

# FULL YEAR REPORT JANUARY-DECEMBER 2019

## Enhanced project portfolio from a successful year

## Key events during the fourth quarter 2019

- BioArctic initiated a research collaboration with Eisai aimed at further studying the unique profile of the drug candidate BAN2401
- BioArctic strengthened its management team with two strategic recruitments
- BioArctic and Eisai presented data on the drug candidate BAN2401 at the international CTAD conference (Clinical Trials on Alzheimer's Disease) in San Diego
- BioArctic announced results from the interim analysis of the Phase 1/2 study with SC0806, a potential treatment
  for patients with complete spinal cord injury. BioArctic decided to close the project as the results did not show
  any convincing effect

## Key events after the period

• There are no key events to report after the period

## Financial summary January - December 2019

- Net revenues for the period amounted to MSEK 281.8 (714.0). The change is primarily attributable to lower revenue from milestone payments as well as from the Parkinson's program
- Operating profit amounted to MSEK 112.5 (488.8) and the operating margin was 39.9 percent (68.5) for the period
- Profit for the period amounted to MSEK 88.5 (381.6) and earnings per share were SEK 1.00 (4.33)
- Cash flow from operating activities amounted to MSEK 327.2 (-200.1)
- Cash and cash equivalents at the end of the period amounted to MSEK 1 112.8 (917.3)

## **Key financial performance indicators**

MSEK	Oct-Dec 2019	Oct-Dec 2018	Jan-Dec 2019	Jan-Dec 2018
Net revenues	26.4	515.3	281.8	714.0
Other operating income	0.0	0.7	14.8	16.3
Operating profit/loss	-21.1	430.3	112.5	488.8
Operating margin, %	-79.8	83.5	39.9	68.5
Profit/loss for the period	-17.1	335.2	88.5	381.6
Earnings per share, SEK <sup>1</sup>	-0.19	3.81	1.00	4.33
Equity per share, SEK	11.07	11.56	11.07	11.56
Cash flow from operating activities	-54.2	-89.3	327.2	-200.1
Cash flow from operating activities per share,				
SEK	-0.62	-1.01	3.72	-2.27
Equity/assets ratio, %	82.4	73.1	82.4	73.1
Return on equity, %	-1.7	39.4	8.9	46.1
Share price at the end of the period, SEK	94.90	82.00	94.90	82.00

<sup>&</sup>lt;sup>1</sup>There is no dilutive effect as the average market price for the period is lower than the exercise price as of December 31, 2019.

## For further information, please contact

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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 the named contact persons, at 08.00 a.m. CET on February 6, 2020.

## Invitation to presentation of Full Year Report for the period January – December 2019

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, February 6, at 09:30 – 10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson will present BioArctic, comment on the Full Year Report and answer questions.

Webcast: https://tv.streamfabriken.com/bioarctic-q4-2019

To participate in the conference call, please call: +46 8 505 583 55 (Sweden), +45 354 455 77 (Denmark), +49 691 380 3452 (Germany) +31 207 095 189 (Netherlands), +47 235 002 43 (Norway), +41 225 805 976 (Switzerland), +44 333 300 9265 (UK) or +1 833 823 0589 (USA)

The Group is referred to unless otherwise stated in this Full Year 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.

## **Comment from the CEO**

2019 was a successful year that resulted in an enhanced project portfolio. The portfolio is balanced and competitive, consisting of unique product candidates, technology platforms and diagnostic tools. All our projects are focused on disorders of the central nervous system. During the year, two drug candidates, BAN2401 and ABBV-0805, advanced to the next clinical phase in their respective development programs. With the decision to stop further development in the spinal cord injury project, our research is focused on neurodegenerative disorders. During the quarter, our portfolio expanded with two new projects in early research phase.

The BAN2401 project for Alzheimer's disease continues to develop well. Our partner, Eisai, is strongly committed to the overall development of BAN2401 and is either conducting or planning three clinical studies. This past spring, based on the positive outcomes of the large Phase 2b study, Eisai started the global confirmatory Phase 3 study (Clarity AD) with BAN2401 in early Alzheimer's disease. Eisai has stated that they expect results from the Phase 3 study in 2022. The Phase 2b extension study is ongoing and Eisai presented data from the study at the CTAD conference (Clinical Trials on Alzheimer's Disease) in December. The data showed that amyloid reductions in the brain that occurred as a result of treatment with BAN2401 persisted after the conclusion of treatment. Differences in benefits on clinical outcomes were maintained after BAN2401 treatment in the two highest dose groups as compared with the placebo group. Eisai and Alzheimer's Clinical Trials Consortium are preparing a clinical Phase 3 program with BAN2401 aimed at prevention of Alzheimer's disease starting in 2020.

The unique binding profile of BAN2401 has been confirmed in data presented during the year. Professor Lars Lannfelt presented data on BAN2401's binding profile at the CTAD conference. All in all, the results strengthen our conviction that BAN2401's binding profile is important and distinguishes it from other amyloid-beta antibodies. During the quarter, BioArctic initiated a research collaboration with Eisai aimed at further studying BAN2401's unique profile. We look forward to presenting more data on BAN2401's characteristics at the AAT-ADPD meeting in April in Vienna.

In the Parkinson's program, BioArctic's partner AbbVie continues the Phase 1 study of the drug candidate ABBV-0805.

During the year, we continued to pursue two projects in research stages, in partnership with AbbVie, and we have delivered our commitments according to plan. This means we will soon have completed the preclinical activities of this ongoing collaboration.

