



# The US FDA approved Leqembi™ under the accelerated approval pathway for the treatment of Alzheimer's disease

### **EVENTS DURING THE FOURTH QUARTER 2022**

- Detailed and positive lecanemab data from the Phase 3 study, Clarity AD, were presented by Eisai at the CTAD Alzheimer Congress. The results were simultaneously published in the New England Journal of Medicine
- BioArctic started the two new projects, PD-BT2238, a selective antibody against soluble alpha-synuclein aggregates, and GD-BT6822, an enzyme replacement therapy for Gaucher's disease. Both projects are combined with the company's Brain Transporter technology

### **EVENTS AFTER THE END OF THE PERIOD**

- FDA approved lecanemab (name Leqembi) via the accelerated approval pathway for treatment of early Alzheimer's disease
- BioArctic's partner Eisai submitted a supplemental Biologics License Application in the US to FDA for full approval of Leqembi for the treatment of early Alzheimer's disease and submitted Marketing Authorization Applications in the EU and Japan. The submissions in the EU and Japan were also accepted and the one in Japan was granted priority review
- The approval in the US and submissions in the EU and Japan entitles BioArctic to milestones of MEUR 35 in total

### FINANCIAL SUMMARY OCTOBER - DECEMBER 2022

- Net revenues for the period amounted to MSEK 2.1 (4.7)
- Operating profit amounted to MSEK -60.7 (-39.4)
- Profit for the period amounted to MSEK -57.9 (-19.0)
- Earnings per share before and after dilution were SEK -0.66 (-0.22)
- Cash flow from operating activities amounted to MSEK -58.2 (-39.3)
- Cash and cash equivalents at the end of the period amounted to MSEK 805 (848)

### FINANCIAL SUMMARY JANUARY - DECEMBER 2022

- Net revenues for the period amounted to MSEK 228.3 (23.1)
- Operating profit amounted to MSEK -17.4 (-139.7)
- Profit for the period amounted to MSEK -11.2 (-119.8)
- Earnings per share before and after dilution were SEK -0.13 (-1.36)
- Cash flow from operating activities amounted to MSEK -31.6 (-140.5)
- Cash and cash equivalents at the end of the period amounted to MSEK 805 (848)

### **KEY FINANCIAL PERFORMANCE INDICATORS**

	Q	Q4		Dec
MSEK	2022	2021	2022	2021
Net revenues	2.1	4.7	228.3	23.1
Other operating income	-0.8	0.6	1.6	3.5
Operating profit/loss	-60.7	-39.4	-17.4	-139.7
Operating margin, %	neg	neg	neg	neg
Profit/loss for the period	-57.9	-19.0	-11.2	-119.8
Earnings per share before dilution, SEK	-0.66	-0.22	-0.13	-1.36
Earnings per share after dilution, SEK	-0.66	-0.22	-0.13	-1.36
Equity per share, SEK	8.92	8.96	8.92	8.96
Cash flow from operating activities	-58.2	-39.3	-31.6	-140.5
Cash flow from operating activities per share, SEK	-0.66	-0.45	-0.36	-1.60
Equity/assets ratio, %	91.6	87.9	91.6	87.9
Return on equity, %	-7.13	-2.38	-1.42	-14.13
Share price at the end of the period, SEK	272.00	119.20	272.00	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

2022 had every opportunity to become a successful year for BioArctic. Looking back, it's clear that this was the case.

On November 29, our partner Eisai presented the excellent results from the Clarity AD Phase 3 study with lecanemab in patients with early Alzheimer's disease at the CTAD conference in San Francisco. At the same time, the New England Journal of Medicine published the results, which confirmed the data previously announced. The results showed that the primary and all secondary endpoints were met with high statistical significance, and that the safety profile was in line with expectations. The results are clinically relevant, and important to patients, their families, and society. A modelling study, based on the Phase 2b study, published in the spring of 2022 showed that the progression of the disease can be slowed and that the late stages can be delayed by about three years.

The focus is now on providing patients access to lecanemab as quickly as possible. It is impressive to see how well Eisai prepared for the regulatory procedures around the globe. Shortly after the end of the quarter, Eisai announced that the US Food and Drug Administration had approved lecanemab via the accelerated approval pathway. The approval was based on data from the Phase 2b study, and on the same day Eisai submitted a supplementary biologics license application to the FDA for full approval. Full approval is a prerequisite for a broader reimbursement of Leqembi, which is the brand name for lecanemab in the US. As a result of the accelerated approval in the US, Legembi became available to patients in the country already in January. Eisai has announced a gradual launch strategy with the goal of making the drug available to as many patients as possible of those who could benefit from the treatment.

