

## Groundbreaking results for lecanemab in Phase 3 study in early Alzheimer's disease

### EVENTS DURING THE THIRD QUARTER 2022

- Lecanemab showed positive results in the pivotal Phase 3 study, Clarity AD, in early Alzheimer's disease, and both primary and all key secondary endpoints were met with high statistical significance
- New lecanemab data were presented by Eisai at the Alzheimer's Association International Conference (AAIC), including data on a subcutaneous formulation of lecanemab
- The FDA accepted the Biologics License Application (BLA) and granted priority review for lecanemab for treatment of early Alzheimer's disease under the accelerated approval pathway, which resulted in a milestone of MEUR 15 from Eisai in the quarter

### FINANCIAL SUMMARY JULY – SEPTEMBER 2022

- Net revenues for the period amounted to MSEK 218.2 (4.0)
- Operating profit amounted to MSEK 133.0 (-37.4)
- Profit for the period amounted to MSEK 136.8 (-37.6)
- Earnings per share before dilution were SEK 1.55 (-0.43) and earnings per share after dilution were SEK 1.54 (-0.43)
- Cash flow from operating activities amounted to MSEK 111.9 (-34.8)
- Cash and cash equivalents at the end of the period amounted to MSEK 863 (892)

### FINANCIAL SUMMARY JANUARY – SEPTEMBER 2022

- Net revenues for the period amounted to MSEK 226.2 (18.4)
- Operating profit amounted to MSEK 43.2 (-100.4)
- Profit for the period amounted to MSEK 46.7 (-100.8)
- Earnings per share before and after dilution were SEK 0.53 (-1.15)
- Cash flow from operating activities amounted to MSEK 26.6 (-101.2)
- Cash and cash equivalents at the end of the period amounted to MSEK 863 (892)

### KEY FINANCIAL PERFORMANCE INDICATORS

MSEK	Q3		Jan-Sep		Jan-Dec
	2022	2021	2022	2021	2021
Net revenues	218.2	4.0	226.2	18.4	23.1
Other operating income	1.4	0.7	2.3	3.0	3.5
Operating profit/loss	133.0	-37.4	43.2	-100.4	-139.7
Operating margin, %	61.0	neg	19.1	neg	neg
Profit/loss for the period	136.8	-37.6	46.7	-100.8	-119.8
Earnings per share before dilution, SEK	1.55	-0.43	0.53	-1.15	-1.36
Earnings per share after dilution, SEK	1.54	-0.43	0.53	-1.15	-1.36
Equity per share, SEK	9.51	9.17	9.51	9.17	8.96
Cash flow from operating activities	111.9	-34.8	26.6	-101.2	-140.5
Cash flow from operating activities per share, SEK	1.27	-0.39	0.30	-1.15	-1.60
Equity/assets ratio, %	92.5	86.3	92.5	86.3	87.9
Return on equity, %	17.80	-4.55	5.74	-11.76	-14.13
Share price at the end of the period, SEK	271.60	162.60	271.60	162.60	119.20

Unless otherwise stated, this Interim report refers to the Group. Figures in parentheses refer to the corresponding period last year. The amounts stated are rounded, which sometimes leads to some totals not being exact.

## Comments from the CEO

On September 28, the results from the Clarity AD Phase 3 study of lecanemab in patients with early Alzheimer’s disease were communicated and we were pleased to note that both the primary and all key secondary endpoints were met with high statistical significance. Moreover, the side effect profile was within expectations based on observations from previous studies – which underscores the favorable risk/benefit profile for lecanemab.

The results of the Phase 3 study met all our expectations, and more. The robust and consistent results are a big step on the path toward fundamentally improving the treatment of this severely vulnerable patient population. Among patients who were treated with lecanemab, the clinical decline was slowed by 27 percent compared with placebo after 18 months of treatment – and this effect increased over time. According to a publication by Eisai earlier this year modelling long-term effects of lecanemab based on the Phase 2b results, a change of this kind could mean delaying the progress of the disease by several years; naturally, this is very valuable not only for patients but also for their families and society.

In July, the U.S. Food and Drug Administration (FDA) accepted Eisai’s Biologics License Application (BLA) for lecanemab under the Accelerated Approval Pathway and granted Priority Review, announcing that a decision on a potential approval would come January 6, 2023 at the latest.

This decision will be followed by further applications. Our partner, Eisai, aims to file for full approval in the US as well as submitting marketing authorization applications in Japan and the EU by the end of the first quarter of 2023 at the latest. The treatment could thereby be made available to patients across large parts of the globe already in 2023 or 2024, depending on geography. Subject to approvals, Eisai has the marketing rights to lecanemab worldwide. BioArctic has the right to market lecanemab in the Nordics and preparations for this are ongoing together with Eisai. At the same time BioArctic’s work to build a commercial organization is being intensified.

Additionally, Eisai is developing a subcutaneous formulation of lecanemab to make the treatment as convenient as possible. In the ongoing AHEAD 3-45 Phase 3 study for persons with pre-symptomatic Alzheimer’s disease, the potential effects of lecanemab in slowing the progress of the disease in even earlier phases of the disease are being investigated.

I would like to extend my warmest thanks to the patients and their relatives, physicians and other hospital staff who have been involved in the Clarity AD study, as well as our partner Eisai and our fantastic employees, all our long-term shareholders, and our other partners. Without you, it would not have been possible for BioArctic to contribute to a better treatment for Alzheimer’s disease. At the same time, I would



*“The results of the Phase 3 study met all our expectations, and more.”*

like to emphasize that the company is at the start of a long journey, with the goal of generating innovative medicines that improve the lives of patients with disorders of the central nervous system. The convincing Phase 3 results for lecanemab has increased the possibility of success in our other drug projects, which are also built on our knowledge of misfolded proteins in neurodegenerative diseases. Currently, we are pursuing another five in-house projects in Alzheimer’s disease, and the Phase 1 results for our drug candidate BAN0805 against Parkinson’s disease have already proven to be promising. BioArctic is also having two projects against ALS, a severe disease that impacts the body’s ability to control muscular activity and for which there is currently no effective treatment. In parallel with this, our project to increase the ability of antibodies to enter the brain – which we call Brain Transporter – continues to progress well.

