

**LEQEMBI launched in the US**

**EVENTS DURING THE THIRD QUARTER 2023**

- In July, the FDA approved LEQEMBI® for the treatment of Alzheimer’s disease in the US and the Centers for Medicare and Medicaid Services, CMS, announced that LEQEMBI will be reimbursed according to the FDA approved label
- In September, LEQEMBI was approved for the treatment of Alzheimer's disease in Japan, which entitled BioArctic to a milestone payment of EUR 17 M, equivalent to SEK 201.0 M
- The board has decided to initiate a Phase 2a study of exidavnebab (BAN0805) in Parkinson's disease. The study is expected to start in the second half of 2024

**EVENTS AFTER THE END OF THE THIRD QUARTER**

- Data presented at the CTAD congress further support LEQEMBI, among other things showing that subcutaneous treatment with LEQEMBI leads to a greater reduction of amyloid plaques than the intravenous treatment
- BioArctic and Eisai have agreed on commercialization and co-promotion for the Nordic countries
- Eisai aims to have 10,000 patients on treatment at the end of March 2024, and to achieve 10 billion yen (M ~700 SEK) level revenue from LEQEMBI in their fiscal year 2023 ending March 2024

**FINANCIAL SUMMARY JULY – SEPTEMBER 2023**

- Net revenues for the period amounted to SEK 208.8 M (218.2)
- Operating profit amounted to SEK 131.0 M (132.4)
- Profit for the period amounted to SEK 124.9 M (136.8)
- Earnings per share before dilution was SEK 1.42 (1.55) and after dilution SEK 1.41 (1.54)
- Cash flow from operating activities amounted to a negative SEK -52.9 M (111.8)
- Cash and cash equivalents and short term investments at the end of the period amounted to SEK 998 M (863)

**FINANCIAL SUMMARY JANUARY – SEPTEMBER 2023**

- Net revenues for the period amounted to SEK 605.0 M (226.2)
- Operating profit amounted to SEK 330.7 M (43.2)
- Profit for the period amounted to SEK 316.5 M (46.7)
- Earnings per share was SEK 3.59 (0.53) before dilution and SEK 3.58 (0.53) after dilution
- Cash flow from operating activities amounted to SEK 182.3 M (26.6)
- Cash and cash equivalents and short term investments at the end of the period amounted to SEK 998 M (863)

**KEY FINANCIAL PERFORMANCE INDICATORS**

SEK M	Q3		Jan-Sep		Jan-Dec
	2023	2022	2023	2022	2022
Net revenues	208.8	218.2	605.0	226.2	228.3
Other operating income	0.3	0.7	3.6	1.3	0.3
Operating profit/loss	131.0	132.4	330.7	42.4	-17.3
Operating margin, %	62.7	60.7	54.7	18.8	neg
Profit/loss for the period	124.9	136.8	316.5	46.7	-11.2
Earnings per share before dilution, SEK	1.42	1.55	3.59	0.53	-0.13
Earnings per share after dilution, SEK	1.41	1.54	3.58	0.53	-0.13
Equity per share, SEK	12.78	9.51	12.78	9.51	8.92
Cash flow from operating activities	-52.9	111.8	182.3	26.6	-31.6
Cash flow from operating activities per share, SEK	-0.60	1.27	2.07	0.30	-0.36
Equity/assets ratio, %	90.9	92.5	90.9	92.5	91.6
Return on equity, %	11.77	17.80	33.05	5.74	-1.42
Share price at the end of the period, SEK	283.00	271.60	283.00	271.60	272.00

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.

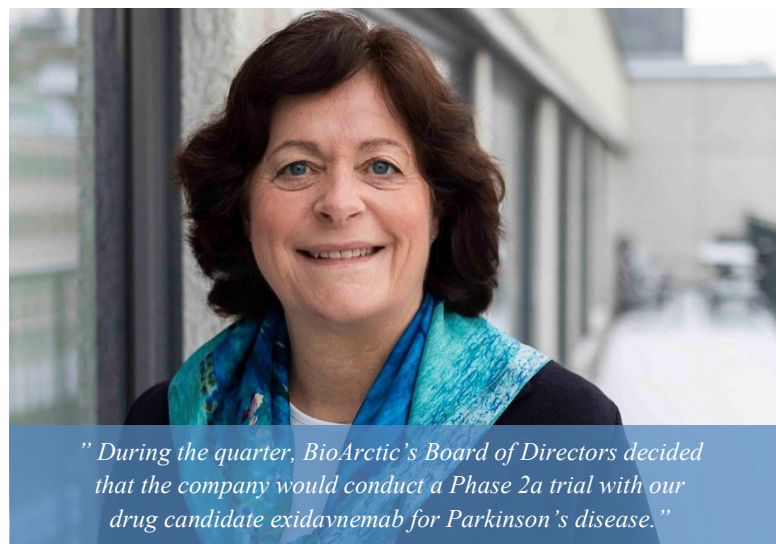
## Comments from the CEO

Since July 6, lecanemab has been fully approved in the US, reimbursed by Medicare and sold under the brand name Leqembi. Following the approval, our partner Eisai intensified its efforts to ensure that our patients will have access to treatment as soon as possible. This is an effort that requires great patience. Since Leqembi is the first fully approved disease-modifying treatment for Alzheimer's disease, there are many parts of the medical treatment process that need to be reviewed and adjusted. Eisai is very pleased with developments so far, as are we. 60% of the top 100 Integrated Delivery Networks (IDN) in the U.S. have now approved LEQEMBI, and more than 2,500 neurologists or other Alzheimer disease (AD) specialists are ready to diagnose, treat and monitor patients. Eisai estimates that 800 patients were on treatment towards the end of October and have reiterated their aim that the number of patients will reach 10,000 by the end of March 2024. In addition, Eisai aims to achieve 10 billion yen (M ~700 SEK) level revenue from LEQEMBI in their fiscal year 2023, ending March 2024, of which BioArctic has right to high single digit royalty. Royalty for the third quarter was SEK 2.5 M.