Early 2023, Eisai also submitted applications for market approval in the EU and Japan. In China, the application process was started at the end of last year and lecanemab was registered as Category 1, which indicates that China is highly committed to Alzheimer's disease and that lecanemab is regarded as an innovative product. All in all, the regulatory development means that BioArctic will receive milestone payments of MEUR 35 from Eisai.

BioArctic has right to commercialize lecanemab in the Nordics under certain conditions and the ramp-up of our Nordic marketing organization continues.

The successes of lecanemab in 2022 have further strengthened BioArctic, supporting the continued development of our project portfolio in neurodegenerative diseases. At present, BioArctic's experienced researchers and drug developers are involved primarily in our preclinical projects as well as the company's Brain Transporter (BT) technology. Several advances were made and new projects started during the quarter. In parallel with the advance and expansion of our project portfolio, we are continuously prepared to re-prioritize, and at the end of the year we made a



"The successes of 2022 have strengthened us ahead of the continued development of our attractive project portfolio in neurodegenerative diseases."

data-driven decision to discontinue the AD1801 project in Alzheimer's disease.

In November, BioArctic obtained an additional patent in the US for our BT technology, and we initiated a new project in which we are combining BT with an enzyme that needs to be transported into the brain in patients who are suffering from Gaucher disease. During the quarter, our project portfolio also expanded with the PD-BT2238 project in Parkinson's disease, where we combine BT with a selective antibody targeted at soluble alpha-synuclein aggregates. Moreover, we have nominated a drug candidate in the AD1503 Alzheimer's project, which means it is now renamed BAN1503. The plan is to also develop this molecule further toward truncated forms of Aß in combination with BT, under the project name AD-BT2803. The successful development of this technology means that combination projects are being pursued in all of our priority indications, generating the potential to further increase the efficacy and value of our drug candidates.

BioArctic turns 20 this year, and barely five years after listing, BioArctic qualified for Nasdaq Stockholm Large Cap. It is astonishing to think that patients with Alzheimer's disease now can have the opportunity of an effective treatment, affecting the underlying disease. At the same time, it is incredibly motivating to imagine the future potential we have to help even more critically ill patients who are suffering from various neurodegenerative diseases. We will continue to work in the efficient, creative, and scientifically-driven manner that has become BioArctic's signature – because for the patient, every day matters.

Gunilla Osswald CEO, BioArctic AB

### BioArctic in short

BioArctic AB (publ) is a Swedish biopharma company which, based on ground-breaking research, develops new drugs that can delay or stop the course of a disease for patients with neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease and other neurological diseases. The company was founded in 2003 based on innovative research from Uppsala University and Karolinska Institute. BioArctics B-share is listed on Nasdaq Stockholm Large Cap (short name BIOA B).

## Strategy for sustainable growth

BioArctic's vision is to, through research, create pharmaceutical drugs that improve life for patients with severe diseases and become a world-leading biopharma company in neurodegenerative diseases. Our work is based on groundbreaking scientific discoveries, and the company's scientists collaborate with strategic partners such as research groups at universities and major pharmaceutical companies.

BioArctic is a biopharma company that develops, markets and sells disease-modifying drugs against difficult-to-treat neurodegenerative diseases. Within the company, we have vast experience from scientific excellence as well as drug development from idea to market. Under BioArctic's business model, the company pursues project development internally, and, at an appropriate juncture, seeks to license out commercial rights and development to pharmaceutical companies. Based on BioArctic's core competencies in biological understanding of neurodegenerative diseases, antibody and protein technology, the company develops new improved product candidates for i.a, Alzheimer's disease, Parkinson's disease and ALS.

