

Applications for market approval of lecanemab submitted on three continents

EVENTS DURING THE FIRST QUARTER 2023

- On January 6, the FDA approved lecanemab (Leqembi™) via the accelerated approval pathway for the treatment of Alzheimer's disease
- BioArctic's partner Eisai has 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 Prescription Drug User Fee Act (PDUFA) action date for full approval in the US is July 6, 2023
- The approval in the US and submissions in the EU and Japan entitled BioArctic to milestones of MEUR 35 in total, which were recognized as revenue and paid during the first quarter
- U.S. Veterans' Health Administration decided to provide coverage of Leqembi for veterans with early Alzheimer's disease
- New lecanemab-data was presented at the AD/PD congress regarding health-related quality of life outcomes, safety and the unique binding profile of the antibody

EVENTS AFTER THE END OF THE PERIOD

- A recently 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

FINANCIAL SUMMARY JANUARY – MARCH 2023

- Net revenues for the period amounted to MSEK 393.4 (3.7)
- Operating profit amounted to MSEK 300.6 (-44.2)
- Profit for the period amounted to MSEK 293.9 (-44.3)
- Earnings per share before dilution were SEK 3.33 (-0.50) and SEK 3.31 (-0.50) after dilution.
- Cash flow from operating activities amounted to MSEK 299.0 (-39.7)
- Cash and cash equivalents at the end of the period amounted to MSEK 1,106 (801)

KEY FINANCIAL PERFORMANCE INDICATORS

MSEK	Q1		Jan-Dec
	2023	2022	2022
Net revenues	393.4	3.7	228.3
Other operating income	3.3	0.4	0.3
Operating profit/loss	300.6	-44.2	-17.3
Operating margin, %	76.4	neg	neg
Profit/loss for the period	293.9	-44.3	-11.2
Earnings per share before dilution, SEK	3.33	-0.50	-0.13
Earnings per share after dilution, SEK	3.31	-0.50	-0.13
Equity per share, SEK	12.31	8.46	8.92
Cash flow from operating activities	299.0	-39.7	-31.6
Cash flow from operating activities per share, SEK	3.39	-0.45	-0.36
Equity/assets ratio, %	94.0	88.0	91.6
Return on equity, %	31.40	-5.77	-1.42
Share price at the end of the period, SEK	251.40	103.20	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 January 6 of this year, lecanemab has been approved for treatment of Alzheimer’s disease under the accelerated approval pathway in the US. In the first quarter of 2023, our partner Eisai continued to submit a number of applications for market approval of lecanemab, and regulatory reviews are now in progress on three continents. By July 6 at the latest, the US Food and Drug Administration (FDA) will release information on a potential full approval of lecanemab, which is being marketed under the brand name Leqembi in the US. The medical product authorities in the EU and Japan have begun their reviews, with lecanemab being granted a priority review in Japan. The same applies in China, where the National Medical Products Administration (NMPA) initiated a review of lecanemab in December. In total, these regulatory advances resulted in BioArctic receiving MEUR 35 in milestone payments during the first quarter.

The fact that authorities around the world – so soon after the Phase 3 results were presented – are reviewing lecanemab demonstrates both Eisai’s strategic focus and operational capacity to fully manage the potential in lecanemab, and the willingness of society to prioritize a new, potentially revolutionary treatment of Alzheimer’s disease.

The next important step for patients to gain access to lecanemab as quickly as possible are the reimbursement processes that are initiated when a new drug is approved. In the US, the Veterans’ Health Administration has already decided to reimburse Leqembi for US veterans who are living with early stages of Alzheimer’s disease. In parallel, the Centers for Medicare and Medicaid Services (CMS), who decide which pharmaceuticals are to be reimbursed in public healthcare insurance, announced that they would review their position if the FDA issues a full approval of Leqembi. Eisai is preparing for similar procedures around the world, placing great emphasis on demonstrating the value of lecanemab for both patients and society as a whole. A recently 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.

