

# INTERIM REPORT

October - December 2020

# New data provides further support for BAN2401 (lecanemab)

#### **EVENTS DURING THE FOURTH QUARTER**

- BioArctic's drug candidate BAN2401 was assigned an international nonproprietary name (INN): lecanemab.
- Further data for drug candidate lecanemab (BAN2401) from the Phase 2b open-label extension study were presented at the Clinical Trials on Alzheimer's Disease (CTAD) conference.

# IMPACT OF COVID-19 ON THE COMPANY HAS BEEN LIMITED

- The spread and negative effects of the coronavirus during the year had a serious impact on society, the economy and the lives
  of private individuals. During the year, BioArctic successfully advanced its own projects without noticeable disruptions
  despite COVID-19. The company's revenue and costs for the year were only marginally impacted by the pandemic.
- Eisai increased the number of participants in Clarity AD study to ensure a robust dataset. Eisai still expects readout by September 2021.

# FINANCIAL SUMMARY OCTOBER - DECEMBER 2020

- Net revenues for the period amounted to MSEK 8.4 (26.4)
- Operating profit amounted to MSEK -30.2 (-21.1)
- Profit for the period amounted to MSEK -13.2 (-17.1) and earnings per share were SEK -0.15 (-0.19)
- Cash flow from operating activities amounted to MSEK -25.3 (-54.2)
- Cash and cash equivalents at the end of the period amounted to MSEK 999.9 (1,112.8)

# FINANCIAL SUMMARY JANUARY - DECEMBER 2020

- Net revenues for the period amounted to MSEK 62.3 (281.8)
- Operating profit amounted to MSEK -85.0 (112.5)
- Profit for the period amounted to MSEK -68.5 (88.5) and earnings per share were SEK -0.78 (1.00)
- Cash flow from operating activities amounted to MSEK -90.9 (327.2)
- Cash and cash equivalents at the end of the period amounted to MSEK 999.9 (1,112.8)

# KEY FINANCIAL PERFORMANCE INDICATORS

	<u> </u>	4	Jan-Dec		
MSEK	2020	2019	2020	2019	
Net revenues	8.4	26.4	62.3	281.8	
Other operating income	1.4	0.0	3.6	14.8	
Operating profit/loss	-30.2	-21.1	-85.0	112.5	
Operating margin, %	-360.7	-79.8	-136.4	39.9	
Profit/loss for the period	-13.2	-17.1	-68.5	88.5	
Earnings per share before dilution, SEK	-0.15	-0.19	-0.78	1.00	
Earnings per share after dilution, SEK	-0.15	-0.19	-0.78	1.00	
Equity per share, SEK	10.30	11.07	10.30	11.07	
Cash flow from operating activities	-25.3	-54.2	-90.9	327.2	
Cash flow from operating activities per share, SEK	-0.29	-0.62	-1.03	3.72	
Equity/assets ratio, %	86.4	82.4	86.4	82.4	
Return on equity, %	-1.44	-1.74	-7.28	8.88	
Share price at the end of the period, SEK	95.40	94.90	95.40	94.90	

Unless otherwise stated, this Interim report refers to the Group. Figures in parentheses refer to the corresponding period last year.

# Comments from the CEO



2020 was an eventful year, with positive momentum and advanced positions in our drug development projects. While the COVID-19 pandemic has entailed tremendous hardship for the world around us, we have done our utmost to keep the pandemic from impacting our operations. By changing our work procedures, BioArctic's important efforts to improve the quality of life for patients with diseases of the central nervous system could be carried on according to plan. Our ambition remains: together with our partners, we intend to be one of the first companies to successfully develop disease-modifying treatments for Alzheimer's and Parkinson's diseases.

BioArctic's drug candidate BAN2401, which was recently assigned the international nonproprietary name lecanemab by the World Health Organization, continues to show promising results. Baseline data for the patients participating in Clarity AD, the confirmatory Phase 3 study, were shown to be consistent with baseline in the Phase 2b study. The participants in the Clarity AD study are also representative of a population with early Alzheimer's disease. BioArctic's partner Eisai recently communicated that it had implemented a small expansion of the number of participants in the confirmatory Phase 3 study. The decision was taken proactively to ensure a robust dataset and to mitigate the potential impact of patients who temporarily missed doses due to the COVID-19 pandemic. Eisai also confirmed that time for data readout for Clarity AD remains unchanged and is still expected by September 2022.

We are also pleased with the findings from the open-label extension of the Phase 2b study with lecanemab, which demonstrated a rapid and continual decrease in amyloid levels in the brain after three, six and twelve months of treatment in the patients who previously received placebo. Another finding supporting the safety of lecanemab is that even though patients were treated with the highest dose of lecanemab right from the start, the frequency of the side effect ARIA-E, was at the same low level as in the Phase 2b study. This distinguishes lecanemab from other drug candidates in late-stage clinical development that demonstrate higher frequencies of these side effects. Lecanemab therefore can be administered at the intended dose already from the start, without titration.

During the year, Eisai initiated an additional global Phase 3 program: AHEAD 3–45, the purpose of which is to study and delay the development of the disease through treatment with lecanemab at the very earliest stages of the disease. Positive study results could be of great help for more individuals in slowing the disease at an early stage, and would entail additional market potential for lecanemab.

As regards Parkinson's disease, our partner AbbVie is preparing a Phase 2 program with drug candidate ABBV-0805 based on the Phase 1 study.

BioArctic's early-stage proprietary projects are also continuing to perform well. The preclinical data for our bloodbrain barrier technology are extremely promising, and work is under way to obtain additional patent protection. Initially, the technology will be used in existing projects in our pipeline, but there are also business opportunities in offering the technology for antibodies from other companies.

