



Annual Report

BIOARCTIC

2022



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### The year in brief

An intense year with positive Phase 3 results, regulatory progress, continued build-up of a Nordic commercial organization, and a project portfolio that was expanded with several new projects.



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### Comments from the CEO

The results of the Phase 3 study with lecanemab instill hope for patients with Alzheimer's disease. For us at BioArctic, it also gives us confidence and financial conditions to continue developing our diversified project portfolio.

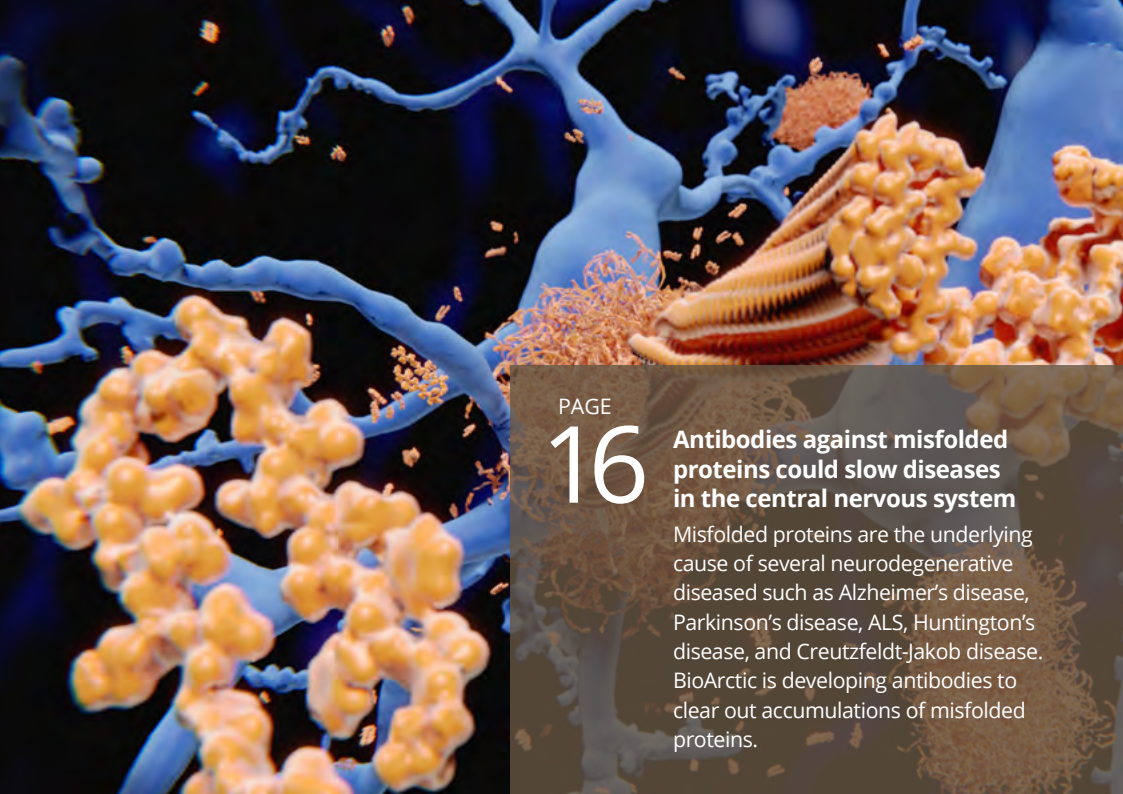


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### A word from our founders

20 years after Lars Lannfelt and Pär Gellerfors founded BioArctic, their conviction and persistence resulted in healthcare facing a paradigm shift in the treatment of Alzheimer's disease.



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**Antibodies against misfolded proteins could slow diseases in the central nervous system**

Misfolded proteins are the underlying cause of several neurodegenerative diseases such as Alzheimer’s disease, Parkinson’s disease, ALS, Huntington’s disease, and Creutzfeldt-Jakob disease. BioArctic is developing antibodies to clear out accumulations of misfolded proteins.



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**Positive results from the major clinical Phase 3 study of early Alzheimer’s disease**

Lecanemab reduces clinical degeneration by 27 percent after 18 months of treatment, according to the results from the Clarity AD Phase 3 study that was presented in September. Lecanemab is now approved in the US under the accelerated approval pathway, and applications for full approval have been submitted in the EU, Japan, China and the US.

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# BioArctic in 3 minutes

BioArctic develops drug candidates with the potential to revolutionize the treatment of severe neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease and ALS. The company's drug candidate lecanemab is the first disease-modifying treatment for Alzheimer's disease with clear positive Phase 3 results showing a ability to reduce cognitive decline. BioArctic's research portfolio consists primarily of unique antibodies targeted at the misfolded proteins that form the basis for the emergence of various neurodegenerative diseases. The antibodies focus selectively on the soluble – and pathogenic – aggregations that are formed by misfolded proteins. The antibodies binds to the soluble aggregates and clears these away, which slows the progress of the disease.



BioArctic in 3 minutes

## ALZHEIMER'S DISEASE

The drug candidate lecanemab was developed by BioArctic, and has been outlicensed to the Japanese pharma company Eisai since 2007. In September 2022, Eisai presented positive results from a large global Phase 3 study in patients with early Alzheimer's disease. Lecanemab was approved in the US in January 2023 under the accelerated approval pathway. Applications for full approval in the US, the EU, and Japan were also submitted in January 2023. An application process has also been initiated in China. Under the agreement with Eisai, BioArctic is entitled to milestone payments, as well as royalties based on sales. Additionally, BioArctic holds commercial rights for lecanemab in the Nordic region. BioArctic also has a number of proprietary antibodies against Alzheimer's disease with various mechanisms of action that are currently in an early research and development phase.

## ALS

In its ND3014 project, BioArctic is working on developing selective antibodies targeted at TDP-43, a protein that is misfolded in ALS patients. The antibodies make it easier for the immune system to detect and eliminate the harmful aggregations of TDP-43, which is believed to potentially lead to the progress of the disease being slowed and a disease-modifying effect being achieved. BioArctic has expanded its ALS portfolio with an additional project, ND-BT3814, which is a combination with the company's Brain Transporter technology.

## PARKINSON'S DISEASE

BioArctic, following the collaboration that ended with AbbVie during the year, fully owns a portfolio of potential disease-modifying antibodies against alpha-synuclein. BAN0805 is a unique monoclonal antibody that selectively binds to and eliminates neurotoxic aggregates of alpha-synuclein. Together with robust Phase 1 data, the results from a comprehensive preclinical development program provide support for the continued development of the drug candidate in Phase 2. BioArctic has an active Investigational New Drug (IND) application in the US, and a robust manufacturing process for BAN0805. The antibodies in the Parkinson program also have potential for the treatment for Lewy body dementia and multiple systemic atrophy. BioArctic further expanded its portfolio in late 2022 with the PD-BT2238 project, which combines the company's Brain Transporter technology with a selective alpha-synuclein antibody.

## BRAIN TRANSPORTER TECHNOLOGY

The blood-brain barrier controls the passage of substances between the blood stream and the brain, and protects the brain from hazardous substances. At the same time however the passage of drugs to the brain becomes more difficult. BioArctic's Brain Transporter (BT) technology consists of a molecular module that, when combined with antibodies, allows the antibody to be actively transported into the brain through an existing cellular transport path. The BT technology is now being applied in two drug projects for Alzheimer's disease, AD-BT2802 and AD-BT2803; the PD-BT2238 Parkinson's project; and the ND-BT3814 ALS project as well as in a new treatment for Gaucher disease, GD-BT6822.

## FINANCIAL OVERVIEW

	2022	2021
Net revenue, MSEK	228.3	23.1
Operating profit/loss, MSEK	-17.4	-139.7
Profit/loss for the year, MSEK	-11.2	-119.8
Cash flow from operating activities, MSEK	-31.6	-140.5
Equity/asset ratio, %	91.6	87.9
Return on equity, %	-1.42	-14.13
Earnings per share, SEK	-0.13	-1.36
Equity per share, SEK	8.92	8.96
Cash flow per share, SEK	-0.36	-1.60
Share price at December 31, SEK	272	119.20
Cash and cash equivalents, net, MSEK	805.4	848.4

## NET REVENUE, MSEK

228

BioArctic's net revenue in 2022 consists partly of milestone payments from license agreements and research collaboration with Eisai as well as the now-concluded partnership with AbbVie.

## OPERATING PROFIT, MSEK

-17

Operating profit during the financial year improved compared with the preceding year. The improvement is attributable primarily to milestone payments totaling MSEK 161.5 from Eisai and final settlement of the Parkinson's project, which brought in MSEK 47.9 in revenue.

## CASH AND CASH EQUIVALENTS, MSEK

805

BioArctic's business model, which generates revenue streams from collaboration and license agreements, brought BioArctic's cash balances to SEK 805 million at the end of 2022. The company's strong financial position creates a high degree of flexibility and facilitates future efforts.

# BioArctic's business model and project portfolio

BioArctic specializes in the development of new drug candidates for neurodegenerative disorders of the central nervous system (CNS). Today's treatments frequently offer only the relief of symptoms, and tremendous resources and big commitment are put into developing more efficacious drugs in order to slow the progress of these diseases. BioArctic creates value with a unique competence and innovative development of new drug candidates, as well as the capacity for commercializing them by partnership and licensing agreements with international pharma companies.

To achieve its goals more rapidly, BioArctic has several ongoing partnerships with pharma companies and external research groups that provide expertise and resources in preclinical and clinical drug development, regulatory activities, production, and marketing. In parallel, BioArctic is building up its own marketing organization ahead of a potential launch of its drug candidate lecanemab in the Nordic region. With the build-up of its marketing organization, BioArctic is establishing itself as an integrated biopharma company with a strong position in the Nordic market.

The company's research portfolio consists

of a large number of projects, from the early research stage to the clinical development phase and the market, with the goal of developing and improving the treatment of Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis (ALS) and other disorders of the central nervous system.

In addition, the company is also developing a technology to facilitate the transport of drugs into the brain. Some 50 coworkers work dedicated on research and development at BioArctic's head office in central Stockholm to enable new scientific breakthroughs.

## VISION

Through its research, BioArctic will create drugs that improve the lives of patients, and become a world leading biopharma company in neurodegenerative diseases.

## MISSION

Together, we generate the medicines of the future for patients with severe neurodegenerative diseases.

## BUSINESS CONCEPT

BioArctic is a Swedish biopharma company that develops new drugs based on groundbreaking research for patients with serious diseases. The objective is to create the treatment methods of the future that can delay or stop the progress of neurodegenerative diseases such as Alzheimer's disease.

BioArctic generates revenue and shareholder value in the company by:

- outlicensing drug candidates that are developed in-house
- marketing and selling its own and inlicensed drugs in the Nordic region and, over the long term, in the rest of Europe as well.

BioArctic's business model and project portfolio

## BIOARCTIC'S PROJECT PORTFOLIO

BioArctic has a broad, diversified project portfolio focused on disorders of the central nervous system. The company has an established partnership with the Japanese pharma company Eisai for lecanemab, its drug candidate against early Alzheimer's disease. Lecanemab is approved in the US under the accelerated approval pathway, and applications for full approval have been submitted in the US, the EU, and Japan. The application process has also begun in China. In addition, BioArctic is pursuing in-house development of additional drug candidates in the preclinical phase against Alzheimer's disease, Parkinson's disease, ALS, and Gaucher disease. The company is also developing Brain Transporter technology to facilitate the passage of biological drugs into the brain. All projects are focused on significant medical needs and have great commercial potential. The combination of fully financed projects and in-house investments in new groundbreaking research and development provides a healthy balance in the company's portfolio.

- 1) Partner with Eisai since 2007 regarding lecanemab for treatment of Alzheimer's disease. Eisai has partnered with Biogen regarding BAN2401 (lecanemab) since 2014
- 2) Mild cognitive impairment as a consequence of Alzheimer's disease and mild Alzheimer's disease
- 3) Normal cognitive function with intermediate or elevated levels of amyloid-beta in the brain
- 4) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury

Project portfolio as of December 31, 2022.

