

### 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<sup>1</sup> 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 <sup>1</sup>	0.15	0.18	4.33
Equity per share, SEK <sup>1</sup>	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 <sup>1</sup>	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

<sup>1</sup> No share-based incentive program exists, thus there is no dilutive effect

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This information is information that BioArctic AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of Christina Astrén, IR & Communications Director, at 08.00 a.m. CET on May 9, 2019.

#### Invitation to presentation of Interim Report for the first quarter 2019

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>

To participate in the conference call, please call: +46 8 505 583 53 (Sweden), +45 781 501 07 (Denmark), +49 692 222 203 80 (Germany) +31 207 219 495 (Netherlands), +47 235 002 36 (Norway), +41 225 805 976 (Switzerland), +44 333 300 9262 (UK) or +1 833 526 8381 (USA)

## 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

## Project portfolio

BioArctic builds a unique and competitive portfolio of product candidates, diagnostics and technology in the company's indication areas. We run projects in three areas where effective treatments are lacking today: Alzheimer's disease, Parkinson's disease and complete spinal cord injury. The company's projects are in various phases: from early research phase to late clinical phase.

### Summary at March 31, 2019:

- Three drug candidates in clinical phase: BAN2401 for early Alzheimer's disease, ABBV-0805 for Parkinson's disease and SC0806 for complete spinal cord injury
- Two drug projects in preclinical phase: BAN2401 for Down's syndrome with dementia and Traumatic Brain Injury and BAN2401 back-up for Alzheimer's disease
- Five projects in research phase: three projects for Alzheimer's disease (AD1801, AD1502, AD 1503) and two projects for Parkinson's disease (PD1601, PD1602)
- Biomarker and diagnostics projects for Alzheimer's disease and Parkinson's disease, as well as a blood-brain barrier technology project

	Product candidate	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	
Neurodegenerative diseases	<b>BAN2401:</b> anti-A $\beta$ antibody	Alzheimer's Disease	Eisai, Biogen <sup>1</sup>	→					
	<b>BAN2401:</b> anti-A $\beta$ antibody	Down's syndrome <sup>2</sup> Traumatic Brain Injury	BioArctic	→					
	<b>BAN2401 BACK-UP:</b> anti-A $\beta$ antibody	Alzheimer's Disease	Eisai	→					
	<b>AD1801:</b> Undisclosed information	Alzheimer's Disease	BioArctic	→					
	<b>AD1502:</b> Undisclosed information	Alzheimer's Disease	BioArctic	→					
	<b>AD1503:</b> Undisclosed information	Alzheimer's Disease	BioArctic	→					
	<b>ABBV-0805<sup>3</sup>:</b> anti- $\alpha$ -synuclein antibody	Parkinson's Disease	AbbVie	→					
	<b>PD1601:</b> anti- $\alpha$ -synuclein antibody	Parkinson's Disease	AbbVie	→					
	<b>PD1602:</b> anti- $\alpha$ -synuclein antibody	Parkinson's Disease	AbbVie	→					
Diagnostics & Technology	<b>IMAGING AND BIOCHEMICAL BIOMARKERS:</b> A $\beta$	Alzheimer's Disease	BioArctic	→					
	<b>IMAGING AND BIOCHEMICAL BIOMARKERS:</b> $\alpha$ -synuclein	Parkinson's Disease	AbbVie	→					
	<b>BBB-TECHNOLOGY:</b> blood-brain barrier	Multiple application areas	BioArctic	→					
Spine	<b>SC0806:</b> FGF1/medical device	Complete Spinal Cord Injury	BioArctic	→					

<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

### Neurodegenerative diseases

The key molecular event in Alzheimer's disease and Parkinson's disease is believed to be abnormal 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 a unique aggregated protein. Characteristic for Alzheimer's disease is amyloid beta (A $\beta$ ), while alpha-synuclein ( $\alpha$ -synuclein) is the signature protein for Parkinson's disease.

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

#### Drug candidate BAN2401

##### *Alzheimer's disease (collaboration with Eisai):*

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's unique profile is highly selective for A $\beta$  oligomers/protofibrils and binds more than 1,000 times

stronger to these than to A $\beta$  monomers and 10 - 15 times stronger than to A $\beta$  fibrils.

During 2018 results were presented from the Phase 2b-study with BAN2401 in 856 patients with early Alzheimer's disease. The results demonstrated consistent dose-dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints and 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 amyloid 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 potential disease modifying effect on clinical function as well as clearance of amyloid beta in the brain, and effect on neurodegenerative biomarkers. BAN2401 showed a good tolerability. The data support the positive effect of BAN2401 in all subgroups of early Alzheimer's disease.