In January, the European Patent Office approved our application for a patent on antibodies against truncated amyloid beta, which has a pronounced ability to form toxic aggregates that could cause Alzheimer's disease. This approval further demonstrates the strength of the company's research and its ability to find new and innovative ways to intervene in various stages of the course of Alzheimer's disease. In the future, several alternatives and combinations of treatments may be needed to address different types of Alzheimer's disease patients.

BioArctic's research rests on a solid scientific foundation, and our value-driven leadership supports the work of developing the company further. I am extremely proud that our goal-oriented diversity initiatives are yielding results; one proof of this is that we were awarded the Allbright Award for gender equality in 2020. I can conclude that, together with our partners, we have a fantastic opportunity to create the medicines of the future and to improve life for patients and their loved ones.

Gunilla Osswald CEO, BioArctic AB

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# BioArctic in short

BioArctic AB (publ) is a Swedish biopharma company developing 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 Alzheimer's disease, Parkinson's disease and other neurological 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 to generate 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 vast experience in developing drugs from idea to market. Under BioArctic's business model, the company at an early stage itself pursues project development and then, at an appropriate juncture, licenses commercial rights and late phase development to global pharmaceutical companies. In recent years, BioArctic has successfully delivered high quality drug projects that have resulted in significant strategic license and partnership agreements in two major disease areas with high 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 an appropriate time for partnership or exit
- EXPAND the portfolio with new projects and indications with high unmet medical need

# **Operations**

BioArctic conducts its research in five focus areas:

- Alzheimer's disease
- · Parkinson's disease
- Other CNS disorders
- Blood-brain barrier technology
- Diagnostics

Neurodegenerative disorders are conditions in which cells in the brain degenerate and die. 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 problem.

A key cause of Alzheimer's disease and Parkinson's disease is believed to be misfolding and aggregation of proteins. 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 Parkinson's disease. BioArctic's aim with the antibodies currently in clinical phase, is to achieve a disease-modifying effect through the selectivity of antibodies, binding and elimination of the harmful soluble aggregated forms of the amyloid beta protein (oligomers/protofibrils) in the brain.

# Project portfolio

BioArctic has a balanced, competitive portfolio consisting of unique product candidates, technology platforms and methods for diagnostics. All projects are focused on disorders of the central nervous system. The projects are 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.

As of December 31, 2020, the project portfolio consisted of:

- Two drug candidates in clinical phase: lecanemab (BAN2401) for early Alzheimer's disease (Phase 3) and for preclinical (asymptomatic) Alzheimer's disease (Phase 3), and ABBV-0805 for Parkinson's disease (Phase 1)
- Three projects in preclinical phase: lecanemab (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
- A blood-brain barrier technology for increased uptake of antibodies and other biologic drugs into the brain

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) Clarity AD	Eisai <sup>1</sup>	Early Alzheim	er's disease <sup>4</sup>			
	Lecanemab (BAN2401) AHEAD 3-45	Eisai <sup>1</sup>	Preclinical (as	ymptomatic) Alzi	neimer's dise	ase <sup>5</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	Lecanemab (BAN2401)		Down's syndro Traumatic brai				
	ND3014						
BLOOD-BRAIN BARRIER TECHNOLOGY	BBB technology platform						
DIAGNOSTICS	Imaging and biochemical biomarkers – Alzheimer's disease						
1) Partnered with Fisci for leconomical	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

- 1) Partnered with Eisai for lecanemab for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding BAN2401 (lecanemab) in 2014
- 2) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805
- 3) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury
- 4) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease
- 5) Normal cognitive function with intermediate or elevated levels of amyloid in the brain

### **ALZHEIMER'S DISEASE**

BioArctic has developed several unique and selective antibodies with the potential to slow the progress of Alzheimer's disease. The most advanced drug candidate, lecanemab (BAN2401) is currently being evaluated in two Phase 3 studies: Clarity AD for early Alzheimer's disease and AHEAD 3-45 for preclinical (asymptomatic) Alzheimer's disease. Lecanemab previously showed convincing results in a large Phase 2b study in patients with early Alzheimer's disease. The development of lecanemab against Alzheimer's disease is being financed and pursued by BioArctic's partner Eisai, which also owns the rights to the BAN2401 back-up in Alzheimer's disease. BioArctic has four additional antibodies against Alzheimer's disease in its project portfolio.

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

In Alzheimer's disease, the amyloid beta protein clumps together into increasingly larger aggregates in the brain — from the harmless form with a normal function (monomers) to larger forms such as oligomers, protofibrils, fibrils and finally amyloid plaques containing fibrils. Oligomers and protofibrils are considered the most harmful forms of amyloid beta that initiate the process of Alzheimer's disease. Lecanemab is a drug candidate which functions by eliminating these forms of amyloid from the brain and thereby has the potential to slow down the progression of disease. BioArctic's partner Eisai is responsible for the clinical development of lecanemab in Alzheimer's disease and the project is based on research from Uppsala University, Sweden.

Eisai is conducting two global Phase 3 studies with lecanemab, one in patients with early Alzheimer's disease (Clarity AD) and one in cognitively unimpaired individuals with intermediate or elevated amyloid levels in the brain who have not yet developed symptoms of Alzheimer's disease (AHEAD 3-45).

Clarity AD is the pivotal and confirmatory Phase 3 study. It is based on the Phase 2b study with lecanemab in 856 patients with early Alzheimer's disease which demonstrated dose dependent, clinically meaningful, and statistically significant effects of lecanemab on several clinical endpoints and on biomarkers and showed good tolerability.