In September, lecanemab was approved in Japan. The efforts on price and subsidization are in progress, and we look forward to launch in Japan as well shortly. In conjunction with Japanese approval, BioArctic received a milestone payment of MEUR 17. The approval shows, once again, that Eisai has been working diligently to ensure that this treatment reaches patients around the world. Applications for approval have been submitted in EU, China, Canada, Great Britain, Australia, Switzerland, South Korea, Israel, Singapore, Taiwan, Brazil and Hong Kong.

Moreover, we have come to an agreement with Eisai on how we are to collaborate to commercialize and market lecanemab in the Nordic region. We have already been working together on preparations, and these efforts will intensify upon approval in the EU, which Eisai expects to happen in the first quarter of 2024.

In parallel with the market introductions, Eisai continues to present new data for lecanemab. During the Clinical Trials on Alzheimer's Disease conference (CTAD), which was held in Boston in late October, Eisai presented further results that, gratifyingly enough, showed that treatment with the subcutaneous (SC) formulation of lecanemab – which is under development – appears to be a potentially excellent alternative to intravenous (IV) treatment. The data showed that SC resulted in a greater amyloid plaque removal compared with IV, a better side-effect profile as regards infusion reaction rates and ARIA similar to IV. Eisai intends to submit an application for market approval in the US for the subcutaneous formulation by the end of March next year. Furthermore, data was presented indicating that patients could have even better efficacy if treatment is begun early in the progression of the disease before any greater tau pathology has built up in the brain, as well as data showing that treatment after the 18 months of the Phase 3 study continued to have an effect. Professor Lars Lannfelt also held an oral



presentation on how the binding profile for lecanemab could explain why it shows a significantly lower frequency of the ARIA-E side effect compared with other antibodies.

During the quarter, BioArctic's Board of Directors decided that the company will conduct a Phase 2a study with our drug candidate exidavnemab (BAN0805) for Parkinson's disease. For some time, intensive efforts have been underway to transfer all data generated by our former partner, AbbVie, analyze it, write a final report for the Phase 1 study and prepare production of new drug products ahead of continued clinical studies. We expect to initiate the Phase 2 study in the second half of 2024. Expanded patient protection for exidavnemab was granted in Japan in August, which means that we now have a very long patent both there and in the US until 2046, including patent extension.

Exidavnemab, like our other antibodies against proteins in the progression of Alzheimer's disease, ALS and Parkinson's disease, is grounded in our unique competence in developing highly specific and selective antibodies against pathological misfolded proteins that generate diseases in the central nervous system. All projects – as well as our BrainTransporter technology – are continuing to perform well. Our conviction that the BrainTransporter technology will work was further strengthened after positive clinical data for a similar technology was presented at CTAD. It is a sign of BioArctic's strength that, owing to our successes with lecanemab, we can continue to develop our project portfolio with a high degree of scientific quality and at a high tempo.

We are experiencing a paradigm shift in the treatment of Alzheimers disease. I am extremely proud of the fact that the world's first fully approved disease-modifying drug originates from BioArctic's research. It is highly gratifying that we can now help patients, their families and society as a whole.

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. BioArctic's 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 collaborates 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 as well as a technology that improves transport of biological drugs into the brain.

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 mainly 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, the protein alpha-synuclein ( $\alpha$ -synuclein) is involved in Parkinson's disease, while for ALS it is the protein TDP-43. 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 (oligomers/protofibrils) of the amyloid beta protein 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 September 30, 2023, the project portfolio consisted of:

	Project	Partner	Research	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory & Market
ALZHEIMER'S DISEASE	Lecanemab	Eisai <sup>1</sup>	Early Alzheimer's disease <sup>2</sup>					
	Lecanemab AHEAD 3-45	Eisai <sup>1</sup>	Preclinical (asymptomatic) Alzheimer's disease <sup>3</sup>					
	Lecanemab back-up	Eisai						
	BAN1503 (PyroGlu A $\beta$ )							
	AD-BT2802							
	AD-BT2803 (PyroGlu A $\beta$ with BT)							
	AD2603							
PARKINSON'S DISEASE	Exidavnemab (BAN0805) ( $\alpha$ -synuclein)							
	PD1601 ( $\alpha$ -synuclein)							
	PD1602 ( $\alpha$ -synuclein)							
	PD-BT2238 ( $\alpha$ -synuclein with BT)							
OTHER CNS DISORDERS	Lecanemab							Down's syndrome <sup>4</sup> , Traumatic brain injury <sup>4</sup>
	ND3014 (TDP-43)							ALS
	ND-BT3814 (TDP-43 with BT)							ALS
	GD-BT6822 (GCCase with BT)							Gaucher disease
BLOOD-BRAIN BARRIER	BrainTransporter™ (BT)-technology							

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

<sup>2</sup>) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease

<sup>3</sup>) Normal cognitive function with intermediate or elevated levels of amyloid in the brain

<sup>4</sup>) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury



## ALZHEIMER'S DISEASE

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. BioArctic has developed several unique and selective antibodies with the potential to slow or halt the progression of Alzheimer's disease. The most advanced drug candidate is lecanemab, which is the first and only fully approved disease-modifying drug for Alzheimer's disease. The drug is approved in the US and in Japan under the brand name LEQEMBI. 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 another antibody called lecanemab back-up. BioArctic has four additional antibodies projects against Alzheimer's disease in its project portfolio, two of which are connected with the BrainTransporter-technology.

### Drug candidate lecanemab (collaboration with Eisai), brand name LEQEMBI

Lecanemab, which is the result of a long-term strategic research collaboration between BioArctic and Eisai, is a humanized monoclonal antibody against Alzheimer's disease. Eisai is responsible for the clinical development of lecanemab in Alzheimer's disease. The project is based on research from BioArctic, Uppsala University and Karolinska Institutet, Sweden.