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

Our partner Eisai has discussed the next stage in the development of BAN2401 with regulatory authorities. In March 2019, Eisai announced that they have initiated the confirmatory Phase 3 study with BAN24019 in early Alzheimer patients.

The confirmatory Phase 3 study (named Clarity AD/ Study 301) is a global placebo-controlled, double-blind, parallel-group, randomized study in 1,566 patients with early Alzheimer's disease i.e. mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease with confirmed amyloid pathology in the brain. Patients are allocated in a 1:1 ratio to receive either placebo or treatment. In the treatment group, BAN2401 will be administered at a dosage of 10 mg/kg twice a month. The primary endpoint is the change from baseline in the cognition and function scale Clinical Dementia Rating-Sum of Boxes (CDR-SB) at 18 months of treatment. Changes in the clinical scales AD composite score (ADCOMS) and AD Assessment Scale-Cognitive Subscale (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 2022.

Eisai is furthermore exploring the potential for a Phase 3 study with BAN2401 in subjects with amyloid pathology in the brain, who are in earlier stages of Alzheimer's disease than the patients previously studied. Eisai refers to this population as preclinical Alzheimer's disease and is also exploring the potential addition of Eisai's BACE inhibitor elenbecestat in the study.

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

*Down's syndrome with dementia (own project BioArctic):* 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 (own project BioArctic):* 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.

### **Drug candidate BAN2401 back-up**

*Alzheimer's disease (collaboration with Eisai):*

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.

### **Drug candidates AD1801, AD1502 and AD1503**

*Alzheimer's disease (own projects BioArctic):*

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 novel targets.

### **Drug candidate ABBV-0805**

*Parkinson's disease (collaboration with AbbVie):*

The drug candidate ABBV-0805 is a monoclonal antibody that selectively binds and eliminates oligomers and protofibrils of alpha-synuclein. The goal is to develop a disease modifying treatment that stops or slows down disease progression. A collaboration with AbbVie was entered in 2016 concerning the continued development of BioArctic's Parkinson program focusing on BAN0805, now under the designation ABBV-0805, and additional antibodies as well as diagnostics.

At the end 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. In February 2019, the U.S. Food and Drug Administration, FDA, approved the application to conduct a clinical study with ABBV-0805 and the Phase 1 study started already in March. AbbVie will progress and finance the clinical development of ABBV-0805. The project is based on research from Uppsala University.

### **Drug candidates PD1601 and PD1602**

*Parkinson's disease (collaboration with AbbVie):*

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

### **Diagnostics and technology**

*Alzheimer's and Parkinson's diseases diagnostics:*

In collaboration with scientists at 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. Within the Parkinson field, the development of diagnostic methods based on BioArctic's antibodies is part of the collaboration with AbbVie. The goal is to create tools to better diagnose the disease, follow the disease progression and objectively measure the effect of drug treatment.

BioArctic also 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 scientists at the University of Gothenburg, Sweden.

*Blood-brain barrier technology:*

The blood-brain barrier controls the exchange of substances between the blood and the brain. The barrier protects the brain from toxins and other pathogens, but it may also limit the delivery of therapeutic agents to the brain. Together with scientists at 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 commercial potential and could be a general technology for improved and more effective treatment of brain diseases.

### **Complete Spinal Cord Injury**

#### **Product candidate SC0806**

*Traumatic complete spinal cord injury (own project BioArctic):*

The product candidate SC0806 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 for inclusion of patients 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. The first patient in the second panel has received treatment with SC0806 and hereby the second part of the Phase 1/2 study has been initiated. An interim analysis of the first panel regarding efficacy and safety is planned no later than first half of 2020.

SC0806 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 U.S., respectively.

The project is licensed from Swenora Biotech AB and is based on research from Karolinska Institutet and Karolinska University Hospital, in Sweden.

### **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 to the financial reporting

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

### 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 first quarter amounted to MSEK 63.4 (52.3), an increase of MSEK 11.1 compared with the same period the previous year. The increase during the quarter is attributable to net revenues from the Parkinson program.

Other operating income relates to research grants and operating exchange rate gains and amounted to MSEK 6.9 (11.4) for the first quarter. The decrease during the first quarter relates to lower revenue recognition from research grants and lower unrealized exchange rate gains.