The experiences from the introduction in other countries will be crucial when BioArctic, in conjunction with potential approval from the European Medicines Agency, prepares to launch lecanemab in the Nordic market together with Eisai. BioArctic has now established subsidiaries in Denmark, Finland, and Norway, and the Stockholm-based marketing organization continues to grow. As a result of the organization expansion, we are also pleased to welcome Anders Martin-Löf as the new CFO as of May 1. He succeeds Jan Mattsson, who has made valuable contributions in the same function over the last several years, and is now transitioning to a newly instated position as VP Finance.



“Our greatest driving force is the patients, and since every day matters for them we are working to have development move as quickly as possible.”

At the end of March, it was once again time for the international AD/PD conference, which gathers world-leading experts in neurodegenerative diseases. It was extra exciting that this year’s conference was held in Gothenburg, and that HRH Queen Silvia inaugurated the meeting with a warm and crucial message. At AD/PD, Eisai presented large amounts of new and detailed data, all of which confirmed the safety of lecanemab and the efficacy in patients with early Alzheimer’s disease. BioArctic also presented new data through Professor Lars Lannfelt.

The rest of our project portfolio continues to evolve at a rapid pace, and our Brain Transporter (BT) technology has performed so well that it has now advanced from the research phase to the preclinical phase. The goal of the BT technology is to dramatically improve the transport of antibodies into the brain, which is assumed will lead to better clinical efficacy so that lower doses can be used. We see great potential in our technology further increasing the efficacy of the antibodies that are now being developed for diseases in the brain – both by ourselves and by others.

The tempo is currently quite high in all parts of BioArctic, from our research projects all the way to the preparations ahead of a potential Nordic market introduction of lecanemab. The hope is that our drug candidates will be able to help millions of people around the world. Our greatest driving force is the patients, and since every day matters for them, we are working to speed up development as much as possible for the benefit not only of patients, but also 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'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 β) is involved in Alzheimer's disease, while the protein alpha-synuclein (α -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 March 31, 2023, the project portfolio consisted of:

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

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

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 the progression of Alzheimer's disease. The lead drug candidate is lecanemab (BAN2401), for which positive results were presented from the Phase 3 study Clarity AD in early Alzheimer's disease in September 2022. 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. In addition, BioArctic conducts research in diagnostics to support its own projects in Alzheimer's disease.

Drug candidate lecanemab (collaboration with Eisai)

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 β 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 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 such as 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 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. For patients, this could equal remaining in the earlier stages of the disease for an additional 2-3 years, according to a modeling study, published by Eisai.

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 Phase 1 studies for subcutaneous dosing of lecanemab and a subcutaneous formulation is currently being evaluated in a substudy of the open-label extension part of Clarity AD.

In addition, since July 2020, Eisai's Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical Alzheimer's disease, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, 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), led by Washington University School of Medicine in St. Louis.

On January 6, 2023, lecanemab (Brand Name in the U.S.: LEQEMBI™) was granted accelerated approval by the U.S. Food and Drug Administration (FDA) under the accelerated approval pathway for treatment of Alzheimer's disease. The approval was based on clinical, biomarker and safety data from the Phase 2b study in 856 people with early Alzheimer's disease with confirmed presence of amyloid pathology. The approval resulted in a milestone payment to BioArctic from Eisai amounting to EUR 25 million. The payment was received and recognized as revenue in the first quarter of 2023.

On January 6, 2023, Eisai submitted a Supplementary Biologics Application (sBLA) to the FDA for full approval in

the US. On March 6, 2023, the FDA accepted the sBLA and granted priority review for Leqembi, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023.

Further Eisai submitted applications for marketing authorization in the EU on January 9 2023, and in Japan on January 16. The Japanese application was granted priority review. In conjunction with the submission in Japan, and formal acceptance of the application in the EU, BioArctic was entitled to a milestone payment of EUR 5 million per region, i.e., a total of EUR 10 million. The payment has been received and recognized as revenue in 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. 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.

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 (pE3-A β), 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 β) and is linked to the company's project BAN1503.

