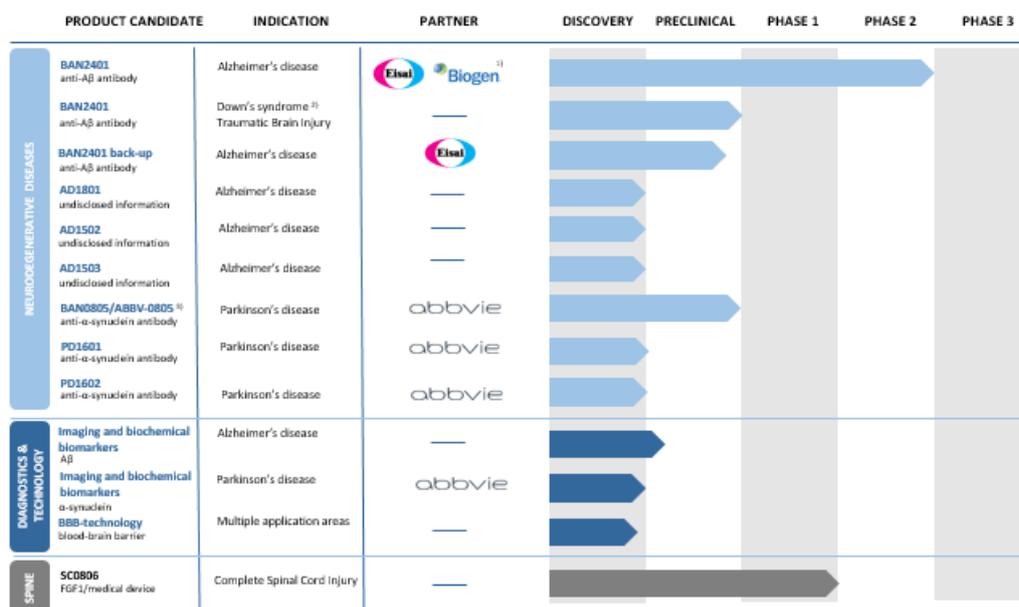
The recent accomplishments in the projects have created a very good basis for a bright future for BioArctic. I am pleased to lead this innovative company and with all co-workers continue our work to improve the quality of life for patients with central nervous system disorders. Finally, I would like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



Gunilla Osswald  
CEO, BioArctic AB

## Project portfolio

### Preclinical and clinical research:



<sup>1)</sup> Partner with Eisai on BAN2401 for treatment of Alzheimer's disease. Eisai partnered with Biogen on BAN2401 in 2014

<sup>2)</sup> Dementia and cognitive impairment associated with Down's syndrome and Traumatic Brain Injury

<sup>3)</sup> AbbVie in-licensed BAN0805 in late 2018 and will continue to develop BAN0805, now with the designation ABBV-0805

*BioArctic's project portfolio at December 31, 2018:*

*Two projects in the clinical phase: BAN2401 for Alzheimer's disease and SC0806 for patients with Complete Spinal Cord Injury.*

*Three drug projects in preclinical phase: BAN2401 for Down's Syndrome with dementia and Traumatic Brain Injury, BAN2401 back-up for Alzheimer's disease; and BAN080/ABV-0805 for Parkinson's disease and biomarker and diagnostics projects for Alzheimer's disease.*

*Three projects in the research phase for Alzheimer's disease (AD1801, AD1502, AD1503) and two projects for Parkinson's disease (PD1601, PD1602) and biomarker and diagnostics projects for Parkinson's disease, as well as a blood-brain barrier technology project.*

### Neurodegenerative diseases

The key molecular event in Alzheimer's disease and Parkinson's disease is believed to be protein misfolding and aggregation. The spreading of soluble aggregates leads to neuronal dysfunction, cell death, brain damage and symptoms of disease. Each neurodegenerative disease is characterized by its unique aggregated protein. The hallmark of Alzheimer's disease is amyloid-beta (A $\beta$ ), whereas alpha-synuclein ( $\alpha$ -synuclein) is the signature protein of Parkinson's disease.

BioArctic's disease modifying treatment strategy is to eliminate toxic aggregated forms (oligomers/protofibrils) in the brain by means of the company's selective antibodies.

### BAN2401

*Alzheimer's disease:* The antibody BAN2401 selectively binds to the soluble, toxic amyloid-beta aggregates that are believed to contribute to the neurodegenerative process in Alzheimer's disease and neutralizes and eliminates them. BAN2401 is highly selective for amyloid-beta oligomers/protofibrils and binds more than 1,000 times stronger to oligomers/protofibrils than to monomers and 10 - 15 times stronger than to amyloid-beta fibrils.

Eisai presented the 18 months analysis of BAN2401 Phase 2b study with 856 patients with early Alzheimer's disease at the AAIC®

conference in Chicago on July 25 and at the CTAD conference in Barcelona on October 25. The results demonstrated consistent dose-dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints as well as dose-dependent and significant effects also on biomarkers including amyloid-PET and was well tolerated.

A reduced degree of decline compared with placebo exceeding 25% was predefined as clinically relevant. At the analysis after 18 months of treatment a dose-dependent slowing of cognitive decline in the clinical cognition scale ADCOMS of 30% was demonstrated with the highest BAN2401 dose of 10 mg/kg twice a month. A statistically significant slowing of decline on ADCOMS was observed as early as at 6 months as well as at 12 months. With the cognition scale ADAS-Cog a significantly reduced degree of decline of 47% was seen with the highest dose. With the cognition scale CDR-SB a reduced decline of 26% compared with placebo was seen at 18 months.