Lecanemab has a unique binding profile that distinguishes it from other amyloid beta antibodies. It selectively binds to neutralize and eliminate soluble toxic A $\beta$  aggregates (protofibrils) that are thought to contribute to the neurodegenerative process in Alzheimer's disease. 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 18-month Phase 3 placebo-controlled, double-blind, parallel-group, randomized study in 1,795 people with early Alzheimer's disease. 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. Eisai's recruitment strategy led to 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 including anticoagulants were allowed. Eisai also ensured greater inclusion of ethnic and racial populations, resulting in approximately 25 percent of the total US enrollment including persons of Latino and African American origin living with early Alzheimer's disease.

Results from the pivotal Phase 3 study Clarity AD showed that 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 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. For patients, this could equal remaining in the earlier stages of the disease for an additional 2-3 years longer, according to a modeling study, performed and published by Eisai.

Furthermore, the safety profile of lecanemab was in line with expectations based on the Phase 2b study. An open-label extension study of Clarity AD is ongoing for those patients who completed the core 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.

In addition, since July 2020, Eisai's Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical Alzheimer's disease, having intermediate or elevated levels of amyloid in their brains but no symptoms, is ongoing. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium that provides the infrastructure for academic clinical trials in Alzheimer's disease and related dementias in the U.S, funded by the National Institute on Aging, part of the National Institutes of Health and Eisai.

Since January 2022, the Tau NexGen clinical study for Dominantly Inherited AD (DIAD) is ongoing, where lecanemab is given as a background anti-amyloid treatment when exploring combination therapies with an anti-tau treatment. The study is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU).

### Process of approval of leqembi in the world: [USA](#)

- On July 6, 2023, FDA granted LEQEMBI traditional approval for the treatment of Alzheimer's disease. In conjunction with the approval the Centers for Medicare

and Medicaid Services, CMS, announced that Medicare will provide broad coverage of LEQEMBI according to the FDA approved label

#### EU

- On January 9, 2023, Eisai submitted applications for marketing authorization in the EU

#### Japan

- On September 25, 2023, LEQEMBI was approved in Japan for the treatment of Alzheimer's disease

#### The rest of the world

- In China, Eisai initiated submission of data for BLA to the National Medical Products Administration (NMPA) of China in December 2022. At the end of February, the Biologics License Application (BLA) for lecanemab was designated Priority Review by the National Medical Products Administration (NMPA) in China
- Eisai has also submitted applications for approval of lecanemab in China, Canada, Great Britain, Australia, Switzerland, South Korea, Israel, Singapore, Taiwan, Brazil and Hong Kong.. In Israel, the applications have been designated for priority review, and in Great Britain, lecanemab has been designated for the Innovative Licensing and Access Pathway (ILAP), which aims to reduce the time to market for innovative medicines

#### **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 (PyroGlu-A $\beta$ ). That form of A $\beta$  has a pronounced ability to aggregate and become toxic.

#### **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 — BrainTransporter, or BT — to facilitate uptake of antibodies in the brain. AD-BT2803 target a shorter (truncated) form of amyloid beta (PyroGlu-A $\beta$ ) and is linked to the company's project BAN1503.

## PARKINSON'S DISEASE

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

#### **Drug candidate Exidavnemab (BAN0805) and drug projects PD1601, PD1602 and PD-BT2238**

The objective of the project portfolio is to develop disease-modifying treatments for Parkinson's disease, Lewy body dementia and multiple system atrophy.

Exidavnemab 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 exidavnemab. The article contains data

demonstrating the antibody's ability to selectively bind toxic soluble alpha-synuclein aggregates. In May 2022, an additional drug substance patent for exidavnemab was granted in the US, which is valid until 2041, with a possible extension until 2046. In August 2023, an extended drug substance patent for exidavnemab was granted in Japan, which is valid until 2041, with a possible extension until 2046.

The board of BioArctic has decided to initiate a phase 2a study of exidavnemab in individuals with Parkinson's disease. The study is expected to start in the second half of 2024.

The PD1601 and PD1602 antibody projects also target alpha-synuclein for treatment of Parkinson's disease.

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 and protofibrils) with BioArctic's BrainTransporter technology

## 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 2022, BioArctic's project portfolio was expanded with a new project focused on enzyme replacement therapy for Gaucher disease in combination with the company's BrainTransporter technology to address the CNS-symptoms of the disease.

### **BLOOD-BRAIN BARRIER TECHNOLOGY (BRAINTRANSPORTER™) (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 it difficult for drugs to reach the brain.

BioArctic is now developing the second generation of this technology, which has already demonstrated a profound increase and improved exposure of antibodies 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 disease, GD-BT6822. The technology, which is now in the pre-clinical phase, has significant potential for many treatments for diseases of the brain.



# Comments to the financial development, revenues and result

Revenues consist of milestone payments, royalty and payments from research agreements and research grants. Because of the nature of the business operations, the revenues may fluctuate significantly from quarter to quarter, 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 SEK 208.8 M (218.2). Net revenues for the third quarter included a milestone payment of SEK 201.0 M, equivalent to EUR 17 M related to the LEQEMBI approval in Japan. Net revenues for the nine-month period amounted to SEK 605.0 M (226.2). The increase is mainly explained by four milestone payments received, amounting to a total of SEK 592.0 M, equivalent to EUR 52 M.

Other operating income relates to research grants and operating exchange rate gains. Other operating income amounted to SEK 0.3 M (0.7) in the third quarter and for the nine-month period to SEK 3.6 M (1.3).

Total operating expenses for the third quarter amounted to SEK 78.1 M (86.4) and for January-September period to SEK 277.9 M (185.1). Project expenses for BioArctic's proprietary projects increased during the period due to that several projects are in a later phase and that the pace of the development of the projects has increased. Also, expenses for personnel increased to SEK 40.7 M (38.1) for the third quarter and to SEK 160.1 M (83.4) for the nine-month period. The increase in the nine-month period can mainly be explained by one-off effects from variable remuneration to the employees linked to achieved milestones, repurchase of employee stock options from the CEO, increased costs for the incentive programs and, in addition, an increase in the number of employees. Other external costs increased during the quarter and for the period as a result of an increase in the scope of the business. Other operating expenses mainly consist of realized operating exchange rate losses.

Since BioArctic's proprietary projects are in an early research phase they do not meet the criteria for capitalization of R&D expenses so 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.