The positive Phase 3 results for lecanemab validate both Professor Lars Lannfelt’s original hypothesis on the role of soluble misfolded proteins (protofibrils) in the progress of the disease, and increase the likelihood that several of BioArctic’s other projects can succeed. Through professional, dedicated and persistent effort, we now stand before a potential breakthrough in the treatment of Alzheimer’s disease. Next year marks 20 years since the founding of BioArctic by Lars Lannfelt and Pär Gellerfors, and a few days ago we celebrated the fifth anniversary of the company’s listing. This is still only the beginning of our efforts to develop new drugs for neurodegenerative diseases, and I look forward to hopefully soon being able to help patients to a better life.

Gunilla Osswald  
CEO, BioArctic AB

## 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 developed high quality drug projects that have resulted in 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 four focus areas:

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

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 global 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 selective binding of antibodies, and elimination of the harmful soluble aggregated forms of the amyloid beta protein (oligomers/protofibrils) and the alpha-synuclein protein in the brain.

# Project portfolio

BioArctic has a balanced, competitive portfolio consisting of unique product candidates and technology platforms. 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 September 30, 2022, the project portfolio consisted of:

	Project	Partner	Research	Preclinical	Phase 1	Phase 2	Phase 3
<b>ALZHEIMER'S DISEASE</b>	Lecanemab (BAN2401) <i>Clarity AD</i>	Eisai <sup>1</sup>	Early Alzheimer's disease <sup>2</sup>				
	Lecanemab (BAN2401) <i>AHEAD 3-45</i>	Eisai <sup>1</sup>	Preclinical (asymptomatic) Alzheimer's disease <sup>3</sup>				
	BAN2401 back-up	Eisai					
	AD1801						
	AD1503						
	AD-BT2802						
	AD-BT2803						
	AD2603						
<b>PARKINSON'S DISEASE</b>	BAN0805						
	PD1601						
	PD1602						
<b>OTHER CNS DISORDERS</b>	Lecanemab (BAN2401)		Down's syndrome <sup>4</sup> Traumatic brain injury <sup>4</sup>				
	ND3014		ALS				
	ND-BT3814		ALS				
<b>BLOOD-BRAIN BARRIER</b>	Brain Transporter (BT) technology platform						

1) Partner with Eisai for lecanemab for treatment of Alzheimer's disease since 2007. Eisai entered partnership with Biogen regarding BAN2401 (lecanemab) in 2014

2) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease

3) Normal cognitive function with intermediate or elevated levels of amyloid in the brain

4) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury

## ALZHEIMER'S DISEASE

*BioArctic has developed several unique and selective antibodies with the potential to slow the progression of Alzheimer's disease. Recently, positive results from the Phase 3 study Clarity AD in early Alzheimer's disease of the most advanced drug candidate lecanemab (BAN2401) were communicated. Lecanemab is also currently being evaluated in the Phase 3 study AHEAD 3-45 for preclinical (asymptomatic) Alzheimer's disease. The development of lecanemab against Alzheimer's disease is being financed and pursued by BioArctic's partner Eisai, which also co-owns the rights to the lecanemab back-up. Eisai aims to file for full approval in the US, and apply for marketing authorization in Japan and the EU by the end of the first quarter of 2023 at the latest. BioArctic has five additional antibodies projects against Alzheimer's disease in its project portfolio. In addition, BioArctic conducts research in diagnostics to support its own projects in Alzheimer's disease.*

### Drug candidate lecanemab (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 designed to eliminate 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. The project is based on research from Uppsala University and Karolinska Institutet, Sweden.

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

Currently, lecanemab is being developed as the only late-phase anti-A $\beta$  antibody that can be used for the treatment of early Alzheimer's disease without the need to titrate the dose.

Clarity AD is a global confirmatory Phase 3 placebo-controlled, double-blind, parallel-group, randomized study in 1,795 people with early AD. The treatment group was administered lecanemab 10 mg/kg bi-weekly, with participants allocated in a 1:1 ratio to receive either placebo or lecanemab for 18 months. The study has a broad inclusion of patients to be as similar as possible to the early Alzheimer's population in society. In the study, patients with a wide range of other diseases and concurrent medication with other drugs such as anticoagulants were allowed. Eisai's recruitment strategy for the Clarity AD clinical trial ensured greater inclusion of ethnic and racial populations in the U.S., resulting in approximately 25% of the total U.S. enrollment including Hispanic and African American persons living with early AD. Due to the inclusive eligibility criteria and the successful recruitment of

diverse ethnic and racial populations in the U.S., Clarity AD's population aims to be generally comparable to the country's Medicare population.

Results from the pivotal Phase 3 study Clarity AD showed that after 18 months of treatment, lecanemab achieved the primary endpoint of reducing clinical decline from baseline on the global cognitive and functional scale CDR-SB (Clinical Dementia Rating-Sum of Boxes) compared to placebo with 27 percent, with high statistical significance ( $p=0.00005$ ). Already at 6 months and across all time points thereafter, lecanemab showed high statistical significance compared to placebo ( $p<0.01$ ) in slowing clinical decline. All secondary efficacy measures were also achieved with high statistical significance ( $p<0.01$ ). Furthermore, the safety profile of lecanemab was in line with expectations. An open-label extension study of Clarity AD is ongoing for the patients who completed the main study, to further evaluate the safety and efficacy of lecanemab.