In November, BioArctic announced the results from the interim analysis from the Phase 1/2 study with SC0806 for treatment of patients with complete spinal cord injuries. The results showed no convincing effects on the primary or secondary endpoints of the study. Even though it was disheartening that the SC0806 treatment did not have the effect the preclinical results indicated, we contributed with the Phase 1/2 study to increased knowledge about spinal cord injuries. We will conclude the study in a responsibly manner. BioArctic's decision to close the entire project means we will continue to focus on our core operations: research and development of drugs for Alzheimer's, Parkinson's and other disorders of the central nervous system.

Our project portfolio continues to expand, and now includes two new projects in the research phase: one aimed at Alzheimer's disease and one with potential in various CNS disorders. Additionally, development in our blood-brain barrier technology platform is progressing favorably. The technology is intended to facilitate the passage of antibodies into the brain. We are looking forward to developing the projects and the technology platform over the coming years.

The management team and the organization overall have been strengthened so that the company can take advantage of the many opportunities with the project portfolio. In January, our new Chief Medical Officer (CMO) took up office. The former CMO remains with the company in another senior role.

BioArctic's cash and overall financial position remain strong and our strategic partners finance and conduct the costly clinical studies in Alzheimer's and Parkinson's diseases. This creates the possibility for the continued positive development of the project portfolio.

We have had another successful year resulting in an expanded and strengthened project portfolio. I am proud to lead this innovative company and pleased, along with my colleagues and partners, to generate the medicines of the future for patients with central nervous system disorders.

Gunilla Osswald CEO, BioArctic AB

## **BioArctic in short**

BioArctic AB (publ) is a Swedish biopharma company that develops new drugs based on groundbreaking research for patients with central nervous system disorders. For a global market, the aim is to generate transformative medicines that can stop or slow down the progression of diseases, principally Alzheimer's and Parkinson's diseases. BioArctic was founded in 2003 based on innovative research from Uppsala University, Sweden. BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B).

## Strategy for sustainable growth

BioArctic's vision is that our research generates innovative medicines that improve life for patients with disorders in the central nervous system. Our work is based on groundbreaking scientific discoveries, and the company's researchers collaborate with strategic partners such as research groups at universities and major pharmaceutical companies.

The company has scientific excellence and experience in developing drugs from idea to market. Under BioArctic's business model, the company itself pursues project development at an early stage and then, at an appropriate juncture, licenses certain commercial rights to global pharmaceutical companies. In recent years, BioArctic has successfully delivered innovative drug projects that have resulted in advantageous partnership agreements in two major disease areas with significant unmet medical need.

Three important cornerstones of BioArctic's strategy are:

CONTINUE supporting the partnered projects with great market potential

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

EXPAND the portfolio with new projects and indications with high unmet medical need

## **Focus areas**

BioArctic conducts its research in five focus areas:

- Alzheimer's disease
- Parkinson's disease
- Other CNS disorders
- Blood-brain barrier technology
- Diagnostic tools

Neurodegenerative disorders are conditions in which cells in the brain degenerate and die. These cells do not regenerate, which causes damages to the nervous system. Normally the neurodegenerative processes begin long before any symptoms appear. Neurodegenerative disorders affect the lives of millions of people and constitute a growing health care challenge.

A key cause of Alzheimer's disease and Parkinson's disease is believed to be protein misfolding and aggregation. The spreading of aggregated soluble forms of proteins leads to neuronal dysfunction, cell death, brain damage and symptoms of disease. Each neurodegenerative disorder is characterized by different aggregated proteins. The protein amyloid beta  $(A\beta)$  is involved in Alzheimer's disease, while the protein alpha-synuclein ( $\alpha$ -synuclein) is involved in Parkison's disease. BioArctic's antibodies currently in clinical phase bind selectively and eliminate the toxic soluble aggregated forms (oligomers/protofibrils) of these proteins in the brain with the aim of having a disease modifying effect.

## **Project portfolio**

BioArctic has a balanced, competitive portfolio consisting of unique product candidates, technological platforms and diagnostic tools. All our projects are focused on disorders of the central nervous system. The project portfolio is a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market- and out-licensing potential. The projects are in various phases: from discovery to late clinical phase.

During the year two drug candidates, BAN2401 and ABBV-0805, advanced to the next clinical phase in their respective development programs. In November, the Board of BioArctic decided to close the spinal cord injury project as the results from the interim analysis from the Phase 1/2 study with the product candidate SC0806 did not show any convincing effect. During the quarter, our portfolio expanded with two new projects in the early research phase.

At December 31, 2019, the project portfolio consisted of 14 projects:

- Two drug candidates in clinical phase: BAN2401 for early Alzheimer's disease (Phase 3) and ABBV-0805 for Parkinson's disease (Phase 1)
- Three projects in preclinical phase: BAN2401 for other indications such as Down's syndrome with dementia; BAN2401 back-up for Alzheimer's disease; and biomarkers and diagnostics for Alzheimer's disease
- Eight projects in research phase: four projects for Alzheimer's disease (AD1801, AD1502, AD1503, AD2603); two projects for Parkinson's disease (PD1601, PD1602); one project for other CNS-disorders (ND3014); and biomarkers and diagnostics for Parkinson's disease
- One blood-brain barrier technology platform

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	BAN2401	Eisai, Biogen <sup>1</sup>					
	BAN2401 back-up	Eisai					
	AD1801						
	AD1502						
	AD1503						
	AD2603						
PARKINSON'S DISEASE	ABBV-0805 <sup>2</sup>	AbbVie					
	PD1601	AbbVie					
	PD1602	AbbVie					
OTHER CNS DISORDERS	BAN2401 Down's syndrome <sup>3</sup> Traumatic brain injury						
	ND3014						
BLOOD-BRAIN BARRIER TECHNOLOGY	BBB technology platform						
DIAGNOSTIC TOOLS	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

<sup>1)</sup> Partnered with Eisai for BAN2401 for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding BAN2401 in 2014

<sup>2)</sup> AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805

<sup>3)</sup> Dementia and cognitive impairment associated with Down's syndrome

#### Alzheimer's disease

BioArctic has been collaborating with Eisai in the field of Alzheimer's disease since 2005. The company has signed research and licensing agreements concerning the BAN2401 and BAN2401 back-up antibodies. Within BioArctic, research is also underway to develop new antibodies for disease modifying treatment of Alzheimer's disease with the goal of slowing or stopping the course of the disease with other innovative target molecules.