PARKINSON'S DISEASE (owned by BioArctic)

In Parkinson's disease, BioArctic has a portfolio of potential disease-modifying 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

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

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 alpha-synuclein aggregates. 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.

The PD1601 and PD1602 antibody projects also target alpha-synuclein for treatment of Parkinson's disease and are part of the portfolio which was previously being developed in partnership with AbbVie. In the second quarter 2022, however, AbbVie informed BioArctic that it had taken a strategic business decision to terminate the collaboration regarding BioArctic's alpha-synuclein project portfolio. BioArctic has therefore redeemed the project portfolio and is currently working on various options, including a new potential partnership, to take the project forward.

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.

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 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 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, 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 first quarter amounted to MSEK 393.4 (3.7). The increase is mainly explained by three milestone payments of MSEK 391.1 (MEUR 35).

Other operating income relates to research grants, operating exchange rate gains and forwarded costs. Other operating income amounted to MSEK 3.3 (0.4) in the first quarter.

Total operating expenses for the first quarter amounted to MSEK -96.1 (-48.4). Project expenses for projects fully owned by BioArctic increased during the quarter due to the expanded project portfolio. Also, expenses for personnel increased. The main explanation for this is variable remuneration to the employees linked to BioArctic's achieved milestones. The increase in personnel costs is also a result of an increase in the number of employees. Other external costs increased during the quarter 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 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 300.6 (-44.2) for the first quarter. The increase in operating profit was primarily attributable to received milestone payments.

Net financial items totaled MSEK 3.3 (0.0) for the first quarter. Financial income consists of interest income and financial expenses consist of exchange rate losses and interest on leasing liabilities.

Profit (loss) amounted to MSEK 293.9 (-44.3) for the first quarter.

Earnings per share before dilution amounted to SEK 3.33 (-0.50) and SEK 3.31 (-0,50) after dilution for the first quarter.

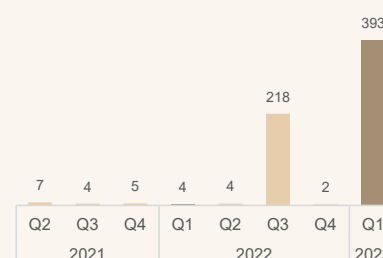
LIQUIDITY AND FINANCIAL POSITION

Equity amounted to MSEK 1,085 as of March 31, 2023 compared with MSEK 786.2 as of December 31, 2022. This corresponds to equity per outstanding share of SEK 12.31 (8.92). The equity/asset ratio was 94.0 percent as of March 31, 2023 compared with 91.6 percent as of December 31, 2022.

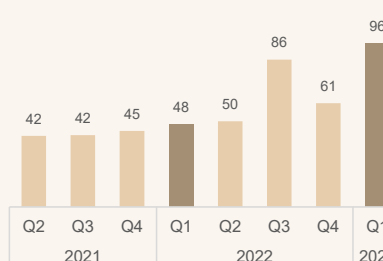
The Group's cash and cash equivalents consist of bank balances that at the end of the quarter amounted to MSEK 1,106.0 compared with MSEK 805.4 as of December 31, 2022. The increase is attributable to milestone payments received. There were no loans as of March 31, 2023 and no loans have been taken since 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.

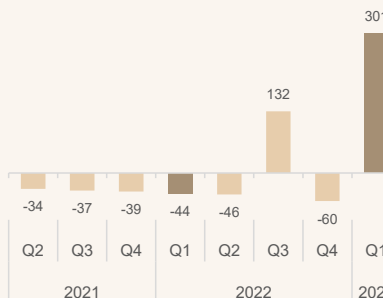
Net revenues (MSEK)



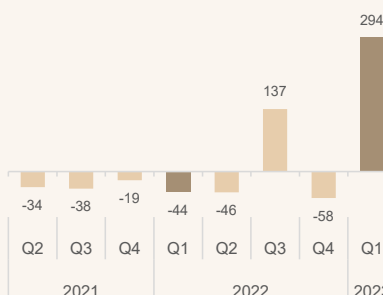
Operating expenses (MSEK)



Operating profit/loss (MSEK)



Profit/loss for the period (MSEK)



CASH FLOW AND INVESTMENTS

Cash flow from operating activities for the first quarter amounted to MSEK 299.0 (-39.7). The main explanation to the increase is the received milestone payments.

