

# INTERIM REPORT

July - September 2020

# An additional Phase 3 study in Alzheimer's disease

### **KEY EVENTS DURING THE THIRD QUARTER 2020**

- BioArctic's partner Eisai has started an additional global clinical Phase 3 program (AHEAD 3-45) to evaluate the effect of BAN2401 in individuals who have not yet developed symptoms of Alzheimer's disease but have intermediate or elevated amyloid levels in the brain.
- Eisai presented new data regarding BAN2401 from the open-label extension study at the Alzheimer's Association
  International Conference® (AAIC). The data indicated a rapid and continual reduction in amyloid levels in the brain in
  connection with BAN2401 treatment in patients who received placebo in the earlier study. The study continued to show a
  good safety profile.
- BioArctic's partner AbbVie decided to stop recruitment into the second part of the Phase 1 study of ABBV-0805 in Parkinson's disease patients. A detailed plan to accelerate ABBV-0805 into a Phase 2 Proof of Concept study in Parkinson's disease patients is currently being prepared by AbbVie.

### FINANCIAL SUMMARY JULY - SEPTEMBER 2020

- Net revenues for the period amounted to MSEK 10.5 (20.6)
- Operating profit amounted to MSEK -20.7 (-10.5)
- Profit for the period amounted to MSEK -20.7 (-8.3) and earnings per share were SEK -0.23 (-0.09)
- Cash flow from operating activities amounted to MSEK -9.4 (-49.4)
- Cash and cash equivalents at the end of the period amounted to MSEK 1,036 (1,170)

### FINANCIAL SUMMARY JANUARY - SEPTEMBER 2020

- Net revenues for the period amounted to MSEK 54.0 (255.4)
- Operating profit amounted to MSEK -54.9 (133.6)
- Profit for the period amounted to MSEK -55.3 (105.6) and earnings per share were SEK -0.63 (1.20)
- Cash flow from operating activities amounted to MSEK -65.6 (381.4)
- Cash and cash equivalents at the end of the period amounted to MSEK 1,036 (1,170)

### **KEY FINANCIAL PERFORMANCE INDICATORS**

	Q	3	Jan-	Jan-Sep		
MSEK	2020	2019	2020	2019	2019	
Net revenues	10.5	20.6	54.0	255.4	281.8	
Other operating income	0.9	8.6	2.2	14.8	14.8	
Operating profit/loss	-20.7	-10.5	-54.9	133.6	112.5	
Operating margin, %	-196.3	-50.9	-101.6	52.3	39.9	
Profit/loss for the period	-20.7	-8.3	-55.3	105.6	88.5	
Earnings per share before dilution, SEK	-0.23	-0.09	-0.63	1.20	1.00	
Earnings per share after dilution, SEK	-0.23	-0.09	-0.63	1.20	1.00	
Equity per share, SEK	10.45	11.26	10.45	11.26	11.07	
Cash flow from operating activities	-9.4	-49.4	-65.6	381.4	327.2	
Cash flow from operating activities per share, SEK	-0.11	-0.56	-0.74	4.33	3.72	
Equity/assets ratio, %	85.5	80.0	85.5	80.0	82.4	
Return on equity, %	-2.22	-0.84	-5.84	10.51	8.88	
Share price at the end of the period, SEK	88.95	61.75	88.95	61.75	94.90	

The Group is referred to unless otherwise stated in this Interim report. Figures in parentheses refer to the corresponding period last year.

# Comments from the CEO



Almost exactly three years ago, on October 12, 2017, BioArctic was listed at Nasdaq Stockholm. Since then, our drug projects against Alzheimer's disease and Parkinson's disease have made significant advances, new projects have been added and the company's market value has more than tripled. We are proud and pleased to have developed the company into one of the foremost in the world today in the development of disease-modifying treatments for neurodegenerative disorders such as Alzheimer's disease and Parkinson's disease. These diseases cause a great deal of suffering, limit the quality of life for millions of people, and give rise to enormous costs to society.