	Project	Partner	Research	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory and Market
ALZHEIMER'S DISEASE	Lecanemab	Eisai <sup>1</sup>	Early Alzheimer's disease <sup>2</sup>					
	Lecanemab <i>AHEAD 3-45</i>	Eisai <sup>1</sup>	Preclinical (asymptomatic) Alzheimer's disease <sup>3</sup>					
	Lecanemab back-up	Eisai						
	BAN1503 (Truncated Aβ)							
	AD-BT2802							
	AD-BT2803 (Truncated Aβ with BT)							
	AD2603							
PARKINSON'S DISEASE	BAN0805 (α-synuclein)							
	PD1601 (α-synuclein)							
	PD1602 (α-synuclein)							
	PD-BT2238 (α-synuclein with BT)							
OTHER NEURODEGENERATIVE DISEASES	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 (GCase with BT)		Gaucher disease					
BLOOD-BRAIN BARRIER	Brain Transporter (BT) technology							

# The year in brief

In September 2022, BioArctic's partner Eisai presented positive results from Clarity AD, a Phase 3 study with lecanemab in patients with early Alzheimer's disease. During the year, the company also expanded its project portfolio with new projects in diseases such as Parkinson's disease and Gaucher disease.

## The first patient is included in the DIAN-TU Phase 2/3 study

In January, it was announced that the first patient had been included in Tau NexGen, the DIAN-TU Phase 2/3 study led by the Washington University School of Medicine in St. Louis, Missouri, in partnership with Eisai. The study evaluates drug candidates targeted at tau in regards of safety and tolerability, as well as the effect on biomarkers and cognition, in individuals who have a genetic mutation that causes Alzheimer's disease. The study includes lecanemab as a backbone treatment in combination with a tau treatment, or alternately placebo.

## Lecanemab data submitted for preliminary review in Japan

In March, BioArctic's partner Eisai announced that it had commenced submission of clinical lecanemab data in Japan for preliminary review, with the goal of obtaining early marketing approval.

## Continued build-up of the Nordic marketing organization

In February, BioArctic provided an update on the continued build-up of the Nordic marketing organization ahead of a potential launch of lecanemab in the Nordic region. Several key persons were recruited to the organization during the spring, and the company took the first steps towards establishing itself as a complete biopharma company with a strong position in the Nordic market.

## Scientific article models the clinical value of lecanemab

In April, a scientific article was published, based on a modeling, that demonstrated that treatment with lecanemab can slow the progress of Alzheimer's disease and that patients who are treated remain longer in the earlier stages of the disease. The article was published in *Neurology and Therapy*.

## AbbVie terminates partnership on alpha-synuclein portfolio

In April, AbbVie announced that, due to a strategic business decision, it had decided to terminate its partnership with BioArctic regarding ABBV-0805 and the portfolio of alpha-synuclein antibodies against Parkinson's disease. BioArctic has reclaimed all rights, and data that has been generated in the project. The project has resumed its original name: BAN0805.

## New compound patent for BAN0805

In May, the US Patent Office granted a new compound patent for the antibody BAN0805 (formerly ABBV-0805), which was developed by BioArctic as a potential treatment for Parkinson's disease. The patent expires in 2041, with a possible patent term extension up through 2046.

## Rolling submission to the US Food and Drug Administration completed

In May, Eisai completed the rolling submission to the US Food and Drug Administration (FDA) via the accelerated approval pathway for lecanemab as a treatment of early Alzheimer's disease.



*The year in brief***The US Food and Drug Administration accepts the biologics license application**

In July, the FDA accepted the biologics license application and, based on the Phase 2 results, granted priority review of lecanemab for treatment of early Alzheimer's disease under the accelerated approval pathway. In conjunction with the FDA accepting the biologics license application, BioArctic was granted the right to a milestone payment of MEUR 15 from Eisai.

**New data with subcutaneous formulation of lecanemab**

In August, BioArctic's partner Eisai presented new data with a subcutaneous formulation of lecanemab at the Alzheimer's Association International Conference (AAIC).

**New project against Gaucher disease**

In November, BioArctic announced that the company had initiated a project to develop a treatment for Gaucher disease. The project is focused on combining BioArctic's Brain Transporter technology with an enzyme replacement therapy in order to treat the neuro-pathic form of the disease.

**Positive results reported from Clarity AD**

In September, BioArctic's partner Eisai reported positive top-line results from Clarity AD, the confirmatory Phase 3 study that included 1,795 patients with early Alzheimer's disease. The study met the primary endpoint on the Clinical Dementia Rating-Sum of Boxes (CDR-SB) scale, and demonstrated a slowing of clinical decline with high statistical significance. All key secondary endpoints were also met, with high statistical significance.

**Parkinson's project combined with BT technology**

In November, BioArctic announced that the company had expanded its project portfolio with the PD-BT2238 project, a selective antibody targeted at soluble alpha-synuclein aggregates that had been combined with the company's Brain Transporter technology. The goal is to increase the amount of antibodies that reach the brain to increase the efficacy of a potential treatment for Parkinson's disease.

**Detailed results from Clarity AD presented**

In November, the company's partner Eisai presented the detailed results from Clarity AD at the 2022 Clinical Trials on Alzheimer's Disease (CTAD) conference. The results were simultaneously published in the New England Journal of Medicine.

**Eisai initiated submission of biologics license application for lecanemab in China**

In December, BioArctic's partner Eisai announced that it had begun the submission of data for the biologics license application for lecanemab to the Chinese National Medical Products Association (NMPA). To begin with data from the Phase 2b study and initial data from the Clarity AD global Phase 3 study was submitted to the NMPA.



## Comments from the CEO

2022 was, just as we had hoped, a historic year for BioArctic. The results from the Phase 3 study of lecanemab in patients with early Alzheimer's disease met all our expectations and more. This breakthrough fills patients around the world and their families with hope, and the first patients already have access to the drug after the US Food and Drug Administration (FDA) approved lecanemab in the US under the accelerated approval pathway. It also gives us at BioArctic self-confidence and the financial muscles to continue developing our diversified project portfolio.

September 28, 2022 will always be a red-letter day in the 20-year history of BioArctic. Our partner Eisai communicated the results from the Clarity AD Phase 3 study, which became world news. For the first time, a major Phase 3 program had clearly shown that a drug could slow the progress of Alzheimer's disease in patients suffering from the condition. We feel great pride and joy about the antibody, developed by our founder Lars Lannfelt with colleagues at Uppsala University and further developed by BioArctic and our partner Eisai. That thought, the antibody, after two decades of persistent effort, can come to make a major difference for millions of patients, is hard to describe.

**THE RESULTS FROM CLARITY AD** showed that in patients who were treated with lecanemab, clinical decline was slowed by 27 percent compared with placebo after 18 months of treatment – and that this effect increased over time. For the patient, this could mean delaying the development of the disease by several years, and that the period of serious illness could be put off – which Eisai demonstrated earlier in 2022 using models based on the Phase 2b results.

**TO PREPARE FOR** a positive outcome, Eisai worked intensively on all the regulatory processes during the year. Back in May, Eisai completed the rolling application under the accelerated approval pathway to the FDA for lecanemab as a treatment of early Alzheimer's disease. The application, which was based on data from the Phase 2b study, was accepted in July and on January 6, 2023 the FDA announced that lecanemab had been approved. That same day, Eisai submitted a supplementary biologics license application based on the Phase 3 results to the FDA for full approval of lecanemab – or Leqembi, which will be its brand name in the US. In early January 2023, Eisai also submitted applications for market approval in Japan and the EU. The applications in both markets have been accepted for review, and the application in Japan has also been granted a priority review. In China, the application process began in December 2022, and lecanemab has been registered there as Category

1 – that is only given to drugs that China regards as extremely innovative for diseases with a major unmet medical need. In addition lecanemab has been granted priority review in China.

**WE ARE PLEASED** that Eisai has a very well-prepared, responsible and gradual launch strategy with the goal of making the drug available to the largest share possible of patients who could benefit from the treatment. During the year, we at BioArctic were engaged both strategically and operationally in building up our own marketing organization in order to carry out, in partnership with Eisai, a successful launch in the Nordic market provided that lecanemab is approved in Europe.

**THE REMAINDER OF BIOARCTIC'S PROJECT PORTFOLIO** has also developed well during the year. Based on our research with antibodies against misfolded proteins, we now have a diversified portfolio with new antibodies against Alzheimer's disease, Parkinson's disease, and ALS under development. In parallel, we are developing our Brain Transporter (BT) technology that helps transport antibodies across the blood-brain barrier, which – it is hoped – will increase the clinical efficacy of a single treatment.

**IN NOVEMBER, WE EXPANDED** our project portfolio with PD-BT2238, the Parkinson's project that is a selective antibody targeted at alpha-synuclein aggregates combined with our Brain Transporter technology. At roughly the same time, we initiated a new project with the goal of developing a new treatment for Gaucher disease. In this project, we are combining BT with an enzyme that needs to be transported into the brain so that patients will not suffer from the severe neurological symptoms that otherwise characterize the disease. The fact

that we have at least one BT project in all of the disease areas where we are engaged in developing new and better treatments is evidence of the strength of our BT technology.

**SINCE ABBVIE** chose to terminate our partnership around antibodies against alpha-synuclein, we are now pursuing all of our Parkinson's projects in-house. BAN0805 (formerly ABBV-0805) is the most advanced, with both strong preclinical data and promising Phase 1 results. Preparations for Phase 2 are under way while we are evaluating which path is the best for taking the project further.

**BIOARCTIC WAS FOUNDED IN 2003** by Lars Lannfelt and Pär Gellerfors. Right from the start, their objective was to build up a new, successful Swedish pharma company with the capacity to provide patients around the world with access to new and effective treatments based on groundbreaking research. Together, they saw the potential in Lars Lannfelt's scientific discovery, and step by step they laid the foundation for the company that, since 2014, I have had the privilege of leading. Celebrating the company's 20th anniversary with the knowledge that the first patients have been given access to groundbreaking drugs against Alzheimer's disease which BioArctic was involved in developing, while our project portfolio is growing and advancing with high-quality projects for treatment of several severe neurodegenerative diseases is an honor. In 2022, BioArctic enabled a historic shift in Alzheimer's disease.

**Gunilla Osswald**  
CEO, BioArctic

” The results from Clarity AD showed that in patients who were treated with lecanemab, clinical decline was slowed by 27 percent. For the patient, this could mean delaying the development of the disease by several years.

# Everything begins with a good hypothesis

When Lars Lannfelt and Pär Gellerfors founded BioArctic, it was with two seemingly unattainable goals in mind: to develop an effective drug against Alzheimer's disease and at the same time lay the foundation for a new large Swedish pharmaceutical company. 20 years later, they know what it took to succeed.

They first met in a lab in the cellar of Sankt Görans Hospital in Stockholm. It was the early 1980s; one of them was a physician and the other a biochemist. Together, they were trying to map the genetics and biochemistry behind intermittent porphyria, a hereditary disease. Pär had just returned from two years as a guest researcher in the US, bringing new knowledge – and a molecular biology cookbook – with him.

“Cloning genes and finding mutations was completely new then, and there was no knowledge of these methods in the daily life of the clinic where I was working as a physician. I was really impressed by Pär and that book. All the recipes worked, so we just had to start working,” Lars Lannfelt says.

The book – *Molecular Cloning: A Laboratory Manual*, written by US author Tom Maniatis et al. – is now a classic work in molecular biology. For Lars and Pär, the techniques they learned were the start of a journey that today has resulted in one of the first disease-modifying drug against Alzheimer's disease.



“ It was a solid hypothesis, the rest was just hard work and technical problem-solving.

*Everything begins with a good hypothesis*

### One career in academics, one in industry

After years together in the laboratory, two parallel paths began. Pär entered the pharma industry, where he worked on developing both drugs and business – including 14 years at Kabi Vitrum/Pharmacia. He also helped found HemeBiotech, a company that was later renamed Zymenex and was purchased by the Italian pharma company Chiesi Pharma.