Eisai has also conducted a Phase 1 study for subcutaneous dosing of lecanemab and the subcutaneous formulation is currently being evaluated in the open-label extension study of Clarity AD.

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 program, that was started 2020, include individuals that are clinically normal but have intermediate or elevated levels of brain amyloid and have a high risk of developing Alzheimer's disease. The program 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.

DIAN-TU has chosen to include lecanemab as the backbone anti-amyloid treatment in its NextGen-study in combination with potential tau treatments in patients with dominant hereditary Alzheimer's disease. The aim of the study is to assess the safety and tolerability of certain drug candidates as well as their effect on biomarkers and cognition in patients with hereditary Alzheimer's disease.

In 2021, lecanemab was granted Breakthrough Therapy designation and Fast Track designation by the FDA, which is a program intended to facilitate and expedite development of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition.

In early July, Eisai announced that the FDA had accepted the Biologics License Application (BLA) under the accelerated approval pathway for lecanemab. The submission is based on clinical, biomarker and safety data from the Phase 2b study in 856 people with early AD with confirmed presence of amyloid pathology, biomarker and safety data from the Phase 2b open-label extension study (180 subjects), and blinded safety data from the confirmatory Clarity AD Phase 3 study (1,795 subjects). The application was granted Priority Review with a

Prescription Drug User Fee Act (PDUFA) action date on January 6, 2023.

Eisai aims to file for traditional approval in the U.S., and to submit marketing authorization applications in Japan and Europe by the end of the first quarter 2023.

#### **Back-up candidate to lecanemab (collaboration with Eisai)**

The antibody is a refined version of lecanemab for the treatment of Alzheimer's disease. The antibody was developed 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, AD1503 and AD2603 (owned by BioArctic)**

BioArctic has three 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 have 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.

#### **Drug projects AD-BT2802 and AD-BT2803 (blood-brain barrier technology owned by BioArctic)**

BioArctic has two antibody projects against Alzheimer's disease that are being combined with the blood-brain barrier technology — Brain Transporter, or BT — to facilitate uptake of antibodies in the brain.

#### **PARKINSON'S DISEASE (OWNED BY BIOARCTIC)**

*In the Parkinson's disease treatment area, BioArctic has been collaborating with AbbVie since 2016. In the second quarter of 2022 AbbVie announced that they had taken a decision to end the collaboration for strategic reasons. BioArctic has in the third quarter 2022 agreed with AbbVie to take back the projects.*

#### **Drug candidate BAN0805 and drug projects PD1601 and PD1602**

BAN0805 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. The project is based on research from Uppsala University.

At the International Congress of Parkinson's Disease and Movement Disorders® (MDS) in September 2021, BioArctic presented preclinical results and AbbVie presented results from the Phase 1 study that support continued development of the antibody in a Phase 2 study with dosing once a month. In November 2021, *Neurobiology of Disease* published an article from BioArctic that describes new preclinical data for the anti-alpha synuclein antibody BAN0805. The article contains data

demonstrating the antibody's ability to selectively bind harmful soluble alpha-synuclein aggregates.

The PD1601 and PD1602 antibody projects are also targeted against alpha-synuclein for treatment of Parkinson's disease. The objective of the project portfolio is to develop disease-modifying treatments for Parkinson's disease, Lewy body dementia and multiple system atrophy.

In the second quarter 2022, AbbVie informed BioArctic that it had taken a strategic business decision to terminate the collaboration regarding BioArctic's alpha-synuclein project portfolio. During the third quarter, BioArctic agreed with AbbVie to take back the projects and the transfer of data is ongoing.

In May 2022, an additional drug substance patent for BAN0805 was granted in the US, which is valid until 2041, with a possible extension until 2046.

#### **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 (indications other than Alzheimer's disease, owned by BioArctic)**

Lecanemab can potentially also be used for other indications which in that case would be owned by BioArctic. The antibody is in the preclinical phase as a potential treatment of cognitive disorders in conjunction with Down's syndrome and traumatic brain injury. BioArctic has presented findings supporting that lecanemab also could be developed into a disease modifying treatment benefiting individuals with Down's syndrome with dementia.

#### **Project ND3014 and ND-BT3814 (owned by BioArctic)**

The drug projects ND3014 and ND-BT3814 are focused on developing antibody drugs against TDP-43, a protein that is believed to play a key role in the development of the rare neurodegenerative disease ALS. The ND-BT3814 project is linked to BioArctic's blood-brain barrier technology. The projects are in research phase.

#### **BLOOD-BRAIN BARRIER TECHNOLOGY (BRAIN TRANSPORTER) (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 is now developing the second generation of this technology, which has already demonstrated a profound increase in antibodies and improved exposure in the brain. The technology is now being used in three earlier projects, two against Alzheimer's disease, AD-BT2802, AD-BT2803 and one in ALS ND-BT3814. The technology has shown highly encouraging results and has significant potential for many different treatments for various diseases of the brain. Together with Uppsala University, BioArctic received grants from Sweden's Innovation Agency, Vinnova, for continued research in the blood-brain barrier project.

# 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 third quarter amounted to MSEK 218.2 (4.0). Net revenues for the nine-month period amounted to MSEK 226.2 (18.4). The increase in the quarter and in the period is mainly explained by the milestone payment of MSEK 161.5 (15 MEUR) from the strategic partner Eisai when the FDA accepted the application under the accelerated approval pathway for lecanemab. Further the final settlement of the Parkinson project that took place during the quarter contributed with MSEK 47.9 to revenues.

Other operating income relates to research grants and operating exchange rate gains. Other operating income amounted to MSEK 1.4 (0.7) in the third quarter and for the nine-month period January-September to MSEK 2.3 (3.0).