BioArctic continued its positive performance this quarter as well. Eisai, our partner in Alzheimer's disease, initiated an additional broad Phase 3 program with BAN2401 together with the Alzheimer's Clinical Trials Consortium (ACTC). The intent of the program is to study the benefit of treatment in the very earliest stages of Alzheimer's disease, before the emergence of symptoms. The new and extremely ambitious program, which is expected to encompass 1,400 persons, emphasizes Eisai's strong commitment to BAN2401 and, if successful, could enable more people in the future to have access to a treatment with the potential to slow the progress of the disease.

At the same time, the Clarity-AD Phase 3 study is continuing with BAN2041, the purpose of which is to confirm the positive results of the Phase 2b study. Eisai expects the study to be fully enrolled by the end of the year, and the results of the study to be available in 2022. This past summer, new data, from the open-label extension of the previously concluded Phase 2b study with BAN2401, was presented that was consistent with the previously shown biomarker effect and safety profile. The patients who received placebo in the earlier study and are now being treated with BAN2401 have shown a rapid and continual decrease in amyloid levels after three and additionally after six months and twelve months. The occurrence of the ARIA-E side effect remains low: less than 10 per cent of the patients studied. Results from the effect on clinical outcomes are expected to be presented in the future.

BioArctic has a project portfolio with several promising proprietary preclinical projects with the aim to develop next generation medicines. Today, more than 30 million people suffer from Alzheimer's disease, a number that unfortunately is expected to rise dramatically over the next few decades as populations age. We recently informed that one of our preclinical projects, AD1801, is linked to ApoE, which is the most common genetic risk factor for the disease. This new approach creates additional opportunities to develop alternative treatments for Alzheimer's disease.

Our collaboration with AbbVie to develop a new type of treatment against Parkinson's disease continues to progress well. A comprehensive Phase 1 study with ABBV-0805 is in progress, and AbbVie recently decided to halt recruitment for the second part of the Phase 1 study to instead develop a detailed plan for advancing the drug candidate to a Phase 2 study. ABBV-0805 has the potential to become one of the first disease-modifying treatments for Parkinson's disease, which could improve quality of life for patients.

With committed, highly specialized and experienced employees, dedicated academic and global industrial partners as well as approximately SEK 1 billion in cash, we will continue our work to bring new effective medicines to patients. In the portfolio of early projects, the focus is on our efforts in the blood-brain barrier technology and on our own drug projects oriented to disorders of the central nervous system. As a consequence of the COVID-19 pandemic, we have adjusted our work processes, and it is gratifying to see that the company's own projects continue to develop as planned. After three successful years as a listed company, we are continuing our work to be able to offer disease-modifying treatments for patients with neurodegenerative disorders, all based on high-quality research resting on a solid scientific basis.

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, Parkinson's diseases 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 long 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 high quality drug projects that have resulted in significant strategic 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 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, technology platforms and diagnostics. All our 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 September 30, 2020, the project portfolio consisted of:

- Two drug candidates in clinical phase: *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: 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 for increased uptake into the brain of antibodies and other biologic drugs

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	BAN2401 Clarity AD	Eisai <sup>1</sup>	Early Alzheime	er's disease <sup>4</sup>			
	BAN2401 AHEAD 3-45	Eisai <sup>1</sup>	Preclinical (as	ymptomatic) Alz	heimer's dise	ease <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	BAN2401		Downs syndro Traumatic brai				
	ND3014						
BLOOD-BRAIN BARRIER TECHNOLOGY	BBB technology platform						
DIAGNOSTICS	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie		>			

- 1) Partnered with Eisai for BAN2401 for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding BAN2401 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, 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. BAN2401 previously showed convincing results in a large Phase 2b study in patients with early Alzheimer's disease. The development of BAN2401 in 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 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. BAN2401 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 BAN2401 in Alzheimer's disease and the project is based on research from Uppsala University, Sweden.