Statistically significant and dose-dependent reduction of amyloid-beta in the brain was seen with amyloid-PET at 18 months. The reduction was statistically significant for all doses. After 18 months treatment a drastic reduction in the brain could be demonstrated with amyloid-PET. 81% of the patients with the highest dose went from amyloid-positive to amyloid-negative. I.e., they could no longer be classified as having Alzheimer's disease.

A major reduction of amyloid-beta in the brain was demonstrated in the whole study population of early Alzheimer patients and in all subgroups: ApoE4-carriers and non-ApoE4-carriers, mild cognitive impairment with Alzheimer pathology (MCI) and mild Alzheimer's disease, with or without concomitant symptomatic medication. The dose-dependent amyloid reduction in the brain correlated with the clinical effects of BAN2401 and the clinical effects of the

treatment were shown to increase with longer treatment time. Significant effects were seen with the two highest doses after 18 months on a number of biomarkers in cerebrospinal fluid, such as total tau, phospho-tau, neurogranin and neurofilament light chain. These effects of BAN2401 on biomarkers in cerebrospinal fluid are very important as they indicate that BAN2401 interferes in the neurodegenerative process downstream of the A $\beta$  pathology.

BAN2401 was well tolerated during the 18 months treatment. The most common adverse events were reactions at the injection site and ARIA-E (Amyloid Related Imaging Abnormalities-Edema). The reactions at the injection site were mostly mild to moderate in severity. The incidence of ARIA-E was not more than 10% in any of the treatment arms. The vast majority with this adverse event, 90%, were without any symptoms and could only be seen after MRI scans.

This is the first study in late clinical phase that demonstrates a potentially disease modifying effect on clinical function as well as a reduced aggregation of amyloid-beta in the brain, with good tolerability.

An open-label extension study, without placebo control, with continued BAN2401 treatment with the highest study dose for the participants in the Phase 2b-study was started at the end of the year.

For more information about the BAN2401 Phase 2b-study, visit [www.bioarctic.com](http://www.bioarctic.com).

Our partner Eisai is currently discussing the next stage in the development of BAN2401 with regulatory authorities and is preparing for initiation of a single Phase 3 confirmation study within the first quarter 2019. Eisai announced on February 4, 2019 that they continue to seek opportunities for potential earlier approval for BAN2401.

Eisai is responsible for the clinical development in Alzheimer's disease. The project is based on research at Uppsala University, Sweden.

*Down's syndrome with dementia:* BAN2401, which is now being clinically evaluated for the treatment of Alzheimer's disease, can potentially also be used for other indications, such as Down's syndrome with dementia, as these patients develop dementia at around 40 years of age.

*Traumatic brain injury (TBI):* BioArctic has submitted a patent application for the antibodies BAN2401/BAN2401 back-up for the treatment of Traumatic Brain Injury. Some of these patients develop dementia after the injury.

#### **BAN2401 back-up**

The antibody is a further developed version of BAN2401 for the treatment of Alzheimer's disease. The antibody was developed by BioArctic in collaboration with Eisai, which led to a new license agreement in 2015. The project is driven by Eisai and is in late preclinical phase.

#### **AD1801**

In August 2018, BioArctic obtained exclusive rights to develop antibody treatments for Alzheimer's disease from a research project previously jointly owned with Eisai. The partner Eisai has the rights to develop small molecule treatment from this research project with a different target than those in the projects BAN2401 and BAN2401 back-up.

#### **AD1502 and AD1503**

At BioArctic research is in progress to develop new antibodies for the treatment of Alzheimer's disease aimed at slowing down or stopping disease progression by addressing two new targets.

#### **BAN0805/ABBV-0805**

BAN0805/ABBV-0805 is an antibody against alpha-synuclein and a drug candidate for the treatment of Parkinson's disease. The goal is to develop a disease modifying treatment that stops or slows down disease progression. A collaboration with AbbVie started in 2016 regarding the continued development of BioArctic's Parkinson program, focusing on

BAN0805 and additional antibodies as well as diagnostics.

At the of 2018 AbbVie exercised its option to license BioArctic's alpha-synuclein antibody portfolio for Parkinson's disease and other potential indications. The license was acquired after clearance by the U.S. competition authority and triggered a milestone payment of USD 50 million. AbbVie will progress and finance the clinical development of BAN0805, now known as ABBV-0805. FDA has approved the IND-application for ABBV-0805. The first clinical study is planned to start in 2019. The project is based on research from Uppsala University.

#### **PD1601 and PD1602**

The antibodies PD1601 and PD1602 are targeting alpha-synuclein for treatment of Parkinson's disease. The aim is to develop a disease modifying treatment that stops or slows down disease progression. The projects are conducted by BioArctic in collaboration with AbbVie.

#### **Diagnostics and technology**

*Alzheimer's disease diagnostics:* In collaboration with Uppsala University, BioArctic is developing a new type of PET tracer for imaging of the brain in Alzheimer's disease by using BioArctic's antibodies. The goal is to create tools to better diagnose the disease, follow the disease progression and objectively measure the effect of drug treatment.

*Improved biochemical methods:* BioArctic develops improved biochemical methods for the identification and precise measurement of responses to treatment of Alzheimer's disease and Parkinson's disease, and for the measurement of disease progression. This is done in collaboration with Brain Biomarker Solutions in Gothenburg AB and the University of Gothenburg, Sweden.

*Blood-brain barrier technology:* Together with Uppsala University, BioArctic is developing a technology that enables better passage of

antibodies into the brain across the blood-brain barrier. This technology has great technical and commercial potential and could be a general technology for improved and more effective treatment of brain diseases.