Total operating expenses for the third quarter amounted to MSEK -86.6 (-42.1) and for the nine-month period January-September to MSEK -185.3 (-121.8). Project expenses for projects fully owned by BioArctic increased due to the expanded project portfolio. The expenses for personnel for the third quarter and for the period increased. The main explanation for this is the increase in the company's share price, and consequently the value of the options on which social security contributions are calculated, which has increased the costs of the employee option program. The increase in personnel costs is also a result of an increase in the number of employees. Other external costs increased during the quarter and for the period as a result of the fact that the scope of the business has increased. 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. The external projects are owned by our partners and BioArctic has no costs for their the clinical programs.

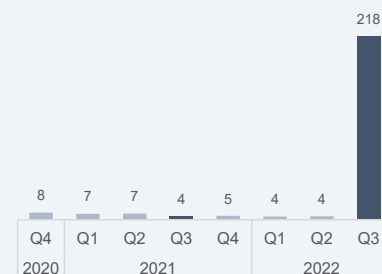
Operating profit before financial items (EBIT) amounted to MSEK 133.0 (-37.4) for the third quarter and to MSEK 43.2 (-100.4) for the nine-month period. The increase in operating profit was primarily attributable to the Eisai milestone payment but also to the final settlement of the Parkinson project.

Net financial items totaled MSEK 3.8 (-0.2) for the third quarter and to MSEK 3.5 (-0.5) for the nine-month period. Financial income consists of financial exchange rate gains on cash and equivalents and financial expenses consists of negative interest on cash and cash equivalents and interest on leasing liabilities.

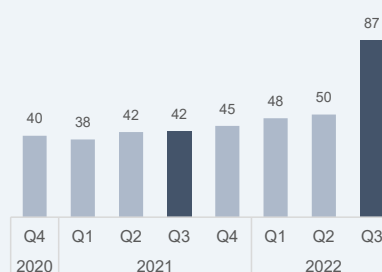
Profit (loss) amounted to MSEK 136.8 (-37.6) for the third quarter and to MSEK 46.7 (-100.8) for the nine-month period.

Earnings per share before dilution amounted to SEK 1.55 (-0.43) for the third quarter and to SEK 0.53 (-1.15) for the nine-month period. Earnings per share after dilution amounted to SEK 1.54 (-0.43) for the third quarter and to SEK 0.53 (-1.15) for the nine-month period.

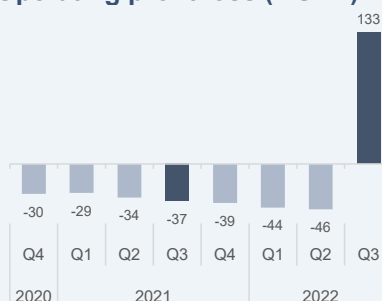
### Net revenues (MSEK)



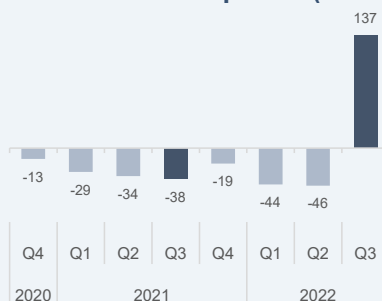
### Operating expenses (MSEK)



### Operating profit/loss (MSEK)



### Profit/loss for the period (MSEK)



## LIQUIDITY AND FINANCIAL POSITION

Equity amounted to MSEK 837.4 as of September 30, 2022 compared with MSEK 788.7 as of December 31, 2021. This corresponds to equity per outstanding share of SEK 9.51 (9.17). The equity/asset ratio was 92.5 percent as of September 30, 2022 compared with 87.9 percent as of December 31, 2021. Compared with the third quarter last year, the equity/asset ratio increased from 86.3 percent to 92.5 percent.

The Group's cash and cash equivalents consist of bank balances that at the end of the quarter amounted to MSEK 863.2 compared with MSEK 848.4 as of December 31, 2021. There were no loans as of September 30, 2022 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 111.9 (-34.8) and to MSEK 26.6 (-101.2) for the nine-month period. The main reason for the increase is related to the Eisai milestone payment.

For the third quarter cash flow from investing activities amounted to MSEK -1.4 (-1.5). For the nine-month period cash flow from investing activities amounted to MSEK -9.1 (-2.5). The investments were mainly related to laboratory equipment. Cash flow from financing activities amounted to MSEK -2.0 (-1.9) for the third quarter and to MSEK -6.1 (-5.5) for January – September and relates to the amortization of leasing liabilities.

## PARENT COMPANY

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

## EVENTS

### THE FIRST QUARTER 2022

- Eisai initiated submission of lecanemab data in Japan under the prior assessment consultation system, with the objective of obtaining fast regulatory marketing approval.

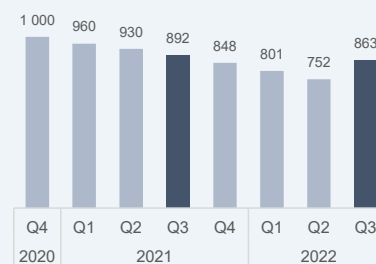
### THE SECOND QUARTER 2022

- Eisai completed the rolling submission for lecanemab for treatment of early Alzheimer's disease to the US Food and Drug Administration (FDA) under the accelerated approval pathway.
- An additional drug substance patent for BAN0805 was granted in the US, which is valid until 2041, with possible extension until 2046.
- An article in Neurology and Therapy based on disease modeling indicates that lecanemab could delay the progression to Alzheimer's dementia by several years.
- AbbVie took a strategic business decision to terminate its collaboration with BioArctic regarding its alpha-synuclein projects in Parkinson's disease. BioArctic is now working with AbbVie to bring back the projects with the intention of finding a new partner.