BioArctic's business model contributes to creating revenue and shareholder value for the company by:

- -licensing out proprietary drug candidates
- -marketing and selling pharmaceutical drugs in the Nordics and eventually also in the rest of Europe

### Three important cornerstones of BioArctic's strategy are:

- CONTINUE supporting partnered projects with great 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

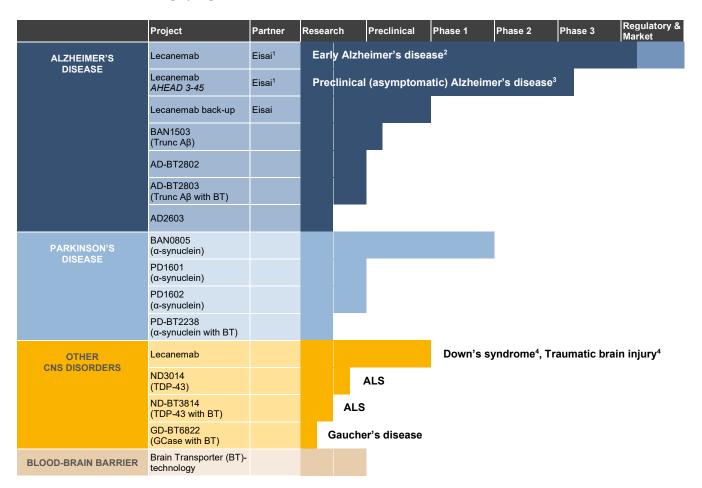
Neurodegenerative disorders are conditions in which cells in the brain degenerate and die. Normally the neurodegenerative processes begin long before any symptoms appear. Neurodegenerative disorders affect the lives of millions of people and constitute a growing global health care problem.

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 market.

As of December 31, 2022, the project portfolio consisted of:



- 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. In early 2023, Eisai receive an accelerated approval for lecanemab in the US and also applied for full approval, and submitted applications for marketing authorizations in the EU and Japan. Eisai began the submission of data for Biologics License Application (BLA) to the National Medical Products Administration (NMPA) of China for lecanemab) in December 2022. BioArctic has four 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.

Clarity AD was 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.

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). For patients, this could equal remaining in the earlier stages of the disease for an additional 2.5-3.1 years, according to a modeling study, based on the Phase 2b study, published in the spring of 2022. 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).

Notably, lecanemab slowed functional deterioration by 37 percent as measured by the ADCS MCI-ADL scale, which measures how well the patient manages activities in daily life, and positively affected biomarkers for amyloid, tau and neurodegeneration. This shows that lecanemab affects the underlying disease.

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.

On January 6, 2023, lecanemab (Brand Name in the U.S.: LEQEMBI<sup>TM</sup>) was granted accelerated approval by the U.S. Food and Drug Administration (FDA) under the accelerated approval pathway. The FDA has assigned the suffix –irmb to lecanemab.

The approval was 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 approval resulted in a milestone payment to BioArctic from Eisai amounting to EUR 25 million. The payment will be recognized as revenue and received in the first quarter of 2023.

On January 6 2023, Eisai submitted an application for full approval to the FDA in the US. Further Eisai submitted applications for marketing authorization in the EU on January 9 2023, and in Japan on January 16. In conjunction with the submission in Japan, and formal acceptance of the application in the EU, BioArctic is entitled to a milestone payment of EUR 5 million per region, i.e., a total of EUR 10 million. The payment will be recognized as revenue and received during the first quarter of 2023.

In China, Eisai initiated submission of data for BLA to the National Medical Products Administration (NMPA) of China in December 2022.

### Lecanemab back-up candidate (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 BAN1503 and AD2603 (owned by BioArctic)

BioArctic has two additional antibody projects against Alzheimer's disease in its project portfolio in research phase. These antibodies have the potential to become a disease-modifying treatments for Alzheimer's disease. BAN1503 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. During the quarter a drug candidate was nominated for the project.

## 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. AD-BT2803 target a shorter (truncated) form of amyloid beta (pE3-A $\beta$ ) and are linked to the company's project BAN1503.

### PARKINSON'S DISEASE (owned by BioArctic)

In Parkinson's disease, BioArctic has a portfolio of potential disease-modified antibodies against alpha-synuclein. BAN0805 is a monoclonal antibody that selectively binds to and eliminates neurotoxic alpha-synuclein oligomers.

## 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, preclinical results and results from the Phase 1 study that support continued development of the antibody in a Phase 2 study with dosing once a month were presented. 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 alphasynuclein 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. At the end of 2022, BioArctic expanded the project portfolio in Parkinson's disease with project PD-BT2238, which combines a selective antibody directed against soluble alpha-synuclein aggregates (so-called oligomers) with BioArctic's Brain Transporter technology.

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.