### **Complete Spinal Cord Injury**

#### **SC0806**

SC0806 is an innovative treatment for patients with traumatic complete spinal cord injury. The product candidate is a combination of a biodegradable medical device and a drug substance (FGF1). The first patient was treated in 2016 with subsequent rehabilitation for 18 months. Since August 2017, the patients receiving SC0806 treatment in the ongoing Phase 1/2 clinical trial have been given the option of 12 months additional participation in an extension study. The inclusion of patients with complete spinal cord injury to the first of three panels of BioArctic's ongoing clinical Phase 1/2 study was completed in April 2018. The study is approved by the regulatory authorities and ethics committees in Sweden, Estonia, Norway and Finland. A safety evaluation of all the patients in the first panel has been performed and provided support to start the next panel. Recruiting of patients for the next panel is ongoing. The first patient in the second panel has received treatment with SC0806 and hereby the Phase 2 part of the study has been initiated. An interim analysis of the first panel regarding efficacy and safety is planned no later than first half of 2020.

The product obtained orphan drug designation in 2010 in the EU and in 2011 in the U.S., which may give the company 10 and 7 years of market exclusivity in Europe and the US, respectively.

#### **Patent**

Patents are crucial to the company's future commercial opportunities. BioArctic has therefore an active patent strategy covering all major pharmaceutical markets, including the US, EU, Japan and China. BioArctic's patent portfolio consisted at the end of the

period of 12 patent families with more than 200 granted patents.

### **Comments on the report**

The Group is referred to unless otherwise stated in this interim report. Figures in parentheses refer to the corresponding period last year. Amounts are expressed in kSEK (SEK thousands) unless otherwise stated. All amounts stated are rounded up or down, which may lead to some totals not matching exactly.

BioArctic has decided to change from income statement by function to income statement by nature of expense starting from the Interim Report for the period January – June 2018. The reason for the change is that management and the Board control the operations in this way. The comparative periods have been changed accordingly. The calculation of the key ratios has not been changed.

#### **Revenues and results**

Because of the nature of the business operations, there may be large fluctuations between revenues for different periods. Revenues may consist of milestone payments, payments from research agreements and research grants.

Net revenues in the fourth quarter amounted to SEK 515.3 million (51.0), an increase of SEK 464.3 million compared with the same period the previous year. The increase during the quarter is mainly attributable to the USD 50 million milestone payment from AbbVie attributable to BioArctic's out-licensing of the Parkinson portfolio which was fully recognized in 2018. Net revenues for the full year amounted to SEK 714.0 million (140.7), which is an increase of 573.3 MSEK. The increase is attributable to the USD 50 million milestone payment from AbbVie and the increased activities in the Parkinson program.

Other operating income relates to research grants, operating exchange rate gains and

rental income and amounted to SEK 0.7 million (10.4) for the fourth quarter and to SEK 16.3 million (19.0) for the full year. The decrease during the fourth quarter relates to lower revenue recognition from research grants and the decrease during the full year is a combined effect from lower revenue recognition from research grants and positive currency effects.

Operating expenses amounted to SEK 85.7 million (46.7) for the fourth quarter and to SEK 241.4 million (140.5) for the full year. The increase for the fourth quarter as well as the full year is primarily explained by increased project expenses mainly attributable to the Parkinson program and other projects in the portfolio and to increased personnel expenses as a consequence of reservation of cost for the incentive programs that are based on targets within the Parkinson and the Alzheimer program respectively. Other operating expenses consisted of operating exchange rate losses.

Since BioArctic did not meet all the conditions to capitalize R&D costs, all such costs have been charged to the P&L.

Operating profit before financial items (EBIT) amounted to SEK 430.3 million (14.7) for the fourth quarter and to SEK 488.8 million (19.3) for the full year. The increase in the operating profit for the quarter is mainly attributable to the milestone payment from AbbVie and the increase for the full year is related to the milestone payment from AbbVie that was fully recognized in 2018 and to the increased activity in the Parkinson program.

Net financial items totaled SEK -0.4 million (0.6) for the fourth quarter and to SEK 0.8 million (0.4) for the full year. Financial income consists of financial exchange rate gains and financial expenses consists of negative interest on cash and cash equivalents.

Profit for the period amounted to SEK 335.2 million (11.8) for the fourth quarter and SEK 381.6 million (15.2) for the full year.

Earnings per share before and after dilution amounted to SEK 3.81 (0.16) for the fourth quarter and to SEK 4.33 (0.22) for the full year.

### **Financial position**

Equity amounted to SEK 1,107.7 million (636.1) at December 31, 2018. This corresponds to an equity per outstanding share of SEK 11.56 (7.22) before and after dilution.

The equity/asset ratio has increased from 55.8% at December 31, 2017 to 73.1% at December 31, 2018. The increase is related to the strong result in 2018.

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to SEK 917.3 million (1,110.4). The milestone payment of USD 50 million for the licensing to AbbVie was received in February 2019. There were no loans at December 31, 2018 and no loans have been taken since this date. The Group has no other credit facility or loan commitments.

In order to reduce foreign exchange exposure some liquid funds are invested in foreign currency. This has reporting effects in connection with the recalculation of currency to the current rate. These effects are recognized in the operating profit and in financial income and expenses.

### **Investments and cash flow**

Investments in the fourth quarter amounted to SEK 1.7 million (-0.5) and SEK 3.1 million (2.8) for the full year. The investments are mainly related to laboratory equipment.

Cash flow from operating activities for the fourth quarter amounted to SEK -89.3 million (-45.7) and SEK -200.1 million (-135.3) for the full year.