This Phase 3 study is a global placebo-controlled, doubleblind, parallel-group, randomized study in approx. 1,760 patients with early Alzheimer's disease i.e. mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease. Patients are allocated in a 1:1 ratio to receive intravenous infusion twice a month, either with placebo or with lecanemab 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), AD Assessment Scale-Cognitive Subscale (ADAS-Cog) and a clinical scale focusing of activities of daily living particularly relevant in mild cognitive impairment, (ADCS-ADL-MCI), will be key secondary endpoints together with brain amyloid levels as measured by amyloid-PET. According to Eisai, the goal is to

be able to present results from the study in 2022 and thereafter submit an application for marketing approval.

An open-label extension study, without placebo control, with continued treatment with lecanemab with the highest study dose for all the participants in the Phase 2b study is in progress. At the Alzheimer's Association International Conference 2020 (AAIC) and at Clinical Trials on Alzheimer's Disease 2020 (CTAD), Eisai presented new data from the study showing that the patients who had previously received placebo in the Phase 2b study had rapidly and continually decreasing amyloid levels in the brain after three, six and twelve months of treatment with lecanemab. Additionally, with treatment with lecanemab less than 10 percent of patients experienced ARIA-E side effects, consistent with previously reported data.

Lecanemab's unique binding profile has been confirmed in laboratory analyses, which are ongoing in parallel with the clinical development program. These results strengthen BioArctic's conviction that lecanemab has a unique binding profile that distinguishes it from other amyloid beta antibodies. BioArctic has an ongoing research collaboration with Eisai in order to further deepen the knowledge about the drug candidate lecanemab's unique binding profile.

Lecanemab was selected by the Alzheimer's Clinical Trials Consortium (ACTC) and Eisai to be evaluated in a second clinical Phase 3 program which aims to evaluate the effects of lecanemab on preclinical asymptomatic Alzheimer's disease (AHEAD 3-45). The clinical program, that was recently started, include individuals that are at a very early stages of Alzheimer's disease with a high risk of developing the disease. The program that is being conducted with funding from the United States National Institute on Aging (NIA) and Eisai, consists of two clinical sub-studies: A3 and A45. After a joint screening process, the participants are included in one of the randomized, double-blind and placebo-controlled sub-studies based on amyloid levels in the brains of the specific individuals. AHEAD 3-45 is a global program that is expected to include approximately 1,400 individuals.

# Back-up candidate to BAN2401 (collaboration with Eisai)

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

# Projects AD1801, AD1502, AD1503 and AD2603 (owned by BioArctic)

BioArctic has four additional antibody projects against Alzheimer's disease in its project portfolio, all of which are in the research phase. These antibodies have different targets, and each has the potential to become a disease-modifying treatment for Alzheimer's disease. All of them are being developed to treat early Alzheimer's disease. AD1801 is an antibody project where the mechanism of action is linked to ApoE, which is the most common genetic risk factor for Alzheimer's disease. AD1503 is an antibody project against a shorter (truncated) form of amyloid beta, which has a

pronounced ability to aggregate and create toxic forms that could cause Alzheimer's disease.

### PARKINSON'S DISEASE

In the Parkinson's disease treatment area, BioArctic has been collaborating with AbbVie since 2016. In 2018, AbbVie acquired a license to develop and commercialize BioArctic's portfolio of antibodies against alpha-synuclein for Parkinson's disease and other potential indications.

# Drug candidate ABBV-0805 (collaboration with AbbVie)

The drug candidate ABBV-0805 is a monoclonal antibody that selectively binds to and eliminates oligomers and protofibrils of alpha-synuclein. The goal is to develop a disease modifying treatment that stops or slows down disease progression.

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 in March 2019. In July 2020, AbbVie decided to develop a detailed plan to accelerate ABBV-0805 into a Phase 2 study in Parkinson's disease patients. 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.

# Projects PD1601 and PD1602 (collaboration with AbbVie)

The antibody projects PD1601 and PD1602 target alphasynuclein 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 included in the collaboration with AbbVie.

# **OTHER CNS DISORDERS**

BioArctic aims 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 against other diseases in the central nervous system.

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

Lecanemab (BAN2401), which is currently being clinically evaluated for Alzheimer's disease, can potentially also be used for other indications. BioArctic owns the rights for all such indications. The antibody lecanemab is in the preclinical phase as a potential treatment of cognitive disorders in conjunction with Down's syndrome and traumatic brain injury.

# Project ND3014 (owned by BioArctic)

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

# BLOOD-BRAIN BARRIER TECHNOLOGY (owned by BioArctic)

The blood-brain barrier controls the passage of substances between the blood and the brain. It protects the brain from harmful substances, but at the same time it can make the delivery of therapeutic agents to the brain more difficult. BioArctic and researchers 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 grants from Sweden's Innovation Agency, Vinnova, for continued research in the blood-brain barrier project. The technology, which is at an early stage, has shown highly encouraging results and has significant potential in the treatment of several different diseases of the brain.

### **DIAGNOSTICS**

# Alzheimer's disease diagnostics (owned by BioArctic) and Parkinson's disease diagnostics (in collaboration with AbbVie)

BioArctic is engaged in the development of new diagnostic methods that improve 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 projects to improve the diagnostic imaging (PET) of the brain of 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)

BioArctic's clinical study of SC0806, with the aim to restore motor function in patients with complete spinal cord injuries, has been terminated. As no clinical effect had been observed in an interim analysis of this study at the end of 2019 the company decided to wind-down the study and close the project. This does not impact BioArctic's research and development of drugs for Alzheimer's disease, Parkinson's disease and other disorders of the central nervous system.

The clinical study of SC0806 received partial financing from the EU Horizon 2020 research and development program (Grant Agreement No. 643853).

# Comments to the financial development

### **REVENUES AND RESULT**

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 in revenues for different periods, as revenues from milestone payments are recognized at the point in time when performance obligations are fulfilled.