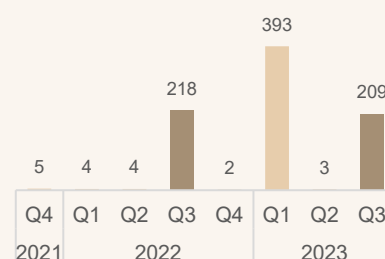
Operating profit before net financial items (EBIT) amounted to SEK 131.0 M (132.4) for the third quarter and to SEK 330.7 M (42.4) for the nine-month period. The profit increase during the third quarter is due to milestone compensation received and royalty from sales of leqembi in the USA. The improvement compared to the nine-month period of the previous year was primarily attributable to received milestone payments.

Net financial items totaled SEK 9.6 M (4.3) for the third quarter and to SEK 21.4 M (4.3) for the nine-month period. The increase is attributable to higher interest rates. Financial income consists of interest income and financial expenses consist of exchange rate losses and interest on leasing liabilities.

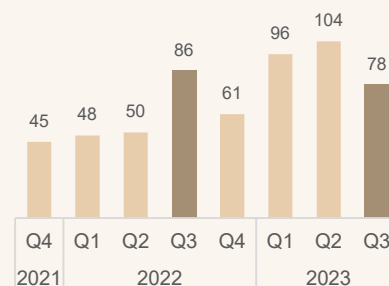
The profit for the period amounted to SEK 124.9 M (136.8) for the third quarter and to SEK 316.5 M (46.7) for the nine-month period.

Profit per share before dilution amounted to SEK 1.42 (1.55) and after dilution to SEK 1.41 (1.54) for the third quarter. For the nine-month period profit per share before dilution amounted to SEK 3.59 (0.53) and profit per share after dilution amounted to SEK 3.58 (0.53).

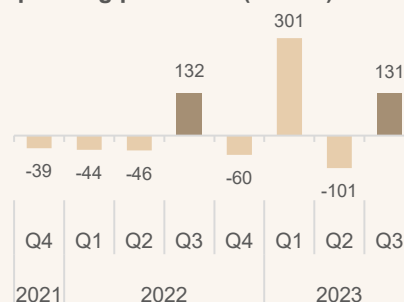
## Net revenues (SEK M)



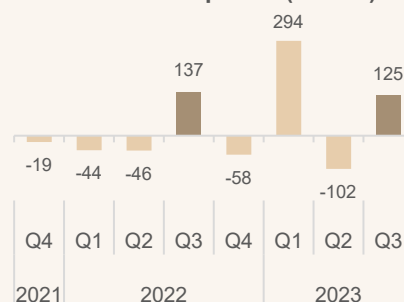
## Operating expenses (SEK M)



## Operating profit/loss (SEK M)



## Profit/loss for the period (SEK M)





**LIQUIDITY AND FINANCIAL POSITION**

Equity amounted to SEK 1,128.7 M as of September 30, 2023 compared with SEK 786.2 M as of December 31, 2022. This corresponds to equity per outstanding share of SEK 12.78 (8.92). The equity/asset ratio was 90.9 percent as of September 30, 2023 compared with 91.6 percent as of December 31, 2022.

The Group's cash and cash equivalents consist of bank balances of SEK 697.8 M and short-term placements of SEK 300.0, i.e. a total of SEK 997.8 M as of September 2023 compared with SEK 805.4 M as of December 31, 2022. The increase is attributable to milestone payments received. There were no loans as of September 30, 2023, 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 implications on reporting in conjunction with revaluation of currency to current rate. These effects are recognized in financial income and expenses.

## CASH FLOW AND INVESTMENTS

Cash flow from operating activities for the third quarter amounted to SEK -52.9 M (111.8) and to SEK 182.3 M (26.6) for the nine-month period. The explanation for the reduced cash flow during the quarter is due to the fact that BioArctic received a larger payment for a milestone in third quarter of 2022. The increase for the nine-month period is mainly explained by the larger received milestone payments.

Cash flow from investing activities for the third quarter amounted to a negative SEK 301.8 M (neg.: 1.4). During the quarter, BioArctic invested in short-term placements of SEK 300.0 M and the remainder were mainly related to laboratory equipment. For the nine-month period cash flow from investing activities amounted to a negative SEK 302.8 M (neg.: 9.1). Cash flow from financing activities amounted to SEK 10.9 M (neg.: 2.0) for the third quarter and to SEK 13.0 M (neg.: 6.1) for January – September and relates to the amortization of leasing liabilities and the share issue connected to exercised employee warrants in the first, second and third quarter.

## PARENT COMPANY

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

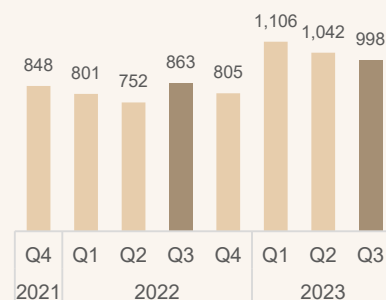
## EVENTS DURING THE FIRST QUARTER 2023

- BioArctic was as of January 2, 2023, moved to Nasdaq Stockholm's marketplace for large companies (Large cap)
- On January 6, the FDA approved LEQEMBI via the accelerated approval pathway for the treatment of Alzheimer's disease
- Eisai filed for full approval for lecanemab in the US, EU, Japan and China. The submissions have all been accepted for review with the ones in the US, Japan and China being granted priority review
- The approval in the US and submissions in the EU and Japan entitled BioArctic to milestones of MEUR 35 in total
- The subsidiaries BioArctic Denmark ApS, BioArctic Finland Oy and BioArctic Norway A/S were formed
- U.S. Veterans' Health Administration decided to provide coverage for LEQEMBI for veterans with early Alzheimer's disease
- New lecanemab-data was presented at the AD/PD congress with a focus on health-related quality of life outcomes, safety and the unique binding profile of the antibody
- Eisai published three articles regarding lecanemab's phase 2b study which further strengthens previously published data