## Other information

### Nomination Committee

According to the resolution of the Annual General Meeting 2018, the Nomination Committee for the 2019 Annual General Meeting has been appointed and announced. The Nomination Committee comprises: Margareta Öhrvall (Demban AB), Claes Andersson (Ackelsta AB) and Gunnar Blix (The Third Swedish National Pension Fund). The Annual General Meeting 2019 will be held on May 9 in Stockholm.

### Dividend

The Board of Directors proposes a dividend of SEK 1.50, a total of SEK 132 million.

The Board has concluded that the company's financial resources are sufficient to finance its projects and programs as planned without additional share issue.

### Employees

At the end of the period, the number of employees in the Group was 31 (25) of which 12 (10) are men and 19 (15) women. Approximately 90% are active in R&D and approximately 75% are PhDs; of these, one is Associate Professor and two are Professors.

### Consultants

A cost efficient organization at BioArctic is achieved by hiring key consultants for specific assignments and for tasks in competence areas that the company lacks or only has a need for periodically. As of December 31, 2018, these amounted to a total corresponding to 10 (12) full-time positions.

### Risks and uncertainty factors

The management makes assumptions, judgments and estimates that affect the content of the financial statements. Actual

results may differ from these assumptions and estimates, as is also stated in the accounting principles. The objective of the Group's risk management is to identify, measure, control and limit the risks of the business. Significant risks are the same for the Parent Company and the Group. The risks can be divided into financial risks on the one hand and operational and external risks on the other. BioArctic's operational and external risks mainly consist of risks related to research and development, clinical trials and dependence on key employees.

A detailed description of exposure and risk management is presented in the Annual Report for 2017, pp 41-42.

### Parent Company

All the Group's business operations are conducted in the Parent Company.

## Consolidated income statement<sup>1</sup>

kSEK	Oct-Dec 2018	Oct-Dec 2017	Jan-Dec 2018	Jan-Dec 2017
Net revenues (note 4)	515,320	51,021	713,970	140,706
Other operating income	707	10,366	16,259	19,044
<b>Total operating income</b>	<b>516,027</b>	<b>61,387</b>	<b>730,229</b>	<b>159,750</b>
<b>Operating expenses</b>				
Project related expenses	-48,030	-27,085	-145,357	-63,641
Other external expenses	-10,042	-13,328	-31,949	-36,197
Personnel expenses	-23,629	-9,285	-57,039	-32,936
Depreciations of tangible assets	-667	-594	-2,059	-1,993
Other operating expenses	-3,339	3,637	-5,031	-5,689
<b>Operating profit</b>	<b>430,320</b>	<b>14,731</b>	<b>488,794</b>	<b>19,294</b>
Financial income	-112	905	2,171	1,043
Financial expenses	-304	-340	-1,371	-647
<b>Profit before tax</b>	<b>429,905</b>	<b>15,297</b>	<b>489,593</b>	<b>19,690</b>
Tax	-94,699	-3,461	-107,991	-4,534
<b>Profit for the period</b>	<b>335,205</b>	<b>11,836</b>	<b>381,602</b>	<b>15,157</b>
<b>Earnings per share</b>				
Earnings per share, SEK <sup>2,3</sup>	3.81	0.16	4.33	0.22

<sup>1</sup> BioArctic has decided to change to income statement by nature of expense and the comparative periods have been changed accordingly

<sup>2</sup> There are no potential shares. Thus; there is no dilutive effect

<sup>3</sup> The comparative figures have been recalculated as a result of the 15:1 split executed on August 1, 2017

## Consolidated statement of comprehensive income

kSEK	Oct-Dec 2018	Oct-Dec 2017	Jan-Dec 2018	Jan-Dec 2017
Profit for the period	335,205	11,836	381,602	15,157
Other comprehensive income	-	-	-	-
<b>Comprehensive income for the period</b>	<b>335,205</b>	<b>11,836</b>	<b>381,602</b>	<b>15,157</b>

## Consolidated balance sheet – summary

kSEK	Dec 31, 2018	Dec 31, 2017
<b>ASSETS</b>		
Tangible fixed assets	9,289	7,093
Deferred tax assets	189	230
Other financial assets	1,500	2,675
Current assets excluding cash and cash equivalents	464,757	20,119
Cash and cash equivalents	917,307	1,110,367
<b>TOTAL ASSETS</b>	<b>1,393,042</b>	<b>1,140,483</b>
<b>EQUITY AND LIABILITIES</b>		
Equity	1,017,736	636,134
Deferred tax liabilities	32,520	5,487
Other current liabilities	91,996	12,160
Accrued expenses and deferred income	250,791	486,702
<b>EQUITY AND LIABILITIES</b>	<b>1,393,042</b>	<b>1,140,483</b>

## Consolidated statement of changes in equity – summary

kSEK	Dec 31, 2018	Dec 31, 2017
<b>Opening balance at 1 January</b>	<b>636,134</b>	<b>60,760</b>
Comprehensive income for the period	381,602	15,157
<i>Transactions with shareholders:</i>		
Share issue	-	600,000
Expenses for share issue	-	-39,782
<b>Closing balance</b>	<b>1,017,736</b>	<b>636,134</b>