#### Drug candidate BAN2401 (collaboration with Eisai)

In Alzheimer's disease, soluble, toxic amyloid beta aggregates are believed to contribute to the neurodegenerative process. The antibody BAN2401 selectively binds to these forms of amyloid beta and eliminates them. BAN2401's unique binding profile is highly selective for A $\beta$  oligomers/protofibrils and binds more than 1,000 times more strongly to these than to A $\beta$  monomers and approximately 10 times more strongly than to A $\beta$  fibrils.

During 2018, positive and robust results were presented from the Phase 2b study with BAN2401 in 856 patients with early Alzheimer's disease. The results demonstrated dose dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints and on biomarkers and was well tolerated.

At the analysis after 18 months of treatment a dose-dependent slowing of cognitive decline in the clinical cognition scale ADCOMS was demonstrated with 30% reduced decline 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. These effects of BAN2401 on biomarkers in cerebrospinal fluid are very important as they indicate that BAN2401 interferes in the neurodegenerative process.

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 on MRI scans.

The Phase 2b study demonstrated potential disease modifying effects on both clinical function and clearance of amyloid beta in the brain. Furthermore, the Phase 2b study also demonstrated effects on neurodegenerative biomarkers. BAN2401 showed a good tolerability. The data support the positive effect of BAN2401 in all subgroups of early Alzheimer's disease.

Based on the results of the Phase 2b clinical study and after discussion with regulatory agencies, our partner Eisai has started and is now conducting the global confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease patients to support a regulatory filing for BAN2401. The start of the study triggered a MEUR 15 milestone payment to BioArctic in May 2019

The Phase 3 study (Clarity AD) 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. Patients are dosed twice a month with placebo or BAN2401 10 mg/kg. 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, results from the study are targeted for 2022.

In July, BioArctic and Eisai presented BAN2401 data at the Alzheimer's Association International Conference® (AAIC®) in Los Angeles. The presentations included additional analyses from the Phase 2b study and details of the binding profile of BAN2401. The results were consistent with previously presented outcomes.

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 in progress. A subset of patients from the core Phase 2b study enrolled in the open-label extension study. Eisai presented data from the extension study at the CTAD conference (Clinical Trials on Alzheimer's Disease) in San Diego in December. Measurements taken at the start of the extension study were compared with the earlier measurements taken when the core Phase 2b study was concluded. The patients in the open-label extension study went without treatment from the conclusion of the core Phase 2b study to the start of the extension phase. Data showed that amyloid reduction in the brain that occurred as a result of treatment with BAN2401 persisted after the conclusion of treatment. Differences in benefits on clinical outcomes were maintained after BAN2401 treatment in the two highest dose groups as compared with the placebo group.

The unique binding profile of BAN2401 has been confirmed in data presented during the year, and the results correspond well with previous studies of BAN2401. All in all, the results strengthen BioArctic's conviction that BAN2401's unique binding profile is important and that it differs from other amyloid beta antibodies. Professor Lars Lannfelt presented details on the binding profile at the AAIC® conference in July and at the CTAD conference in December. BioArctic will present further data on BAN2401's characteristics at the AAT-AD/PD conference (Advances in Alzheimer's and Parkinson's Therapies, AAT-AD/PD™) in April 2020 in Vienna. In December, BioArctic announced that the company had initiated a research collaboration with Eisai for deeper study of the unique binding profile of drug candidate BAN2401. Remuneration to BioArctic for implementing the research collaboration totals MEUR 3.25 (approximately MSEK 34) and is expected to be received over an 18-month period.

During 2019 BAN2401 has been selected by the Alzheimer's Clinical Trials Consortium (ACTC) and Eisai to be evaluated in an upcoming clinical Phase 3 program focused on prevention of Alzheimer's disease (AHEAD 3-45). The planned clinical program will include individuals that are at risk for, or at a very early stages of, Alzheimer's disease. The program will be conducted with funding from various sources including the United States National Institute on Aging (NIA), part of the National Institutes of Health (NIH), and Eisai. According to ACTC and Eisai, the study will be starting during 2020.

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

## Drug candidate BAN2401 back-up (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 and financed by Eisai and is in preclinical phase.

## **AD1801, AD1502, AD1503 and AD2603** (owned by 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. The four projects are in research phase and are all different from each other.

## Parkinson's disease

In the Parkinson's disease treatment area, BioArctic has been collaborating with AbbVie since 2016 when a research agreement was entered into. AbbVie was granted the option to license the right to develop and commercialize BioArctic's portfolio of antibodies against alpha-synuclein for Parkinson's disease and other potential indications. At the end of 2018, AbbVie exercised this option.

## Drug candidate ABBV-0805 (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.

AbbVie's option to license the portfolio was effective after clearance by the U.S. Antitrust legislation and triggered a milestone payment of MUSD 50 at the end of 2018. 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 finances and progresses the clinical development of ABBV-0805.

The scope of the drug candidate ABBV-0805 may be expanded to include, for example, Lewy body dementia and multiple system atrophy.

The project is based on research from Uppsala University.