Eisai is conducting two global Phase 3 studies with BAN2401, one in patients with early Alzheimer's disease (Clarity AD) and one in individuals with intermediate or elevated amyloid levels in the brain who have not yet developed symptoms of Alzheimer's disease (AHEAD 3-45).

Eisai is conducting the pivotal and confirmatory Clarity AD Phase 3 study. The study is based on the Phase 2b study with BAN2401 in 856 patients with early Alzheimer's disease which demonstrated dose dependent, clinically meaningful, and statistically significant effects of BAN2401 on several clinical endpoints and on biomarkers and was well tolerated.

This Phase 3 study is a global placebo-controlled, doubleblind, 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. Patients are allocated in a 1:1 ratio to receive either placebo or treatment. Patients receive placebo or BAN2401 10 mg/kg every other week through intravenous infusion. The primary endpoint is the change from baseline in the cognition and function scale Clinical Dementia Rating-Sum of Boxes (CDR-SB) at 18 months of treatment. Changes in the clinical scales AD composite score (ADCOMS) and AD Assessment Scale-Cognitive Subscale (ADAS-Cog) will be key secondary endpoints together with brain amyloid levels as measured by amyloid-PET. According to Eisai, the 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 BAN2401 treatment with the highest study

dose for the participants in the Phase 2b study is in progress. At the Alzheimer's Association International Conference 2020 (AAIC), 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 BAN2401. Additionally, after treatment with BAN2401 less than 10 percent of patients experienced ARIA-E side effects, consistent with previously reported data.

BAN2401'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 BAN2401 has a unique binding profile that distinguishes it from other amyloid beta antibodies. Further, BioArctic has an ongoing research collaboration with Eisai for deeper study of the unique binding profile of drug candidate BAN2401.

BAN2401 has been selected by the Alzheimer's Clinical Trials Consortium (ACTC) and Eisai to be evaluated in a second upcoming clinical Phase 3 program focused on evaluating the therapeutic effects on the progression of preclinical 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, doubleblind and placebo-controlled sub-studies based on amyloid levels in the brains of the specific individuals. In total, the AHEAD 3-45 program includes approximately 1,400 individuals.

# Back-up candidate to BAN2401 (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.

# 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 be 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.

### **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 Proof of Concept 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 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 included in the collaboration with AbbVie.

### **OTHER CNS DISORDERS**

BioArctic targets 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 for other diseases in the central nervous system.

# 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.

### 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 new 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 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 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.

### **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, owned by BioArctic)

BioArctic's clinical study of SC0806, with the aim to restore motor function in patients with complete spinal cord injuries, has concluded. No clinical effect had been observed in an interim analysis of this study at the end of 2019 and the decision was thus taken to wind-down the study and close the project. This does not impact BioArctic's research and development of drugs for Alzheimer's, Parkinson's 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 a point in time when performance obligations are fulfilled.

Net revenues in the third quarter amounted to MSEK 10.5 (20.6). Net revenues for the period January – September amounted to 54.0 MSEK (255.4). 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 – September 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, operating exchange rate gains and expenses incurred but onward invoiced. Other operating income amounted to MSEK 0.9 (8.6) for the third quarter and for the period January – September to MSEK 2.2 (14.8).

Total operating expenses for the third quarter amounted to MSEK 32.2 (39.7) and to MSEK 111.1 (136.5) for the nine-month period. Project expenses for the third quarter and for the period decreased compared to the equivalent period in 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 for the third quarter and for the period January – September increased. The increase is attributable to an increase in the number of employees. Other operating expenses mainly 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 income statement.

Operating profit before financial items (EBIT) amounted to MSEK -20.7 (-10.5) for the third quarter and to MSEK -54.9 (133.6) for the period January — September. The decrease in operating profit both for the quarter and for the period year-on-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 0.0 (0.0) for the third quarter and to MSEK -0.6 (0.9) for the period January – September. 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) amounted to MSEK -20.7 (-8.3) for the third quarter and to MSEK -55.3 (105.6) for the period January – September.

Earnings per share before and after dilution amounted to SEK -0.23 (-0.09) for the third quarter and to SEK -0.63 (1.20) for the period January – September.