BioArctic is currently working on various options, including a new partnership, to take the project forward.

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 NEURODEGENERATIVE DISEASES

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, ND-BT3814 and GD-BT6822 (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. During the end of the year, BioArctic's project portfolio was expanded with a new project focused on enzyme replacement therapy for Gaucher disease in combination with the company's Brain Transporter technology.

## 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 five earlier projects, two against Alzheimer's disease, AD-BT2802, AD-BT2803, one in Parkinson's disease, PD-BT2238, one in ALS, ND-BT3814, and one in Gaucher's disease, GD-BT6822. 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 fourth quarter amounted to MSEK 2.1 (4.7). Net revenues for the full year January – December amounted to MSEK 228.3 (23.1). The increase for the full year is mainly explained by the milestone payment of MSEK 161.5 (MEUR 15) from the strategic partner Eisai when the FDA accepted the application under the accelerated approval pathway for lecanemab in the third quarter. Further the final settlement of the Parkinson project that took place in the third quarter contributed with MSEK 47.9 to revenues.

Other operating income relates to research grants, operating exchange rate gains and forwarded costs. Other operating income amounted to MSEK -0.8 (0.6) in the fourth quarter and for the full year to MSEK 1.6 (3.5).

Total operating expenses for the fourth quarter amounted to MSEK -62.0 (-44.6) and for the full year to MSEK -247.3 (-166.4). Project expenses for projects fully owned by BioArctic increased during 2022 due to the expanded project portfolio. The expenses for personnel for the fourth quarter and for the full year increased. The main explanation for this is that the company's share price, and consequently the value of the options on which social security contributions are calculated, 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 the clinical programs.

Operating profit before financial items (EBIT) amounted to MSEK -60.7 (-39.4) for the fourth quarter and to MSEK -17.4 (-139.7) for the full year January - December. The increase in operating profit for the full year was primarily attributable to the Eisai milestone payment but also to the final settlement of the Parkinson project.

Net financial items totaled MSEK 2.8 (-0.3) for the fourth quarter and to MSEK 6.3 (-0.8) for the full year. 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 -57.9 (-19.0) for the fourth quarter and to MSEK -11.2 (-119.8) for the full year January - December.

Earnings per share before and after dilution amounted to SEK -0.66 (-0.22) for the fourth quarter and to SEK -0.13 (-1.36) for the full year.



### LIQUIDITY AND FINANCIAL POSITION

Equity amounted to MSEK 786.2 as of December 31, 2022 compared with MSEK 788.7 as of December 31, 2021. This corresponds to equity per outstanding share of SEK 8.92 (8.96). The equity/asset ratio was 91.6 percent as of December 31, 2022 compared with 87.9 percent as of December 31, 2021.

The Group's cash and cash equivalents consist of bank balances that at the end of the quarter amounted to MSEK 805.4 compared with MSEK 848.4 as of December 31, 2021. There were no loans as of December 31, 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 fourth quarter amounted to MSEK -58.2 (-39.3) and to MSEK -31.6 (-140.5) for the full year January – December 2022. The main reason for the increase for the full year is related to the Eisai milestone payment received in the third quarter.

For the fourth quarter cash flow from investing activities amounted to MSEK -3.7 (-1.9). For the full year cash flow from investing activities amounted to MSEK -12.8 (-4.4). The investments were mainly related to laboratory equipment. Cash flow from financing activities amounted to MSEK 3.3 (-1.9) for the fourth quarter and to MSEK -2.8 (-7.4) for January – December and relates to the amortization of leasing liabilities and the share issue connected to exercised employee warrants in the fourth quarter.

### **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.
- BioArctic has agreed with AbbVie to take back the projects and transfer of data is ongoing
- New lecanemab data were presented by Eisai at the Alzheimer's Association International Conference (AAIC), including data regarding a subcutaneous formulation of lecanemab

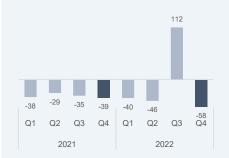
### Cash and cash equivalents (MSEK)



### Financial position (MSEK)

	31 Dec	31 dec
	2022	2021
Non-current lease liabilities	1.2	7.8
Current lease liabilities	8.9	8.1
Cash and cash equivalents	805.4	848.4
Net cash position	795.3	832.5

## Cash flow from operating activities (MSEK)





 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. FDAs acceptance entitled BioArctic to a milestone payment from Eisai of MEUR 15