Lars instead began working at Bengt Winblad's laboratory at Karolinska Institutet, which is a leader in Alzheimer's disease research. It was not long before Lars got a tip about a family in Norrland County where an unusually high number of people suffered from Alzheimer's disease at an early age. With his knowledge of how to identify mutations behind illnesses using modern methods, he began his survey. It was then, in 1992, that he found what would come to be called the Swedish mutation, a mutation that allowed a protein, amyloid beta, to aggregate and form accumulations, or plaque. When the mutation – and the accumulations of amyloid beta – were clearly seen among the family members who were ill but not among those who were healthy, it was clear that this was the start of the disease.

"There were many first-rate scientific publications based on the discovery of the Swedish mutation. Additionally, a researcher in the US who I was working with at the time applied for a patent. He explained to me that there could only be one name on a patent application and I unfortunately believed him; patents weren't talked about in academia in Sweden in the early 1990s. But I learned a lot from that and when I made the next discovery, I asked Pär instead," Lars says.

### Did you know?

The first three letters in the name of the antibody **lecanemab** come from **Lannfelt – Eisai – Collaboration**.

### The Arctic mutation and a financial crisis

It was 1999 when Lars's research group discovered the Arctic mutation. This mutation led to amyloid beta misfolding and taking on a different form. A different fault than with the Swedish mutation, but with the same effect: amyloid beta starts aggregating. Bit by bit, Lars and his colleagues were putting the puzzle together. Amyloid beta was the villain, and a particular size of aggregates – which Lars calls protofibrils – most likely to trigger the disease. In pace with more pieces of the puzzle falling into place, it also became clear that the connection did not apply only to the patients who had a hereditary form of Alzheimer's disease.

"Mutations often lead to an exaggerated picture of a natural phenomenon. The same accumulations of protofibrils also exist in those who suffer from spontaneous Alzheimer's disease later in life. The reason that amyloid beta misfolds and starts to accumulate varies; in older patients it is due in part to the brain having greater difficulty in clearing amyloid beta away – but again, the effect on the brain is the same. I understood then that we had to develop a drug that removes protofibrils, and that was what I sought to patent. But I also knew that I really didn't have the right skills to write that application. Once I had submitted the patent in the summer of 2000, I had 12 months to correct the patent application – and that's where Pär came in," Lars says.

Pär had just left HemeBiotech and happened to get in touch with Lars right at the time when the patent needed to be updated. A new partnership began.

"I quickly understood the potential. It was unusual to have such clear clinical evidence so early that the right target molecule had been found. Together with a competent patent consultant, we spent a few months adjusting the patent application," Pär says.

It was now the early 2000s. The IT crash on the stock market had taken biotech with it, and it was essentially impossible to find external capital. The first patent invoices were slipped into Lars's and Pär's household finances, and when the invoices became too large they managed to get a year's deferment on payments.



"Since no one wanted to invest a single penny in us, we decided to find a company that could finance the development. We really wanted to partner with Eisai, a Japanese company, since they stood behind Aricept – which at the time was the leading drug against Alzheimer's disease," Pär says.

### A Japanese door opener

From previous experience, Pär was used to negotiating with Japanese companies. He had learned the business culture, but above all he had worked up a Japanese business contact who could interpret and was well-established in the Japanese pharma industry. He called, and asked for help in contacting the right person at the right level at Eisai.

"My contact called back quickly and said that Eisai was interested in hearing more. But we weren't welcomed to the head office in Tokyo initially. They had part of their research organization in London, and they wanted to meet us first," Pär says.

On June 26, 2003, Lars and Pär took a flight to London. Once there, they gave their presentation to a group of researchers from Eisai and prepared for a long wait – the Japanese are not known for making quick decisions.

"But the day after, they called me at home and asked if we

*Everything begins with a good hypothesis*

could go to Tokyo,” Pär says.

A new, longer flight. A new, much larger meeting.

“I gave a presentation on the research that led up to our idea about how Alzheimer’s disease could be treated. The auditorium was packed. They were interested, but that was all. We went home without an agreement,” Lars says.

BioArctic was formed that year, but operations in the company were on the back burner. Instead, the focus was on academia. Lars had a professorship and a large research group at Uppsala University, where Pär was also conducting research. Eisai kept to the background, carefully monitoring the group’s results. Interest increased in pace with the publication of more data that strengthened the hypothesis, and two years after the initial visit to Tokyo, BioArctic signed its first research agreement with Eisai. The goal was clear: develop an antibody against amyloid beta protofibrils.

**The company and the antibody were built in parallel**

It was 2005, and everything was happening simultaneously.



Their days consisted of continual problem-solving. The most difficult problem was creating the antigen itself, meaning the protofibrils that the antibody was to bind to. Once that problem was solved, the challenges in making the antibody itself continued. During those years, the researchers built an even more finely meshed net of knowledge regarding how Alzheimer’s disease developed and how the progress of the disease could be counteracted, all the while in close contact with the daily activities of the clinic.

“Medical research is enormously complex, and I made great use of my clinical perspective, which made drawing the right conclusions easier. There is a great risk of missing something by looking only at cells and reactions in test tubes,” Lars says.

Finally, the protofibril-selective antibody mAb158 was generated at Lars’s lab in Uppsala. Lars continued leading his research group at Uppsala University, and a few years later – in 2006 – Pär became CEO full time and BioArctic hired its first researchers.

“One of BioArctic’s key tasks at the beginning was humanizing mAb158 – that is, an antibody coded by human antibody genes to reduce the risk of immunological side effects, which we succeeded at. When we presented the antibody to Eisai in 2007 we had also developed a mouse model with Alzheimer’s-like changes, which meant that we had convincing data that the mAb158 antibody worked,” Lars says.

The success with the mAb158 antibody, which today has been developed into lecanemab, led to the long-term licensing agreement signed with Eisai in 2007. Lars and Pär had always agreed on the goal: the agreement would lead to an effective drug against Alzheimer’s disease – and lay the foundation for a new major Swedish pharma company.

“That is why the agreement, right from the beginning, gave us rights to the Nordic market. We didn’t want to just develop drugs – we want to sell them as well, since we are part of developing medical care and gain a better understanding of the whole,” Lars says.

“Everything rested on the discovery Lars made about

“ We already have ideas for at least another 20 years.

protofibrils. It was a solid hypothesis, the rest was just hard work and technical problem-solving,” says Pär, summing up the company’s first years.

**Never disagreements on strategy, only on details**

Twenty years together as founders, scientists and builders of a company. New projects and indications are added; some were put aside but most developed positively. More and more employees were hired, new agreements were signed, new premises, new management. An endless mountain of major decisions that seem obvious in hindsight, but at that moment were clouded by uncertainty. Despite this, they are just as good friends today as when they first met in a cellar in the 1980s.

“We have never disagreed on any of the major decisions. We’ve always known where we were headed. The company was built on good science, good molecules, and good employees. We sometimes disagree on how matters should be solved purely technically, but in these cases the best argument always wins so there is nothing to worry about,” Pär says.

“We also have Gunilla Osswald to thank for a lot. It is her leadership over the past ten years that has meant that BioArctic is now well on its way to becoming a major Swedish pharmaceutical company,” says Lars.

BioArctic’s first drug has now been approved in the US and is being hailed globally as a major breakthrough in Alzheimer’s disease. But this is still just the beginning.

“We have good molecules and solid hypotheses today in several serious diseases of the central nervous system, and our Brain Transporter technology will further improve our development projects. It’s just a question of getting down to work, we already have ideas for at least another 20 years,” Lars states.

# Unique research discovery succeeded in attracting Eisai

Haruo Naito, the CEO of Eisai, has worked in the pharma industry for decades, and in Alzheimer's research just as long. With the positive results from the Clarity AD study, he can at last present a new treatment for patients – who are Eisai's highest priority.

**Eisai has partnered with BioArctic since 2005. What was it about BioArctic's research that piqued your interest?**

“Above all it was the discovery of amyloid beta, and in particular the protofibrils, which nobody knew much about at the time. BioArctic showed that it was a key player in the neurotoxic amyloid beta cascade, and that discovery – together with the discovery of the Arctic mutation in the Swedish families who had large amounts of protofibrils in their brains – was unique. It was a fantastic foundation for the hypothesis that the drug development is based on. It was also the first time that protofibrils, and not the cascade as a whole, had been defined as central to the neurotoxic reaction. By removing the toxic protofibril, we could see that we had improved the clinical symptoms in Alzheimer's patients, which then led to the success of lecanemab in the Clarity AD study.”

**How did you get in contact with BioArctic?**

“We had been following Lars' efforts for a long time and heard about the discovery of the Arctic mutation in Swedish families, as well as other discoveries in the early stages of research. It was fantastic, and the opportunity to develop a new Alzheimer's drug after Aricept – which we launched in 1996 and were very proud of – was attractive to us. We

initiated a scientific dialogue and exchanged thoughts and ideas, and together we noticed many advantages and realized that the combination would be a good foundation in a partnership.”

**You have worked in the pharma industry for several decades. How did you react when you learned about the results from the Clarity AD study?**

“In the 40 years we have conducted research into Alzheimer's disease, we have worked with a corporate philosophy of ‘human health care’, which means that we establish and maintain contact with patients and their families. We consider the patients and their families to be of the highest priority, and try to understand their feelings by being with them and sharing experiences. A common question that the patients and their families have is when can we present a new treatment, and how will it work?”

“The first thing I thought of when I heard the results was that the burden had been eased, and that at last I had an answer to give them. Now I can present this fantastic drug as a new treatment for Alzheimer's disease. It is the ultimate feeling of achievement for a representative of the pharma industry who has been working in the field for years.”



**What will the care of Alzheimer's disease look like in ten years, compared with today?**

“It will probably look very different. Now that we have confirmed the amyloid beta hypothesis, we believe that lecanemab will comprise the base of the drug treatment. It will be possible to replace the expensive and invasive methods used today in pace with progress in the development of new biomarker-based diagnostic methods. The biomarker tests could also be used to define the stage of the disease and facilitate the prescription of more specific treatment targeted at tau, neurosynapses, or potentially stem cells. The combination of various treatments could vary and be tailored to each patient.”

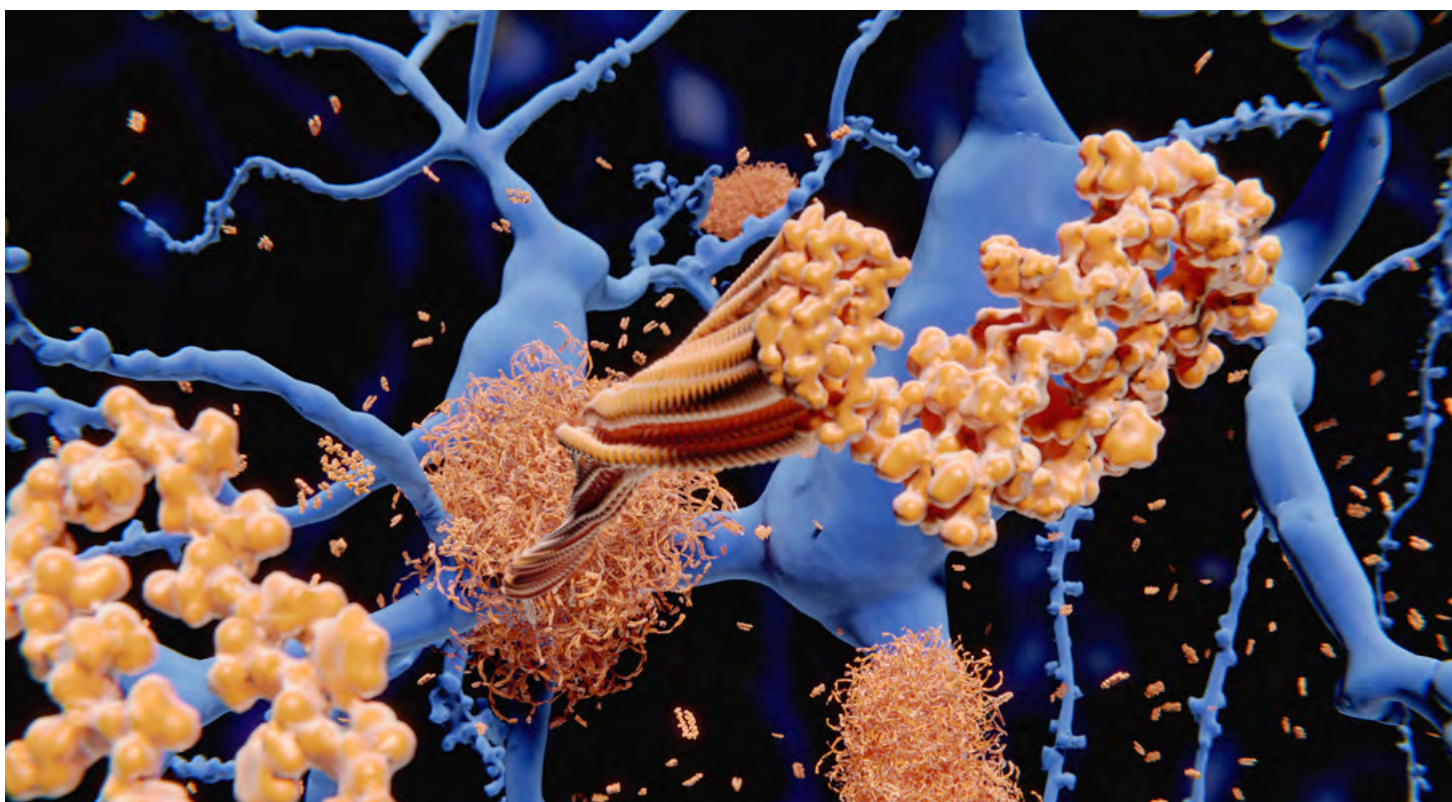
# Antibodies against **misfolded proteins** could slow diseases in the central nervous system