# **Net revenues (MSEK)** 171 2018 Operating expenses (MSEK) Q4 Q1 Q3 Q2 Q1 Q2 2018 2019 2020 Operating profit/loss (MSEK) 430 127 Ω4 Ω1 Ω2 Ω3 Ω1 Ω2 Ω3 Profit/loss for the period (MSEK) 335 -21 Q1 2018

2020

### LIQUIDITY AND FINANCIAL POSITION

Equity amounted to MSEK 920.2 (991.3) as of September 30, 2020. This corresponds to equity per outstanding share of SEK 10.45 (11.26).

The equity/asset ratio has increased from 82.4 percent as of December 31, 2019 to 85.5 percent as of September 30, 2020. Compared with the third quarter last year, the equity/asset ratio increased from 80.0 percent to 85.5 percent.

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to MSEK 1,036.3 (1,170.2). The leasing liabilities as of September 30, 2020 of MSEK 22.0 relate to financial leasing and is an effect from the application of IFRS 16 Leases as of January 1, 2019. There were no loans as of September 30, 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 third quarter amounted to MSEK -9.4 (-49.4) and to MSEK -65.6 (381.4) for the period January – September. The cash flow for the period from the preceding year included milestone payments of MUSD 50 or MSEK 460 received from AbbVie and MEUR 15 or MSEK 162 from Eisai

Investments in the third quarter amounted to MSEK 3.3 (1.6) and for the period January – September to MSEK 5.1 (2.9). The investments are mainly related to laboratory equipment.

Cash flow from financing activities amounted to MSEK -0.9 (-1.5) for the third quarter and relates to the amortization of lease debt. During the period January – September cash flow from financing activities amounted to MSEK -5.3 (-137.0). Cash flow from financing activities last year 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 - SEPTEMBER**

- BioArctic's partner Eisai has started a further global clinical Phase 3 program
  (AHEAD 3-45) to evaluate the effect of BAN2401 in individuals who have not
  yet developed symptoms of Alzheimer's disease but have intermediate or
  elevated amyloid levels in the brain.
- Eisai presented new data regarding BAN2401 from the open-label extension study at the Alzheimer's Association International Conference (AAIC). The data indicated a rapid and continual reduction in amyloid levels in the brain in connection with BAN2401 treatment in patients who received placebo in the earlier study. The study continued to show a good safety profile, with a similar level of side effects 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 accelerate ABBV-0805 into a Phase 2 Proof of Concept 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.
- 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 of COVID-19 has affected both Sweden and the rest of the world during 2020. BioArctic is carefully monitoring the development and is

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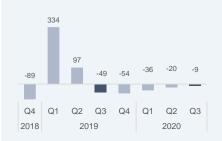
### **Financial position (MSEK)**

2019

2018

30 Sep	2020	2019
Non-current lease liabilities	15.2	22.2
Current lease liabilities	6.9	6.2
Current lease liabilities	6.9	6.3
Cash and cash equivalents	1,036.3	1,170.2
Net cash position	1,014.2	1,141.7

# Cash flow from operating activities (MSEK)





complying with guidelines from government authorities. To date, BioArctic has succeeded in running its own projects without any noteworthy disruptions owing to the COVID-19 pandemic.

# Other information

### **KEY EVENTS AFTER THE REPORTING PERIOD**

There are no key events to report after the end of the reporting 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 and more than 150 granted patents and more than 70 ongoing patent applications.

# COLLABORATIONS, PARTNERSHIPS 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 63 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. 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.

### **RISKS AND UNCERTAINTY FACTORS**

The management makes assumptions, judgments and estimates that affect the content of the financial statements. Actual results may differ from these assumptions and estimates, as is also stated in the accounting principles. The objective of the Group's risk management is to identify, measure, control and limit the risks of the business. Significant risks are the same for the Parent Company and the Group.

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. The Board of Directors notes that to date, COVID-19 has not had any major impact on operations. 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 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, diagnostics, 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.