### **THE FOURTH QUARTER 2022**

- New lecanemab data including the Phase 3 study, Clarity AD, were presented by Eisai at the CTAD Alzheimer Congress. The results were simultaneously published in the New England Journal of Medicine
- BioArctic started the two new projects, PD-BT2238, a selective antibody directed against soluble alpha-synuclein aggregates, and GD-BT6822, an enzyme replacement therapy for Gaucher's disease. Both projects are combined with the company's Brain Transporter technology
- The number of shares in the company increased by 71.586 as a result of the subscription of shares by participants in the staff warrant program 2019/2028
- · BioArctic's partner Eisai began submission of data for Biologics License Application (BLA) for lecanemab in China

### Other information

### **EVENTS AFTER THE YEAR END**

- BioArctic was as of January 2, 2023 moved to Nasdaq
   Stockholm's marketplace for large companies (Large cap)
- FDA approved Leqembi via the accelerated approval pathway for the treatment of early Alzheimer's disease
- BioArctic's partner Eisai submitted a supplemental registration application to FDA for full approval of Leqembi for the treatment of Alzheimer's disease and applied for marketing authorization in the EU and Japan. The application in Japan has been granted Priority

  Review
- The approval in the US and submissions in the EU and Japan entitles BioArctic to milestones of MEUR 35 in total
- BioArctic's Chairman of the Board of Directors, Wenche Rolfsen, informed the Nomination Committee that she declines re-election at the company's Annual General Meeting on June 1, 2023. The Nomination Committee has started the work to find a replacement
- During the first quarter of 2023 the subsidiary BioArctic Denmark ApS was formed

#### **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 December 2022, BioArctic's patent portfolio consisted of 13 patent families with more than 240 granted patents and over 70 ongoing patent applications.

### PARTNERSHIPS, COLLABORATIONS AND MAJOR AGREEMENTS

Collaborations and license agreements with leading pharma and biopharma companies are an important part of BioArctic's strategy. In addition to financial compensation, BioArctic benefits from the expertise the company's partners contribute in drug development, manufacturing and commercialization. BioArctic has entered into a number of such agreements with the Japanese global pharma company Eisai and the American global biopharma company AbbVie. These strategic partnerships with leading global companies confirm that BioArctic's research is of very high quality. In the future BioArctic may enter into additional agreements that can contribute further funding and research and development competence for BioArctic's product candidates in preclinical and clinical phase, manufacturing and marketing competence, geographic coverage and other resources.

BioArctic has been collaborating with Eisai in the field of Alzheimer's disease since 2005. The company has signed research and licensing agreements concerning the lecanemab and BAN2401 back-up antibodies. The total value of these agreements may amount to MEUR 222 in addition to royalties. As of 31 December 2022, up to 136 MEUR in

milestone payments remains from Eisai, of which MEUR 35 will be recognized as revenue in the first quarter of 2023. After that, milestone payments of up to MEUR 101 remain.

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 and BioArctic is closely following the course of events in the world around us. The assessment is that the invasion does not have any direct impact on the company's operations.

The macroeconomic situation in the world is characterized by rising interest and cost inflation. BioArctic has no loans and, as a result of its business operation, has a limited impact from the above macroeconomic factors.

### **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 330 – 380 for the fiscal year January – December 2023. During 2022 operating expenses were MSEK 247, which was in line with earlier communicated expectation. During the last three years the average annual level of the operating expenses has been approximately MSEK 188. 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 2023.

### **EMPLOYEES**

At the end of the fourth quarter, the number of employees was 61 (49) of which 24 (19) are men and 37 (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 December 31, 2022, these corresponded to 7 (11) full-time positions.

### **ANNUAL GENERAL MEETING 2023**

BioArctic's Annual General Meeting will take place on June 1 at 16:30. More details about the meeting will be presented in more detail in a notice.

### **NOMINATION COMMITTEE**

In accordance with the resolution at the 2022 AGM, the Nomination Committee for the 2023 AGM has been appointed and announced. The Nomination Committee consists of: Jannis Kitsakis, Chairman (Fourth Swedish National Pension Fund), Margareta Öhrvall (Demban AB) and Claes Andersson (Ackelsta AB). The company's chairman Wenche Rolfsen is co-opted in the nomination committee.

### **DIVIDEND**

The Board proposes that no dividend be paid for the 2021 financial year.