### THE THIRD QUARTER 2022

- Lecanemab showed positive results in the pivotal Phase 3 study, Clarity AD, conducted by Eisai in early Alzheimer's disease, achieving both primary and all key secondary endpoints with high statistical significance
- BioArctic has agreed with AbbVie to take back the projects and transfer of data is ongoing

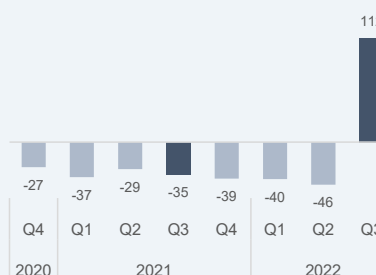
## Cash and cash equivalents (MSEK)



## Financial position (MSEK)

	30 Sep 2022	31 dec 2021
Non-current lease liabilities	1.3	7.8
Current lease liabilities	8.8	8.1
Cash and cash equivalents	863.2	848.4
<b>Net cash position</b>	<b>853.1</b>	<b>832.5</b>

## Cash flow from operating activities (MSEK)



Cash position  
(MSEK)

**863.2**



- New lecanemab data were presented by Eisai at the Alzheimer's Association International Conference (AAIC), including data regarding a subcutaneous formulation of lecanemab
- The FDA accepted the Biologics License Application (BLA) from Eisai and granted priority review of lecanemab for treatment of early Alzheimer's disease under the accelerated approval pathway, with a decision on conditional approval no later than 6 January 2023

# Other information

## 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 September 2022, BioArctic's patent portfolio consisted of 13 patent families with more than 240 granted patents and over 50 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. As of 30 September 2022, up to 136 MEUR in milestone payments remains from Eisai.

BioArctic has been collaborating with AbbVie in the field of Parkinson's disease since 2016 and over the course of the contract, BioArctic has received MUSD 130. In light of the collaboration being terminated, no further milestone payments or royalties will be paid to BioArctic from AbbVie.

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 business risks. 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 2021 on pages 56-59.

Russia's invasion of Ukraine is a tragedy, above all for the people in the war zone or who have been forced to flee. There is a great deal of uncertainty regarding how the situation will develop and how it will impact the global economy over both the short and long term. BioArctic is closely following the course of events in the world around us and is presently of the opinion that the invasion does not have any direct impact on the company's operations.

## FLUCTUATIONS IN REVENUE GENERATION

Currently, BioArctic does not have any drugs on the market. BioArctic is developing a number of drug candidates for chronic neurodegenerative diseases in partnership with global pharma companies. The company also conducts research for wholly owned projects including new potential antibody treatments 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. Milestone payments may also be paid upon submissions of applications to regulatory authorities, approvals and sales milestones. 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 and an innovative blood-brain barrier technology, 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 220 – 260 for the fiscal year January – December 2022. During 2021 operating expenses were MSEK 166. During the last three years the average annual level of the operating expenses has been approximately MSEK 170. The build-up of the commercial organization prior to the potential launch of lecanemab, and costs for the expanded in-house project portfolio, explain the expected higher level of costs for 2022.

## EMPLOYEES

At the end of the third quarter, the number of employees was 56 (49) of which 22 (19) are men and 34 (30) women. Around 80 percent work in R&D and around 70 percent are PhDs.

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 September 30, 2022, these corresponded to 12 (10) 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, 2022<sup>1</sup>

	Number		Share of (%)	
	A-shares	B-shares	capital, %	votes, %
Demban AB (Lars Lannfelt)	8,639,998	22,635,052	35.5	50.1
Ackelsta AB (Pär Gellerfors)	5,759,998	15,093,201	23.7	33.4
Fourth Swedish National Pension Fund	-	4,200,000	4.8	1.9
Swedbank Robur Funds	-	4,097,307	4.7	1.9
Third Swedish National Pension Fund	-	2,992,088	3.4	1.4
Unionen	-	2,391,835	2.7	1.1
Investment AB Öresund	-	1,320,000	1.5	0.6
Hans Edvin Öhman	-	921,777	1.1	0.4
SEB Funds	-	838,218	1.0	0.4
Handelsbanken Funds	-	825,287	0.9	0.4
<b>Tot. 10 largest shareholders</b>	<b>14,399,996</b>	<b>55,314,765</b>	<b>79.3</b>	<b>91.6</b>
Other	-	18,345,224	20.7	8.4
<b>Total</b>	<b>14,399,996</b>	<b>73,659,989</b>	<b>100.0</b>	<b>100.0</b>

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 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, 765,000 employee warrants were allocated, of which 170,000 were allocated during the first quarter 2022 and 20,000 during the second quarter 2022. No employee warrants were allocated during the third quarter. The allocation of employee warrants had a dilutive effect corresponding to 765,000 shares, or 0.9 percent, at the end of the period. More information is available on [www.bioarctic.com](http://www.bioarctic.com)

The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on October 20, 2022.

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

Stockholm, Sweden, October 20, 2022

Gunilla Osswald  
CEO, BioArctic AB (publ)

### INVITATION TO PRESENTATION OF THE REPORT FOR JULY – SEPTEMBER 2022

BioArctic invites investors, analysts, and media to an audiocast with teleconference (in English) today, October 20, 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-q3-2022>

To participate in the conference, please call:

+46 8 519 993 83 (Sweden)

+44 333 300 0804 (UK), pin code: 87560307#

+1 631 913 1422 (USA), pin code: 87560307#

### CALENDAR 2022

Full Year Report Jan-Dec 2022

February 3, 2023, at 08:00 a.m. CET

Quarterly Report Jan-Mar 2023

April 27, 2023, at 08:00 a.m. CET

Half-Year Report Jan-Jul 2023

July 12, 2023, at 08:00 a.m. CET

Quarterly Report Jan-Sep 2023

November 8, 2023, at 08:00 a.m. CET



### FOR FURTHER INFORMATION, PLEASE CONTACT

Jan Mattsson, CFO, [jan.mattsson@bioarctic.se](mailto:jan.mattsson@bioarctic.se), phone +46 70 352 27 72

Oskar Bosson, VP Communications & Investor Relations, [oskar.bosson@bioarctic.se](mailto:oskar.bosson@bioarctic.se), phone +46 70 410 71 80



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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*

# Report on Review of Interim Financial Information

## INTRODUCTION

We have reviewed the accompanying balance sheet of BioArctic AB (publ) as of September 30, 2022 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, 2022, and of its financial performance and its cash flows for the nine-month period then ended in accordance with IFRS.