### **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 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 projects in early phase and therefore are less costly. BioArctic's focus areas comprise unique drug candidates, innovative bloodbrain barrier technology and diagnostics, 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 investment in earlier stage projects and the continued positive development of BioArctic.

# EXPECTED DEVELOPMENT OF OPERATING EXPENSES

Operating expenses are expected to be in the range of MSEK 150 – 170 for the fiscal year January – December 2020. Previous guidance for the same period was MSEK 160 – 190. During 2019 operating expenses were MSEK 184.

### **EMPLOYEES**

At the end of the period, the number of employees was 45 (41) of which 17 (15) are men and 28 (26) 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 September 30, 2020, these corresponded to 10 (12) 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 SEPTEMBER 30, 2020<sup>1</sup>

	Num	ber	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	-	3,810,032	4.3	1.8
Unionen	-	2,562,723	2.9	1.2
Gladiator	-	2,065,344	2.3	0.9
Handelsbanken Funds	-	2,024,091	2.3	0.9
Swedbank Robur Funds	-	1,734,059	2.0	0.8
Investment AB Öresund	-	1,584,645	1.8	0.7
Norron Funds	-	1,541,840	1.8	0.7
Tot. 10 largest shareholder	14,399,996	57,337,087	81.5	92.5
Other	-	16,322,902	18.5	7.5
Total	14,399,996	73,659,989	100.0	100.0

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

### **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, 510,000 employee warrants were allocated, of which 5,000 were allocated in the first quarter and 25,000 in the second quarter. The allocation of employee warrants had a dilutive effect corresponding to 45,000 shares, or 0.05 percent, at the end of the period. More information is available on www.bioarctic.com

In addition to the employee warrant program described above, BioArctics's two principal owners Demban AB and Ackelsta AB, independent of the company, 2017 issued stock options to board members and senior executives. During the second quarter, 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 08:00 a.m. CET on October 14, 2020.

This interim report has been subject to review by BioArctic's auditors.

Stockholm, Sweden, October 14, 2020

Cjale Cerd

Gunilla Osswald CEO, BioArctic AB (publ)

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

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, October 14, at 09:30-10:30 a.m. CET. CEO Gunilla Osswald and VP Communications & Investor Relations Oskar Bosson will present BioArctic, comment on the interim report and answer questions.



Webcast: https://tv.streamfabriken.com/bioarctic-q3-2020

To participate in the conference, please call: +46 8 505 583 59 (Sweden), +45 781 501 07 (Denmark), +31 207 219 496 (Netherlands), +47 235 002 36 (Norway), +41 225 805 976 (Switzerland), +44 333 300 92 61 (UK), +49 691 380 34 52 (Germany) or +1 833 526 8395 (USA)

### **CALENDAR 2020/2021**

Full Year Report Jan-Dec 2020 Interim report Jan-Mar 2021 Half-Year report Jan-Jun 2021 Interim report Jan-Sep 2021 Full Year Report Jan-Dec 2021 February 4, 2021, at 8:00 a.m. CET April 21, 2021, at 08:00 a.m. CET July 9, 2021, at 08:00 a.m. CET Oct 21, 2021, at 08:00 a.m. CET Feb 3, 2022, at 08:00 a.m. CET



### FOR FURTHER INFORMATION, PLEASE CONTACT

Gunilla Osswald, CEO, gunilla.osswald@bioarctic.se, phone +46 8 695 69 30 Jan Mattsson, CFO, jan.mattsson@bioarctic.se, phone + 46 70 352 27 72 Oskar Bosson, VP Communications & Investor Relations, oskar.bosson@bioarctic.se, phone +46 70 410 71 80



# BioArctic AB (publ)

Swedish Corporate Identity Number 556601-2679 Warfvinges väg 35, SE-112 51, Stockholm, Sweden Telephone +46 (0)8 695 69 30 www.bioarctic.com

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.