For the first quarter cash flow from investing activities amounted to MSEK -0.1 (-6.0). The investments were mainly related to laboratory equipment. Cash flow from financing activities amounted to MSEK 1.3 (-2.0) for the first quarter and relates to the amortization of leasing liabilities and the share issue connected to exercised employee warrants in the first quarter.

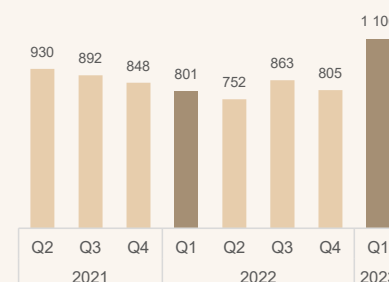
PARENT COMPANY

The main part of the Group's business operations are 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 lecanemab (Leqembi™) via the accelerated approval pathway for the treatment of Alzheimer's disease
- Eisai has 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 Prescription Drug User Fee Act (PDUFA) action date for full approval in the US is July 6, 2023
- The approval in the US and submissions in the EU and Japan entitled BioArctic to milestones of MEUR 35 in total
- 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
- 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 will propose to the 2023 annual general meeting that Eugen Steiner, currently board member of BioArctic, succeed Wenche Rolfsen as chairman of the company, and that Ivar Verner continue as deputy chairman of the board
- The nomination committee further proposed the re-election of board members Ivar Verner, Håkan Englund, Pär Gellerfors, Lars Lannfelt, Lotta Ljungqvist, Mikael Smedeby and Eugen Steiner and that Cecilia Edström be elected for a term of office that extends until the end of the next annual general meeting
- The subsidiaries BioArctic Denmark ApS, BioArctic Finland Oy and BioArctic Norway A/S were formed
- Anders Martin-Löf has been hired as new Chief Financial Officer. Current CFO Jan Mattsson will remain in his role until May 1 when Martin-Löf takes office and will then transition to a newly established role as VP Finance
- Eisai has published three articles regarding lecanemab's phase 2b study which further strengthens previously published data

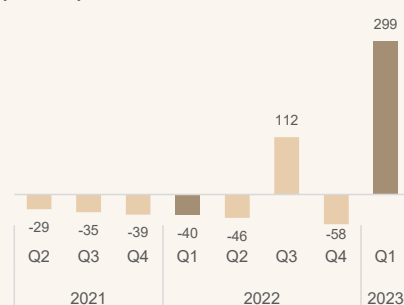
Cash and cash equivalents (MSEK)



Financial position (MSEK)

	31 Mar 2023	31 dec 2022
Non-current lease liabilities	0.7	1.2
Current lease liabilities	7.2	8.9
Cash and cash equivalents	1,106.0	805.4
Net cash position	1,098.1	795.3

Cash flow from operating activities (MSEK)



Cash position (MSEK)

1 106

Other information

EVENTS AFTER THE END OF THE PERIOD

- A recently 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

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 March 2023, BioArctic's patent portfolio consisted of 15 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 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 BAN2401 back-up antibodies. The total value of these agreements may amount to MEUR 222 in addition to royalties. As of 31 March 2023, up to 101 MEUR in milestone payments remains from Eisai.

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.

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 only has minimal sales of a drug approved under the accelerated approval pathway in the US, via its partner Eisai. BioArctic is developing a number of drug candidates for chronic neurodegenerative diseases in partnership with global pharma companies such as Eisai. 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 neurodegenerative disorders and have great market potential. BioArctic's ambition is to generate the medicines of the future for patients with neurodegenerative 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 246, 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 first quarter, the number of employees was 69 (55) of which 25 (21) are men and 44 (34) women. Around 80 percent work in R&D and of these around 85 percent are PhDs.

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.