## EVENTS DURING THE SECOND QUARTER 2023

- The U.S. Food and Drug Administration's (FDA) Advisory Committee voted unanimously that the data from Eisai's Phase 3 Clarity AD clinical trial confirms the clinical benefit of LEQEMBI
- Eisai submitted applications for marketing authorization for lecanemab to the pharmaceutical authorities in South Korea and Great Britain
- Health Canada initiated the review of New Drug Submission for lecanemab as treatment for early Alzheimer's disease
- A published modeling study based on Phase 3 data showed that treatment with lecanemab resulted in a 2 to 3 years delay in the average time to progress to more severe stages of Alzheimer's disease
- Anders Martin-Löf was hired as new Chief Financial Officer. Current CFO Jan Mattsson has transitioned to a newly established role as VP Finance

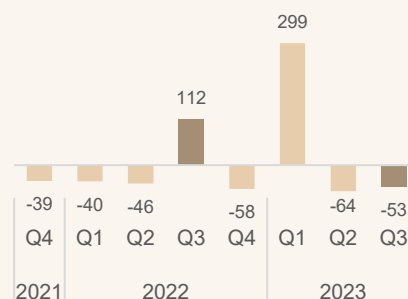
## Cash, cash equivalents and short term investments (SEK M)



## Financial position (SEK M)

	30 Sep 2023	31 Dec 2022
Non-current lease liabilities	1,2	1,2
Current lease liabilities	1,9	8,9
Cash, cash equivalents and short term investments	997,8	805,4
<b>Net cash position</b>	<b>994,7</b>	<b>795,3</b>

## Cash flow from operating activities (SEK M)



## Cash, cash equivalents and short term investments (SEK M)

# 998

## EVENTS DURING THE THIRD QUARTER 2023

- In July, the FDA approved LEQEMBI for the treatment of Alzheimer's disease in the US and the Centers for Medicare and Medicaid Services, CMS, announced that LEQEMBI will be reimbursed according to the FDA approved label
- In September, LEQEMBI was approved for the treatment of Alzheimer's disease in Japan. The approval entitled BioArctic to a milestone payment of EUR 17 M, equivalent to SEK 201.0 M
- The board has decided to initiate a Phase 2a study of exidavnemab in Parkinson's disease. The study is expected to start in the second half of 2024

## Other information

### EVENTS AFTER THE END OF THE THIRD QUARTER

- Data presented at the CTAD congress further support LEQEMBI, among other things showing that subcutaneous treatment with LEQEMBI leads to a greater reduction of amyloid plaques than the intravenous treatment
- BioArctic and Eisai have agreed on commercialization and co-promotion for the Nordic countries
- Eisai aims to have 10,000 patients on treatment at the end of March 2024, and to achieve 10 billion yen (M ~700 SEK) level revenue from LEQEMBI in their fiscal year 2023 ending March 2024

### 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 2023, BioArctic's patent portfolio consisted of 16 patent families with close to 250 granted patents and approx. 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 previously also with 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 new 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 lecanemab back-up antibodies. The total value of these agreements may amount to EUR 222 M in addition to royalty. As of 30 September 2023, up to EUR 84 M in milestone payments remains from Eisai.

BioArctic and Eisai have agreed on commercialization and co-promotion for the Nordic countries based on a fifty-fifty profit share for the region with no royalty. According to the agreement Eisai will be responsible for pricing and reimbursement as well as distribution whereas BioArctic will take on a larger share of the customer-facing organization. Eisai is the Marketing Authorization Holder in Europe, and the intention is that BioArctic will be local representative at the point of commercial launch. The collaboration will be governed by a joint Nordic commercialization committee.

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 2022 on pages 49-52.

### FLUCTUATIONS IN REVENUE GENERATION

BioArctic is developing a number of drug candidates for chronic neurodegenerative diseases in partnership with global pharma companies. The company also conducts research for proprietary 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 royalty, 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. BioArctic also receives royalty income from the sale of LEQEMBI and as these revenues increase, the fluctuations will decrease.

### 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. With LEQEMBI receiving full market approval in the US and Japan, royalty income for BioArctic is expected to increase, which changes the revenue mix and has the potential to give the company a more even revenue flow over time. 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 neurodegenerative disorders and have great market potential. BioArctic's ambition is to generate the drugs of the future for patients with neurodegenerative disorders.

### EXPECTED DEVELOPMENT OF OPERATING EXPENSES

Operating expenses are expected to be in the range of SEK 350 – 370 M for the fiscal year January – December 2023. The build-up of the commercial organization in the Nordics prior to the potential launch of lecanemab, and costs for the expanded in-house project portfolio, explain the expected higher cost level for 2023.

### EMPLOYEES

At the end of the third quarter, the number of full-time employees was 83 (56) of which 30 (22) are men and 53 (34) women. Around 70 percent work in R&D and of these around 85 percent are PhDs.

### THE SHARE AND SHAREHOLDINGS

The share capital in BioArctic amounts to SEK 1,765,990 divided by 88,299,485 shares which is split between 14,399,996 A-shares and 73,899,489 B-shares. The number of shares increased during the third quarter by 73,000 shares as a result of the subscription of shares by participants in the employee stock option 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 SEPTEMBER 30, 2023<sup>1</sup>

	Number		Share of (%)	
	A-shares	B-shares	capital,	votes,
Demban AB (Lars Lannfelt)	8,639,998	20,885,052	33.4	49.2
Ackelsta AB (Pär Gellerfors)	5,759,998	13,343,201	21.6	32.6
Fjärde AP-fonden	-	3,720,086	4.2	1.7
Swedbank Robur Funds	-	3,394,973	3.8	1.6
Tredje AP-fonden	-	3,340,378	3.8	1.5
RA Capital Management LP	-	3,117,736	3.5	1.4
Handelsbanken Funds	-	2,051,833	2.3	0.9
Nordea Funds	-	1,804,450	2.0	0.8
Unionen	-	1,610,223	1.8	0.7
Vanguard	-	1,226,811	1.4	0.6
<b>Tot. 10 largest shareholders</b>	<b>14,399,996</b>	<b>54,494,743</b>	<b>78.0</b>	<b>91.1</b>
Other	-	19,404,746	22.0	8.9
<b>Total</b>	<b>14,399,996</b>	<b>73,899,489</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

BioArctic has two ongoing long-term incentive programs that were approved at the AGM 2019 and at the AGM 2023.