### THE SHARE AND SHAREHOLDINGS

The share capital in BioArctic amounts to SEK 1,762,632 divided by 88,131,571 shares which is split between 14,399,996 A-shares and 73,731,575 B-shares. The number of shares increased during the fourth quarter by 71,586 shares as a result of the subscription of shares by participants in the employee warrent program 2019/2028. The quotient value for both A- and B-shares is SEK 0.02. The A-share has 10 votes per share and the B-share has 1 vote per share.

### LARGEST SHAREHOLDERS AS OF DECEMBER 31, 2022<sup>1</sup>

	Nun	Number		of (%)
	A-shares	B-shares	capital,	votes, %
Demban AB (Lars Lannfelt)	8,639,998	20,885,052	33.5	49.3
Ackelsta AB (Pär Gellerfors)	5,759,998	13,343,201	21.7	32.6
Fourth Swedish National Pension Fund	-	3,713,640	4.2	1.7
Swedbank Robur Funds	-	3,592,454	4.1	1.6
Third Swedish National Pension Fund	-	3,297,088	3.7	1.5
Handelsbanken Funds	-	2,263,611	2.6	1.0
Unionen	-	2,200,000	2.5	1.0
Nordea Funds	-	1,056,394	1.2	0.5
Investment AB Öresund	-	1,000,000	1.1	0.5
SEB Funds	-	950,301	1.1	0.4
Tot. 10 largest shareholders	14,399,996	52,301,741	75.7	90.2
Other	-	21,429,834	24.3	9.8
Total	14,399,996	73,731,575	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 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, 845,000 employee warrants were allocated. During 2022, 260,000 employee warrants were allocated of which 70,000 during the fourth quarter. The number of forfeited warrants amounted to 10,000 and the number of exercised employee warrants amounted to 71,586 as of December 31, which means that 763,414 employee warrants remain outstanding at year-end. The allocation of employee warrants had a dilutive effect corresponding to 693,414 shares, or 0.8 percent, at the end of the period.

The information was submitted for publication, though the agency of the named contact persons, at 8:00 a.m. CET on February 3, 2023.

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

Stockholm, Sweden, February 3, 2023

Gunilla Osswald CEO, BioArctic AB (publ)

## INVITATION TO PRESENTATION OF THE REPORT FOR OCTOBER - DECEMBER 2022

BioArctic invites investors, analysts, and media to an audiocast with teleconference (in English) today, February 3, 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://ir.financialhearings.com/bioarctic-q4-2022/register

### **CALENDAR 2023**

Quarterly Report Jan-Mar 2023 April 27, 2023, at 08:00 a.m. CET
Annual report in Swedish published
Annual General Meeting 2023 June 1, 2023, at 16:30 a.m. CET
Half-Year Report Jan-June 2023 July 12, 2023, at 08:00 a.m. CET
Quarterly Report Jan-Sep 2023 November 8, 2023, at 08:00 a.m. CET
Full Year Report Jan-Dec 2023 February 8, 2024, at 08:00 a.m. CET



### FOR FURTHER INFORMATION, PLEASE CONTACT

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 applies

## Financial statements, Group

### **CONSOLIDATED INCOME STATEMENT**

	Q4	1	Jan-Dec		
kSEK	2022	2021	2022	2021	
Net revenues (note 4)	2,090	4,706	228,291	23,147	
Other operating income	-774	569	1,570	3,541	
Operating revenues	1,316	5,275	229,861	26,688	
Operating expenses					
Project related expenses	-14,141	-16,528	-74,326	-55,067	
Other external expenses	-9,850	-7,418	-33,015	-24,851	
Personnel expenses	-32,214	-17,078	-115,650	-72,499	
Depreciations of tangible assets	-3,853	-3,253	-14,633	-13,108	
Other operating expenses	-1,917	-355	-9,679	-886	
Operating expenses	-61,974	-44,632	-247,303	-166,411	
Operating profit/loss	-60,658	-39,357	-17,442	-139,722	
Financial income	2,918	40	7,025	194	
Financial expenses	-132	-305	-751	-984	
Profit/loss before tax	-57,872	-39,622	-11,168	-140,512	
Tax	-6	20,666	-11	20,722	
Profit/loss for the period	-57,878	-18,956	-11,179	-119,790	
Earnings per share					
Earnings per share before dilution, SEK	-0.66	-0.22	-0.13	-1.36	
Earnings per share after dilution, SEK	-0.66	-0.22	-0.13	-1.36	