Several serious neurodegenerative diseases are due to proteins starting to misfold, becoming harmful to nerve cells. BioArctic's research and development are focused on developing antibody drugs that help the body identify and remove harmful accumulations of misfolded proteins.

Proteins are fundamental for cell and body functions, and the chemical structure of a protein is both simple and complex. In its simple aspect, a protein consists of a long chain of a few hundred amino acids, whose sequence is determined by our DNA. The more complex aspect comes in when the chain, a few microseconds after its formation, begins to fold. The amino acids that these chains consist of, and the sequence of these acids, affect which chemical bonds arise and thereby also which specific three-dimensional form the protein takes. In turn, this form determines what function the protein has in the body. If a single amino acid is replaced, the three-dimensional form and function can change radically. Similarly, the form of the protein can be changed depending on the surrounding environment. For example, temperature, pH, or the concentration of other proteins can change how an individual protein folds and functions.

## Misfolded proteins cause several neurodegenerative diseases

The research in genetics and biochemistry of the last few decades has led to increased knowledge on the significance of misfolded proteins for various diseases. This has become especially clear for diseases of the central nervous system: Alzheimer's disease, Parkinson's disease, Huntington's disease, Creutzfeldt-Jakob's disease, and ALS are all due to various





### *Antibodies against misfolded proteins could slow diseases in the central nervous system*

proteins – for one reason or another – beginning to misfold.

Several things could happen when a protein begins to misfold. The protein could lose its function, which means that the cell's processes no longer work like they should. A misfolded protein can also begin affecting some other process in the cell than what it was intended for, thereby creating disorder. Or – as is particularly common in neurodegenerative diseases – they can start forming increasingly larger aggregates of misfolded proteins. In certain diseases, such as Alzheimer's disease, these

aggregates finally form such large aggregates that they are no longer soluble but harden and form visible clumps called plaque. These can be shown with, for example, positron emission tomography (PET).

However, these aggregates cause the greatest damage while they are still soluble, since they are still biologically active and can impact various functions in the cells. These soluble aggregates are called oligomers, or protofibrils, and BioArctic's drug development focuses on these forms.

### **Antibodies against well-defined targets**

To slow or stop neurodegenerative diseases that are due to misfolded proteins, the harmful accumulations must be cleared away. BioArctic is developing antibodies that work by binding to the misfolded proteins in the brain and clear them away.

For an antibody treatment of this kind to be effective, it must be clear which misfolded protein causes the disease. Only when this is known can an antibody be developed that is selective toward that specific target and thus efficiently clear away the protein that is engendering the disease.

### **The Arctic mutation laid the foundation for a growing project portfolio**

When in the 1990s one of BioArctic's founders, Professor Lars Lannfelt, successfully identified the Arctic mutation in a family that was hit by a hereditary form of Alzheimer's disease, it laid the foundation for BioArctic's technology platform. The discovery led to the insight that it is the soluble aggregates – protofibrils – of the misfolded protein amyloid beta that causes Alzheimer's disease. The development of an antibody against amyloid beta protofibrils specifically began on the basis of this insight. Today, the antibody has become BioArctic's first approved drug candidate – lecanemab.

The technique for identifying harmful, soluble aggregate forms of misfolded proteins and developing antibodies that clean out these proteins specifically have subsequently been used to broaden BioArctic's project portfolio. In Parkinson's disease, the hypothesis is that it is the protein alpha-synuclein that is misfolded, and as regards ALS BioArctic is of the hypothesis that the protein TDP-43 is the problem. BioArctic's researchers are continually engaged in identifying new targets where the company's capacity for developing selective antibodies against misfolded proteins in the central nervous system could make a difference for severely ill patients.



# Neurodegenerative diseases

1

## Nerve cells break down

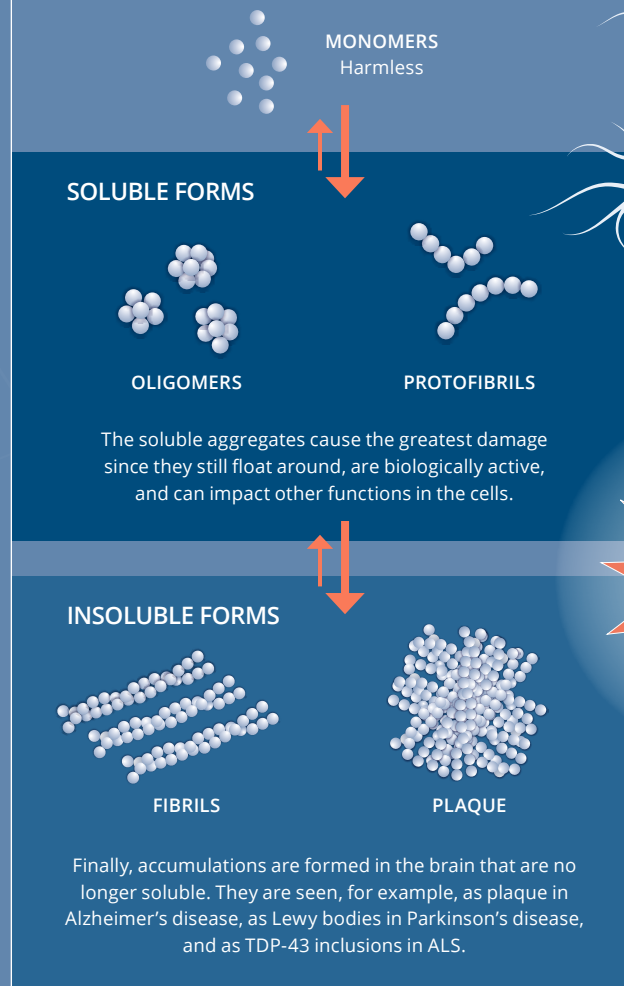
In neurodegenerative diseases, nerve cells break down and they gradually lose their function. For the person affected, this means impairment or loss of either cognitive ability or mobility – or both.



2

## Accumulation of misfolded proteins damages cells

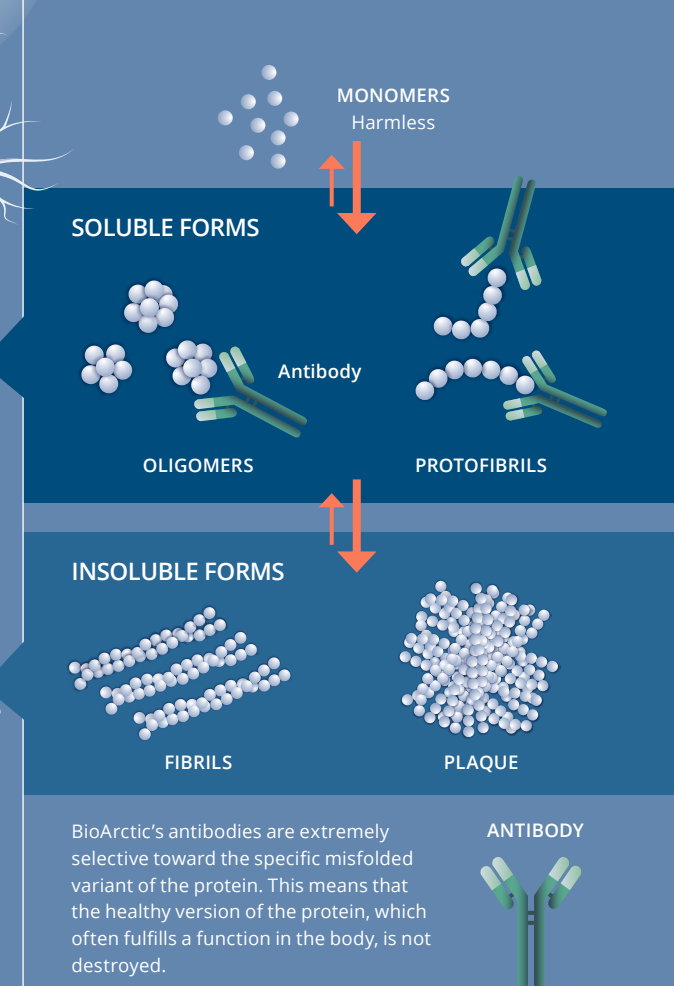
Proteins that misfold begin clumping together and form increasingly larger accumulations, or aggregates.