A maximum of 1,000,000 stock options may be granted within the Stock Option Program 2019/2028. To enable the company's delivery of shares under program, the Annual General Meeting approved a directed issue of a maximum of 1,000,000 warrants. The employee stock options may be exercised three to five years after grant. As of the end of the period, a total of 915,000 options have been granted, and no further grants may occur.

The number of lapsed and repurchased options amounted to 70,000 and the number of exercised options amounted to 239,500 as of September 30, which means that 605,500 employee stock options remain outstanding at the end of the period corresponding to a dilutive effect of up to 0.7 percent of the share capital at the end of the reporting period.

The Performance Share Unit (PSU) program 2023/2026 is a three-year incentive program including a maximum of 125,000 PSUs that, provided that the share price increases by at least 30 percent during a three-year period, entitles the participants to receive shares free of charge or a cash payment. 10,500 performance share units were allocated during the third quarter, which meant that a total of 117,500 share units have been allocated and no further allocation will take place. If the board decides to utilize warrants to deliver the B-shares according to the terms and conditions of the program or for financing the company's costs for the program, the dilutive effect would be a maximum of 0.1 per cent of the share capital outstanding at the end of the period.

### REVIEW AND SUBMISSION OF REPORT

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

Stockholm, Sweden, November 8, 2023

Gunilla Osswald, CEO BioArctic AB (publ)



# BioArctic AB (publ)

## INVITATION TO PRESENTATION OF THE THIRD QUARTER REPORT FOR JULY – SEPTEMBER 2023

BioArctic invites investors, analysts, and media to an audiocast with teleconference (in English) today, November 8, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Anders Martin-Löf will present BioArctic, comment on the interim report and answer questions.

Webcast:

<https://ir.financialhearings.com/bioarctic-q3-report-2023>

## CALENDAR 2023-2024

Full Year Report Jan-Dec 2023	February 14, 2024, at 08:00 a.m. CET
Quarterly Report Jan-Mar 2023	May 17, 2024, at 08:00 a.m. CET
Annual General Meeting 2024	May 22, 2024, at 16:30 p.m. CET
Half-Year Report Jan-June 2024	August 29, 2024, at 08:00 a.m. CET
Quarterly Report Jan-Sep 2024	November 14, 2024, at 08:00 a.m. CET
Full Year Report Jan-Mar 2024	February 13, 2025 at 08:00 a.m. CET

## FOR FURTHER INFORMATION, PLEASE CONTACT

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Telephone +46 (0)8 695 69 30  
[www.bioarctic.com](http://www.bioarctic.com)

The interim report is such information as BioArctic AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation.

The information was submitted for publication, through the agency of the contact persons set out on this page, at 08.00 CET on November 8, 2023.

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, 2023 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, 2023, and of its financial performance and its cash flows for the nine-month period then ended in accordance with IFRS.

Stockholm November 8, 2023

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
	2023	2022	2023	2022	2022
Net revenues (note 4)	208,838	218,225	604,970	226,201	228,291
Other operating income (note 5)	297	669	3,634	1,315	334
<b>Operating revenues</b>	<b>209,135</b>	<b>218,894</b>	<b>608,605</b>	<b>227,516</b>	<b>228,625</b>
<b>Operating expenses</b>					
Project related expenses	-15,464	-30,888	-61,130	-60,185	-74,326
Other external expenses	-11,132	-7,276	-33,833	-23,165	-33,015
Personnel expenses	-40,675	-38,087	-160,082	-83,437	-115,650
Depreciations of tangible assets	-4,590	-3,649	-13,586	-10,780	-14,633
Other operating expenses (note 5)	-6,261	-6,544	-9,247	-7,502	-8,337
<b>Operating expenses</b>	<b>-78,122</b>	<b>-86,444</b>	<b>-277,877</b>	<b>-185,070</b>	<b>-245,961</b>
<b>Operating profit/loss</b>	<b>131,012</b>	<b>132,450</b>	<b>330,728</b>	<b>42,446</b>	<b>-17,336</b>
Financial income (note 5)	9,923	4,657	23,283	5,161	8,285
Financial expenses (note 5)	-337	-312	-1,870	-903	-2,117
<b>Profit/loss before tax</b>	<b>140,598</b>	<b>136,795</b>	<b>352,140</b>	<b>46,704</b>	<b>-11,168</b>
Tax	-15,648	-4	-35,648	-5	-11
<b>Profit/loss for the period</b>	<b>124,950</b>	<b>136,791</b>	<b>316,492</b>	<b>46,699</b>	<b>-11,179</b>
<b>Earnings per share</b>					
Earnings per share before dilution, SEK	1.42	1.55	3.59	0.53	-0.13
Earnings per share after dilution, SEK	1.41	1.54	3.58	0.53	-0.13

## SOLIDATED INCOME STATEMENT CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

kSEK	Q3		Jan-Sep		Jan-Dec
	2023	2022	2023	2022	2022
Profit/loss for the period	124,950	136,791	316,492	46,699	-11,179
Exchange rate differences connected to foreign operations	-38	-	-	-	-
<b>Comprehensive income for the period</b>	<b>124,911</b>	<b>136,791</b>	<b>316,492</b>	<b>46,699</b>	<b>-11,179</b>

**CONSOLIDATED BALANCE SHEET**

kSEK	30 Sep 2023	30 Sep 2022	31 Dec 2022
<b>Assets</b>			
Tangible fixed assets	20,789	21,119	23,531
Right-to-use assets	5,299	11,356	11,733
Deferred tax assets	554	602	596
Other financial assets	1,648	1,595	1,606
Current assets excluding cash and cash equivalents	516,162	7,745	15,454
Cash and cash equivalents	697,785	863,159	805,386
<b>Total assets</b>	<b>1,242,237</b>	<b>905,577</b>	<b>858,307</b>
<b>Equity and liabilities</b>			
Equity	1,128,713	837,400	786,241
Deferred tax liabilities	-	-	-
Non-current lease liabilities	1,183	1,345	1,182
Current lease liabilities	1,866	8,820	8,857
Other current liabilities	59,487	11,143	26,919
Accrued expenses and deferred income	50,987	46,868	35,108
<b>Equity and liabilities</b>	<b>1,242,237</b>	<b>905,577</b>	<b>858,307</b>