# Report on Review of Interim Financial Information

### INTRODUCTION

We have reviewed the accompanying balance sheet of BioArctic AB (publ) as of September 30, 2020 and the related statements of income, changes in equity and cash flows for the nine-month period then ended, and a summary of significant accounting policies and other explanatory notes. Management is responsible for the preparation and fair presentation of this interim financial information in accordance with IFRS. Our responsibility is to express a conclusion on this interim financial information based on our review.

### **SCOPE OF REVIEW**

We conducted our review in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity." A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the accompanying interim financial information does not give a true and fair view of the financial position of the entity as at September 30, 2019, and of its financial performance and its cash flows for the nine-month period then ended in accordance with IFRS.

Stockholm October 14, 2020

Grant Thornton Sweden AB

Mia Rutenius Authorized public accountant Auditor in charge Therese Utengen Authorized public accountant

# Financial statements, Group

### **CONSOLIDATED INCOME STATEMENT**

	Q	3	Jan-S	Jan-Dec	
kSEK	2020	2019	2020	2019	2019
Net revenues (note 4)	10,549	20,631	53,986	255,351	281,772
Other operating income	904	8,602	2,238	14,791	14,826
Operating revenues	11,452	29,234	56,224	270,142	296,598
Operating expenses					
Project related expenses	-10,664	-13,488	-36,866	-51,451	-72,422
Other external expenses	-4,382	-7,013	-17,285	-23,365	-31,169
Personnel expenses	-13,957	-11,316	-46,453	-44,447	-59,715
Depreciations of tangible assets	-2,849	-2,414	-7,938	-7,175	-9,199
Other operating expenses	-308	-5,512	-2,536	-10,092	-11,554
Operating profit/loss	-20,708	-10,510	-54,853	133,612	112,538
Financial income	234	270	234	1,793	1,630
Financial expenses	-222	-301	-820	-891	-1,192
Profit/loss before tax	-20,696	-10,541	-55,440	134,514	112,976
Тах	45	2,210	122	-28,950	-24,507
Profit/loss for the period	-20,650	-8,331	-55,319	105,564	88,468
Earnings per share					
Earnings per share before dilution, SEK	-0.23	-0.09	-0.63	1.20	1.00
Earnings per share after dilution, SEK	-0.23	-0.09	-0.63	1.20	1.00

### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Q3		Jan-S	Jan-Dec	
kSEK	2020	2019	2020	2019	2019
Profit/loss for the period	-20,650	-8,331	-55,319	105,564	88,468
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	-20,650	-8,331	-55,319	105,564	88,468

### **CONSOLIDATED BALANCE SHEET**

kSEK	30 Sep 2020	30 Sep 2019	31 dec 2019
ASSETS			
Tangible fixed assets	11,011	9,969	9,590
Right-to-use assets	23,125	28,335	27,544
Deferred tax assets	419	357	298
Other financial assets	1,534	1,511	1,511
Current assets excluding cash and cash equivalents	3,716	29,248	31,619
Cash and cash equivalents	1,036,295	1,170,178	1,112,770
TOTAL ASSETS	1,076,101	1,239,598	1,183,332
EQUITY AND LIABILITIES			
Equity	920,163	991,267	974,497
Deferred tax liabilities	38,685	32,520	38,685
Non-current lease liabilities	15,155	22,187	20,927
Current lease liabilities	6,870	6,277	6,439
Other current liabilities	8,994	35,169	24,030
Accrued expenses and deferred income	86,233	152,178	118,753
EQUITY AND LIABILITIES	1,076,101	1,239,598	1,183,332

### CONSOLIDATED STATEMENT OF CHANGE IN EQUITY (CONDENSED)

	30 Sep 2020	30 Sep 2019	31 dec 2019
Opening balance at 1 January	974,497	1,017,736	1,017,736
Comprehensive income for the period	-55,319	105,564	88,468
Share-based payments	984	57	383
Paid dividend	-	-132,090	-132,090
Closing balance	920,163	991,267	974,497