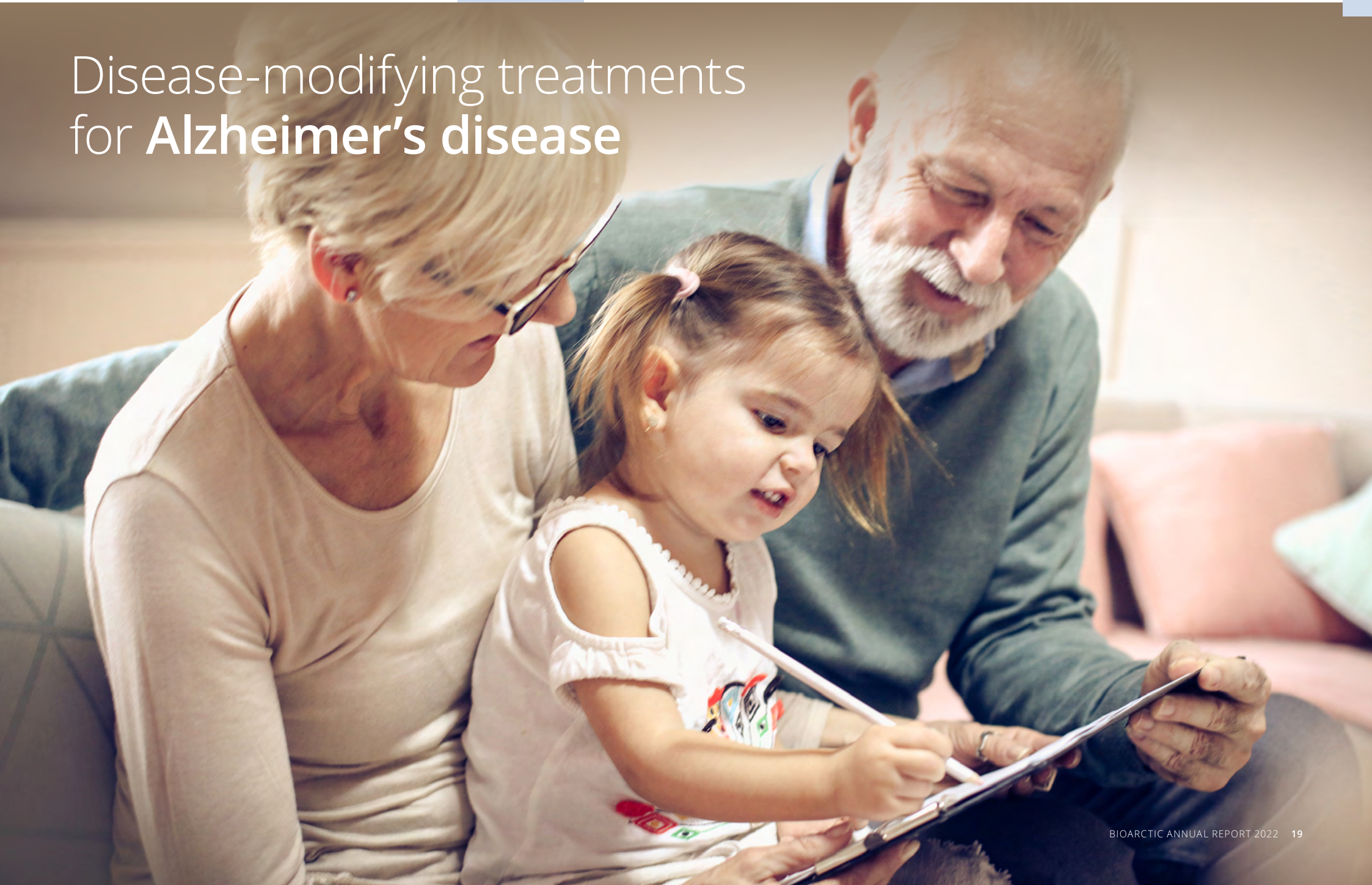
3

## Antibodies clear away the harmful forms of misfolded proteins

BioArctic is developing antibodies that binds to amyloid-beta and specifically identifies the misfolded and harmful aggregation forms and clear them out.



# Disease-modifying treatments for **Alzheimer's** disease



*Disease-modifying treatments of Alzheimer's disease*

BioArctic's lecanemab is one of the world's first disease-modifying drugs against Alzheimer's disease. Lecanemab has been approved in the US under the accelerated approval pathway, and applications for full approval have been submitted in the US, the EU, and Japan. The application process has begun in China as well. BioArctic's researchers are working on several preclinical projects with other antibodies against Alzheimer's disease.

Today, some 30 million people around the world are living with various stages of Alzheimer's disease. The disease is characterized by the death of brain cells, which causes a gradual impairment of memory and cognitive skills such as intellectual capacity, language, orientation, recognition and learning ability. The disease can also lead to changes in personality and psychiatric symptoms such as apathy, depression, disorientation, paranoia, and aggression.

The cause of Alzheimer's disease lies in the misfolding and clumping together of the protein amyloid beta into increasingly larger aggregations. When amyloid beta circulates in tissues, the blood, and other bodily fluids as an individual molecule, known as a monomer, it is harmless. But in Alzheimer's disease, the monomers begin binding to each other and forming larger aggregations. These aggregations accumulate increasing numbers of molecules, finally forming insoluble fibrils that accumulate in brain tissue and form plaque.

Until recently, patients have had access solely to treatments that alleviated the symptoms, only temporarily. BioArctic's drug, lecanemab, is one of the world's first drugs that not only alleviate the symptoms but also slow the underlying progression of Alzheimer's disease.

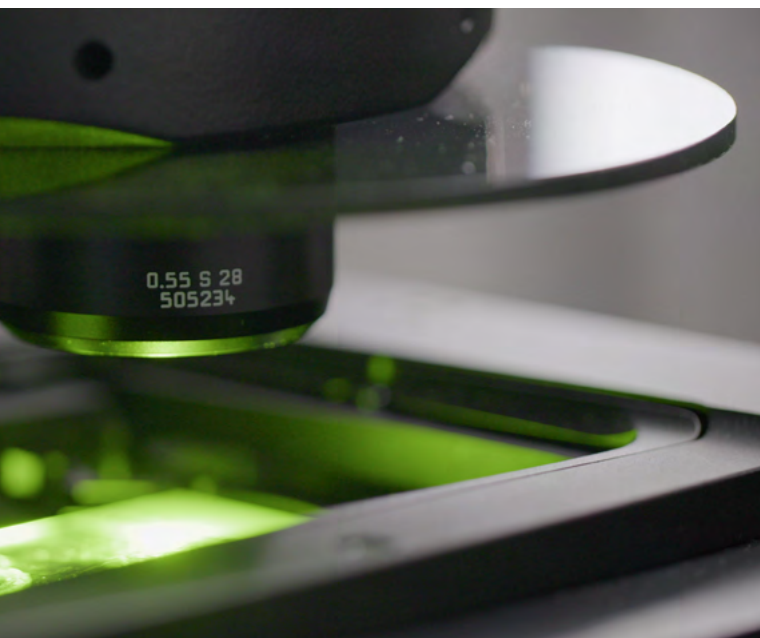


*Disease-modifying treatments of Alzheimer's disease***Lecanemab breaks new ground**

BioArctic's drug, lecanemab, is a monoclonal antibody that binds specifically to the most harmful form of aggregates of misfolded amyloid beta, known as protofibrils. Once lecanemab is bound to the protofibrils, these can be cleared out.

The high selectivity for protofibrils specifically is unique for lecanemab. For example, the antibody binds 1,000 times more to the harmful forms than to the harmless monomers.

Since 2007, lecanemab has been outlicensed to Eisai, the global Japanese pharma company, for Alzheimer's disease. The partnership also includes the lecanemab back-up antibody that BioArctic has developed. BioArctic holds the rights to lecanemab and lecanemab back-up for treatment of indications other than Alzheimer's disease, and holds the commercial rights for Alzheimer's disease in the Nordic region together with Eisai.

**Convincing Phase 3 data for lecanemab**

In September 2022, Eisai reported the results from Clarity AD, the global pivotal Phase 3 study with lecanemab. Detailed data was presented at the CTAD (Clinical Trials in Alzheimer's Disease) congress in November, while the results of the study were simultaneously published in the New England Journal of Medicine<sup>1</sup>. The study was a placebo-controlled, double blind, randomized parallel group study of 1,795 individuals with early Alzheimer's disease. The treatment group was administered 10 mg/kg of lecanemab every other week. The results showed a reduction, with a high statistical significance ( $p=0.00005$ ), in clinical decline measured using the Clinical Dementia Rating – Sum of Boxes (CDR-SB). Compared with placebo, clinical decline decreased by 27 percent for the patients treated with lecanemab for 18 months and an explicit, statistically significant difference compared with placebo was seen after only six months of treatment. Even all key secondary endpoints – such as the change from the baseline of amyloid levels in the brain after 18 months of treatment compared with placebo, for example – displayed a high degree of statistical significance. The ARIA-E side effect, which occurs in treatment with anti-amyloid antibodies, was 12.6 percent in the lecanemab group and 1.7 percent in the placebo group. Symptomatic ARIA-E, however,

occurred in only 2.8 percent of the lecanemab group, which is lower than has been shown for other anti-amyloid antibodies.

In April 2022, an article was published in the scientific journal *Neurology and Therapy*<sup>2</sup> that, based on modeling, evaluated the potential clinical benefits of lecanemab for early Alzheimer's patients. The simulation model was based on the results from the clinical Phase 2b study of lecanemab. The concluding assessment of the researchers was that treatment with lecanemab slows the progress of the disease, prolongs the early stages of the disease and limits the time with moderate and severe disease. The model extended the time when patients transitioned to the next stage of Alzheimer's disease by over 2.5 years for patients who were treated with lecanemab compared with the group of patients who only received the standard treatment. A delay of this kind is valuable not only for patients, who can live an active life together with their families, it is also valuable for society since it delays and reduces the need for resource-intensive care.

The company's research in the field has enabled lecanemab to become the first disease-modifying drug in the world that, in a major clinical program, demonstrated significant effect on the clinical degeneration of Alzheimer's disease. The Clarity AD study results, together with the Phase 2b data, form the

1) Data published in New England Journal of Medicine, November 29, 2022, doi: 10.1056/NEJMoa2212948

2) Data published in *Neurology and Therapy*, April 25, 2022, doi: 10.1007/s40120-022-00350-y

3) Alzheimer's Association 2015: Changing the Trajectory of Alzheimer's Disease: How a Treatment by 2025 Saves Lives and Dollars

## Treatments that slow diseases mean great savings for society

Over 55 million people around the globe suffer from some form of dementia. Some 60 to 70 percent of these patients have Alzheimer's disease. Globally, the total cost of these diseases is estimated at USD 1.3 trillion a year and the cost is expected to rise to USD 2.8 trillion by 2030 in pace with an increase in diagnoses and overhead costs<sup>1</sup>. The estimates for the US population alone indicate that if there is a treatment by 2025 that slows the onset of Alzheimer's disease, the total cost of care only five years later – in 2030 – could decrease by USD 83 billion a year. By 2050, the savings could be USD 367 billion a year compared with no disease-modifying treatment being available<sup>3</sup>.

### *Disease-modifying treatments of Alzheimer's disease*

foundation of the application for complete approval in the US, Europe, and Japan that were submitted in the first quarter of 2023. The application process has begun in China as well. In the US, lecanemab was granted approval under the accelerated approval pathway from the FDA in January 2023 based on a previously completed Phase 2b study in 856 patients and blinded safety data from Clarity AD.

#### **Lecanemab is also being evaluated in asymptomatic disease**

In 2020, Eisai initiated a further global clinical Phase 3 program (AHEAD 3-45) to evaluate the effect of lecanemab on individuals with preclinical asymptomatic Alzheimer's disease (i.e. who have not yet developed symptoms but have intermediate or elevated levels of amyloid in the brain). The program is conducted in partnership with the Alzheimer's Clinical Trials Consortium (ACTC), a network for clinical testing in the US that seeks to identify and treat Alzheimer's disease at an early stage. In total, AHEAD 3-45 will include approximately 1,400 people who, after joint screening, will be included in one of the program's two trials, A3 or A45, depending on amyloid levels in the brain as measured with positron emission tomography. The program aims to prevent development of clear clinical indications of the disease, and thereby also dementia, in the very early stages.

In November 2021, the DIAN-TU research network decided to include lecanemab as the backbone treatment for hereditary Alzheimer's disease in a clinical study in combination with treatment with tau. Tau is a protein that also appears in increased amounts in the brain in conjunction with Alzheimer's disease, but not as early on in the course of the disease as amyloid.

#### **Subcutaneous lecanemab under development**

Lecanemab is currently administered intravenously once every two weeks. To increase user-friendliness and accessibility to the treatment, Eisai is also evaluating a subcutaneous formulation of lecanemab that can be taken as an injection into the skin, which facilitates treatment at home or in outpatient care.

The subcutaneous dosage is being evaluated in the open-label extension study for Clarity AD.

#### **Additional antibodies under development**

BioArctic has four additional antibody projects against Alzheimer's disease in its project portfolio, all of which are in the research or the preclinical phase. These antibodies with unique mechanisms of action have the potential to be developed into new disease-modifying treatments. BAN1503 is an antibody project against truncated forms of amyloid-beta, which has a pronounced ability to aggregate and create toxic forms that could cause Alzheimer's disease. The mechanism of action for AD2603 has not yet been disclosed. AD-BT2802 and AD-BT2803 are two antibody projects against Alzheimer's disease that are being combined with BioArctic's blood-brain barrier technology – Brain Transporter, or BT – to facilitate uptake of antibodies in the brain. BioArctic fully owns the rights to all four projects.