Stockholm October 20, 2022

Grant Thornton Sweden AB

Mia Rutenius  
Authorized public accountant  
Auditor in charge

Therese Utengen  
Authorized public accountant

# Financial statements, Group

## CONSOLIDATED INCOME STATEMENT

kSEK	Q3		Jan-Sep		Jan-Dec
	2022	2021	2022	2021	2021
Net revenues (note 4)	218,225	3,952	226,201	18,440	23,146
Other operating income	1,408	737	2,345	2,973	3,542
<b>Operating revenues</b>	<b>219,633</b>	<b>4,689</b>	<b>228,546</b>	<b>21,413</b>	<b>26,688</b>
<b>Operating expenses</b>					
Project related expenses	-30,888	-13,884	-60,185	-38,539	-55,067
Other external expenses	-7,276	-4,784	-23,165	-17,433	-24,851
Personnel expenses	-38,087	-19,896	-83,437	-55,421	-72,499
Depreciations of tangible assets	-3,649	-3,318	-10,780	-9,854	-13,108
Other operating expenses	-6,699	-216	-7,762	-531	-886
<b>Operating expenses</b>	<b>-86,599</b>	<b>-42,098</b>	<b>-185,330</b>	<b>-121,778</b>	<b>-166,411</b>
<b>Operating profit/loss</b>	<b>133,034</b>	<b>-37,409</b>	<b>43,216</b>	<b>-100,365</b>	<b>-139,723</b>
Financial income	3,918	37	4,107	154	194
Financial expenses	-157	-214	-619	-679	-984
<b>Profit/loss before tax</b>	<b>136,795</b>	<b>-37,586</b>	<b>46,704</b>	<b>-100,890</b>	<b>-140,512</b>
Tax	-4	15	-5	56	20,722
<b>Profit/loss for the period</b>	<b>136,791</b>	<b>-37,571</b>	<b>46,699</b>	<b>-100,834</b>	<b>-119,789</b>
<b>Earnings per share</b>					
Earnings per share before dilution, SEK	1.55	-0.43	0.53	-1.15	-1.36
Earnings per share after dilution, SEK	1.54	-0.43	0.53	-1.15	-1.36

## SOLIDATED INCOME STATEMENT CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

kSEK	Q3		Jan-Sep		Jan-Dec
	2022	2021	2022	2021	2021
Profit/loss for the period	136,791	-37,571	46,699	-100,834	-119,789
Other comprehensive income	-	-	-	-	-
<b>Comprehensive income for the period</b>	<b>136,791</b>	<b>-37,571</b>	<b>46,699</b>	<b>-100,834</b>	<b>-119,789</b>

**CONSOLIDATED BALANCE SHEET**

kSEK	30 Sep 2022	30 Sep 2021	31 dec 2021
<b>Assets</b>			
Tangible fixed assets	21,119	16,373	16,963
Right-to-use assets	11,356	18,678	16,785
Deferred tax assets	602	607	608
Other financial assets	1,595	1,588	1,588
Current assets excluding cash and cash equivalents	7,745	6,451	13,380
Cash and cash equivalents	863,159	891,525	848,405
<b>Total assets</b>	<b>905,577</b>	<b>935,222</b>	<b>897,730</b>
<b>Equity and liabilities</b>			
Equity	837,400	807,185	788,676
Deferred tax liabilities	-	20,666	-
Non-current lease liabilities	1,345	9,783	7,785
Current lease liabilities	8,820	8,030	8,092
Other current liabilities	11,143	11,537	15,737
Accrued expenses and deferred income	46,868	78,021	77,438
<b>Equity and liabilities</b>	<b>905,577</b>	<b>935,222</b>	<b>897,730</b>

**CONSOLIDATED STATEMENT OF CHANGE IN EQUITY (CONDENSED) <sup>1</sup>**

kSEK	30 Sep 2022	30 Sep 2021	31 dec 2021
Opening balance at 1 January	788,676	907,299	907,299
Correction of opening balance	-	-402	-402
Comprehensive income for the period	46,699	-100,834	-119,789
Share-based payments	2,025	1,121	1,567
<b>Closing balance</b>	<b>837,400</b>	<b>807,185</b>	<b>788,676</b>

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

kSEK	Q3		Jan-Sep		Jan-Dec
	2022	2021	2022	2021	2021
Operating profit	133,034	-37,409	43,216	-100,365	-139,723
Adjustment for non-cash items	-49,200	1,713	-44,977	3,670	5,230
Interest received/paid	-157	-178	-619	-526	-597
Income tax paid	-439	-425	779	116	-309
<b>Cash flow from operating activities before changes in working capital</b>	<b>83,239</b>	<b>-36,299</b>	<b>-1,601</b>	<b>-97,105</b>	<b>-135,398</b>
Change in working capital	28,681	1,527	28,171	-4,098	-5,059
<b>Cash flow from operating activities after changes in working capital</b>	<b>111,919</b>	<b>-34,772</b>	<b>26,569</b>	<b>-101,203</b>	<b>-140,457</b>
<b>Cash flow from investing activities</b>	<b>-1,369</b>	<b>-1,530</b>	<b>-9,054</b>	<b>-2,524</b>	<b>-4,412</b>
<b>Cash flow from financing activities</b>	<b>-1,977</b>	<b>-1,917</b>	<b>-6,086</b>	<b>-5,453</b>	<b>-7,388</b>
<b>Cash flow for the period</b>	<b>108,573</b>	<b>-38,219</b>	<b>11,429</b>	<b>-109,180</b>	<b>-152,257</b>
Cash and cash equivalents at beginning of period	751,750	929,570	848,405	999,940	999,940
Exchange rate differences in cash and cash equivalents	2,836	174	3,325	765	723
<b>Cash and cash equivalents at end of period</b>	<b>863,159</b>	<b>891,525</b>	<b>863,159</b>	<b>891,525</b>	<b>848,405</b>