### **CONSOLIDATED STATEMENT OF CASH FLOW (CONDENSED)**

		13	Jan-	Jan-Dec	
kSEK	2020	2019	2020	2019	2019
Operating profit	-20,708	-10,510	-54,853	133,612	112,538
Adjustment for non-cash items	1,584	-22,177	-21,758	-84,245	-107,485
Interest received/paid	-222	-311	-820	-701	-757
Income tax paid	-367	-2,067	-11,850	-78,851	-80,919
Cash flow from operating activities before changes in working					
capital	-19,713	-35,066	-89,282	-30,186	-76,622
Change in working capital	10,284	-14,366	23,712	411,558	403,787
Cash flow from operating activities after changes in working capital	-9,429	-49,432	-65,570	381,372	327,165
Cash flow from investing activities	-3,332	-1,586	-5,077	-2,865	-3,273
Cash flow from financing activities	-942	-1,529	-5,341	-136,962	-138,506
Cash flow for the period	-13,702	-52,547	-75,988	241,544	185,385
Cash and cash equivalents at beginning of period	1,049,934	1,218,437	1,112,770	917,307	917,307
Exchange rate differences in cash and cash equivalents	63	4,287	-486	11,326	10,077
Cash and cash equivalents at end of period	1,036,295	1,170,178	1,036,295	1,170,178	1,112,770

### CONSOLIDATED QUARTERLY DATA

	2020	2020	2020	2019	2019	2019	2019	2018
MSEK	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Income statement								
Net revenues	10.5	7.0	36.4	26.4	20.6	171.3	63.4	515.3
Other operating income	0.9	-2.1	3.4	0.0	8.6	-0.7	6.9	0.7
Operating expenses	-32.2	-42.9	-36.0	-47.5	-39.7	-43.8	-53.0	-85.7
Operating profit/loss	-20.7	-37.9	3.8	-21.1	-10.5	126.8	17.3	430.3
Operating margin, %	-196.3	-541.5	10.4	-79.8	-50.9	74.0	27.3	83.5
Profit/loss for the period	-20.7	-38.2	3.6	-17.1	-8.3	100.3	13.6	335.2
Balance sheet								
Fixed assets	36.1	35.4	36.7	38.9	40.2	41.0	42.6	11.0
Current assets	3.7	14.5	28.6	31.6	29.2	15.9	16.3	464.8
Cash and cash equivalents	1,036.3	1,049.9	1,077.3	1,112.8	1,170.2	1,218.4	1,255.6	917.3
Equity	920.2	940.5	978.4	974.5	991.3	999.5	1,031.4	1,017.7
Deferred tax liabilities	38.7	38.7	38.7	38.7	32.5	32.5	32.5	32.5
Lease liabilities	22.0	22.9	24.6	27.4	28.5	30.0	31.5	-
Current liabilities	95.2	97.8	100.9	142.8	187.3	213.2	219.0	342.8
Cash flow								
From operating activities	-9.4	-19.8	-36.3	-54.2	-49.4	97.2	333.6	-89.3
From investing activities	-3.3	-1.5	-0.3	-0.4	-1.6	-0.7	-0.6	-1.7
From financing activities	-0.9	-1.6	-2.8	-1.5	-1.5	-133.6	-1.8	-
Cash flow for the period	-13.7	-22.9	-39.4	-56.2	-52.5	-37.1	331.2	-91.0
Data per share								
Earnings per share before dilution, SEK	-0.23	-0.43	0.04	-0.19	-0.09	1.14	0.15	3.81
Earnings per share after dilution, SEK	-0.23	-0.43	0.04	-0.19	-0.09	1.14	0.15	3.81
Equity per share, SEK	10.45	10.68	11.11	11.07	11.26	11.35	11.71	11.56
Cash flow operating activities per share, SEK	-0.11	-0.22	-0.41	-0.62	-0.56	1.10	3.79	-1.01
Share price at the end of the period, SEK	88.95	73.35	61.50	94.90	61.75	74.40	78.00	82.00
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	88,082	88,060	88,060	88,060	88,060	88,060	88,060	88,060