## Consolidated statement of cash flow

kSEK	Oct-Dec 2018	Oct-Dec 2017	Jan-Dec 2018	Jan-Dec 2017
<b>Operating profit</b>	<b>430,320</b>	<b>14,731</b>	<b>488,794</b>	<b>19,294</b>
Adjustment for non-cash items	-515,360	-63,180	-726,886	-143,453
Interest received/paid	-264	-275	-1,331	-582
Income tax paid	-2,067	-386	-10,889	-7,739
<b>Cash flow from operating activities before changes in working capital</b>	<b>-87,371</b>	<b>-49,110</b>	<b>-250,313</b>	<b>-132,481</b>
Change in working capital	-1,882	3,411	50,256	-2,846
<b>Cash flow from operating activities after changes in working capital</b>	<b>-89,253</b>	<b>-45,700</b>	<b>-200,057</b>	<b>-135,327</b>
<b>Cash flow from investing activities</b>	<b>-1,715</b>	<b>521</b>	<b>-3,080</b>	<b>-2,813</b>
<b>Cash flow from financing activities</b>	<b>-</b>	<b>560,218</b>	<b>-</b>	<b>560,218</b>
<b>Cash flow for the period</b>	<b>-90,969</b>	<b>515,040</b>	<b>-203,136</b>	<b>422,078</b>
Cash and cash equivalents at beginning of period	1,008,522	590,677	1,110,367	692,530
Exchange rate differences in cash and cash equivalents	-247	4,650	10,076	-4,241
<b>Cash and cash equivalents at end of period</b>	<b>917,307</b>	<b>1,110,367</b>	<b>917,307</b>	<b>1,110,367</b>

## Parent Company income statement<sup>1</sup>

kSEK	Oct-Dec 2018	Oct-Dec 2017	Jan-Dec 2018	Jan-Dec 2017
Net revenues	515,320	51,021	713,970	140,706
Other operating income	707	10,366	16,259	19,044
<b>Total operating income</b>	<b>516,027</b>	<b>61,387</b>	<b>730,229</b>	<b>159,750</b>
<b>Operating expenses</b>				
Project related expenses	-48,030	-27,085	-145,357	-63,641
Other external expenses	-10,042	-13,328	-31,949	-36,196
Personnel expenses	-23,629	-9,285	-57,039	-32,936
Depreciations of tangible assets	-667	-594	-2,059	-1,993
Other operating expenses	-3,339	3,637	-5,031	-5,689
<b>Operating profit</b>	<b>430,321</b>	<b>14,731</b>	<b>488,794</b>	<b>19,295</b>
Financial income	-112	905	2,171	1,043
Financial expenses	-304	-340	-1,371	-647
<b>Profit after financial items</b>	<b>429,905</b>	<b>15,296</b>	<b>489,594</b>	<b>19,691</b>
Change in tax allocation reserves	-122,876	-6,141	-122,876	-6,141
<b>Profit before tax</b>	<b>307,029</b>	<b>9,155</b>	<b>366,718</b>	<b>13,550</b>
Tax	-67,667	-2,110	-80,959	-3,183
<b>Profit for the period</b>	<b>239,363</b>	<b>7,046</b>	<b>285,759</b>	<b>10,367</b>

<sup>1</sup> BioArctic has decided to change to income statement by nature of expense and the comparative periods have been changed accordingly

There are no items in the parent company recognized as other comprehensive income, thus comprehensive income conforms to the result for the year.

## Parent Company balance sheet – summary

kSEK	Dec 31, 2018	Dec 31, 2017
<b>ASSETS</b>		
Tangible fixed assets	9,289	7,093
Deferred tax assets	189	230
Other financial assets	1,600	2,775
Current assets excluding cash and cash equivalents	464,757	20,119
Cash and cash equivalents	917,209	1,110,269
<b>TOTAL ASSETS</b>	<b>1,393,044</b>	<b>1,140,484</b>
<b>EQUITY AND LIABILITIES</b>		
Equity	902,441	616,682
Tax allocation reserve	147,817	24,941
Other current liabilities	91,996	12,160
Accrued expenses and deferred income	250,791	486,702
<b>EQUITY AND LIABILITIES</b>	<b>1,393,044</b>	<b>1,140,484</b>

## Notes

### Note 1 General information

This Full Year Report covers the Swedish Parent Company BioArctic AB, Swedish Corporate Identity Number 556601-2679, and the two fully owned subsidiaries SpineMedical AB, Swedish Corporate Identity Number 559003-7080, and LPB Sweden AB, Swedish Corporate Identity Number 559035-9112. All the Group's business operations are conducted in the Parent Company.

The Parent Company is a Swedish limited liability company registered in and with its registered office in Stockholm. The head office is located at Warfvinges väg 35, SE-112 51, Stockholm, Sweden.

The BioArctic Group's Full Year Report for the period January – December 2018 was approved by the Board on February 13, 2019.

### Note 2 Accounting principles

The consolidated financial statements for BioArctic AB have been prepared in accordance with IFRS (International Financial Reporting Standards) as adopted by the EU, the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's RFR 1 Supplementary Accounting Rules for Groups. The Parent Company's financial statements are presented in accordance with the Swedish Annual Accounts Act and RFR 2 Accounting for Legal Entities.

The Full Year Report for 2018 is presented in accordance with IAS 34 Interim Financial Reporting and the Swedish Annual Accounts Act. Disclosures in accordance with IAS 34 are presented both in notes and elsewhere in the Full Year Report.

The guidelines of the European Securities and Markets Authority (ESMA) on alternative performance measures have been applied. This involves disclosure requirements for financial measures that are not defined by IFRS. For performance measures not defined by IFRS, see the Calculations of key figures section.