Operating expenses amounted to MSEK 53.0 (44.8) for the first quarter. The increase for the first quarter is explained by increased project expenses for own projects and personnel expenses due to increased number of employees. The increase in depreciations of tangible assets is an effect from the application of IFRS 16 Leases, see note 2. Other operating expenses consisted of realized 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 MSEK 17.3 (18.9) for the first quarter.

Net financial items totaled MSEK 0.1 (0.9) for the first quarter. Financial income consists of financial exchange rate gains and financial expenses consists of negative interest on cash and cash equivalents and interest on leasing debt.

Profit for the period amounted to MSEK 13.6 (15.4) for the first quarter.

Earnings per share before and after dilution amounted to SEK 0.15 (0.18) for the first quarter.

### Financial position

Equity amounted to MSEK 1,031.4 (651.6) at March 31, 2019. This corresponds to an equity per outstanding share of SEK 11.71 (7.4) before and after dilution.

The equity/asset ratio has increased from 73.1 percent at December 31, 2018 to 78.5 percent at March 31, 2019.

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to MSEK 1,255.6 (1,078.7). The interest-bearing liabilities at March 31, 2019 of MSEK 31.5 relates to financial leasing and is an effect from the application of IFRS 16 Leases. There were no loans at March 31, 2019 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 first quarter amounted to MSEK 0.5 (0.2). The investments are mainly related to laboratory equipment.

Cash flow from financing activities amounted to MSEK -1.8 (0.0) and relates to the application of IFRS 16 Leases.

Cash flow from operating activities for the first quarter amounted to MSEK 333.6 (-42.0). The increase in the cash flow is explained by the payment from AbbVie which was received in February 2019.

### Employees

At the end of the period, the number of employees in the Group was 36 (29) of which 13 (12) are men and 23 (17) women. Approximately 90 percent are active in R&D and approximately 75 percent 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 March 31, 2019, these amounted to a total corresponding to 11 (12) full-time positions.

### Key events during the period

- BioArctic announced that the company's partner Eisai will initiate the single confirmatory Phase 3-study with BAN2401 in early Alzheimer's disease and published information concerning the design of the study and timelines
- Eisai initiated the confirmatory Phase 3-study with BAN24091 in early Alzheimer's disease
- The U.S. Food and Drug Administration approved the application to start a clinical study in the Parkinson program with ABBV-0805, previously named BAN0805
- BioArctic announced the start of the clinical Phase 1-study with ABBV-0805 in the Parkinson program
- 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

### The share and shareholdings

The share capital in BioArctic amounts to SEK 1,761,200 divided on 88,059,985 shares which is split on 14,399,996 A-shares and 73,659,989 B-shares. The quotient value for both A- and B-shares is SEK 0.02. The A-shares has 10 votes per share and the B-share has 1 vote per share.

### The largest shareholders at March 31, 2019<sup>1</sup>

Shareholder	Number of A-shares	Number of B-shares	Share of capital, %	Share of votes, %
Demban AB (Lars Lannfelt)	8,639,998	22,848,159	35.8	50.2
Ackelsta AB (Pär Gellerfors)	5,759,998	15,232,989	23.8	33.5
Third Swedish National Pension Fund	-	4,012,032	4.6	1.8
Fourth Swedish National Pension Fund	-	3,500,000	4.0	1.6
Norron Funds	-	3,099,890	3.5	1.4
Handelsbanken Funds	-	3,076,667	3.5	1.4
Investment AB Öresund	-	2,250,000	2.6	1.0
AMF Insurance & Funds	-	2,053,470	2.3	0.9
Unionen	-	1,763,000	2.0	0.8
SEB Funds	-	1,488,985	1.7	0.7
<b>Total 10 largest shareholders</b>	<b>14,399,996</b>	<b>59,325,192</b>	<b>83.7</b>	<b>93.4</b>
Other	-	14,334,797	16.3	6.6
<b>Total</b>	<b>14,399,996</b>	<b>73,659,989</b>	<b>100.0</b>	<b>100.0</b>

<sup>1</sup> Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

### 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 2018, pp 44-46.

### Parent Company

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

### Expected development of operating expenses

Operating expenses are expected to be in the range of MSEK 190 – 250 for the fiscal year January – December 2019.

### Annual General Meeting 2019

The Annual General Meeting 2019 in BioArctic AB (publ) will be held on Thursday, May 9, 2019, at 5 p.m., Grant Thornton Sweden AB, Sveavägen 20, Stockholm, Sweden.