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

kSEK	30 Sep 2023	30 Sep 2022	31 Dec 2022
Opening balance at 1 January	786,241	788,676	788,676
Comprehensive income for the period	316,492	46,699	-11,179
Share issue connected to exercised employee warrants	13,555	-	5,985
Share capital	3	-	-
Share-based payments	12,426	2,025	2,760
Exchange rate differences	-6	-	-
<b>Closing balance</b>	<b>1,128,713</b>	<b>837,400</b>	<b>786,241</b>

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

kSEK	Q3		Jan-Sep		Jan-Dec
	2023	2022	2023	2022	2022
Operating profit	131,012	132,450	330,728	42,446	-17,336
Adjustment for non-cash items (note 6)	-816	-48,706	15,624	-44,216	-41,340
Interest received/paid	4,357	-157	16,184	-619	1,784
Income tax paid	-573	-439	720	779	340
<b>Cash flow from operating activities before changes in working capital</b>	<b>133,980</b>	<b>83,149</b>	<b>363,255</b>	<b>-1,610</b>	<b>-56,552</b>
Change in working capital	-186,910	28,681	-180,992	28,171	24,914
<b>Cash flow from operating activities after changes in working capital</b>	<b>-52,930</b>	<b>111,829</b>	<b>182,263</b>	<b>26,560</b>	<b>-31,637</b>
<b>Cash flow from investing activities</b>	<b>-301,847</b>	<b>-1,369</b>	<b>-302,851</b>	<b>-9,054</b>	<b>-12,763</b>
<b>Cash flow from financing activities</b>	<b>10,944</b>	<b>-1,977</b>	<b>13,003</b>	<b>-6,086</b>	<b>-2,808</b>
<b>Cash flow for the period</b>	<b>-343,832</b>	<b>108,483</b>	<b>-107,584</b>	<b>11,420</b>	<b>-47,209</b>
Cash and cash equivalents at beginning of period	1,042,111	751,750	805,386	848,405	848,405
Exchange rate differences in cash and cash equivalents (note 6)	-493	2,926	-17	3,334	4,190
<b>Cash and cash equivalents at end of period</b>	<b>697,785</b>	<b>863,159</b>	<b>697,785</b>	<b>863,159</b>	<b>805,386</b>



## CONSOLIDATED QUARTERLY DATA

	2023	2023	2023	2022	2022	2022	2022	2021
SEK M	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
<b>Income statement</b>								
Net revenues	209	3	393	2	218	4	4	5
Other operating income	0	0	3	-1	1	0	0	1
Operating expenses	-78	-104	-96	-61	-86	-50	-48	-45
Operating profit/loss	131	-101	301	-60	132	-46	-44	-39
Operating margin, %	62.7	neg	76.4	neg	60.7	neg	neg	neg
Profit/loss for the period	125	-102	294	-58	137	-46	-44	-19
<b>Balance sheet</b>								
Fixed assets	28	31	34	37	35	37	39	36
Current assets	516	13	15	15	8	6	7	13
Cash and cash equivalents	698	1,042	1,106	805	863	752	801	848
Equity	1,129	994	1,085	786	837	700	745	789
Deferred tax liabilities	-	-	-	-	-	-	-	-
Lease liabilities	3	6	8	10	10	12	14	16
Current liabilities	110	86	62	62	58	82	88	93
<b>Cash flow</b>								
From operating activities	-53	-64	299	-58	112	-46	-40	-39
From investing activities	-302	-1	-0	-4	-1	-2	-6	-2
From financing activities	11	1	1	3	-2	-2	-2	-2
Cash flow for the period	-344	-64	300	-59	108	-49	-48	-43
<b>Key ratios</b>								
Equity/asset ratio, %	90.9	91.5	94.0	91.6	92.5	88.1	88.0	87.9
Return on equity, %	11.8	-9.8	31.4	-7.1	17.8	-6.3	-5.8	-2.4
<b>Data per share</b>								
Earnings per share before dilution, SEK	1.42	-1.16	3.33	-0.66	1.55	-0.52	-0.50	-0.22
Earnings per share after dilution, SEK	1.41	-1.16	3.32	-0.66	1.54	-0.52	-0.50	-0.22
Equity per share, SEK	12.78	11.27	12.31	8.92	9.51	7.95	8.46	8.96
Cash flow operating activities per share, SEK	-0.60	-0.72	3.39	-0.66	1.27	-0.52	-0.45	-0.45
Share price at the end of the period, SEK	283.00	282.00	251.40	272.00	271.60	77.45	103.20	119.20
Number of shares outstanding, thousands	88,299	88,226	88,181	88,132	88,060	88,060	88,060	88,060
Average number of shares outstanding, thousands	88,263	88,204	88,156	88,096	88,060	88,060	88,060	88,060