THE SHARE AND SHAREHOLDINGS

The share capital in BioArctic amounts to SEK 1,763,614 divided by 88,180,675 shares which is split between 14,399,996 A-shares and 73,780,679 B-shares. The number of shares increased during the first quarter by 49,104 shares as a result of the subscription of shares by participants in the employee warrant 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 MARCH 31, 2023¹

	Number		Share 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	-	3,426,406	3.9	1.6
Third Swedish National Pension Fund	-	3,297,088	3.7	1.5
Handelsbanken Funds	-	2,021,326	2.3	0.9
Unionen	-	1,957,308	2.2	0.9
Nordea Funds	-	1,140,449	1.3	0.5
Investment AB Öresund	-	1,000,000	1.1	0.5
SEB Funds	-	977,175	1.1	0.4
Tot. 10 largest shareholders	14,399,996	51,761,645	75.0	89.9
Other	-	22,019,034	25.0	10.1
Total	14,399,996	73,780,679	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, 915,000 employee warrants were allocated. Of these 70,000 employee warrants were allocated during the first quarter 2023. The number of forfeited warrants amounted to 10,000 and the number of exercised employee warrants amounted to 120,690 as of March 31, which means that 784,310 employee warrants remain outstanding at end of quarter. The allocation of employee warrants had a dilutive effect corresponding to 714,310 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 April 27, 2023.

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

Stockholm, Sweden, April 27, 2023

Gunilla Osswald
CEO, BioArctic AB (publ)

INVITATION TO PRESENTATION OF THE REPORT FOR JANUARY – MARCH 2023

BioArctic invites investors, analysts, and media to an audiocast with teleconference (in English) today, April 27, 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-q1-2023/register>

CALENDAR 2023

Annual report in Swedish published	April 28, 2023
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

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This report has been prepared in a Swedish original version and translated into English. In the event of any inconsistency between the two versions, the Swedish language version applies

Financial statements, Group

CONSOLIDATED INCOME STATEMENT

kSEK	Q1		Jan-Dec
	2023	2022	2022
Net revenues (note 4)	393,426	3,737	228,291
Other operating income (note 6)	3,299	422	334
Operating revenues	396,725	4,159	228,625
Operating expenses			
Project related expenses	-30,137	-14,927	-74,326
Other external expenses	-11,261	-7,452	-33,015
Personnel expenses	-47,800	-22,169	-115,650
Depreciations of tangible assets	-4,430	-3,474	-14,633
Other operating expenses (note 6)	-2,512	-343	-8,337
Operating expenses	-96,140	-48,365	-245,961
Operating profit/loss	300,584	-44,206	-17,336
Financial income (note 6)	5,448	353	8,285
Financial expenses (note 6)	-2,101	-403	-2,117
Profit/loss before tax	303,932	-44,256	-11,168
Tax	-10,075	-0	-11
Profit/loss for the period	293,857	-44,256	-11,179
Earnings per share			
Earnings per share before dilution, SEK	3.33	-0.50	-0.13
Earnings per share after dilution, SEK	3.31	-0.50	-0.13

SOLIDATED INCOME STATEMENT CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

kSEK	Q1		Jan-Dec
	2023	2022	2022
Profit/loss for the period	293,857	-44,256	-11,179
Other comprehensive income	-	-	-
Comprehensive income for the period	293,857	-44,256	-11,179

CONSOLIDATED BALANCE SHEET

kSEK	31 Mar 2023	31 Mar 2022	31 dec 2022
Assets			
Tangible fixed assets	21,817	21,472	23,531
Right-to-use assets	9,954	15,176	11,733
Deferred tax assets	577	607	596
Other financial assets	1,613	1,588	1,606
Current assets excluding cash and cash equivalents	14,973	7,111	15,454
Cash and cash equivalents	1,106,000	800,846	805,386
Total assets	1,154,934	846,800	858,307
Equity and liabilities			
Equity	1,085,374	745,130	786,241
Deferred tax liabilities	-	-	-
Non-current lease liabilities	717	5,850	1,182
Current lease liabilities	7,203	8,316	8,857
Other current liabilities	26,368	11,318	26,919
Accrued expenses and deferred income	35,272	76,186	35,108
Equity and liabilities	1,154,934	846,800	858,307