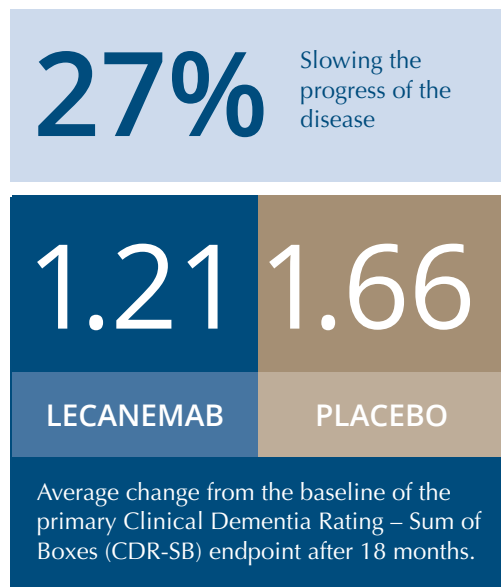
## Licensing agreement with Eisai provides revenue to BioArctic

In 2007, Eisai acquired the global rights to lecanemab for treatment of Alzheimer's disease. In turn, Eisai partners with Biogen on the future commercialization. BioArctic has had no costs for the clinical development of lecanemab. The agreements grant the right to a maximum of MEUR 222 (approximately SEK 2.4 billion) in milestone payments. As of December 31, 2022, up to MEUR 136 in milestone payments remained to be received from Eisai, of which MEUR 35 to be received in the first quarter 2023. Apart from the milestone payments, royalty payments are due to BioArctic based on the global sales of lecanemab, which have the potential to provide significant revenue. Together with Eisai, BioArctic has retained rights to commercialize and sell lecanemab for treatment of Alzheimer's disease in the Nordic countries.



# Results from Clarity AD

During the autumn of 2022, detailed results were presented from Eisai's and Biogen's clinical Phase 3 study with lecanemab in patients with early Alzheimer's disease.



**5.5 MONTHS**

slower progress of the disease was seen during the 18 months the study was in progress. It took 25.5 months to deteriorate to the same level that the placebo reached at 18 months based on CDR-SB data on a curve that extrapolates data up to 2 years of treatment.



**2.5–3.1 YEARS**

Can the progress of the disease be slowed? Modeling simulations from the Phase 2b study with lecanemab, which had similar efficacy data as Clarity AD, show that it can.



**31%**

Lower risk of progressing to the next stage of the disease in conjunction with treatment with lecanemab, according to the CRD scale. CDR-SB is a numeric scale used to quantify various degrees of the severity of symptoms of dementia based on an assessment of cognitive and functional ability in six areas: memory, orientation, ability to assess and problem-solving, social functions, home and leisure, and personal care.

## OTHER ENDPOINTS, %

**26** The extent that lecanemab slowed the progress of the disease, measured on the ADAS-Cog scale after 18 months.

**37** The extent that lecanemab slowed impairment in daily activities after 18 months. Measured on the ADCS MCI-ADL scale, which assesses ability in individuals with mild cognitive impairment relating to activities in daily life (ADL), based on 24 questions for the patient's partner on current abilities in daily life.

**38** Degree of reduced burden on caregiver (Zarit Burden Interview).

## SIDE EFFECTS, %

**26.4** Of patients in the lecanemab group had infusion reactions. The similar prevalence in the placebo group was 7.4 percent.

<b>17.3</b>	<b>9.0</b>
LECANEMAB	PLACEBO

Of patients developed ARIA-H, micro- and macrobleeds, and superficial siderosis.

<b>12.6</b>	<b>1.7</b>
LECANEMAB	PLACEBO

Of patients developed ARIA-E, swelling/edema. 2.8 of patients developed symptomatic ARIA-E.

## MORTALITY RATE, %

<b>0.7</b>	<b>0.8</b>
LECANEMAB	PLACEBO

Of patients died during the 18-month study.

# Positive results for lecanemab important for both patients and the research field

Dennis Selkoe, MD, the Coates Professor of Neurologic Diseases at Harvard Medical School, is a renowned researcher that has made pioneering contributions to the understanding of the biochemical mechanisms underlying the development of Alzheimer's disease. He welcomes the contribution lecanemab will bring both to patients and the research field.

## How do you see the current development in the Alzheimer's field and the recent results from the pivotal study of lecanemab?

"It has been a difficult and long journey to reach what appears to be a truly disease-modifying treatment, and I am delighted that the results for lecanemab appear so positive. We have had many unnecessary misunderstandings in the science behind Alzheimer's disease, but with the positive clinical data for lecanemab the controversy around amyloid-beta is finally fading out. This success again shows that genetics never lie. The Arctic mutation discovered by Lars Lannfelt and colleagues, together with several other mutations that have been found in the last two decades, has created an understanding of how amyloid-beta builds up to cause the disease. The Clarity AD data add to this knowledge with its clear clinical effect of lecanemab as an anti-amyloid treatment."

## How come the different anti-amyloid antibodies have so diverse outcomes in late-stage clinical trials?

"If you take a closer look at the results from these different trials, you will find that the ones which have failed clinically,

showed no evidence of actually lowering amyloid levels. And if you do not lower amyloid levels in the brain, you have not addressed the amyloid hypothesis. Altogether, the recent antibody trials indicate that the greater the lowering of amyloid, the more likely you are to get a slowing of clinical decline. Then you still have a difference in efficacy – and side effects – that can be explained by the molecular features of the different antibodies. Also, one should remember that clinical trials have various strengths and weaknesses in their design. What regard to lecanemab, a very good antibody from BioArctic was combined with a very well-executed clinical trial by Eisai."

## What is your opinion on the possibility for lecanemab and other late-stage therapies to help patients?

"Any therapeutic agent that actually slows the disease process in the brain, and not just treats the symptoms, is of potential clinical value. We most likely have not seen the full clinical value of these new antibodies yet, as such disease-modifying treatments don't have any immediate clinical effect. The true value comes out over a couple of years, when the



disease hasn't progressed as quickly. I know that some people question the relevance of a 27 percent decrease in disease progression, as seen in the Clarity AD trial, but when asked if they would like access to such a disease-modifying treatment if they or their loved ones were diagnosed with Alzheimer's disease, the answer is almost always yes. For me that is answer enough, this is clinically relevant if patients decline more slowly. Now, of course, we need to work harder to learn which patients are most likely to benefit from the treatment, that is an important next step."

## Do you see any implications for other CNS diseases based on the progress made in Alzheimer's disease?

"Yes, there are a number of brain diseases, like Parkinson's disease and frontotemporal dementia, that are caused by build-up of misfolded proteins. It is probable that the lecanemab success story will elevate the likelihood of other protein misfolding disorders being treated with specialized therapeutic antibodies in the future."



# Next step: to **find patients before** they exhibit clinical symptoms

The ongoing clinical trial AHEAD-3-45 investigates whether lecanemab can lower people's risk of memory loss due to Alzheimer's disease when initiated already at a presymptomatic stage. Reisa Sperling, Professor of Neurology at Harvard Medical School, is one of the researchers leading the trial.

## What impact will the results from Clarity-AD have on the Alzheimer's field?

"I think the results are exciting and clarifying. I was particularly excited about the lecanemab data showing results in the early stages of the disease, as it confirms that we chose the right antibody for the AHEAD study. In addition, the positive results from Clarity AD will hopefully accelerate the enrolment of patients in the AHEAD study."

## What is the purpose of the AHEAD study?

"In the future care of Alzheimer's disease, the goal is to find the patients earlier. For that, we need to collect data to see how these patients can be identified and at what stages it is most efficient to start treatments. The results from the AHEAD study will provide important data as it is a large global, multicenter study. There are several other ongoing studies on presymptomatic Alzheimer's disease, and all results will hopefully converge into an increased understanding of how Alzheimer's disease can be prevented."

## What is the biggest challenge in treating Alzheimer's disease at a presymptomatic stage?

"The biggest hurdle for all trials on early Alzheimer's disease is to find the individuals that are most likely to have a quick decline in cognitive function. Those are the ones most likely to benefit from early treatment, and we need to constantly improve methods to find these persons. New diagnostic tools are crucial to accomplish this, and we have had very positive progress with blood tests lately, measuring for example phospho-tau. Since we initiated the study, we have gained substantially more knowledge on how to predict who should be included based on blood and plasma samples, even if we still need PET scans.

Still, my biggest concern remains: are we finding the right individuals? It is not only a question about diagnostics, but we also struggle with the fact that people who volunteer for a clinical trial are highly educated and have less vascular disease which means they are least likely to decline quickly in cognitive function. This is a well-known phenomenon, so we need to power the study based on this, which we have done."



## Will we screen healthy individuals to detect Alzheimer's disease in the future?

"It depends. If we find a clear positive result in the AHEAD study, strong enough to show that we at least bend the curve of cognitive decline, then I think it will be rational to screen for Alzheimer's disease with blood tests. Implementation of new treatments will be challenging in the coming years, but in the future, I hope we get to a point where we can predict an individual's likelihood of a quick cognitive decline. And we need a clearly defined risk score system that is globally accepted, much like the one that already exists within cardiovascular diseases and other indications."



# Antibody treatment that breaks new ground in **Parkinson's** disease

*Antibody treatment that breaks new ground in Parkinson's disease*

Parkinson's disease is caused by the protein alpha-synuclein beginning to misfold. BioArctic develops selective antibodies with the potential to become one of the first disease-modifying treatments for this severe neurodegenerative disease.

Over ten million people around the world live with Parkinson's disease. The disease is normally detected around the age of sixty, and approximately one percent of the world's population over the age of 60 will be affected. The initial symptoms are often impaired sleep, mild tremors in one hand, or a decreased sense of smell. As the disease progresses, the tremors worsen, movements become slower and the body's muscles stiffen.

Current treatments only alleviate the symptoms, and are often most efficacious in the early stages of the disease. In pace with disease progression, the treatments lose their effect and the patient is gradually forced into a more limited lifestyle. In its later stages, living a normal and independent life becomes increasingly difficult.



### Misfolded alpha-synuclein is the underlying cause

The motor functions of the body depend on the signal substance dopamine, and Parkinson's disease emerges when the nerve cells that produce dopamine cease functioning. This in turn depends on the protein alpha-synuclein beginning to misfold and aggregate in the nerve cells. Misfolded alpha-synuclein first forms aggregates that are soluble – oligomers and protofibrils – and subsequently form insoluble aggregates known as Lewy bodies.

The soluble aggregate is believed to be the most harmful to nerve cells. These forms can also move among the nerve cells and spread the misfolding to neighboring cells, which could explain how the disease spreads in the brain.

BioArctic, in partnership with Uppsala University, has developed antibodies that selectively bind to the toxic and soluble aggregates of alpha-synuclein. The antibodies make it possible to detect and eliminate the harmful accumulations of alpha-synuclein, and the progress of the disease can hopefully be slowed. BioArctic has had a collaboration with AbbVie in Parkinson's disease that was terminated by AbbVie in 2022 due to strategic reasons. BioArctic's fully owned portfolio in Parkinson's disease encompasses four antibody projects: BAN0805, PD1601, PD1602 and PD-BT2238.

### BAN0805 on the way to Phase 2

Preclinical data shows that the drug candidate BAN0805 is highly selective in relation to soluble aggregates of alpha-synuclein, and is expected to have a slowing effect on the progress of the disease. Data from studies of brain samples from patients with Parkinson's disease also shows that the antibody binds to pathological alpha-synuclein. Positive results from a Phase 1 study with BAN0805 were reported in 2021. The

## A growing market

Parkinson's disease is today the second-most common neurodegenerative disease. Today, 10 million people are living with the disease and the number of patients continues to increase<sup>1</sup>. The affected patient population is relatively young and most are still of working age when they fall ill, which means that the costs to society are significant. According to an estimate that applies to the US market alone, the total costs are estimated at over USD 54 billion per year, of which around half consists of the costs of direct care and the other half consists of indirect costs<sup>2</sup>. Since current pharmaceuticals only relieve the symptoms, it would be a major advancement to provide a disease-modifying drug candidate that can slow the development of the disease in a meaningful way.

results, which were presented by BioArctic's former partner AbbVie, showed favorable pharmacokinetics and a favorable safety profile for the antibody. All together, all the data points to continued clinical development, and BioArctic is currently planning for Phase 2, in which BAN0805 will be administered intravenously to patients once a month. In parallel, the company is investigating partnership opportunities to take the project further to late-stage clinical development.