Net revenues in the fourth quarter amounted to MSEK 8.4 (26.4). Net revenues for the period January – December amounted to 62.3 MSEK (281.8). The decrease in the quarter compared to last year relates to lower revenue from the Parkinson's program, which was according to plan. The decrease for the period January –December is attributable to the milestone payment from Eisai of MEUR 15 or MSEK 162, which was received in the second quarter 2019, and to lower revenue from the Parkinson's program.

Other operating income relates to research grants and operating exchange rate gains. Other operating income amounted to MSEK 1.4 (0.0) for the fourth quarter and for the period January – December to MSEK 3.6 (14.8). The decrease is mainly attributable to exchange rate gains.

Total operating expenses for the fourth quarter amounted to MSEK 39.9 (47.5) and to MSEK 151.0 (184.1) for the period January – December. Project expenses for the fourth quarter and for the period January – December decreased compared to the previous year due to lower activity in the Parkinson's program as planned, offset by increased expenses for own projects. The expenses for personnel in the fourth quarter and for the period January – December increased as a result of an increase in the number of employees. Other external costs decreased during the year by MSEK 7.8 million as a result of reduced consultant costs and travel. Other operating expenses mainly consist of realized operating exchange rate losses. The reversal of untaxed reserves in the Parent Company in 2020 resulted in a decrease in deferred tax liability in the Group, and the change is recognized in the income statement.

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 income statement. The external projects are owned by our partners and BioArctic has no costs for the clinical programs.

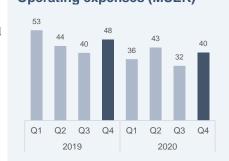
Operating profit before financial items (EBIT) amounted to MSEK -30.2 (-21.1) for the fourth quarter and to MSEK -85.0 (112.5) for the period January – December. The decrease in operating profit both for the quarter and for the full year compared with the same period last year was primarily attributable to the milestone payment that was received from Eisai in the second quarter last year but also due to lower revenue from the Parkinson's program, which was according to plan.

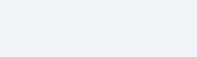
Net financial items totaled MSEK -1.1 (-0.5) for the fourth quarter and to MSEK -1.7 (0.4) for the period January – December. Financial income consists of financial exchange rate gains and financial expenses consists of negative interest on cash and cash equivalents and interest on leasing liabilities according to IFRS 16 Leases.

Profit (loss) amounted to MSEK -13.2 (-17.1) for the fourth quarter and to MSEK -68.5 (88.5) for the period January – December.

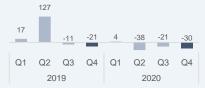
Earnings per share before and after dilution amounted to SEK -0.15 (-0,19) for the fourth quarter and to SEK -0.78 (1.00) for the period January – December.

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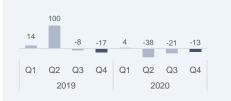




Operating profit/loss (MSEK)



# Profit/loss for the period (MSEK)



### LIQUIDITY AND FINANCIAL POSITION

Equity amounted to MSEK 907.3 (974.5) as of December 31, 2020. This corresponds to equity per outstanding share of SEK 10.30 (11.07).

The equity/asset ratio increased from 82.4 percent as of December 31, 2019 to 86.4 percent as of December 31, 2020.

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to MSEK 999.9 (1,112.8). The decrease in right of use assets of MSEK 5.7 is attributable to depreciation in accordance with IFRS 16, which is mainly related to the head office's lease. The leasing liabilities of MSEK 20.8 MSEK (27.4) is related to the above described right of use assets. The reduction in deferred tax liabilities of SEK 18.0 million is due to the dissolution of untaxed reserves in BioArctic AB. There were no loans as of December 31, 2020 and no loans have been taken since this date. The Group has no other credit facility or loan commitments.

In order to neutralize 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.

# **CASH FLOW AND INVESTMENTS**

Cash flow from operating activities for the fourth quarter amounted to MSEK -25.3 (-54.2) and to MSEK -90.9 (327.2) for the period January – December. The cash flow for the full year period from the preceding year included milestone payments of MUSD 50, or MSEK 460, received from AbbVie and MEUR 15, or MSEK 162, from Fisai

Investments in the fourth quarter amounted to MSEK 8.9 (0.4) and for the period January – December to MSEK 14.0 (3.3). The investments are mainly related to laboratory equipment.

Cash flow from financing activities amounted to MSEK -1.3 (-1.5) for the fourth quarter and relates to the amortization of leasing liabilities. During the period January – December cash flow from financing activities amounted to MSEK -6.6 (-138.5). Cash flow from financing activities 2019 included a dividend of MSEK 132.1.

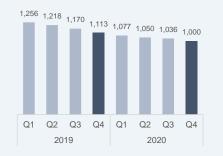
# PARENT COMPANY

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

# **EVENTS DURING THE PERIOD JANUARY - DECEMBER**

- In the fourth quarter, BioArctic's drug candidate BAN2401 was assigned an international nonproprietary name (INN): lecanemab.
- BioArctic's partner Eisai has started an additional global clinical Phase 3 program
  (AHEAD 3-45) to evaluate the effect of lecanemab in individuals who have not yet
  developed symptoms of Alzheimer's disease but have intermediate or elevated
  amyloid levels in the brain.
- Eisai during the third quarter presented new data regarding lecanemab from the open-label extension study at the Alzheimer's Association International Conference (AAIC) and during the fourth quarter at the Clinical Trials on Alzheimer's Disease (CTAD). The data indicated a rapid and continual reduction in amyloid levels in the brain in connection with lecanemab treatment in patients who received placebo in the core study. The study continued to show a good safety profile, with a similar and low level of the side effect ARIA-E as shown in the Phase 2b study.
- BioArctic's partner AbbVie has decided to stop recruitment for the Multiple Ascending Dose (MAD) part of the Phase 1 study of ABBV-0805 in Parkinson's disease patients. A detailed plan to take ABBV-0805 into a Phase 2 study in Parkinson's disease patients is currently being prepared by AbbVie.
- BioArctic communicated that the mechanism for the AD1801 antibody project is linked to ApoE, which is the most common genetic risk factor for Alzheimer's disease.