IFRS 15 *Revenue from Contracts with Customers* regulates the reporting of revenues and came into force on January 1, 2018. IFRS 15 replaces IAS 18 *Revenue* and IAS11 *Construction Contracts* as well as the appropriate SIC and IFRIC. According to IFRS the company shall recognize revenue when or over time as the company meets a performance commitment by transferring the promised service to a customer, who thereby obtains control of the asset. Most of BioArctic's revenue from contracts with customers relates to research collaborations and milestone payments. The transition to IFRS 15 means that the revenue is recognized over time, which corresponds to the previous reporting based on degree of completion. BioArctic has received one-time payments from customers which are accounted when the right to compensation has been established. This point in time corresponds to the time when performance commitments are met according to IFRS 15. The amount recognized as revenue is the compensation the company expects to be entitled to in exchange for transferring promised services to a customer. The Group has not identified any differences in reporting at the transition to IFRS 15, neither regarding amounts, nor when in time the revenue is recognized. The transition has only meant increased disclosure requirements.

IFRS 9 *Financial instruments* replaces IAS 39 *Financial instruments: Recognition and Measurement*. IFRS 9 comes into force for financial years commencing on January 1, 2018 or later. BioArctic has elected not to apply this standard in advance. In principle BioArctic always receives payment from agreements with customers in advance. There are thus no bad debt losses. The Group has thus not identified any differences in reporting when transferring to IFRS 9.

IFRS 16 replaces IAS 17 *Leases* and the appropriate interpretations IFRIC 4, SIC-15 and SIC-27. This standard requires that assets and liabilities attributable to all leasing agreements, with a few exceptions, are recognized in the balance sheet. This reporting is based on the view that an asset is used for a specific period of time and at the same time an obligation arises to pay for this right. The standard is to be applied for financial years commencing on January 1, 2019 or later. BioArctic has elected to apply the modified retrospective approach. The effect of the application of IFRS 16 will be that BioArctic will account for a right-to-use asset and a leasing liability for office premises and parking lots that currently are accounted for as operational leasing contracts. The company has chosen to apply the relief rules concerning short-term agreements and low-value agreements. The effect from using IFRS from 1 January 2019 is calculated as shown below:

- The Group's assets and liabilities will increase with SEK 31.8 million to SEK 1,424.8 million
- Equity assets ratio will decrease with 1.7 percentage points from 73.1 % to 71.4%

BioArctic changed from income statement by function to income statement by nature of expense starting from the Interim Report for the period January – June 2018. The reason for the change is that management and the Board control the operations in this way. The comparative periods have been changed accordingly. The calculation of the key ratios has not been changed.

The accounting principles and calculation methods applied are in all other respects in line with those described in the Annual Report for 2017.

### **Note 3 Segment information**

An operating segment is a part of the Group that conducts operations from which it can generate income and incur costs and for which independent financial information is available. The highest executive decision-maker in the Group follows up the operations on aggregated level, which means that the operations constitute one and the same segment and thus no separate segment information is presented. The Board of Directors is identified as the highest executive decision maker in the Group.

#### Note 4 Net revenues

A breakdown of the Group's Net revenues is shown below:

kSEK	Oct-Dec 2018	Oct-Dec 2017	Jan-Dec 2018	Jan-Dec 2017
<b>Geographic breakdown of net revenues</b>				
Europe	515,320	49,827	712,489	135,494
Other	-	1,194	1,481	5,212
<b>Total net revenues</b>	<b>515,320</b>	<b>51,021</b>	<b>713,970</b>	<b>140,706</b>
<b>Net revenues per revenue type</b>				
Milestone payments	448,550	-	448,550	-
Income from research collaborations	66,770	51,021	265,420	140,275
Other items	-	-	-	431
<b>Total net revenues</b>	<b>515,320</b>	<b>51,021</b>	<b>713,970</b>	<b>140,706</b>

BioArctic's net revenues essentially consist of income from the research collaborations concerning Parkinson's disease with AbbVie and Alzheimer's disease with Eisai.

Under the collaboration agreement with AbbVie, BioArctic received an initial payment of SEK 701.6 million (USD 80 million) during the third quarter 2016. This payment is related to compensation for the preclinical development work that BioArctic will carry out under the agreement. Of the initial payment, SEK 70.4 million was reported as a one-time payment in 2016. The rest of the payment will be accrued based on the costs incurred up until the completion of the project. The project is continuously evaluated with the regard to status and remaining costs. During the third quarter 2018, the total costs were assessed to be lower than in the previous assumptions. A positive one-off effect amounting to SEK 20.1 million has been recognized, and the future margin in the project will increase. As of December 31, 2018, SEK 492.5 million has been recognized and the remaining amount to be recognized as a revenue up until the completion of the project is SEK 209.1 million. In accordance with the collaboration agreement with AbbVie, a milestone payment of SEK 448.6 million (USD 50 million) was recognized during the fourth quarter of 2018 for AbbVie's in-licensing of BioArctic's alpha-synuclein antibody portfolio for disease-modifying treatment for Parkinson's disease and other potential indications.

#### Note 5 Transactions with affiliated parties

Mikael Smedeby, who was elected to the Board of Directors at the Annual General Meeting, is active as lawyer and co-owner of Advokatfirman Lindahl KB, which provides ongoing business legal advice to BioArctic against compensation in line with market rates. During 2017, Advokatfirman Lindahl invoiced fees amounting to approximately SEK 5.2 million, which mainly consisted of costs due to the IPO in October 2017, and for the full year 2018 an amount of approximately SEK 0.6 million was invoiced.

In addition to the compensation to Advokatfirman Lindahl described above, salary and board of director's fee to Lars Lannfelt and Pär Gellerfors, no significant transactions have taken place between the Group and related parties. All transactions have been in line with market rates.