The complete notice to attend the General Meeting and the proposals and documentation that will be presented at the Annual General Meeting are available at [www.bioarctic.com](http://www.bioarctic.com) under the Corporate Governance section.

The Board of Directors proposes the Annual General Meeting 2019 a dividend of SEK 1.50 per share, a total of approximately MSEK 132. The Board has concluded that the company's financial resources are sufficient to finance its projects and programs as planned without additional share issue.

### **Future reports**

The Interim Report for January – June 2019 will be published on July 11, 2019

The Interim Report for January – September 2019 will be published on October 24, 2019

The Full Year Report 2019 will be published preliminary on February 6, 2020

This interim report has not been reviewed by the company's auditors.

Stockholm, Sweden, May 8, 2019

Gunilla Osswald  
CEO

## Financial statements, Group

### Consolidated income statement

kSEK	Jan-Mar 2019	Jan-Mar 2018	Jan-Dec 2018
Net revenues (note 4)	63,388	52,303	713,970
Other operating income	6,931	11,420	16,259
<b>Operating revenues</b>	<b>70,319</b>	<b>63,723</b>	<b>730,229</b>
<b>Operating expenses</b>			
Project related expenses	-29,938	-26,137	-145,357
Other external expenses	-7,973	-8,019	-31,949
Personnel expenses	-12,018	-9,912	-57,039
Depreciations of tangible assets	-2,371	-587	-2,059
Other operating expenses	-684	-165	-5,031
<b>Operating profit</b>	<b>17,335</b>	<b>18,903</b>	<b>488,794</b>
Financial income	330	1,273	2,171
Financial expenses	-257	-363	-1,371
<b>Profit before tax</b>	<b>17,408</b>	<b>19,813</b>	<b>489,593</b>
Tax	-3,778	-4,394	-107,991
<b>Profit for the period</b>	<b>13,629</b>	<b>15,419</b>	<b>381,602</b>
<b>Earnings per share</b>			
Earnings per share, SEK <sup>1</sup>	0.15	0.18	4.33

<sup>1</sup> No share-based incentive program exists, thus there is no dilutive effect

### Consolidated statement of comprehensive income

kSEK	Jan-Mar 2019	Jan-Mar 2018	Jan-Dec 2018
Profit for the period	13,629	15,419	381,602
Other comprehensive income	-	-	-
<b>Comprehensive income for the period</b>	<b>13,629</b>	<b>15,419</b>	<b>381,602</b>

### Consolidated balance sheet (condensed)

kSEK	Mar 31, 2019	Mar 31, 2018	Dec 31, 2018
<b>ASSETS</b>			
Tangible fixed assets	9,148	6,720	9,289
Right-to-use assets	31,669	-	-
Deferred tax assets	277	244	189
Other financial assets	1,500	2,675	1,500
Current assets excluding cash and cash equivalents	16,274	20,278	464,757
Cash and cash equivalents	1,255,567	1,078,746	917,307
<b>TOTAL ASSETS</b>	<b>1,314,435</b>	<b>1,108,664</b>	<b>1,393,042</b>
<b>EQUITY AND LIABILITIES</b>			
Equity	1,031,365	651,553	1,017,736
Deferred tax liabilities	32,520	5,487	32,520
Long-term leasing liabilities	25,357	-	-
Short-term leasing liabilities	6,149	-	-
Other current liabilities	20,398	15,790	91,996
Accrued expenses and deferred income	198,645	435,833	250,791
<b>EQUITY AND LIABILITIES</b>	<b>1,314,435</b>	<b>1,108,664</b>	<b>1,393,042</b>

### Consolidated statement of change in equity (condensed)

kSEK	Mar 31, 2019	Mar 31, 2018	Dec 31, 2018
<b>Opening balance at 1 January</b>	<b>1,017,736</b>	<b>636,134</b>	<b>636,134</b>
Comprehensive income for the period	13,629	15,419	381,602
<b>Closing balance</b>	<b>1,031,365</b>	<b>651,553</b>	<b>1,017,736</b>