## SOLIDATED INCOME STATEMENT CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	Q	1	Jan-Dec		
kSEK	2022	2021	2022	2021	
Profit/loss for the period	-57,878	-18,956	-11,179	-119,790	
Other comprehensive income	-	-	-	-	
Comprehensive income for the period	-57,878	-18,956	-11,179	-119,790	

### **CONSOLIDATED BALANCE SHEET**

kSEK	31 Dec 2022	31 Dec 2021
Assets		<u> </u>
Tangible fixed assets	23,531	16,963
Right-to-use assets	11,733	16,785
Deferred tax assets	596	608
Other financial assets	1,606	1,588
Current assets excluding cash and cash equivalents	15,454	13,380
Cash and cash equivalents	805,386	848,405
Total assets	858,307	897,730
Equity and liabilities		
Equity	786,241	788,676
Non-current lease liabilities	1,182	7,785
Current lease liabilities	8,857	8,092
Other current liabilities	26,919	15,737
Accrued expenses and deferred income	35,108	77,438
Equity and liabilities	858,307	897,730

### CONSOLIDATED STATEMENT OF CHANGE IN EQUITY (CONDENSED) 1

kSEK	31 Dec 2022	31 Dec 2021
Opening balance at 1 January	788,676	907,299
Correction of opening balance	-	-402
Comprehensive income for the period	-11,179	-119,789
Share issue connected to exercised employee warrants	5,985	-
Share-based payments	2,760	1,567
Closing balance	786,241	788,676

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

	Q4		Jan-Dec		
ksek .	2022	2021	2022	2021	
Operating profit	-60,658	-39,357	-17,442	-139,722	
Adjustment for non-cash items	3,743	1,560	-41,234	5,230	
Interest received/paid	2,403	-71	1,784	-597	
Income tax paid	-439	-425	340	-309	
Cash flow from operating activities before changes in working capital	-54,950	-38,293	-56,552	-135,398	
Change in working capital	-3,256	-961	24,914	-5,059	
Cash flow from operating activities after changes in working capital	-58,207	-39,254	-31,638	-140,457	
Cash flow from investing activities	-3,709	-1,888	-12,763	-4,412	
Cash flow from financing activities	3,278	-1,936	-2,808	-7,388	
Cash flow for the period	-58,638	-43,078	-47,209	-152,257	
Cash and cash equivalents at beginning of period	863,159	891,525	848,405	999,940	
Exchange rate differences in cash and cash equivalents	865	-42	4,190	723	
Cash and cash equivalents at end of period	805,386	848,405	805,386	848,405	

<sup>1)</sup> 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**

	2022	2022	2022	2022	2021	2021	2021	2021
MSEK	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Income statement								
Net revenues	2	218	4	4	5	4	7	7
Other operating income	-1	1	0	1	1	1	1	2
Operating expenses	-62	-87	-50	-48	-45	-42	-42	-38
Operating profit/loss	-61	133	-46	-44	-39	-37	-34	-29
Operating margin, %	neg	61.0	neg	neg	neg	neg	neg	neg
Profit/loss for the period	-58	137	-46	-44	-19	-38	-34	-29
Balance sheet								
Fixed assets	37	35	37	39	36	37	39	40
Current assets	15	8	6	7	13	6	5	5
Cash and cash equivalents	805	863	752	801	848	892	930	960
Equity	786	837	700	745	789	807	844	879
Deferred tax liabilities	-	_	_	_	_	21	21	21
Lease liabilities	10	10	12	14	16	18	19	19
Current liabilities	62	58	82	88	93	90	89	87
Cash flow								
From operating activities	-58	112	-46	-40	-39	-35	-29	-37
From investing activities	-4	-1	-2	-6	-2	-2	-0	-1
From financing activities	3	-2	-2	-2	-2	-2	-2	-2
Cash flow for the period	-59	109	-49	-48	-43	-38	-31	-40
Key ratios								
Equity/asset ratio, %	91.6	92.5	88.1	88.0	87.9	86.3	86.7	87.3
Return on equity, %	-7.1	17.8	-6.3	-5.8	-2.4	-4.5	-4.0	-3.3
Data per share								
Earnings per share before dilution, SEK	-0.66	1.55	-0.52	-0.50	-0.22	-0.43	-0.39	-0.33
Earnings per share after dilution, SEK	-0.66	1.54	-0.52	-0.50	-0.22	-0.43	-0.39	-0.33
Equity per share, SEK	8.92	9.51	7.95	8.46	8.96	9.17	9.59	9.98
Cash flow operating activities per share, SEK	-0.66	1.27	-0.52	-0.45	-0.45	-0.39	-0.33	-0.43
Share price at the end of the period, SEK	272.00	271.60	77.45	103.20	119.20	162.60	137.80	91.00
Number of shares outstanding at the end of the period,								
thousands	88,132	88,060	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding before dilution,	00.005	00.000	00.000	00.000	00.000	00.000	00.000	00.000
thousands	88,096	88,060	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding after dilution, thousands	88.825	88,690	88,577	88.605	88,610	88,585	88,560	88,560
- Indudurius	00,023	00,000	00,011	00,000	00,010	00,000	00,000	00,000