## PD1601 and PD1602 (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.

#### Other CNS disorders

BioArctic strives to improve the treatment of a number of central nervous system disorders. The company is evaluating the possibility of developing its existing as well as new antibodies in other indication areas.

**Drug candidate BAN2401** (indications other than Alzheimer's disease, owned by BioArctic)

BAN2401, which is currently being clinically evaluated for Alzheimer's disease, can potentially also be used for other indications which are owned by BioArctic. The antibody BAN2401 is in the preclinical phase as a potential treatment of cognitive disorders in conjunction with Down's syndrome and traumatic brain injuries.

#### ND3014 (owned by BioArctic)

Research to develop new antibodies for treating neurodegenerative disorders is under way at BioArctic. ND3014 is intended to be a disease modifying treatment with potential to address various neurodegenerative disorders. The new project is in an early research phase.

## **Blood-brain barrier technology** (owned by BioArctic)

The blood-brain barrier controls the exchange of substances between the blood and the brain. It protects the brain from toxins and pathogens, but at the same time it can make the delivery of therapeutic agents to the brain more difficult. BioArctic and research groups at Uppsala University are collaborating on developing technology that facilitates the passage of antibodies across the blood-brain barrier. Together with Uppsala University, BioArctic received research grants during the year from Sweden's Innovation Agency, Vinnova, for continued research in the blood-brain barrier project. The research, which is at an early stage, has shown highly encouraging results and the technology has significant potential in the treatment of several different diseases of the brain. During the year, BioArctic increased activities in this area and added further expertise.

**Diagnostic tools** (Alzheimer's disease diagnostics is owned by BioArctic and Parkinson's disease diagnostics is in collaboration with AbbVie)

BioArctic is engaged in the development of new diagnostic tools that improves the ability to diagnose and monitor the treatment of Alzheimer's and Parkinson's disease. The company conducts a number of projects in collaboration with commercial and academic partners. Among other things, BioArctic is developing biochemical methods based on the company's antibodies to be applied to cerebral spinal fluid (CSF) testing. Beyond this, the company is exploring the possibilities to measure biomarkers with a simple blood test. BioArctic is also active in a project to improve the diagnostic imaging (PET) of the brain of Alzheimer's patients. The goal is to create tools to better diagnose the disease, follow the disease progression and objectively measure the effect of drug treatment.

## Other

Product candidate SC0806 (traumatic complete spinal cord injury) (operations being phased out, owned by BioArctic)
BioArctic's treatment concept, SC0806, is a biodegradable medical device with the growth factor FGF1 surgically implanted into the injured spinal cord with the goal to restore function. Earlier in the year, a safety evaluation of all patients in the first panel was performed and supported the start of the next panel. BioArctic announced in November that the interim analysis of both safety and efficacy of the first panel showed that none of the patients displayed effects in the form of electric impulses passing over the damaged area after treatment, which is considered a prerequisite for patients regaining motor function. The primary endpoint of the study was thus not met. Nor did the results show any convincing effect on the secondary endpoints of the study concerning motor functions, other functions or quality of life. In light of these results, BioArctic has decided to close the ongoing Phase 1/2 study with SC0806. No additional patients will be enrolled in the study. One patient underwent surgery in the second panel of the study and will be offered completion of treatment with an 18-month training program. The results from the study will be submitted for publication in a suitable scientific journal at some point in the future. BioArctic has also decided that the entire SC0806 project will be closed.

The Phase 1/2 study with SC0806 received partial financing from the EU Horizon 2020 research and development program (Grant Agreement No. 643853).

# **Comments to the financial report**

## **Revenues and results**

Revenues consist of milestone payments, payments from research agreements and research grants. Because of the nature of the business operations, there may be large fluctuations between revenues for different periods, as revenues from milestone payments are recognized at a point in time when performance obligations are fulfilled.

Net revenues in the fourth quarter amounted to MSEK 26.4 (515.3) which was lower compared to the same period previous year which included a milestone payment of MSEK 448.6. Net revenues for the period January – December amounted to MSEK 281.8 (714.0). The decrease during the period January – December is attributable to lower revenue from milestone payments as well as from the Parkinson's program.

Other operating income relates to research grants, operating exchange rate gains and expenses incurred but onward invoiced. Other operating income amounted to MSEK 0.0 (0.7) for the fourth quarter and MSEK 14.8 (16.3) for the period January – December. The decrease during the period January – December is attributable to lower operating exchange rate gains offset by higher revenue recognition from research grants.

Total operating expenses for the fourth quarter amounted to MSEK 47.5 (85.7) compared to the same period previous year and the total operating expenses for the period January – December amounted to MSEK 184.1 (241.4). Project expenses for the fourth quarter and for the period January – December decreased due to lower activity in the Parkinson's program as planned offset by increased expenses for own projects. The personnel expenses for the fourth quarter decreased compared with the same period the previous year. Personnel expenses in the fourth quarter 2018 included a reserve for variable remuneration to employees in connection with the received milestone payment from AbbVie. Other operating expenses consist of realized operating exchange rate losses.

Since BioArctic's own projects are in an early research phase they did not meet all the conditions for R&D costs to be capitalized and thus, all such costs have been charged to the P&L.

Operating profit before financial items (EBIT) amounted to MSEK -21.1 (430.3) for the fourth quarter and to MSEK 112.5 (488.8) for the period January – December. The decrease in operating profit during the fourth quarter as well as the period January – December is mainly attributable to lower revenues from milestone payments and the Parkinson's program.

Net financial items totaled MSEK -0.5 (-0.4) for the fourth quarter and amounted to MSEK 0.4 (0.8) for the period January – December. 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 according to IFRS 16 Leases.