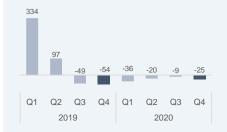
# Cash and cash equivalents (MSEK)



# **Financial position (MSEK)**

31 Dec	2020	2019
Non-current lease liabilities	13.6	20.9
	10.0	
Current lease liabilities	7.1	6.4
Cash and cash equivalents	999.9	1,112.8
Net cash position	979.2	1,085.5

# Cash flow from operating activities (MSEK)





- BioArctic initiated a collaboration with the University of Oslo to increase knowledge about ApoE's role in patients with Alzheimer's disease and to study the mechanism of action and generate pharmacological efficacy data with drug candidates in the ApoE project, AD1801.
- The spread and negative effects of the coronavirus during the year had a serious impact on society, the economy and the lives
  of private individuals. During the year, BioArctic successfully advanced its own projects without noticeable disruptions
  despite COVID-19. The company's revenues and costs for the year were only marginally impacted by the pandemic.

# Other information

# **EVENTS AFTER THE REPORTING PERIOD**

- Eisai increased the number of participants in Clarity AD to ensure a robust dataset. Eisai still expects readout by September 2021.
- BioArctic received patent approval from the European Patent Office for antibodies against truncated amyloid beta, which are linked to the AD1503 project.

# **PATENTS**

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 160 granted patents and more than 70 ongoing patent applications.

# PARTNERSHIPS, COLLABORATIONS AND MAJOR AGREEMENTS

Collaborations and license agreements with leading pharma and biopharma companies are an important part of BioArctic's strategy. In addition to financial compensation, BioArctic benefits from the expertise the company's partners contribute in drug development, manufacturing and commercialization. BioArctic has entered into a number of such agreements with the Japanese global 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 BioArctic's 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 lecanemab and BAN2401 back-up antibodies. The total value of these agreements may amount to MEUR 222 in addition to royalties. To date, approximately MEUR 65 has been received and recognized.

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. At the end of 2018, AbbVie exercised its option to license BioArctic's alphasynuclein antibody portfolio for Parkinson's disease and other potential indications. BioArctic has had 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. For more information regarding BioArctic's two large collaboration partners, please see the Annual Report 2019 on pages 18, 25 and 40.

Collaborating with universities is also of great importance to BioArctic. The company has ongoing collaborations with academic research groups at a number of universities.

### **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, mitigate, measure, control and limit the risks of the business. Significant risks are the same for the Parent Company and the Group.

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 2019 on pages 46-49. In addition to the risks described in the annual report for 2019, the board of directors concluded that COVID-19 has not had any major impact on operations during the year. The company routinely monitors the development of the pandemic to manage any risks over the longer-term.

### **FLUCTUATIONS IN REVENUE GENERATION**

Currently, BioArctic does not have any drugs on the market. The company develops a number of 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, diagnostics, as well as a 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.

### **FUTURE PROSPECTS**

The company enjoys a strong financial position and has a business model in which its revenue and earnings are currently primarily based on non-recurring revenue from research and licensing agreements the company signed. The company's liquidity facilitates continued development of the projects covered by strategic partnership agreements as well as financing of the company's own projects in early phase and therefore are less costly. BioArctic's focus areas comprise unique drug candidates, innovative blood-brain barrier technology and diagnostics, areas with high unmet medical need. All projects are focused on disorders of the central nervous system and have great market potential. BioArctic's ambition is to generate the medicines of the future for patients with central nervous system disorders.

# EXPECTED DEVELOPMENT OF OPERATING EXPENSES

Operating expenses are expected to be in the range of MSEK 180 – 220 for the fiscal year January – December 2021. During 2020 operating expenses were MSEK 151, which was in the range of the forecast of MSEK 150 – 170. During the last three years the average annual level of the operating expenses has been approximately MSEK 190.

### **EMPLOYEES**

At the end of the period, the number of employees was 45 (42) of which 18 (16) are men and 27 (26) women. Just over 80 percent work 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 tasks in competence areas that the company lacks or only has need for periodically. As of December 31, 2020, these corresponded to 12 (11) full-time positions.

#### 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.

# LARGEST SHAREHOLDERS AS OF DECEMBER 31, 2020<sup>1</sup>

	Number		Share	of (%)
	A-shares	B-shares	capital	votes,
Demban AB (Lars Lannfelt)	8,639,998	22,628,052	35.5	50.1
Ackelsta AB (Pär Gellerfors)	5,759,998	15,086,301	23.7	33.4
Fourth AP-Fund	-	4,300,000	4.9	2.0
Third AP-Fund	-	3,203,492	3.6	1.5
Gladiator	-	2,532,785	2.9	1.2
Unionen	-	2,391,835	2.7	1.1
Swedbank Robur Fonder	=	1,843,058	2.1	0.8
Handelsbanken Fonder	-	1,609,175	1.8	0.7
Investment AB Öresund	-	1,530,000	1.7	0.7
Wellington Management	-	1,314,848	1.5	0.6
Tot. 10 largest shareholde	14,399,996	56,439,546	80.4	92.1
Other	-	17,220,443	19.6	7.9
Total	14,399,996	73,659,989	100.0	100.0

### **ANNUAL GENERAL MEETING 2021**

The Annual General Meeting (AGM) for BioArctic will be held on 6 May. As a measure to reduce the risk of spreading the coronavirus and in the light of the uncertainty about what restrictions and guidelines will apply to meetings at the time of the meeting, the Board of Directors of BioArctic has

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

decided that the AGM will be held solely through advance voting using the postal voting method. There will thus be no possibility of physically attending the AGM, either in person or by proxy. More information on the AGM and how to register will be presented in the notice to attend. BioArctic also intends to invite to a digital information meeting that will be held well in advance of the meeting.