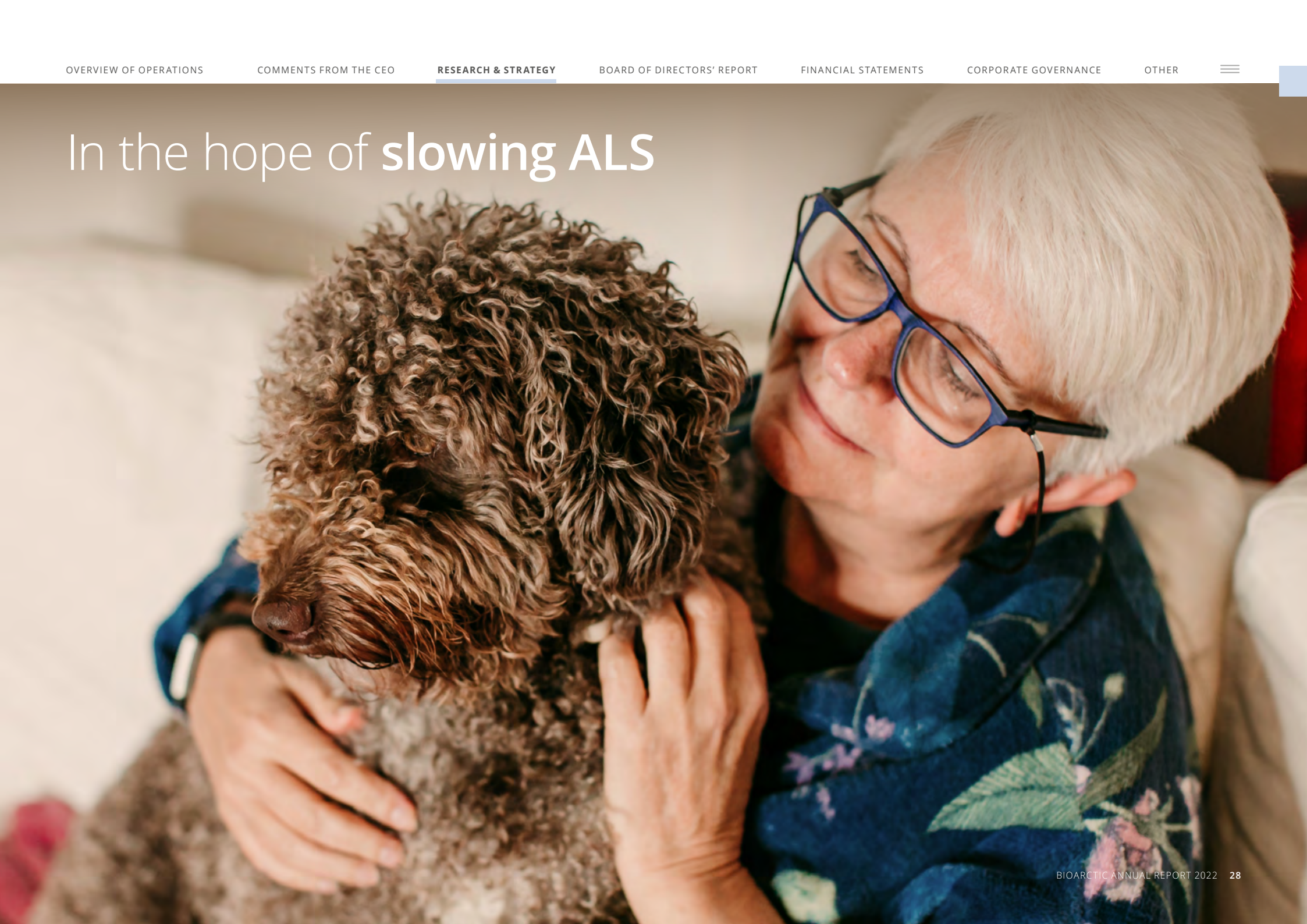
### Three preclinical projects

In addition to BAN0805, BioArctic is developing the antibodies PD1601 and PD1602 that also target aggregate forms of alpha-synuclein for the treatment of Parkinson's disease. In November 2022, the drug candidate PD-BT2238 was also announced, which combines a highly selective alpha-synuclein antibody with BioArctic's Brain Transporter technology, which facilitates greater exposure to the antibody in the brain.

1) Parkinson's Foundation - Understanding Parkinson's, Statistics 2020

2) Yang, W. et al. Current and projected future economic burden of Parkinson's disease in the U.S. 3) Npj Park. Dis. 6, 1-9, 2020

# In the hope of slowing ALS



*In the hope of slowing ALS*

Despite many years of intensive research, the attempt to survey the process that leads to the neurodegenerative disease amyotrophic lateral sclerosis has not been completely successful. What is known is that misfolded forms of the DNA-binding protein 43 (TDP-43) is a contributing factor in the progress of the disease. BioArctic is pursuing two development projects with selective antibodies against TDP-43 with the goal of being able in the future to provide a drug that is disease-modifying and can slow the progression of ALS.

Every year, some 150,000 people around the world fall ill with amyotrophic lateral sclerosis, or ALS. The disease, which is twice as common among men as among women, is a progressive neuromuscular disease that leads to a rapid degeneration of motor neurons, the nerve cells in the central nervous system that control the body's muscle activities. The onset age for ALS is normally around 60, but the disease can also affect younger people. ALS often develops rapidly, and the brain loses the ability to initiate and control the muscles in the body in pace with the motor neurons dying off. When voluntary muscle movement can no longer be controlled, the ability to speak, eat, move, and breathe is affected. The most common cause of death in ALS is respiratory failure. On average, a person dies within three to five years after the initial onset of the symptoms, but certain forms of ALS develop more slowly; in these cases, the patient can live with the disease for over ten years.

Current treatments for ALS encompass drugs that slow the progress of the disease to some extent or alleviate more severe symptoms such as muscle spasms and pain. Even though there are certain treatments that can enable improvements to the patient's quality of life and modify the progress of the disease to some extent, there is no cure for ALS. The need for new and efficacious treatments is therefore significant and urgent.

**Misfolded TDP-43 in the brains of ALS patients**

ALS emerges in the motor neurons of the brain, the brainstem, and the spinal cord – the areas that control the body's movements. Exactly like many other degenerative neurological diseases, the impact of ALS on the motor neurons is linked to an inflammation in the nerve cells. In the brains of individuals with ALS, inclusion

bodies are also found with accumulations of misfolded forms of the protein TDP-43, and a growing mass of data shows that there is a clear link between misfolded TDP-43 and the degeneration of the motor neuron. The protein accumulations do not only prevent the normal function of TDP-43, but the aggregates also disrupt various cellular processes, which leads to the nerve cells rapidly dying off. Misfolded TDP-43 has also been shown in many patients with other neurological diseases, including frontotemporal dementia and Alzheimer's disease.

**Selective antibodies at an early stage**

In its ND3014 project, BioArctic is endeavoring to develop selective antibody treatments that target TDP-43. Antibodies make it easier to detect and eliminate the toxic aggregates of misfolded protein, which it is hoped will have a slowing effect on the progress of the disease. Similar to BioArctic's drug candidates in Alzheimer's disease and Parkinson's disease, the antibodies in the ND3014 project target soluble aggregates of misfolded TDP-43 – the oligomers and protofibrils – since these forms are assumed to be the most harmful to the nerve cells.

BioArctic is also pursuing the ND-BT3814 project, in which an antibody against TDP-43 is being tested in combination with the company's Brain Transporter technology that facilitates the passage of antibodies across the blood-brain barrier. Both projects are currently in the research phase.

**A growing medical need**

ALS is classified as a rare disease, which means that drugs against the disease are developed as orphan drugs. However, a certain increase in incidence has been observed over the past few years<sup>1</sup>. Owing to the increasing average age among the world's population, the number of individuals with ALS is expected to be over 375,000 globally by 2040, meaning an increase of 69 percent from 2015<sup>2</sup>. A number of the patients affected are in midlife and of working age when they fall ill, which means major costs to society. In the US, the cost of ALS is estimated to total over USD 280 million per year<sup>3</sup>. The costs in conjunction with ALS are also higher than for other neurological diseases, which underscores the need for medical advances in the field.

1) Longinetti E and Fang, F. Epidemiology of amyotrophic lateral sclerosis: an update of recent literature. *Current Opinion in Neurology*. Vol 32:5, 2019 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6735526/pdf/coneu-32-771.pdf>

2) Arthur KC et al. *Nature Communications*. 7:12408, 2015 [www.ncbi.nlm.nih.gov/pmc/articles/PMC4987527/pdf/ncomms12408.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4987527/pdf/ncomms12408.pdf)

3) Gladman, M and Zinman, L. The economic impact of amyotrophic lateral sclerosis: a systematic review. *Expert Rev Pharmacoecon Outcomes Res*, 2015 Jun;15(3):439-50 <https://pubmed.ncbi.nlm.nih.gov/2592497/>

# Brain Transporter technology



*Brain Transporter technology*

The blood-brain barrier controls the passage of substances between the bloodstream and the brain. It protects the brain from harmful substances, but at the same time it can make the passage of drugs to the brain more difficult. BioArctic's Brain Transporter technology is being developed to increase the transport of biological drugs across the barrier. The technology is currently being used in all of BioArctic's fields of therapy, and over the long term it can also be outlicensed in order to increase the potential for other drugs that target diseases in the brain.

For a long time, researchers around the world have attempted to find solutions for getting crucial drugs into the brain. BioArctic's Brain Transporter technology uses the transferrin receptor, a channel in the blood-brain barrier that normally transports iron into the brain. By binding to an existing transport receptor, antibodies and other biological drugs can enter the brain more easily and the efficacy of the treatment is thus strengthened.

Distribution improves with a larger amount of antibodies able to pass through the barrier, which means that a lower dosage of the active compound of the drug is

required; this could lead to better efficacy.

BioArctic's Brain Transporter technology has demonstrated an improvement to uptake and distribution, and a robust increase of antibodies in the brain in preclinical models. The technology has now become so effective that it is being combined with antibodies in all of BioArctic's fields of therapy under development.

BioArctic has partnered with Uppsala University, and together the parties have received a research grant from Vinnova for research in parts of the blood-brain barrier project.

## Projects that combine antibodies and the Brain Transporter technology

### Alzheimer's disease

In addition to the development of lecanemab, BioArctic has remained dedicated to and focused on developing new antibody projects against Alzheimer's disease and has two of the research projects, AD-BT2802 and AD-BT2803, linked to its Brain Transporter technology. The projects are in the discovery stage.

### Parkinson's disease

The latest project in the Parkinson's portfolio is PD-BT2238, a project that combines the Brain Transporter technology with a selective antibody that targets soluble alpha-synuclein aggregates. The aim is to increase the amount of antibodies that reach the brain, with the objective of increasing the efficacy of a potential treatment for Parkinson's disease. The project is currently in the discovery stage.

### ALS

In ALS, BioArctic is pursuing two projects, one of which – ND-BT3814 – has been linked to the Brain Transporter technology. The aim of the project is to develop an antibody drug against TDP-43, a protein that is believed to play a key role in the development of the rare neurodegenerative disease ALS. The project is in the discovery phase.

### Gaucher disease

BioArctic has initiated a research project to treat previously untreated CNS symptoms of Gaucher disease by further developing an enzyme replacement treatment. Gaucher disease is a rare genetic disease in which the impaired function of the enzyme glycosylceramidase leads to an accumulation of glycosylceramide in certain organs. Current treatments focus on enzyme replacement therapy, but they cannot treat the harmful consequences of the lack of enzyme in the CNS if the enzyme replacement does not reach the brain. By linking the enzyme replacement to BioArctic's Brain Transporter technology, BioArctic hopes to be able to develop a treatment that takes care of both the CNS and the systematic manifestations of the disease.