# Financial statements, Parent company

## PARENT COMPANY INCOME STATEMENT

kSEK	Q3		Jan-Sep		Jan-Dec
	2023	2022	2023	2022	2022
Net revenues (note 4)	208,838	218,225	604,970	226,201	228,291
Other operating income (note 5, 6)	128	669	3,629	1,315	334
<b>Operating revenues</b>	<b>208,966</b>	<b>218,894</b>	<b>608,599</b>	<b>227,516</b>	<b>228,625</b>
<b>Operating expenses</b>					
Project related expenses	-15,464	-30,888	-61,130	-60,185	-74,326
Other external expenses (note 6)	-17,294	-9,458	-48,573	-29,710	-41,955
Personnel expenses	-37,590	-38,087	-154,464	-83,437	-115,650
Depreciations of tangible assets	-1,872	-1,694	-5,552	-4,920	-6,621
Other operating expenses (note 5)	-6,261	-6,544	-9,247	-7,502	-8,337
<b>Operating expenses</b>	<b>-78,480</b>	<b>-86,671</b>	<b>-278,966</b>	<b>-185,754</b>	<b>-246,890</b>
<b>Operating profit/loss</b>	<b>130,486</b>	<b>132,222</b>	<b>329,633</b>	<b>41,762</b>	<b>-18,265</b>
Financial income (note 5)	9,922	4,657	23,282	5,161	8,285
Financial expenses (note 5)	-277	-184	-1,617	-459	-1,557
<b>Profit/loss after financial items</b>	<b>140,132</b>	<b>136,695</b>	<b>351,299</b>	<b>46,464</b>	<b>-11,537</b>
Change in tax allocation reserves	-	-	-	-	-
<b>Profit/loss before tax</b>	<b>140,132</b>	<b>136,695</b>	<b>351,299</b>	<b>46,464</b>	<b>-11,537</b>
Tax	-15,541	17	-35,472	45	65
<b>Profit/loss for the period</b>	<b>124,591</b>	<b>136,712</b>	<b>315,827</b>	<b>46,508</b>	<b>-11,473</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 2023	30 Sep 2022	31 Dec 2022
<b>Assets</b>			
Tangible fixed assets	20,789	21,119	23,531
Deferred tax assets	513	433	453
Other financial assets	1,767	1,645	1,656
Current assets excluding cash and cash equivalents	519,987	9,759	17,842
Cash and cash equivalents	696,639	863,115	805,342
<b>Total assets</b>	<b>1,239,696</b>	<b>896,071</b>	<b>848,825</b>
<b>Equity and liabilities</b>			
Equity	1,128,610	838,059	786,798
Other current liabilities	60,767	11,143	26,919
Accrued expenses and deferred income	50,320	46,868	35,108
<b>Equity and liabilities</b>	<b>1,239,696</b>	<b>896,071</b>	<b>848,825</b>

## Notes

### NOTE 1 GENERAL INFORMATION

This interim report for the period January – September 2023 covers the Swedish Parent Company BioArctic AB (publ), Swedish Corporate Identity Number 556601-2679, and the fully owned subsidiaries LPB Sweden AB, BioArctic Denmark ApS, BioArctic Finland Oy and BioArctic Norway A/S. The Group's business operations are mainly 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 2023 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 2022. New and amended IFRS standards and interpretations applied from 2023 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
	2023	2022	2023	2022	2022
<b>Geographic breakdown of net revenues</b>					
Europe	-	54,530	-	58,478	58,478
Asia	208,838	163,695	604,970	167,723	169,813
<b>Total net revenues</b>	<b>208,838</b>	<b>218,225</b>	<b>604,970</b>	<b>226,201</b>	<b>228,291</b>
<b>Net revenues per revenue type</b>					
Royalty	2,514	-	2,951	-	-
Co-promotion	3,565	-	3,565	-	-
Milestone payments	200,959	161,460	592,017	161,460	161,460
Research collaborations	1,800	56,765	6,437	64,741	66,831
<b>Total net revenues</b>	<b>208,838</b>	<b>218,225</b>	<b>604,970</b>	<b>226,201</b>	<b>228,291</b>

BioArctic's net revenues have mainly consisted of milestone payments and income from the research collaborations within Alzheimer's disease with Eisai and within Parkinson's disease with AbbVie, which ended in 2022. With effect from 2023 BioArctic receives co-promotions, revenues and royalty generated by the sales of lecanemab. Revenues reported are divided as :

- In total royalty amounted to SEK 2.5 M (0.0) in the third quarter and SEK 3.0 M (0.0) for the nine-month period.
- BioArctic has a collaboration with Eisai, co-promotion, where the parties contribute with resources with the aim of jointly selling lecanemab in the Nordic countries. The result from the collaboration is split evenly between the

parties. In the third quarter and for the nine-month period compensation from this agreement for incurred costs during the period of preparations in advance of launch amounted to SEK 3.6 M (-).

- During the third quarter SEK 201.0 M was recognized as revenue from milestone payments from Eisai and for the nine-month period the amount was SEK 592.0 M.
- BioArctic has a research collaboration agreement with Eisai. In the third quarter SEK 1.8 M (2.2) was recognized as revenue. For the nine-month period SEK 6.4 M (6.3) was recognized. For 2022 revenues from the ended collaboration with AbbVie amounted

to SEK 54.5 M for the third quarter and SEK 58.5 M for the nine-month period.

**NOTE 5 ADJUSTED COMPARATIVE FIGURES**

The comparative figures for other operating income, other operating expenses, financial income and financial expenses for the third quarter of 2022 and the full year of 2022 respectively have been changed due to the reclassification of exchange rate gains and exchange rate losses between exchange rate results of an operating nature and exchange rate results of a financial nature. The reclassification also affected adjustment for non-cash items. The adjustment reduced operating profit by SEK 0.6 M and increased financial items by SEK 0.6 M for the third quarter of 2022. For the full year period of 2022 the effect of the adjustment was an increase in operating profit by SEK 0.1 M and a decrease in financial items by SEK 0.1 M. Profit or loss after financial items was not affected either for the third quarter of 2022 or the full year period of 2022.

**NOTE 6 INTRA-GROUP PURCHASES AND SALES**

The parent company's income from group companies amounted to SEK 0.1 M (-) for the quarter and SEK 0.2 M (-) for the nine-month period and referred to forwarded costs. The parent company's costs from group companies amounted to SEK 3.8 M (-) for the quarter and SEK 6.9 M (-) for the nine-month period and was related to services rendered.



## 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 ( $\alpha$ -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.

## ARIA-H

Combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis.

## 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.

## CNS - Central nervous system

The part of the body's nervous system comprising the brain and spinal cord.

## Clinical studies

Drug trials performed in human subjects.

## CMS - Centers for Medicare and Medicaid

A federal agency in the US Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid.

## 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.