#### **NOMINATION COMMITTEE**

In accordance with the resolution at the 2020 AGM, the Nomination Committee for the 2021 AGM has been appointed and announced. The Nomination Committee consists of: Gunnar Blix, Chairman (Third Swedish National Pension Fund), Margareta Öhrvall (Demban AB) and Claes Andersson (Ackelsta AB).

#### **DIVIDEND**

The Board proposes that no dividend be paid for the 2020 financial year.

#### LONG-TERM INCENTIVE PROGRAMS

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. As of the end of the period, 540,000 employee warrants were allocated, of which 5,000 were allocated in the first quarter, 25,000 in the second quarter and 35,000 in the fourth quarter. The allocation of employee warrants had a dilutive effect corresponding to 500,000 shares, or 0.57 percent, at the end of the period. More information is available on <a href="https://www.bioarctic.com">www.bioarctic.com</a>

In addition to the employee warrant program described above, BioArctics's two principal owners Demban AB and Ackelsta AB, independent of the company, issued stock options in 2017 to board members and senior executives. During the second quarter 2020, all outstanding options had been exercised and the program was terminated.

The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on February 4, 2021.

This interim report has not been subject to review by BioArctic's auditors.

Stockholm, Sweden, February 4, 2021

Cjale Cerd

Gunilla Osswald CEO, BioArctic AB (publ)

# INVITATION TO PRESENTATION OF INTERIM REPORT FOR THE PERIOD JANUARY – DECEMBER 2020

BioArctic invites investors, analysts and media to an audiocast with teleconference (in English) today, February 4, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson will present BioArctic, comment on the interim report and answer questions.



Webcast: https://tv.streamfabriken.com/bioarctic-q4-2020

To participate in the conference, please call: +46 8 505 583 56 (Sweden), +45 781 501 07 (Denmark), +31 207 219 496 (Netherlands), +47 239 636 88 (Norway), +41 225 675 632 (Switzerland), +44 333 300 92 60 (UK), +49 692 222 203 80 (Germany) or +1 833 526 8382 (USA)

# **CALENDAR 2021**

Annual report in Swedish published
Interim report Jan-Mar 2021
Annual General Meeting 2021
Half-Year report Jan-Jun 2021
Interim report Jan-Sep 2021
Full Year Report Jan-Dec 2021

March 31, 2021
April 21, 2021, at 08:00 a.m. CET
May 6, 2021
July 9, 2021, at 08:00 a.m. CET
Feb 3, 2022, at 08:00 a.m. CET



# FOR FURTHER INFORMATION, PLEASE CONTACT

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# BioArctic AB (publ)

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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 applies.

# Financial statements, Group

# **CONSOLIDATED INCOME STATEMENT**

	Q	4	Jan-Dec		
kSEK	2020	2019	2020	2019	
Net revenues (note 4)	8,360	26,422	62,347	281,772	
Other operating income	1,359	35	3,597	14,826	
Operating revenues	9,719	26,457	65,943	296,598	
Operating expenses					
Project related expenses	-13,376	-20,971	-50,242	-72,422	
Other external expenses	-6,084	-7,804	-23,370	-31,169	
Personnel expenses	-16,523	-15,268	-62,977	-59,715	
Depreciations of tangible assets	-3,076	-2,024	-11,013	-9,199	
Other operating expenses	-818	-1,463	-3,353	-11,554	
Operating profit/loss	-30,158	-21,073	-85,012	112,538	
Financial income	-227	-164	7	1,630	
Financial expenses	-866	-301	-1,686	-1,192	
Profit/loss before tax	-31,251	-21,538	-86,691	112,976	
Tax	18,052	4,443	18,174	-24,507	
Profit/loss for the period	-13,198	-17,096	-68,517	88,468	
Earnings per share					
Earnings per share before dilution, SEK	-0.15	-0.19	-0.78	1.00	
Earnings per share after dilution, SEK	-0.15	-0.19	-0.78	1.00	

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Q4		Jan-Dec	
kSEK	2020	2019	2020	2019
Profit/loss for the period	-13,198	-17,096	-68,517	88,468
Other comprehensive income	-	-	-	-
Comprehensive income for the period	-13,198	-17,096	-68,517	88,468

# **CONSOLIDATED BALANCE SHEET**

kSEK	31 Dec 2020	31 Dec 2019
ASSETS		
Tangible fixed assets	18,120	9,590
Right-to-use assets	21,820	27,544
Deferred tax assets	452	298
Other financial assets	1,562	1,511
Current assets excluding cash and cash equivalents	8,420	31,619
Cash and cash equivalents	999,940	1,112,770
TOTAL ASSETS	1,050,313	1,183,332
EQUITY AND LIABILITIES		
Equity	907,299	974,497
Deferred tax liabilities	20,666	38,685
Non-current lease liabilities	13,627	20,927
Current lease liabilities	7,141	6,439
Other current liabilities	17,887	24,030
Accrued expenses and deferred income	83,692	118,753
EQUITY AND LIABILITIES	1,050,313	1,183,332

# CONSOLIDATED STATEMENT OF CHANGE IN EQUITY (CONDENSED)

	31 Dec 2020	31 Dec 2019
Opening balance at 1 January	974,497	1,017,736
Comprehensive income for the period	-68,517	88,468
Share-based payments	1,319	383
Paid dividend	-	-132,090
Closing balance	907,299	974,497