Profit/loss for the period amounted to MSEK -17.1 (335.2) for the fourth quarter and MSEK 88.5 (381.6) for the period January – December. The application of IFRS 16 Leases has affected the profit/loss in the fourth quarter by MSEK 0.3 and in the period January – December by MSEK -0.2.

Earnings per share before and after dilution amounted to SEK -0.19 (3.81) for the fourth quarter and to SEK 1.00 (4.33) for the period January – December.

## **Financial position**

Equity amounted to MSEK 974.5 (1 017.7) as of December 31, 2019. This corresponds to equity per outstanding share of SEK 11.07 (11.56).

The equity/asset ratio has increased from 73.1 percent as of December 31, 2018 to 82.4 percent as of December 31, 2019.

Financial position MSEK	2019-12-31	2018-12-31
Non-current lease liabilities	20,9	_
Current lease liabilities	6,4	_
	•	-
Cash and cash equivalents	1 112,8	917,3
Net cash	1 085,5	917,3

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to MSEK 1,112.8 (917.3). The leasing liabilities as of December 31, 2019 of MSEK 27.4 relate to financial leasing and is an effect from the application of IFRS 16 Leases. There were no loans as of December 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 rate exposure some liquid funds are held 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

Cash flow from operating activities for the fourth quarter amounted to MSEK -54.2 (-89.3), an increase of MSEK 35.0 compared to the same period previous year. The cash flow from operating activities for the period January – December

increased by MSEK 527.2 and amounted to MSEK 327.2 (-200.1). The increase in the cash flow for the period January – December relates to the received milestone payments from AbbVie of MSEK 460.0 and from Eisai of MSEK 162.0.

Investments in the fourth quarter amounted to MSEK 0.4 (1.7) and to MSEK 3.3 (3.1) for the period January – December. The investments are mainly related to laboratory equipment.

Cash flow from financing activities amounted to MSEK -1.5 (0.0) for the fourth quarter and to MSEK -138.5 (0.0) for the period January – December. MSEK 132.1 (0.0) of the cash flow from financing activities relates to the dividend paid and the remaining amount relates to the amortization of lease debt, which is an effect of the application of IFRS 16 Leases.

#### **Parent Company**

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

## Key events during the period January - December

- BioArctic announced in February that the company's partner Eisai will initiate the confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease and published information concerning the design of the study and timelines
- The U.S. Food and Drug Administration approved in February the application to start a clinical study in the Parkinson program with ABBV-0805, previously named BAN0805
- BioArctic's product candidate SC0806 for complete spinal cord injury advanced into Phase 2 in the ongoing Phase 1/2 study in February
- Eisai initiated in March the confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease
- BioArctic announced the start of the clinical Phase 1 study with ABBV-0805 in the Parkinson program in March
- BioArctic received in May MEUR 15 milestone payment from Eisai for start of BAN2401 confirmatory Phase 3 study in early Alzheimer's disease
- Alzheimer's Clinical Trials Consortium and Eisai announced in May that BAN2401 will be evaluated in a clinical study for prevention of Alzheimer's disease
- The Annual General Meeting approved the introduction of an employee warrant program 2019/2028 for the company's management, researchers and other staff and a dividend to shareholders in the amount of SEK 1.50 per share, a total of MSEK 132.1. Ewa Björling was elected new member of the board
- BioArctic and Eisai presented data regarding BAN2401 at the Alzheimer's Association International Conference® (AAIC®) in July that was consistent with previously presented results
- BioArctic announced results from the interim analysis of the Phase 1/2 study of SC0806, a potential treatment for
  patients with complete spinal cord injury. BioArctic decided to close the project as the results did not show any
  convincing effect
- BioArctic and Eisai presented data on the drug candidate BAN2401 at the CTAD conference (Clinical Trials on Alzheimer's Disease) in San Diego
- BioArctic strengthened its management team with two strategic recruitments
- BioArctic initiated a research collaboration with Eisai aimed at further studying the unique profile of the drug candidate BAN2401

## Other information

## Key events after the period

There are no key events to report after the period.

## 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. At the end of the period, BioArctic's patent portfolio consisted of 12 patent families with more than 180 granted patents and over 70 patent applications.

## Collaborations, partnership and major agreements

Collaborating with universities is of great importance to BioArctic. The company has ongoing 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.

BioArctic has been collaborating with Eisai in the field of Alzheimer's disease since 2005. The company has signed research and licensing agreements concerning the BAN2401 and BAN2401 back-up antibodies. The total value of these agreements may amount to MEUR 221 in addition to royalties. To date, approximately MEUR 62 has been received and recognized, of which MEUR 15 was recognized during 2019.

BioArctic has been collaborating with AbbVie in the field of Parkinson's disease since 2016, when a research agreement was signed that included products such as the antibody BAN0805, now designated ABBV-0805. BioArctic has primary responsibility for the preclinical development work and AbbVie is responsible for the clinical development. The total value of the agreement could amount to MUSD 755 in addition to royalty payments. To date, MUSD 130 has been received. MSEK 119 of that amount has been recognized of which MSEK 12 during 2019. For more information regarding BioArctic's two large collaboration partners, please see the Annual Report 2018 on page 10.

## Risk 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 as well as operational and external risks. 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, pages 44-46. The board has determined that the risks are unchanged.

## Fluctuations in revenue generation

Currently, BioArctic does not have any drugs that have been commercialized and are being sold on the market. The company develops certain drug candidates and diagnostics for Alzheimer's and Parkinson's diseases in collaboration with global pharmaceutical companies. The company also conducts research for wholly-owned projects including new potential antibody treatments, diagnostic tools, as well as the blood-brain barrier technology platform. The company signs research and licensing agreements with partners and then receives remuneration for research as well as milestone payments and royalties, which the company uses to finance current and new projects. Milestone payments are normally received when the project reaches predetermined development targets – the start of clinical trials, for example – or when clinical trials move from one phase to a later phase. Thus, these payments arise unevenly over time and are difficult to predict.