CONSOLIDATED STATEMENT OF CHANGE IN EQUITY (CONDENSED)

kSEK	31 Mar 2023	31 Mar 2022	31 dec 2022
Opening balance at 1 January	786,241	788,676	788,676
Comprehensive income for the period	293,857	-44,256	-11,179
Share issue connected to exercised employee warrants	4,051	-	5,985
Share-based payments	1,236	709	2,760
Exchange rate differences	-12	-	-
Closing balance	1,085,374	745,130	786,241

CONSOLIDATED STATEMENT OF CASH FLOW (CONDENSED)

kSEK	Q1		Jan-Dec
	2023	2022	2022
Operating profit	300,584	-44,206	-17,336
Adjustment for non-cash items (note 6)	5,045	2,397	-41,340
Interest received/paid	3,348	-97	1,784
Income tax paid	1,264	1,656	340
Cash flow from operating activities before changes in working capital	310,241	-40,250	-56,552
Change in working capital	-11,225	591	24,914
Cash flow from operating activities after changes in working capital	299,016	-39,659	-31,637
Cash flow from investing activities	-139	-6,020	-12,763
Cash flow from financing activities	1,276	-2,036	-2,808
Cash flow for the period	300,153	-47,716	-47,209
Cash and cash equivalents at beginning of period	805,386	848,405	848,405
Exchange rate differences in cash and cash equivalents (note 6)	461	156	4,190
Cash and cash equivalents at end of period	1,106,000	800,846	805,386

CONSOLIDATED QUARTERLY DATA

	2023	2022	2022	2022	2022	2021	2021	2021
MSEK	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2
Income statement								
Net revenues	393	2	218	4	4	5	4	7
Other operating income	3	-1	1	0	0	1	1	1
Operating expenses	-96	-61	-86	-50	-48	-45	-42	-42
Operating profit/loss	301	-60	132	-46	-44	-39	-37	-34
Operating margin, %	76.4	neg	60.7	neg	neg	neg	neg	neg
Profit/loss for the period	294	-58	137	-46	-44	-19	-38	-34
Balance sheet								
Fixed assets	34	37	35	37	39	36	37	39
Current assets	15	15	8	6	7	13	6	5
Cash and cash equivalents	1,106	805	863	752	801	848	892	930
Equity	1,085	786	837	700	745	789	807	844
Deferred tax liabilities	-	-	-	-	-	-	21	21
Lease liabilities	8	10	10	12	14	16	18	19
Current liabilities	62	62	58	82	88	93	90	89
Cash flow								
From operating activities	299	-58	112	-46	-40	-39	-35	-29
From investing activities	-0	-4	-1	-2	-6	-2	-2	-0
From financing activities	1	3	-2	-2	-2	-2	-2	-2
Cash flow for the period	300	-59	108	-49	-48	-43	-38	-31
Key ratios								
Equity/asset ratio, %	94.0	91.6	92.5	88.1	88.0	87.9	86.3	86.7
Return on equity, %	31.4	-7.1	17.8	-6.3	-5.8	-2.4	-4.5	-4.0
Data per share								
Earnings per share before dilution, SEK	3.33	-0.66	1.55	-0.52	-0.50	-0.22	-0.43	-0.39
Earnings per share after dilution, SEK	3.31	-0.66	1.54	-0.52	-0.50	-0.22	-0.43	-0.39
Equity per share, SEK	12.31	8.92	9.51	7.95	8.46	8.96	9.17	9.59
Cash flow operating activities per share, SEK	3.39	-0.66	1.27	-0.52	-0.45	-0.45	-0.39	-0.33
Share price at the end of the period, SEK	251.40	272.00	271.60	77.45	103.20	119.20	162.60	137.80
Number of shares outstanding at the end of the period, thousands	88,181	88,132	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding before dilution, thousands	88,156	88,096	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding after dilution, thousands	88,860	88,825	88,690	88,577	88,605	88,610	88,585	88,560