1) A minor error was discovered during the transition to a new system for translation in accordance with IFRS 16, which affects the opening balance for equity 2021 by MSEK 0.4, corresponding to 0.05%.

## CONSOLIDATED QUARTERLY DATA

MSEK	2022 Q3	2022 Q2	2022 Q1	2021 Q4	2021 Q3	2021 Q2	2021 Q1	2020 Q4
<b>Income statement</b>								
Net revenues	218	4	4	5	4	7	7	8
Other operating income	1	0	1	1	1	1	2	1
Operating expenses	-87	-50	-48	-45	-42	-42	-38	-40
Operating profit/loss	133	-46	-44	-39	-37	-34	-29	-30
Operating margin, %	61.0	neg	neg	neg	neg	neg	neg	neg
Profit/loss for the period	137	-46	-44	-19	-38	-34	-29	-13
<b>Balance sheet</b>								
Fixed assets	35	37	39	36	37	39	40	42
Current assets	8	6	7	13	6	5	5	8
Cash and cash equivalents	863	752	801	848	892	930	960	1,000
Equity	837	700	745	789	807	844	879	907
Deferred tax liabilities	-	-	-	-	21	21	21	21
Lease liabilities	10	12	14	16	18	19	19	21
Current liabilities	58	82	88	93	90	89	87	102
<b>Cash flow</b>								
From operating activities	112	-46	-40	-39	-35	-29	-37	-27
From investing activities	-1	-2	-6	-2	-2	-0	-1	-7
From financing activities	-2	-2	-2	-2	-2	-2	-2	-1
Cash flow for the period	109	-49	-48	-43	-38	-31	-40	-35
<b>Key ratios</b>								
Equity/asset ratio, %	92.5	88.1	88.0	87.9	86.3	86.7	87.3	86.4
Return on equity, %	17.8	-6.3	-5.8	-2.4	-4.5	-4.0	-3.3	-1.4
<b>Data per share</b>								
Earnings per share before dilution, SEK	1.55	-0.52	-0.50	-0.22	-0.43	-0.39	-0.33	-0.15
Earnings per share after dilution, SEK	1.54	-0.52	-0.50	-0.22	-0.43	-0.39	-0.33	-0.15
Equity per share, SEK	9.51	7.95	8.46	8.96	9.17	9.59	9.98	10.30
Cash flow operating activities per share, SEK	1.27	-0.52	-0.45	-0.45	-0.39	-0.33	-0.43	-0.30
Share price at the end of the period, SEK	271.60	77.45	103.20	119.20	162.60	137.80	91.00	95.40
Number of shares outstanding at the end of the period, thousands	88,060	88,060	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding before dilution, thousands	88,060	88,060	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding after dilution, thousands	88,690	88,577	88,605	88,610	88,585	88,560	88,560	88,332

## NSOLIDATED QUARTERLY DATA



# Financial statements, Parent company

## PARENT COMPANY INCOME STATEMENT

kSEK	Q3		Jan-Sep		Jan-Dec
	2022	2021	2022	2021	2021
Net revenues	218,225	3,952	226,201	18,440	23,146
Other operating income	1,408	737	2,345	2,973	3,542
<b>Operating revenues</b>	<b>219,633</b>	<b>4,689</b>	<b>228,546</b>	<b>21,413</b>	<b>26,688</b>
<b>Operating expenses</b>					
Project related expenses	-30,888	-13,884	-60,185	-38,539	-55,067
Other external expenses	-9,458	-6,899	-29,710	-23,693	-33,224
Personnel expenses	-38,087	-19,896	-83,437	-55,421	-72,499
Depreciations of tangible assets	-1,694	-1,424	-4,920	-4,244	-5,604
Other operating expenses	-6,699	-216	-7,762	-531	-885
<b>Operating expenses</b>	<b>-86,826</b>	<b>-42,319</b>	<b>-186,014</b>	<b>-122,428</b>	<b>-167,279</b>
<b>Operating profit/loss</b>	<b>132,806</b>	<b>-37,630</b>	<b>42,532</b>	<b>-101,015</b>	<b>-140,591</b>
Financial income	3,918	37	4,107	154	194
Financial expenses	-29	-10	-175	-25	-145
<b>Profit/loss after financial items</b>	<b>136,695</b>	<b>-37,603</b>	<b>46,464</b>	<b>-100,886</b>	<b>-140,542</b>
Change in tax allocation reserves	-	-	-	-	94,809
<b>Profit/loss before tax</b>	<b>136,695</b>	<b>-37,603</b>	<b>46,464</b>	<b>-100,886</b>	<b>-45,733</b>
Tax	17	19	45	55	63
<b>Profit/loss for the period</b>	<b>136,712</b>	<b>-37,584</b>	<b>46,508</b>	<b>-100,830</b>	<b>-45,670</b>