## **Future prospects**

BioArctic makes no financial forecasts regarding its future performance. The company enjoys a strong financial position and has a business model in which its revenue and earnings are primarily based on non-recurring revenue from research and licensing agreements the company has signed. The company's liquidity facilitates continued development of the projects covered by strategic partnership agreements as well as in-house financing of the company's own less costly projects. BioArctic's focus areas comprise unique drug candidates, innovative blood-brain barrier technology and diagnostic tools, areas with high unmet medical need. All our projects are focused on disorders of the central nervous system and have great market potential. BioArctic's ambition is to create the drugs of the future for patients with central nervous system disorders. The company's cash holdings remain strong, which creates possibilities for the continued exciting development of BioArctic.

## **Expected development of operating expenses**

Operating expenses are expected to be in the range of MSEK 180 - 230 for the fiscal year January – December 2020. During 2019 operating expenses were MSEK 184.

## **Employees**

At the end of the period, the number of employees was 42 (31) of which 16 (12) are men and 26 (19) women. Approximately 85 percent are active in R&D and approximately 70 percent are PhDs. In the organization there is one Associate Professor, two Professors and three medical doctors.

A cost-efficient organization at BioArctic is achieved by hiring 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, 2019, these corresponded to 11 (10) full-time positions.

In 2020, BioArctic strengthens its management team with two strategic recruitments. As of January 1, Tomas Odergren assumed the role of Chief Medical Officer. The previous Chief Medical Officer Hans Basun has transitioned into the role of Senior Director Clinical Development. In May 2020 Oskar Bosson will assume the role of VP Communications & IR.

## **Annual General Meeting 2020**

The Annual General Meeting 2020 will be held on May 7, at 5:00 p.m. CET at Lindhagens' Conference Center in Stockholm, Sweden.

## **Nomination Committee**

According to the resolution of the Annual General Meeting 2019, the Nomination Committee for the Annual General Meeting 2020 has been appointed and announced. The Nomination Committee comprises of the following: Gunnar Blix, chairman (The Third Swedish National Pension Fund), Margareta Öhrvall (Demban AB) and Claes Andersson (Ackelsta AB).

#### Dividend

The Board of Directors proposes that no dividend is paid for the financial year 2019.

## The share and shareholdings

The share capital in BioArctic amounts to SEK 1,761,200 divided by 88,059,985 shares which is split between 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-share has 10 votes per share and the B-share has 1 vote per share.

## The largest shareholders at December 31, 20191

Shareholder	Number of A- shares	Number of B- shares	Share of capital, %	Share of votes, %
Demban AB (Lars Lannfelt)	8,639,998	22,723,707	35.6	50.1
Ackelsta AB (Pär Gellerfors)	5,759,998	15,150,036	23.7	33.4
Fourth Swedish National Pension Fund	-	3,871,684	4.4	1.8
Third Swedish National Pension Fund	-	3,810,032	4.3	1.8
Unionen	-	2,562,723	2.9	1.2
Handelsbanken Funds	-	2,415,000	2.7	1.1
Norron Funds	-	1,999,363	2.3	0.9
Investment AB Öresund	-	1,550,000	1.8	0.7
Second Swedish National Pension Fund	-	1,441,666	1.6	0.7
Wellington Management	-	1,116,950	1.3	0.5
Total 10 largest shareholders	14,399,996	56,641,161	80.6	92.2
Other	-	17,018,828	19.4	7.8
Total	14,399,996	73,659,989	100.0	100.0

<sup>&</sup>lt;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).

## **Employee warrant program**

The Annual General Meeting 2019 approved the Board of Directors' proposal for resolution concerning an employee warrant program for the company's management, researchers and other staff, a directed issue of warrants and the transfer of warrants or shares in the company to the participants in the employee warrant program.

The employee warrant program 2019/2028 shall include not more than 1,000,000 warrants. To enable the company's delivery of shares under the employee warrant program 2019/2028, the Annual General Meeting approved a directed issue of a maximum of 1,000,000 warrants.

The dilutive effect of the employee warrant program 2019/2028 is estimated to be a maximum of 1.1 percent of the share capital and 0.5 percent of the votes in the company (calculated on the number of existing shares in the company), assuming full exercise of all employee warrants. The employee warrants can be exercised three years after allocation at the earliest. 480,000 employee warrants were allocated by the end of the year. There is no dilutive effect as of December 31, 2019, according to IAS 33.47, as the average market price for the period is lower than the exercise price. More information is available at www.bioarctic.com.

## Calendar 2020/2021

Publication of the Annual Report (Swedish) Interim Report Jan-Mar 2020 Annual General Meeting 2020 Interim Report Jan-Jun 2020 Interim Report Jan-Sep 2020 Full Year Report Jan-Dec 2020 Week commencing March 30, 2020 April 22, 2020, at 8.00 a.m. CET May 7, 2020, at 5:00 p.m. CET July 10, 2020, at 8:00 a.m. CET October 14, 2020, at 8:00 a.m. CET February 4, 2021, at 8:00 a.m. CET