## Consolidated statement of cash flow (condensed)

kSEK	Jan-Mar 2019	Jan-Mar 2018	Jan-Dec 2018
<b>Operating profit</b>	<b>17,335</b>	<b>18,903</b>	<b>488,794</b>
Adjustment for non-cash items	-56,280	-61,859	-726,886
Interest received/paid	-47	-363	-1,331
Income tax paid	-74,717	-1,405	-10,889
<b>Cash flow from operating activities before changes in working capital</b>	<b>-113,710</b>	<b>-44,724</b>	<b>-250,313</b>
Change in working capital	447,338	2,721	50,256
<b>Cash flow from operating activities after changes in working capital</b>	<b>333,629</b>	<b>-42,004</b>	<b>-200,057</b>
<b>Cash flow from investing activities</b>	<b>-563</b>	<b>-215</b>	<b>-3,080</b>
<b>Cash flow from financing activities</b>	<b>-1,829</b>	<b>-</b>	<b>-</b>
<b>Cash flow for the period</b>	<b>331,236</b>	<b>-42,218</b>	<b>-203,136</b>
Cash and cash equivalents at beginning of period	917,307	1,110,367	1,110,367
Exchange rate differences in cash and cash equivalents	7,024	10,597	10,076
<b>Cash and cash equivalents at end of period</b>	<b>1,255,567</b>	<b>1,078,746</b>	<b>917,307</b>

## Consolidated quarterly data

MSEK	2019 Q1	2018 Q4	2018 Q3	2018 Q2	2018 Q1	2017 Q4	2017 Q3	2017 Q2
<b>Income statement</b>								
Net revenues	63.4	515.3	94.0	52.3	52.3	51.0	31.5	32.0
Other operating income	6.9	0.7	0.6	3.6	11.4	10.4	2.8	5.2
Operating profit	17.3	430.3	33.1	6.4	18.9	14.7	0.6	2.5
Profit for the period	13.6	335.2	25.9	5.1	15.4	11.8	-0.1	2.3
Operating margin, %	27.3%	83.5%	35.2%	12.3%	36.1%	28.9%	2.0%	7.7%
<b>Balance sheet</b>								
Fixed assets	42.6	11.0	9.9	10.0	9.6	10.0	10.5	8.2
Current assets	16.3	464.8	13.8	12.0	20.3	20.1	9.8	8.6
Cash and cash equivalents	1,255.6	917.3	1,008.5	1,041.7	1,078.7	1,110.4	590.7	622.1
Equity	1,031.4	1,017.7	682.5	656.7	651.6	636.1	64.1	64.2
Deferred tax liabilities	32.5	32.5	5.5	5.5	5.5	5.5	4.1	4.1
Leasing liabilities	31.5	-	-	-	-	-	-	-
Current liabilities	219.0	342.8	344.2	401.6	451.6	498.9	542.7	570.5
<b>Cash flow</b>								
From operating activities	333.6	-89.3	-31.5	-37.3	-42.0	-45.7	-23.6	-27.6
From investing activities	-0.6	-1.7	-0.5	-0.7	-0.2	0.5	-2.8	-0.4
From financing activities	-1.8	-	-	-	-	560.2	-	-
Cash flow for the period	331.2	-91.0	-32.0	-38.0	-42.2	515.0	-26.4	-28.1
<b>Data per share, SEK<sup>1, 2, 3</sup></b>								
Earnings per share	0.15	3.81	0.29	0.06	0.18	0.16	0.00	0.04
Equity per share	11.71	11.56	7.75	7.46	7.40	7.22	1.02	1.02
Cash flow operating activities	3.79	-1.01	-0.36	-0.42	-0.48	-0.60	-0.37	-0.44
Share price at the end of the period	78.00	82.00	118.90	21.80	21.40	26.00	-	-

<sup>1</sup> No share-based incentive program exists, 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

## Financial statements, Parent company

### Parent company income statement

kSEK	Jan-Mar 2019	Jan-Mar 2018	Jan-Dec 2018
Net revenues	51,957	52,303	713,970
Other operating income	18,362	11,420	16,259
<b>Operating revenues</b>	<b>70,319</b>	<b>63,723</b>	<b>730,229</b>
<b>Operating expenses</b>			
Project related expenses	-29,938	-26,137	-145,357
Other external expenses	-9,504	-8,019	-31,949
Personnel expenses	-12,018	-9,912	-57,039
Depreciations of tangible assets	-704	-587	-2,059
Other operating expenses	-684	-165	-5,031
<b>Operating profit</b>	<b>17,471</b>	<b>18,903</b>	<b>488,794</b>
Financial income	330	1,273	2,171
Financial expenses	-47	-363	-1,371
<b>Profit after financial items</b>	<b>17,753</b>	<b>19,813</b>	<b>489,594</b>
Change in tax allocation reserves	-	-	-122,876
<b>Profit before tax</b>	<b>17,753</b>	<b>19,813</b>	<b>366,718</b>
Tax	-3,852	-4,394	-80,959
<b>Profit for the period</b>	<b>13,901</b>	<b>15,419</b>	<b>285,759</b>