## Consolidated quarterly data

SEKm	2018 Q4	2018 Q3	2018 Q2	2018 Q1	2017 Q4	2017 Q3	2017 Q2	2017 Q1
<b>Income statement</b>								
Net revenues	515.3	94.0	52.3	52.3	51.0	31.5	32.0	26.2
Other operating income	0.7	0.6	3.6	11.4	10.4	2.8	5.2	0.7
Operating profit	430.3	33.1	6.4	18.9	14.7	0.6	2.5	1.5
Profit for the period	335.2	25.9	5.1	15.4	11.8	-0.1	2.3	1.1
Operating margin, %	83.5%	35.2%	12.3%	36.1%	28.9%	2.0%	7.7%	5.6%
<b>Balance sheet</b>								
Fixed assets	11.0	9.9	10.0	9.6	10.0	10.5	8.2	8.2
Current assets	464.8	13.8	12.0	20.3	20.1	9.8	8.6	13.2
Cash and cash equivalents	917.3	1,008.5	1,041.7	1,078.7	1,110.4	590.7	622.1	650.3
Equity	1,017.7	682.5	656.7	651.6	636.1	64.1	64.2	61.9
Deferred tax liabilities	32.5	5.5	5.5	5.5	5.5	4.1	4.1	4.1
Current liabilities	342.8	344.2	401.6	451.6	498.9	542.7	570.5	605.7
<b>Cash flow</b>								
From operating activities	-89.3	-31.5	-37.3	-42.0	-45.7	-23.6	-27.6	-38.4
From investing activities	-1.7	-0.5	-0.7	-0.2	0.5	-2.8	-0.4	-0.1
From financing activities	-	-	-	-	560.2	-	-	-
Cash flow for the period	-91.0	-32.0	-38.0	-42.2	515.0	-26.4	-28.1	-38.5
<b>Data per share, SEK<sup>1, 2, 3</sup></b>								
Earnings per share	3.81	0.29	0.06	0.18	0.16	0.00	0.04	0.02
Equity per share	11.56	7.75	7.46	7.40	7.22	1.02	1.02	0.98
Cash flow operating activities	-1.01	-0.36	-0.42	-0.48	-0.60	-0.37	-0.44	-0.61
Share price end of the period	82.00	118.90	21.80	21.40	26.00	-	-	-

<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

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

## Definition of key ratios

In this financial report BioArctic reports key financial ratios, some of which are not defined by IFRS. The Company assesses that these key ratios are important additional information, since they enable investors, securities analysts, management of the company and other stakeholders to better analyze and evaluate the company's business and financial trends. These key ratios should not be analyzed separately or replace key ratios that have been calculated in accordance with IFRS. These key ratios should not be compared to other key ratios with similar names applied by other companies. This is due to the fact that key ratios cannot always be defined in the same way and other companies may calculate them in a different way than BioArctic.

The key ratios "Net revenues", "Result for the period", "Earnings per share" and "Cash flow from operating activities" are defined according to IFRS.

<b>Key ratios</b>	<b>Definition</b>
Other income	Other income than Net revenues
Operating profit	Result before financial items
Cash flow from operating activities per share, SEK	The period's cash flow from operating activities divided by the weighted number of shares
Equity/asset ratio	Adjusted equity as a percentage of the balance sheet total
Return on equity	Net income divided by equity as a percentage
Equity per share before and after dilution	Adjusted equity divided by the number of shares at the end of the period

The Board and the CEO confirm that this Interim Report provides a true and fair overview of the Company and the Group's operations, position and earnings and describes the material risks and uncertainly factors faced by the Parent Company and the companies within the Group.

This Full Year Report has not been subject to review reviewed by BioArctic's auditors.

Stockholm, Sweden, February 13, 2019

Wenche Rolfsen  
Chairman

Ivar Verner  
Deputy Chairman

Hans Ekelund  
Board member

Pär Gellerfors  
Board member

Lars Lannfelt  
Board member

Mikael Smedeby  
Board member

Eugen Steiner  
Board member

Gunilla Osswald  
President and CEO

## Goal and strategy for sustainable growth

BioArctic's goal is to improve the quality of life for patients with diseases in the central nervous system. We would like to contribute to the society by developing innovative disease-modifying treatments based on antibodies (immunotherapy) for neurodegenerative diseases, i.e. disease where the nervous system atrophies. BioArctic develops entirely new types of treatments that hopefully may halt or delay the disease progression in patients with Alzheimer's disease and Parkinson's disease, unlike today's symptomatic treatments. The company is also developing a new treatment concept for complete spinal cord injuries.

During the year the strategy work has been intensified to enable BioArctic to fully utilize the project portfolio's many opportunities. The company is well positioned to advance the on-going projects in order to build further value and to create new successful collaboration. In combination this creates sustainable growth.

### Strategic target areas

BioArctic focuses on building unique and competitive portfolio of product candidates, diagnostics and technology in the company's indication areas. This is done partly through internal research and development, partly through research collaborations with strategic partners in the form of research groups at universities, in pharma companies, and the health care sector.

Our strategy is to out-license certain commercial rights to global pharma companies at an appropriate time. In line with this strategy, BioArctic's research and development work continues. Important elements of BioArctic's strategy are:

*CONTINUE* to focus on the partnered projects and progress/accelerate the in-house projects with great out-licensing and market potential

*DEVELOP* projects further, up to optimal time for partnering/exit to maximize return on the investment

*EXPAND* the portfolio with new targets, orphan drug indications, new projects and diagnostics

*INVEST* in:

- technologies; antibodies, BBB, diagnostics and biomarkers
- and attract/retain co-workers
- and prepare for commercialization in the Nordic region

### Collaborations and partnerships

Collaborating with universities is of great importance to BioArctic. The company has on-going collaborations with academic research groups at a number of universities. Collaborations and license agreements with leading pharma and biopharma companies are also an important part of BioArctic's strategy. In addition to financial compensation we get access to our partners' skills in drug development, manufacturing and commercialization. BioArctic has entered into a number of such agreements with the Japanese international pharma company Eisai and the American global biopharma company AbbVie. These strategic partnerships with leading global companies confirm that BioArctic's research is of very high quality.