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

Stockholm, Sweden, February 5, 2020

Gunilla Osswald CEO, BioArctic AB

# **Financial statements, Group**

## **Consolidated income statement**

kSEK	Oct-Dec 2019	Oct-Dec 2018	Jan-Dec 2019	Jan-Dec 2018
Net revenues (note 4)	26,422	515,320	281,772	713,970
Other operating income	35	707	14,826	16,259
Operating revenues	26,457	516,027	296,598	730,229
Operating expenses				
Project related expenses	-20,971	-48,030	-72,422	-145,357
Other external expenses	-7,804	-10,042	-31,169	-31,949
Personnel expenses	-15,268	-23,629	-59,715	-57,039
Depreciations of tangible assets	-2,024	-667	-9,199	-2,059
Other operating expenses	-1,463	-3,339	-11,554	-5,031
Operating profit/loss	-21,073	430,320	112,538	488,794
Financial income	-164	-112	1,630	2,171
Financial expenses	-301	-304	-1,192	-1,371
Profit/loss before tax	-21,538	429,905	112,976	489,593
Tax	4,443	-94,699	-24,507	-107,991
Profit/loss for the period	-17,096	335,205	88,468	381,602
Earnings per share				
Earnings per share before dilution, SEK <sup>1</sup>	-0.19	3.81	1.00	4.33
Earnings per share after dilution, SEK <sup>1</sup>	-0.19	3.81	1.00	4.33

<sup>&</sup>lt;sup>1</sup>There is no dilutive effect as the average market price for the period is lower than the exercise price as of December 31, 2019.

## Consolidated statement of comprehensive income

kSEK	Oct-Dec 2019	Oct-Dec 2018	Jan-Dec 2019	Jan-Dec 2018
Profit/loss for the period	-17,096	335,205	88,468	381,602
Other comprehensive income	-	-	-	-
Comprehensive income for the period	-17,096	335,205	88,468	381,602

## **Consolidated balance sheet (condensed)**

kSEK	Dec 31, 2019	Dec 31, 2018
ASSETS		
Tangible fixed assets	9,590	9,289
Right-to-use assets	27,544	-
Deferred tax assets	298	189
Other financial assets	1,511	1,500
Current assets excluding cash and cash equivalents	31,619	464,757
Cash and cash equivalents	1,112,770	917,307
TOTAL ASSETS	1,183,332	1,393,042
EQUITY AND LIABILITIES		
Equity	974,497	1,017,736
Deferred tax liabilities	38,685	32,520
Non-current lease liabilities	20,927	-
Current lease liabilities	6,439	-
Other current liabilities	24,030	91,996
Accrued expenses and deferred income	118,753	250,791
EQUITY AND LIABILITIES	1,183,332	1,393,042

## Consolidated statement of change in equity (condensed)

kSEK	Dec 31, 2019	Dec 31, 2018
Opening balance at 1 January	1,017,736	636,134
Comprehensive income for the period	88,468	381,602
Share-based payments	383	-
Paid dividend	-132,090	-
Closing balance	974,497	1,017,736

# Consolidated statement of cash flow (condensed)

kSEK	Oct-Dec 2019	Oct-Dec 2018	Jan-Dec 2019	Jan-Dec 2018
Operating profit	-21,073	430,320	112,538	488,794
Adjustment for non-cash items	-23,240	-515,360	-107,485	-726,886
Interest received/paid	-56	-264	-757	-1,331
Income tax paid	-2,067	-2,067	-80,919	-10,889
Cash flow from operating activities before				
changes in working capital	-46,436	-87,371	-76,622	-250,313
Change in working capital	-7,771	-1,882	403,787	50,256
Cash flow from operating activities after				
changes in working capital	-54,207	-89,253	327,165	-200,057
Cash flow from investing activities	-408	-1,715	-3,273	-3,080
Cash flow from financing activities	-1,544	-	-138,506	-
Cash flow for the period	-56,159	-90,969	185,385	-203,136
Cash and cash equivalents at beginning of period	1,170,178	1,008,522	917,307	1,110,367
Exchange rate differences in cash and cash				
equivalents	-1,249	-247	10,077	10,076
Cash and cash equivalents at end of period	1,112,770	917,307	1,112,770	917,307

## **Consolidated quarterly data**

MSEK	2019 Q4	2019 Q3	2019 Q2	2019 Q1	2018 Q4	2018 Q3	2018 Q2	2018 Q1
Income statement				~-				
Net revenues	26.4	20.6	171.3	63.4	515.3	94.0	52.3	52.3
Other operating income	0.0	8.6	-0.7	6.9	0.7	0.6	3.6	11.4
Operating profit/loss	-21.1	-10.5	126.8	17.3	430.3	33.1	6.4	18.9
Operating margin, %	-79.8	-50.9	74.0	27.3	83.5	35.2	12.3	36.1
Profit/loss for the period	-17.1	-8.3	100.3	13.6	335.2	25.9	5.1	15.4
Balance sheet								
Fixed assets	38.9	40.2	41.0	42.6	11.0	9.9	10.0	9.6
Current assets	31.6	29.2	15.9	16.3	464.8	13.8	12.0	20.3
Cash and cash equivalents	1,112.8	1,170.2	1,218.4	1,255.6	917.3	1,008.5	1,041.7	1,078.7
Equity	974.5	991.3	999.5	1,031.4	1,017.7	682.5	656.7	651.6
Deferred tax liabilities	38.7	32.5	32.5	32.5	32.5	5.5	5.5	5.5
Lease liabilities	27.4	28.5	30.0	31.5	-	-	-	-
Current liabilities	142.8	187.3	213.2	219.0	342.8	344.2	401.6	451.6
Cash flow								
From operating activities	-54.2	-49.4	97.2	333.6	-89.3	-31.5	-37.3	-42.0
From investing activities	-0.4	-1.6	-0.7	-0.6	-1.7	-0.5	-0.7	-0.2
From financing activities	-1.5	-1.5	-133.6	-1.8	-	-	-	-
Cash flow for the period	-56.2	-52.5	-37.1	331.2	-91.0	-32.0	-38.0	-42.2
Data per share								
Earnings per share before dilution, SEK	-0.19	-0.09	1.14	0.15	3.81	0.29	0.06	0.18
Earnings per share after dilution, SEK <sup>1</sup>	-0.19	-0.09	1.14	0.15	3.81	0.29	0.06	0.18
Equity per share, SEK	11.07	11.26	11.35	11.71	11.56	7.75	7.46	7.40
Cash flow from operating activities per								
share, SEK	-0.62	-0.56	1.10	3.79	-1.01	-0.36	-0.42	-0.48
Share price at the end of the period, SEK	94.90	61.75	74.40	78.00	82.00	118.90	21.80	21.40
Number of shares outstanding at the end								
of the period, thousands	88,060	88,060	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding								
before dilution, thousands	88,060	88,060	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding after dilution, thousands <sup>1</sup>	88,060	88,060	88,060	88,060	88,060	88,060	88,060	88,060