# CONSOLIDATED STATEMENT OF CASH FLOW (CONDENSED)

	Q	4	Jan-Dec		
kSEK	2020	2019	2020	2019	
Operating profit	-30,158	-21,073	-85,012	112,538	
Adjustment for non-cash items	1,767	-23,240	-19,991	-107,485	
Interest received/paid	-859	-56	-1,679	-757	
Income tax paid	-367	-2,067	-12,217	-80,919	
Cash flow from operating activities before changes in working capital	-29,617	-46,436	-118,899	-76,622	
Change in working capital	4,306	-7,771	28,018	403,787	
Cash flow from operating activities after changes in working capital	-25,311	-54,207	-90,881	327,165	
Cash flow from investing activities	-8,907	-408	-13,984	-3,273	
Cash flow from financing activities	-1,257	-1,544	-6,598	-138,506	
Cash flow for the period	-35,475	-56,159	-111,463	185,385	
Cash and cash equivalents at beginning of period	1,036,295	1,170,178	1,112,770	917,307	
Exchange rate differences in cash and cash equivalents	-881	-1,249	-1,367	10,077	
Cash and cash equivalents at end of period	999,940	1,112,770	999,940	1,112,770	

# **CONSOLIDATED QUARTERLY DATA**

	2020	2020	2020	2020	2019	2019	2019	2019
MSEK	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Income statement								
Net revenues	8.4	10.5	7.0	36.4	26.4	20.6	171.3	63.4
Other operating income	1.4	0.9	-2.1	3.4	0.0	8.6	-0.7	6.9
Operating expenses	-39.9	-32.2	-42.9	-36.0	-47.5	-39.7	-43.8	-53.0
Operating profit/loss	-30.2	-20.7	-37.9	3.8	-21.1	-10.5	126.8	17.3
Operating margin, %	-360.7	-196.3	-541.5	10.4	-79.8	-50.9	74.0	27.3
Profit/loss for the period	-13.2	-20.7	-38.2	3.6	-17.1	-8.3	100.3	13.6
Balance sheet								
Fixed assets	42.0	36.1	35.4	36.7	38.9	40.2	41.0	42.6
Current assets	8.4	3.7	14.5	28.6	31.6	29.2	15.9	16.3
Cash and cash equivalents	999.9	1,036.3	1,049.9	1,077.3	1,112.8	1,170.2	1,218.4	1,255.6
Equity	907.3	920.2	940.5	978.4	974.5	991.3	999.5	1,031.4
Deferred tax liabilities	20.7	38.7	38.7	38.7	38.7	32.5	32.5	32.5
Lease liabilities	20.8	22.0	22.9	24.6	27.4	28.5	30.0	31.5
Current liabilities	101.6	95.2	97.8	100.9	142.8	187.3	213.2	219.0
Cash flow								
From operating activities	-25.3	-9.4	-19.8	-36.3	-54.2	-49.4	97.2	333.6
From investing activities	-8.9	-3.3	-1.5	-0.3	-0.4	-1.6	-0.7	-0.6
From financing activities	-1.3	-0.9	-1.6	-2.8	-1.5	-1.5	-133.6	-1.8
Cash flow for the period	-35.5	-13.7	-22.9	-39.4	-56.2	-52.5	-37.1	331.2
Data per share								
Earnings per share before dilution, SEK	-0.15	-0.23	-0.43	0.04	-0.19	-0.09	1.14	0.15
Earnings per share after dilution, SEK	-0.15	-0.23	-0.43	0.04	-0.19	-0.09	1.14	0.15
Equity per share, SEK	10.30	10.45	10.68	11.11	11.07	11.26	11.35	11.71
Cash flow operating activities per share, SEK	-0.29	-0.11	-0.22	-0.41	-0.62	-0.56	1.10	3.79
Share price at the end of the period, SEK	95.40	88.95	73.35	61.50	94.90	61.75	74.40	78.00
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	88,355	88,082	88,060	88,060	88,060	88,060	88,060	88,060

# Financial statements, Parent company

# PARENT COMPANY INCOME STATEMENT

	Q	4	Jan-Dec		
kSEK	2020	2019	2020	2019	
Net revenues	8,360	26,422	62,347	281,772	
Other operating income	1,359	35	3,597	14,826	
Operating revenues	9,719	26,457	65,943	296,598	
Operating expenses					
Project related expenses	-13,376	-20,971	-50,242	-72,422	
Other external expenses	-8,095	-9,680	-31,161	-38,265	
Personnel expenses	-16,523	-15,268	-62,977	-59,715	
Depreciations of tangible assets	-1,241	-786	-3,829	-2,961	
Other operating expenses	-818	-1,463	-3,353	-11,554	
Operating profit/loss	-30,335	-21,711	-85,618	111,681	
Financial income	-227	-164	7	1,630	
Financial expenses	-642	-24	-707	-110	
Profit/loss after financial items	-31,203	-21,898	-86,318	113,200	
Change in tax allocation reserves	81,865	-28,857	81,865	-28,857	
Profit/loss before tax	50,662	-50,755	-4,453	84,344	
Tax	22	10,685	75	-18,390	
Profit/loss for the period	50,684	-40,070	-4,378	65,954	

There are no items recognized as other comprehensive income in the Parent Company. Accordingly, total comprehensive income matches profit for the year.

# PARENT COMPANY BALANCE SHEET (CONDENSED)

	31 Dec 2020	31 Dec 2019
ASSETS		
Tangible fixed assets	18,120	9,590
Deferred tax assets	325	250
Other financial assets	1,612	1,611
Current assets excluding cash and cash equivalents	9,882	31,619
Cash and cash equivalents	999,892	1,112,672
TOTAL ASSETS	1,029,831	1,155,742
EQUITY AND LIABILITIES		
Equity	833,628	836,687
Tax allocation reserve	94,809	176,674
Other current liabilities	17,702	23,810
Accrued expenses and deferred income	83,692	118,571
EQUITY AND LIABILITIES	1,029,831	1,155,742

# **Notes**

#### **NOTE 1 GENERAL INFORMATION**

This Interim Report for the period January – December 2020 covers the Swedish Parent Company BioArctic AB, Swedish Corporate Identity Number 556601-2679, and the fully owned subsidiary 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.