In the future BioArctic may enter into additional agreements that can contribute further funding and research and development competence for product candidates in preclinical and clinical phase, manufacturing and marketing competence, geographic coverage and other resources.

For more information regarding BioArctic's two large collaboration partners, please the Annual Report 2017 on page 11.

## Glossary

### **ADAS-Cog**

ADAS-Cog (Alzheimer's Disease Assessment Scale-cognitive subscale) is a well-established cognition scale whereof parts are included in ADCOMS

### **ADCOMS**

Alzheimer's Disease Composite Score – A cognition scale consisting of parts from three different scales (CDR-SB, ADAS-cog and MMSE) developed by Eisai. The cognition scale enables a sensitive detection of changes in clinical functions of symptoms in early Alzheimer's disease

### **Alpha-synuclein ( $\alpha$ -synuclein)**

A protein in the nervous system, present in Lewy bodies in some structures of the brain in Parkinson's disease

### **Amyloid-beta ( $A\beta$ )**

A 40-42 amino acids long peptide, split from the parent protein APP, amyloid precursor protein.  $A\beta$  is the main constituent of the plaques found in the brain of Alzheimer patients

### **Antibody**

Protein used by the body's immune system to detect and destroy foreign substances

### **ApoE4**

Apolipoprotein E (ApoE) transports fats in the blood. Individuals expressing ApoE4 develop more Alzheimer changes in the form of plaques and amyloid-beta in the brain blood vessel walls.

### **ARIA**

Amyloid-Related Imaging Abnormalities (ARIA) are brain-changes seen in Magnetic Resonance Imaging of Alzheimer's disease patients, which are commonly observed in clinical trials of amyloid-modifying therapies

### **ARIA-E**

There are two types of ARIA; ARIA-E and ARIA-H. ARIA-E refers to observations of edema and

the other ARIA-H to observations of small hemorrhages

### **Biomarker**

A measurable indicator of a medical condition

### **Blood-brain barrier**

A physiological mechanism in which merged capillary walls in the brain's blood vessels regulate the transport of molecules between the blood and the brain tissue, with the function to protect the brain against viruses and other harmful agents

### **CDR-SB**

CDR-SB (Clinical Dementia Rating Sum of Boxes) is a cognition and function scale which is part of ADCOMS

### **Central nervous system**

The central nervous system consists of the brain and the spinal cord

### **Clinical studies**

Drug trials performed in human subjects

### **Complete Spinal Cord Injury**

A complete injury means that the spinal cord is complete severed. In an incomplete injury there are still a few nerve contacts left

### **Disease modifying treatment**

A treatment that interferes with the processes of the disease and changes it in a positive way

### **Dose dependent**

Increased effect at higher dose

### **Drug candidate**

A drug under development that has not yet gained marketing approval

### **Humanized antibody**

An antibody in which the sequence has been changed to resemble a human antibody

### **Interim analysis**

In clinical trials and other scientific studies, an interim analysis is an analysis of data that is conducted before data collection has been completed

**Investigational New Drug (IND) application**

Application to the U.S. Food and Drug Administration (FDA) for the initiation of a clinical study in the US.

**Ligand**

Molecule that binds to the desired target in the body

**Medical device for implantation**

A medical device that is intended to be totally or partially introduced, surgically or medically, into the human body, or through a medical procedure in a body opening, and intended to remain there after the operation

**Milestone payment**

Financial compensation obtained within the framework of a project or collaboration agreement when a certain specified objective has been achieved

**Monoclonal antibody**

An antibody that can be produced so that all copies are exactly alike

**Monomer**

A monomer is the starting molecule in polymerization. The monomers are joined into long molecular chains through the polymerization, resulting in a polymer with the monomer as the repeating unit

**Neurodegenerative disease**

Disease in which the nervous system atrophies

**Oligomer**

A molecular chain consisting of several monomers aggregated

**Orphan drugs**

Drugs for patients with rare and serious disease

**Peptide**

A molecule made up of amino acids connected into a short chain

**PET**

Positron emission tomography, an investigation imaging method

**Phase 1 studies**

Studies mainly of the safety and tolerability of a drug. Performed on a limited number of healthy human volunteers or patients

**Phase 2 studies**

Studies of the safety and efficacy of a drug and dose finding. Performed on a limited number of patients

**Phase 3 studies**

Confirmatory studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients

**Preclinical phase**

Preclinical studies of drug candidates to prepare for clinical studies

**Preclinical studies**

Studies performed in model systems, i.e. not in humans

**Product candidate**

A product under development that has not yet gained marketing approval

**Protofibril**

A molecular chain consisting of several monomers aggregated

**Research phase**

Early research is focused on studying and elucidating the underlying molecular disease mechanisms and development of potential drug candidates

**Statistically significant**

A clinical study result is defined as statistically significant in accordance with the preset criteria for the study or in adherence to a generally recognized standard, most commonly defined as less than 5% probability of obtaining a similar or stronger result due to chance, i.e.  $p < 0.05$

**Tolerability**

How a person reacts to a drug

*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.*

## **BioArctic AB**

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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.