<sup>&</sup>lt;sup>1</sup>There is no dilutive effect as the average market price for the period is lower than the exercise price per December 31, 2019.

## Financial statements, Parent company

## Parent company income statement

kSEK	Oct-Dec 2019	Oct-Dec 2018	Jan-Dec 2019	Jan-Dec 2018
Net revenues	26,422	515,320	281,772	713,970
Other operating income	35	707	14,826	16,259
Operating revenues	26,457	516,027	296,598	730,229
Operating expenses				
Project related expenses	-20,971	-48,030	-72,422	-145,357
Other external expenses	-9,680	-10,042	-38,265	-31,949
Personnel expenses	-15,268	-23,629	-59,715	-57,039
Depreciations of tangible assets	-786	-667	-2,961	-2,059
Other operating expenses	-1,463	-3,339	-11,554	-5,031
Operating profit/loss	-21,711	430,321	111,681	488,794
Financial income	-164	-112	1,630	2,171
Financial expenses	-24	-304	-110	-1,371
Profit/loss after financial items	-21,898	429,905	113,200	489,594
Change in tax allocation reserves	-28,857	-122,876	-28,857	-122,876
Profit/loss before tax	-50,755	307,029	84,344	366,718
Тах	10,685	-67,667	-18,390	-80,959
Profit/loss for the period	-40,070	239,363	65,954	285,759

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	Dec 31, 2019	Dec 31, 2018
ASSETS		
Tangible fixed assets	9,590	9,289
Deferred tax assets	250	189
Other financial assets	1,611	1,600
Current assets excluding cash and cash equivalents	31,619	464,757
Cash and cash equivalents	1,112,672	917,209
TOTAL ASSETS	1,155,742	1,393,044
EQUITY AND LIABILITIES		
Equity	836,687	902,441
Tax allocation reserve	176,674	147,817
Other current liabilities	23,810	91,996
Accrued expenses and deferred income	118,571	250,791
EQUITY AND LIABILITIES	1,155,742	1,393,044

## **Notes**

## **Note 1 General information**

This Full Year Report for the period January – December 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 Warfvinges väg 35, SE-112 51, Stockholm, Sweden.

The BioArctic Group's Full Year Report for the period January – December 2019 was approved by the Company's Board of Directors Board on February 5, 2020.

## **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 the period January – December 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 Full Year Report.

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 on 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 can be seen below:

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

Under IFRS 16 Leases, a marginal interest rate of 4 percent has been used. For more information of the application of IFRS 16 Leases see the Annual Report for 2018, note 3.3.

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

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.

## **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	Oct-Dec 2019	Oct-Dec 2018	Jan-Dec 2019	Jan-Dec 2018
Geographic breakdown of net revenues				
Europe	26,422	515,320	119,796	712,489
Asia	-	-	161,976	1,481
Total net revenues	26,422	515,320	281,772	713,970
Net revenues per revenue type				
Milestone payments, recognized at specific				
timepoints	-	448,550	173,407	448,550
Income from research collaborations, recognized				
over time	26,422	66,770	108,366	265,420
Total net revenues	26,422	515,320	281,772	713,970

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 December 31, 2019, MSEK 600.9 has been recognized as revenue and the remaining amount to be recognized as a revenue up until the completion of the project is MSEK 100.7. During the period January – December, a milestone payment of MSEK 162.0 (MEUR 15.0) was received from the research collaboration with Eisai. This payment was recognized as revenue all performance obligations were fulfilled.

## **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. Neither should they be compared to other key ratios with similar names applied by other companies, as key ratios cannot always be defined in the same way. 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	The period's cash flow from operating activities divided by the weighted	
share, SEK	number of shares	
Equity/asset ratio	Adjusted equity divided by total assets	
Return on equity	Net income divided by equity expressed as a percentage	
Equity per share	Adjusted equity divided by the number of shares at the end of the period	

## **Glossary**

## ADAS-Cog

ADAS-Cog (Alzheimer's Disease Assessment Scalecognitive 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 (α-synuclein)

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

## Amyloid beta (AB)

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 earlier in the form of plaques and amyloid beta in the brain blood vessel walls

## ARIA

Amyloid-Related Imaging Abnormalities (ARIA) are brainchanges 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

## **Binding profile**

A binding profile specifies in which way and to which forms of a protein (such as amyloid-beta or alphasynuclein) an antibody binds

## Biomarkei

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 (CNS)

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

## 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 a in a polymer with the monomer as the repeating unit

## **Neurodegenerative disorders**

Disorder in which the nervous system atrophies

## Oligomer

A molecular chain consisting of several aggregated monomers

## 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 aggregated monomers

#### 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.