Financial statements, Parent company

PARENT COMPANY INCOME STATEMENT

kSEK	Q1		Jan-Dec
	2023	2022	2022
Net revenues	393,426	3,737	228,291
Other operating income (note 6)	3,299	422	334
Operating revenues	396,725	4,159	228,625
Operating expenses			
Project related expenses	-30,137	-14,927	-74,326
Other external expenses	-14,889	-9,614	-41,956
Personnel expenses	-47,113	-22,169	-115,650
Depreciations of tangible assets	-1,835	-1,540	-6,621
Other operating expenses (note 6)	-2,512	-343	-8,337
Operating expenses	-96,485	-48,593	-246,891
Operating profit/loss	300,239	-44,434	-18,265
Financial income (note 6)	5,448	353	8,285
Financial expenses (note 6)	-1,987	-235	-1,557
Profit/loss after financial items	303,700	-44,316	-11,537
Change in tax allocation reserves	-	-	-
Profit/loss before tax	303,700	-44,316	-11,537
Tax	-10,035	12	65
Profit/loss for the period	293,665	-44,304	-11,472

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 Mar 2023	31 Mar 2022	31 dec 2022
Assets			
Tangible fixed assets	21,817	21,472	23,531
Deferred tax assets	473	401	453
Other financial assets	1,746	1,638	1,656
Current assets excluding cash and cash equivalents	17,960	9,126	17,842
Cash and cash equivalents	1,105,927	800,800	805,342
Total assets	1,147,923	833,436	848,825
Equity and liabilities			
Equity	1,085,750	745,932	786,798
Tax allocation reserve	-	-	-
Other current liabilities	26,197	11,318	26,919
Accrued expenses and deferred income	35,975	76,186	35,108
Equity and liabilities	1,147,923	833,436	848,825

Notes

NOTE 1 GENERAL INFORMATION

This interim report for the period January – March 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 majority of 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 period January – March 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	Q1		Jan-Dec
	2023	2022	2022
Geographic breakdown of net revenues			
Europe	-	1,649	58,478
Asia	393,426	2,088	169,813
Total net revenues	393,426	3,737	228,291
Net revenues per revenue type			
Milestone payments, recognized at a given point in time	391,058	-	161,460
Income from research collaborations, recognized over time	2,368	3,737	66,831
Total net revenues	393,426	3,737	228,291

BioArctic's net revenues essentially consist of milestone payments and income from the research collaborations within Alzheimer's disease with Eisai. During the first quarter 2023, BioArctic received and booked milestone payments of in total MSEK 391.1 (MEUR 35) in conjunction with the FDA approving lecanemab under the accelerated approval pathway, and Eisai submitting marketing authorization applications in the EU and Japan.

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 first quarter MSEK 2.4 (2.1) was 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.

NOTE 6 ADJUSTED COMPARATIVE FIGURES

The comparative figures for other operating income, other operating expenses, financial income and financial expenses for the first 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 affects

adjustment for non-cash items. The adjustment reduces operating profit by MSEK 0.1 and increases financial items by MSEK 0.1 for the first quarter of 2022. For the full year period of 2022 the effect of the adjustment is an increase in

operating profit by MSEK 0.1 and a decrease in financial items by MSEK 0.1. Profit or loss after financial items is not affected either for the first quarter of 2022 or the full year period of 2022.

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 ($A\beta$)

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

Antibody

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

ApoE (Apolipoprotein E)

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

ARIA-E

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

Binding profile

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

Biomarker

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

Blood-brain barrier

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

Breakthrough therapy designation

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

Central nervous system (CNS)

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

Clinical studies

Drug trials performed in human subjects.

Disease modifying treatment

A treatment that interferes with the processes of the disease and changes it in a positive way.

Dose dependent

Increased effect at higher dose.

Drug candidate

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

Early Alzheimer's disease

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

Fast Track Designation

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

FDA

The US Food and Drug Administration.

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.