# Financial statements, Parent company

### PARENT COMPANY INCOME STATEMENT

	Q	Q3			Jan-Dec	
ksek	2020	2019	2020	2019	2019	
Net revenues	10,549	20,631	53,986	255,351	281,772	
Other operating income	904	8,602	2,238	14,791	14,826	
Operating revenues	11,452	29,234	56,224	270,142	296,598	
Operating expenses						
Project related expenses	-10,664	-13,488	-36,866	-51,451	-72,422	
Other external expenses	-6,409	-8,858	-23,066	-28,585	-38,265	
Personnel expenses	-13,957	-11,316	-46,453	-44,447	-59,715	
Depreciations of tangible assets	-941	-747	-2,588	-2,175	-2,961	
Other operating expenses	-308	-5,512	-2,536	-10,092	-11,554	
Operating profit/loss	-20,825	-10,688	-55,284	133,392	111,681	
Financial income	234	270	234	1,793	1,630	
Financial expenses	26	-11	-65	-86	-110	
Profit/loss after financial items	-20,566	-10,429	-55,115	135,099	113,200	
Change in tax allocation reserves	-	-	-	-	-28,857	
Profit/loss before tax	-20,566	-10,429	-55,115	135,099	84,344	
Тах	18	2,186	53	-29,075	-18,390	
Profit/loss for the period	-20,548	-8,243	-55,062	106,024	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)

	30 Sep 2020	30 Sep 2019	31 dec 2019
ASSETS			
Tangible fixed assets	11,011	9,969	9,590
Deferred tax assets	302	232	250
Other financial assets	1,634	1,611	1,611
Current assets excluding cash and cash equivalents	5,175	29,248	31,619
Cash and cash equivalents	1,036,200	1,170,080	1,112,672
TOTAL ASSETS	1,054,323	1,211,139	1,155,742
EQUITY AND LIABILITIES			
Equity	782,609	876,432	836,687
Tax allocation reserve	176,674	147,817	176,674
Other current liabilities	8,806	34,903	23,810
Accrued expenses and deferred income	86,233	151,989	118,571
EQUITY AND LIABILITIES	1,054,323	1,211,139	1,155,742

# **Notes**

### **NOTE 1 GENERAL INFORMATION**

This Interim Report for the period January – September 2020 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 Interim Report for the period January – September 2020 was approved by the Company's Board of Directors Board on October 13, 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 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 – September 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 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**

	Q3		Jan-Sep		Jan-Dec
kSEK	2020	2019	2020	2019	2019
Geographic breakdown of net revnues					
Europe	1,680	20,631	31,514	93,375	119,796
Asia	8,868	-	22,472	161,976	161,976
Total net revenues	10,549	20,631	53,986	255,351	281,772
Net revenues per revenue type					
Milestone payments, recognized at a given point in time		-	-	173,407	173,407
Income from research collaborations, recognized over time		20,631	53,986	81,944	108,366
Total net revenues		20,631	53,986	255,351	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 September 30, 2020, MSEK 632.4 has been recognized as revenue and the remaining amount to be recognized as a revenue up until the completion of the project is MSEK 69.2.

A new research collaboration agreement with Eisai began in January 2020. Payments to BioArctic under this research collaboration total up to a potential MEUR 3.25, or MSEK 34, and is planned to continue through the end of June 2021. Income from the research collaboration is recognized over time based on fulfillment of performance criteria. As of September 30, 2020, MSEK 22.5 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 period's cash flow from operating activities 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.

### 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 (Aβ)

A naturally occurring protein in the brain that, in conjunction with Alzheimer's disease, misfolds into harmful structures in brain cells. They 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 (Apolipoprotein E) transports fats in the blood. ApoE comes in three forms. Individuals expressing the ApoE4 form are at greater risk of developing 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-SE

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.

### Milestone payment

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

### Monoclonal antibody

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

### 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.

### **PET**

Positron emission tomography, an investigation imaging method.

### Phase 1 studies

Studies mainly 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.

### 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.

### Research phase

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

### **Tolerability**

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