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 (condensed)

kSEK	Mar 31, 2019	Mar 31, 2018	Dec 31, 2018
<b>ASSETS</b>			
Tangible fixed assets	9,148	6,720	9,289
Deferred tax assets	203	244	189
Other financial assets	1,600	2,775	1,600
Current assets excluding cash and cash equivalents	16,274	20,278	464,757
Cash and cash equivalents	1,255,469	1,078,648	917,209
<b>TOTAL ASSETS</b>	<b>1,282,694</b>	<b>1,108,665</b>	<b>1,393,044</b>
<b>EQUITY AND LIABILITIES</b>			
Equity	916,342	632,101	902,441
Tax allocation reserve	147,817	24,941	147,817
Other current liabilities	20,100	15,790	91,996
Accrued expenses and deferred income	198,435	435,833	250,791
<b>EQUITY AND LIABILITIES</b>	<b>1,282,694</b>	<b>1,108,665</b>	<b>1,393,044</b>

## Notes

### Note 1 General information

This Interim Report for the period January – March 2019 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 Warfvings väg 35, SE-112 51, Stockholm, Sweden.

The BioArctic Group's Interim Report for the period January – March 2019 was approved by the company's board on May 8, 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 Interim Report for the period January – March 2019 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 Interim 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 16 Leases has replaced IAS 17 Leases and the appropriate interpretations IFRIC 4, SIC-15 and SIC-27 as of January 1, 2019. 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. BioArctic has elected to apply the modified retrospective approach. The effect of the application of IFRS 16 Leases 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 effects of applying IFRS 16 Leases on January 1, 2019 were:

- The Group's assets and liabilities have increased with MSEK 33.3 million which means that the balance sheet increased with 2.4 percent
- Equity assets ratio has decreased with 1.7 percentage points from 73.1 percent to 71.4 percent

The accounting principles and calculation methods applied are in all other respects in line with those described in the Annual Report 2018.

### 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

kSEK	Jan-Mar 2019	Jan-Mar 2018	Jan-Dec 2018
<b>Geographic breakdown of net revenues</b>			
Europe	63,388	50,905	712,489
Other	-	1,398	1,481
<b>Total net revenues</b>	<b>63,388</b>	<b>52,303</b>	<b>713,970</b>
<b>Net revenues per revenue type</b>			
Milestone payments	11,431	-	448,550
Income from research collaborations	51,957	52,303	265,420
<b>Total net revenues</b>	<b>63,388</b>	<b>52,303</b>	<b>713,970</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 MSEK 701.6 (MUSD 80) 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, MSEK 70.4 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. As of March 31, 2019, MSEK 544.5 has been recognized and the remaining amount to be recognized as a revenue up until the completion of the project is MSEK 157.2. During the fourth quarter of 2018, a contractual accrued income of MSEK 448.6 (MUSD 50) attributable to the milestone payment from AbbVie was recognized. At the time for the milestone payment in February 2019, the amount had increased in SEK by MSEK 11.4 due to the strengthening of USD versus SEK.

#### 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 the first quarter 2019, Advokatfirman Lindahl invoiced fees amounting to approximately MSEK 0.1 (0.1). The board member Pär Gellerfors has, in addition to the board fee, invoiced through Ackelsta AB a consultant fee in line with market rates of MSEK 0.1 (0.0) during the first quarter of 2019.

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

### Definition of key ratios

In this financial report BioArctic reports key financial ratios, some of which are not defined by IFRS. The Company's 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.

Key ratios	Definition
Other income	Other income than net revenues
Operating profit	Result before financial items
Operating margin, %	Operating profit divided by net revenues
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 divided by 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

### 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).

### 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.

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* focusing on the partnership projects and on driving/intensifying the in-house projects with great out-licensing and market potential

*DEVELOP* projects further, up to the optimal point in time for partnership or exit, in order to maximize return on investment

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

*INVEST* in:

- technologies; antibodies, blood-brain barrier, diagnostics and biomarkers
- attracting/retaining employees
- preparing market activities 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 see the Annual Report 2018 on page 10.

## 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. Amyloid 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 approval to conduct a clinical study in the U.S.

### 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 diseases

**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

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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.*