### **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 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 – December 2020 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 interim report. The accounting principles and calculation methods applied are in accordance with those described in the Annual Report 2019. New and amended IFRS standards and interpretations applied from 2020 have not had a material impact on the financial statements.

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**

	Q4		Jan-Dec	
kSEK	2020	2019	2020	2019
Geographic breakdown of net revnues				
Europe	2,291	26,422	33,805	119,796
Asia	6,069	-	28,541	161,976
Total net revenues	8,360	26,422	62,347	281,772
Net revenues per revenue type				
Milestone payments, recognized at a given point in time	-	-	-	173,407
Income from research collaborations, recognized over time	8,360	26,422	62,347	108,366
Total net revenues		26,422	62,347	281,772

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, or 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. In conjunction with a restatement of the total costs of the Parkinson's program in light of better performance than originally planned, a positive lump sum of MSEK 22.8 in revenue has been

recorded during the first quarter 2020. As of December 31, 2020, MSEK 634.7 has been recognized as revenue and the remaining amount to be recognized as a revenue up until the completion of the project is MSEK 66.9. A new research collaboration agreement with Eisai began in January 2020. Payments to BioArctic under this agreement originally totaled up to a potential MEUR 3.25, or MSEK 34, and runs through the end of June 2021. Following additional orders from Eisai, the potential payments to BioArctic amount to approximately MEUR 3.6. Income from the research collaboration is recognized over time based on fulfillment of performance criteria. As of December 31, 2020, MSEK 28.5 has been recognized as revenue.

# 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 revenue	
Operating profit	Result before financial items	
Operating margin, %	Operating profit divided by net revenues	
Cash flow from operating activities per share, SEK	The cash flow from operating activities for the period divided by the weighted 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 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.

### **ADCS-ADL-MCI**

ADCS-ADL-MCI (Alzheimer's Disease Cooperative Study - Activities of Daily Living - Mild cognitive impairment) is a clinical scale focusing of activities of daily living particularly relevant in mild cognitive impairment.

### Alfa-synuclein (α-synuclein)

A naturally occurring protein in the body that, in conjunction with Parkinson's disease, misfolds and forms harmful structures in the brain.

### Amyloid beta (Aß)

A naturally occurring protein in the brain that, in conjunction with Alzheimer's disease, misfolds into harmful structures in brain cells. Amyloid beta form the plaque around brain cells visible in patients with Alzheimer's disease.

### **Antibody**

A biological molecule originating in the immune system that binds to a target molecule with a high degree of accuracy.

# ApoE (Apolipoprotein E)

ApoE transports fats in the blood. ApoE comes in three forms. Individuals expressing the ApoE4 form are at greater risk of developing Alzheimer's disease.

### **ARIA-E**

A form of cerebral edema that occurs in some patients treated with anti-amyloid monoclonal antibodies for Alzheimer's disease.

# **Binding profile**

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

# **Biomarker**

A measurable molecule, the levels of which can indicate a change in the body and enable diagnosis of a patient or measurement of the effect of a drug.

# **Blood-brain barrier**

A structure of tightly bound cells that surround blood vessels in the brain. This barrier regulates the exchange of nutrients and waste and protects against bacteria and viruses.

### 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 part of the body's nervous system comprising the brain and 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.

# Early Alzheimer's disease

Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease.

### Interim analysis

A statistical analysis conducted during an ongoing clinical trial to evaluate preliminary findings.

### Licensing of product candidate

Agreement where a company that has invented a drug gives another company the right to further develop and sell the drug for certain payments.

### Milestone payment

Financial remuneration received as part of a project or collaboration agreement once a specified goal has been achieved.

### Monomer

An individual molecule with the ability to bind to other similar molecules to form larger structures such as oligomers and protofibrils.

### **Neurodegenerative disorders**

A disorder that entails a gradual breakdown and degeneration in brain and nervous system function.

### Oligomer

Molecules consisting of a number of monomers.

# Open extension study

Clinical study conducted after a completed randomized and placebo-controlled study in which all patients receive active substance.

### PET

Positron emission tomography, an imaging method used to perform medical examinations.

#### Phase 1 studies

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

#### Phase 2 studies

Studies of the safety and efficacy of a drug. Performed in a limited number of patients. Later portions of phase 2 studies can be called phase 2b and evaluate the optimal dose of the studied drug.

# Phase 3 studies

Studies of the efficacy and safety of a drug. Performed in a large number of patients.

# Placebo-controlled

Study design in research which means that some of the patients receive inactive substance to get a relevant comparison group.

# Preclinical (asymptomatic) Alzheimer's disease

Normal cognitive function but with intermediate or elevated levels of amyloid in the brain.

# **Preclinical phase**

Stage of development where preclinical studies of drug candidates are conducted to prepare for clinical studies.

### **Preclinical studies**

Studies conducted in model systems in laboratories prior to conducting clinical trials in humans.

# **Product candidate**

A product under development that has not yet gained marketing approval.

### **Protofibril**

A harmful aggregation of amyloid beta formed in the brain, which gives rise to Alzheimer's disease, or a harmful aggregation of alpha-synuclein formed in the brain that gives rise to Parkinson's disease.

# Truncated amyloid beta

Shortened (truncated) forms of the amyloid beta protein.

# Research phase

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

# **Selective binding**

Tendency of a molecule to bind to a specific receptor.

### **Tolerability**

The degree of side effects from a drug that can be tolerated by a patient.