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)

kSEK	30 Sep 2022	30 Sep 2021	31 dec 2021
<b>Assets</b>			
Tangible fixed assets	21,119	16,373	16,963
Deferred tax assets	433	380	388
Other financial assets	1,645	1,638	1,638
Current assets excluding cash and cash equivalents	9,759	8,417	15,353
Cash and cash equivalents	863,115	891,478	848,359
<b>Total assets</b>	<b>896,071</b>	<b>918,286</b>	<b>882,702</b>
<b>Equity and liabilities</b>			
Equity	838,059	733,919	789,526
Tax allocation reserve	-	94,809	-
Other current liabilities	11,143	11,537	15,737
Accrued expenses and deferred income	46,868	78,021	77,438
<b>Equity and liabilities</b>	<b>896,071</b>	<b>918,286</b>	<b>882,702</b>

# Notes

## NOTE 1 GENERAL INFORMATION

This interim report for the period January – September 2022 covers the Swedish Parent Company BioArctic AB (publ), 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. BioArctic is a Swedish limited liability company registered in and with its registered office in Stockholm. The head office is located at Warfvings väg 35, SE-112 51, Stockholm, Sweden.

## NOTE 2 ACCOUNTING PRINCIPLES

The consolidated financial statements for BioArctic AB (publ) 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 2022 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 2021. New and amended IFRS standards and interpretations applied from 2022 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

kSEK	Q3		Jan-Sep		Jan-Dec
	2022	2021	2022	2021	2021
<b>Geographic breakdown of net revenues</b>					
Europe	54,530	1,863	58,478	6,540	8,466
Asia	163,695	2,089	167,723	11,900	14,681
<b>Total net revenues</b>	<b>218,225</b>	<b>3,952</b>	<b>226,201</b>	<b>18,441</b>	<b>23,147</b>
<b>Net revenues per revenue type</b>					
Milestone payments, recognized at a given point in time	161,460	-	161,460	-	-
Income from research collaborations, recognized over time	56,765	3,952	64,741	18,441	23,147
<b>Total net revenues</b>	<b>218,225</b>	<b>3,952</b>	<b>226,201</b>	<b>18,441</b>	<b>23,147</b>

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

In the third quarter, BioArctic received and recognized as revenue a milestone payment of MSEK 161.5 (15 MEUR) from Eisai relating to the FDA's acceptance of the BLA for lecanemab under the accelerated approval pathway.

The research collaboration agreement with Eisai refers to the period July 2022 to June 2023, which is an extension of the agreement that ended in June 2022. The revenue for the research collaboration is recognized over time based on the fulfillment of the performance obligation. In the third quarter MSEK 2.2 (2.1) was recognized as revenue. For the nine-month period MSEK 6.3 (11.9) was recognized.

Under the collaboration agreement with AbbVie regarding BAN0805, 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 within Parkinson disease that BioArctic was to 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 was accrued based on the costs incurred up until the completion of the project that took place in the third quarter of 2022.

In the second quarter of 2022, AbbVie terminated its collaboration agreement with BioArctic regarding BioArctic's alpha-synuclein project portfolio due to strategic reasons.

During the third quarter of 2022, BioArctic and AbbVie executed a Transition Agreement regarding transfer of the projects to BioArctic and granting BioArctic an exclusive license to AbbVie's know-how developed during the collaboration directly related to BAN0805.

As part of this agreement, AbbVie has the right to receive a low single-digit royalty percentage on global sales if any products developed under AbbVie's license reach the market. AbbVie is not entitled to any milestone payments.

The transfer of data under this Transition Agreement is ongoing.

During the third quarter, MSEK 54.5 (1.9) was recognized as revenue of which MSEK 47.9 as a one-time effect related to the settlement of the project. For the nine-month period MSEK 58.5 (6.5) was recognized as revenue. As of September 30, 2022, consequently the entire payment of MSEK 701.6 has been recognized as revenue.

#### NOTE 5 PLEDGED ASSETS AND CONTINGENT LIABILITIES

During the third quarter, a new contingent liability has been identified:

- BioArctic has agreed with previous partner that if BAN0805 reaches the market, a payment obligation will arise towards the contracting party regarding a low single-digit percentage in royalties on global sales. The commitment is far in the future and is time-limited.

## 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

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Equity per share

Adjusted equity divided by the number of shares at the end of the period

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# Glossary

## Accelerated approval

An application process which gives an opportunity for an early approval of a drug candidate, where the company at a later stage is required to present additional data to verify clinical effect in order to receive full marketing approval.

## Alfa-synuclein ( $\alpha$ -synuclein)

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

## Amyloid beta ( $A\beta$ )

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.

## Breakthrough therapy designation

The breakthrough therapy designation is an FDA program intended to facilitate and accelerate the development and review of drugs for serious or life-threatening conditions.

## 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.

## 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.

## Fast Track Designation

Fast Track designation is an FDA program intended to facilitate and expedite the development and review of drugs for serious or life-threatening conditions.

## FDA

The US Food and Drug Administration.

## Licensing

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 disease

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

## Oligomer

Molecules consisting of a number of monomers.

## Open-label extension study

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

## Pathology

The study of diseases and how they are diagnosed, through analysis of molecules, cells, tissues and organs.

## Phase 1 studies

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

**Phase 2 studies**

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

**Phase 3 studies**

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

**Placebo-controlled**

A study design in research which means that some of the patients receive inactive compound to obtain a relevant control 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 and gives rise to Parkinson's disease.

**Research phase**

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

**Selective binding**

The affinity of a molecule for binding to a specific receptor.

**Subcutaneous treatment**

That the drug is given to the patient through an injection under the skin.

**Titration of dose**

Stepwise increase in medication dose in order to achieve a certain beneficial effect with a delay with the aim of reducing the risk of side effects.

**Tolerability**

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

**Truncated amyloid beta**

Shortened (truncated) forms of the amyloid beta protein.