## Financial statements, Parent company

### PARENT COMPANY INCOME STATEMENT

	Q4		Jan-Dec		
kSEK	2022	2021	2022	2021	
Net revenues	2,090	4,706	228,291	23,146	
Other operating income	-774	569	1,570	3,542	
Operating revenues	1,316	5,275	229,861	26,688	
Operating expenses					
Project related expenses	-14,141	-16,528	-74,326	-55,067	
Other external expenses	-12,246	-9,531	-41,956	-33,224	
Personnel expenses	-32,214	-17,078	-115,650	-72,499	
Depreciations of tangible assets	-1,701	-1,360	-6,621	-5,604	
Other operating expenses	-1,917	-354	-9,679	-885	
Operating expenses	-62,218	-44,851	-248,232	-167,279	
Operating profit/loss	-60,903	-39,576	-18,371	-140,591	
Financial income	2,918	40	7,025	194	
Financial expenses	-16	-120	-191	-145	
Profit/loss after financial items	-58,001	-39,656	-11,537	-140,542	
Change in tax allocation reserves	-	94,809	-	94,809	
Profit/loss before tax	-58,001	55,153	-11,537	-45,733	
Tax	21	8	65	63	
Profit/loss for the period	-57,980	55,161	-11,472	-45,669	

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	31 Dec 2022	31 Dec 2021
Assets		
Tangible fixed assets	23,531	16,963
Deferred tax assets	453	388
Other financial assets	1,656	1,638
Current assets excluding cash and cash equivalents	17,842	15,353
Cash and cash equivalents	805,342	848,359
Total assets	848,825	882,702
Equity and liabilities		
Equity	786,798	789,526
Other current liabilities	26,919	15,737
Accrued expenses and deferred income	35,108	77,438
Equity and liabilities	848,825	882,702

### **Notes**

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

This interim report for the period January – December 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 Warfvinges 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 full year January – December 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**

	Q4		Jan-Dec	
kSEK	2022	2021	2022	2021
Geographic breakdown of net revnues				
Europe	-	1,926	58,478	8,466
Asia	2,090	2,780	169,813	14,681
Total net revenues	2,090	4,706	228,291	23,147
Not assessed and assessed time				
Net revenues per revenue type				
Milestone payments, recognized at a given point in time	-	-	161,460	-
Income from research collaborations, recognized over time	2,090	4,706	66,831	23,147
Total net revenues	2,090	4,706	228,291	23,147

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 (MEUR 15) 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 fourth quarter MSEK 2.1 (2.8) was recognized as revenue and for the period July – December MSEK 4.3 (4.9) 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 2022, MSEK 54.5 was recognized as revenue of which MSEK 47.9 as a one-time effect related to the settlement of the project. During the period January – December 2022 MSEK 58.5 (8.5) was

recognized as revenue. As of December 31, 2022, consequently the entire payment of MSEK 701.6 has been recognized as revenue.

## NOTE 5 PLEDGED ASSETS AND CONTINGENT LIABILITIES

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
Equity per share	Adjusted equity divided by the number of shares at the end of the period

## 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 (α-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 (Aβ)

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.

#### Lecanemab -irmb

Lecanemab has been given the -irmb add-on by the FDA for the approved substance. -irmb is a suffix assigned by the FDA. Suffixes are used to differentiate originator biological products, related biological products, and biosimilar products containing related drug substances

### 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.