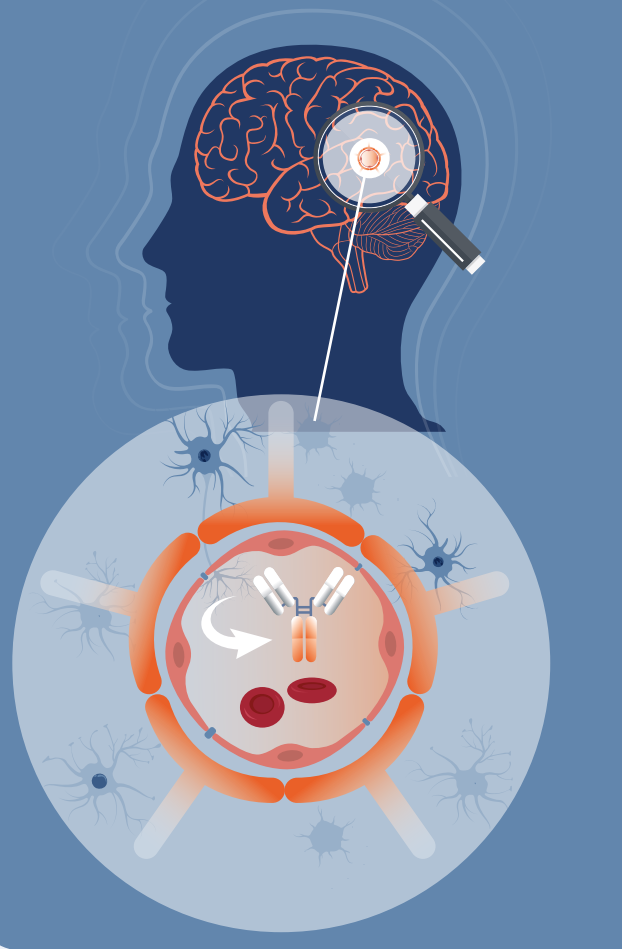


Brain Transporter technology

# Active transport into the brain

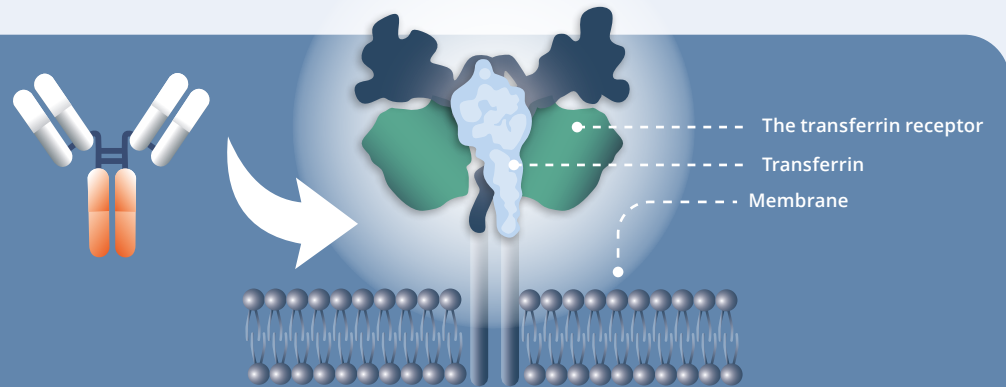
## The challenge

The blood-brain barrier is a 600-kilometer long network that provides energy and protects the brain. At the same time, the barrier makes the transport of drugs to the brain more difficult.



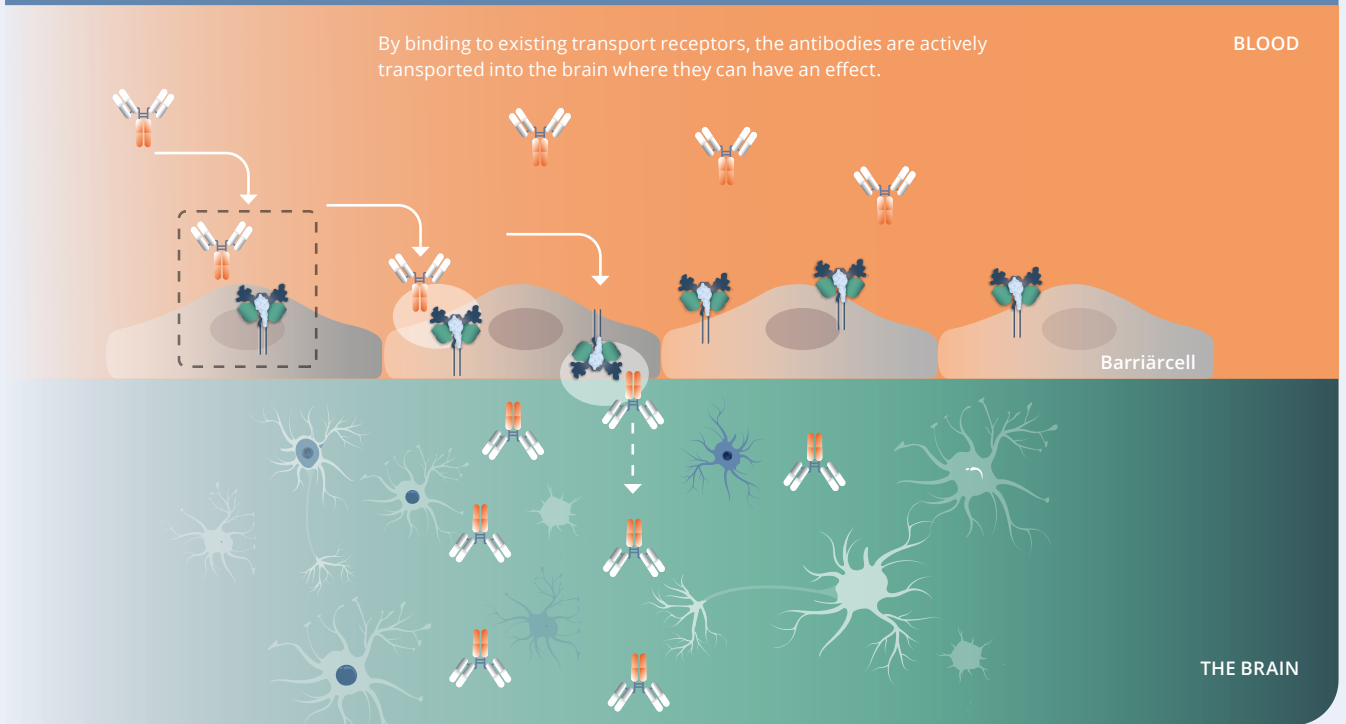
## Bioartctic's solution

The antibody is modified so that it binds to the transferrin receptor, which normally transports iron across the blood-brain barrier.



By binding to existing transport receptors, the antibodies are actively transported into the brain where they can have an effect.

BLOOD



THE BRAIN



# A new organization to prepare for launch of lecanemab in the Nordic region

If lecanemab is approved in the EU, BioArctic has rights to market and sell lecanemab in the Nordic region in accordance with the agreement with Eisai. In 2021, BioArctic began to build up its commercial department to prepare ahead of a potential launch of lecanemab in the Nordic market together with Eisai. In 2022, several key positions with experienced expertise were added.



*A new organization to bring lecanemab to patients*

## Harald Borgeke, Head of Public Affairs

**You have previously worked in various commercial roles at MSD, Novo Nordisk, Lilly and Bristol Meyers Squibb/Celgene. What experience do you bring to BioArctic?**

“I bring an understanding of how drugs can be introduced into the Nordic countries, and an understanding of the issues that both healthcare and those who pay for healthcare face. My experiences from medical care in Sweden and the rest of the Nordic region is that on the whole, it consists of ambitious and competent employees who do their best every day to help patients and their families with the resources and systems they have at hand. At the same time, healthcare is continually changing, where the research-intensive pharma industry plays a major role along with companies in diagnostics, for example. It is important for us to be able to communicate this change, and collaborate so that patients have access to innovations such as precision medicine, for example.”

**What are the greatest differences between the Nordic countries in establishing new treatments?**

“Internationally speaking, the Nordic region is commonly seen as one region, but in fact they are countries with quite different systems for introductions of new drugs. We are working with the systems of each country so that the introduction goes as rapidly and as smoothly as possible. The countries have different languages and traditions as regards the introduction of new drugs. A health economics assessment of the drug is included in all countries, although with slightly different content. Moreover, the processes are different as regards content and time, so it is a matter of understanding the details.”



**What response have you gotten from patient organization and opinion makers since the Phase 3 results from Clarity AD were presented?**

“The response has been very positive. Even if we are early in the process and it is important to let the regulatory process now take its course, I believe that most are pleased with the fact that the Phase 3 results were positive. They are hopeful signals that will help a vulnerable patient population with a disease-modifying treatment for Alzheimer’s disease.”

” The response has been very positive.

A new organization to bring lecanemab to patients

## Mats Ekelund, Head of Market Access

**You have previously worked in major pharma companies such as Biogen, Wyeth, and Pfizer. What experience did you bring to BioArctic?**

“I have 18 years of experience in seeing to it that patients have access to drugs, what is usually known as market access. This has made me deeply familiar with the Nordic pricing and reimbursement procedures, and what is required to compile a successful application. I have also learned a great deal from all my knowledgeable and capable colleagues who I have had the privilege of working with during my time in the pharma industry. I appreciate my contacts with various government authorities throughout the years. Even if government agencies and companies have partially different tasks and goals, it is nearly always possible to unite in the desire for patients to have access to the best possible treatment. This field is also in an exciting phase where I seem to see increased openness for developing existing methods for evaluating, pricing, and monitoring new innovative drugs.”

**How far have the preparations for a potential launch of lecanemab in the Nordic region come?**

“As far as pricing and reimbursement are concerned, Eisai has the ultimate responsibility for these matters. We have started to have some preparatory meetings within the framework of what can be done before a drug has been approved. For example, we have held several horizon-scanning meetings with representatives of health and medical care in the Nordic countries, where we have highlighted lecanemab as a potentially important drug to prioritize for evaluation and an orderly introduction into medical care. We have also begun to survey what the diagnostics chain looks like and functions in the various Nordic countries. Producing data on epidemiology and the costs of the disease is also a key element in preparing the health economics analysis. We have also begun looking at various possibilities for

monitoring and evaluating lecanemab in clinical practice after potential approval.”

**Which aspects of a new treatment are important from a payer perspective?**

“The scope of efficacy is crucial for establishing the value of a new treatment. The people who review the health economics analysis also want to see the highest possible degree of reliability in the results. So well-constructed drug studies and relevant data that describe the consumption of resources in the various stages of the disease are important. The degree of severity of the illness, and the number of sufferers are other essential factors for establishing the willingness to pay. With an increase in the degree of severity, the willingness to pay is higher, as it is for less common diseases.”



” The efficacy is crucial for establishing the value of a new treatment.

*A new organization to bring lecanemab to patients*

## Frida Lekander, Head of Marketing

You have worked in various commercial roles in medtech, biotech and in the pharma industry, above all in Johnson & Johnson and Janssen, and you have experience in drug launches. How are you preparing ahead of a potential launch of lecanemab in the Nordic region?

“Cognitive medicine and Alzheimer’s care are lagging behind. Currently, the emphasis is on care in the final stages of the disease rather than diagnosing patients early on in order to slow the progress of the disease to the more severe stages. Changes throughout the healthcare system are needed, from improved tools for diagnostics to increased capacity for treatment and monitoring at specialist clinics. All this requires training and coordination among various stakeholders, and especially national initiatives and financing. For us it will be important to collaborate with leading specialist physicians, researchers, and other stakeholders on activities that pursue these goals in various ways.”

Where do you begin in building up a marketing strategy for a new drug?

“The starting point is for everything to be in place in the event of a potential approval so that patients have access to the new drug as soon as possible. We want to build partnerships with various stakeholders to prepare health care and facilitate implementation in clinical practice. We also want to use a convincing, evidence-based approach to describe how our treatment potentially could help patients, and are therefore working with a cross-functional communication strategy that builds know-how and differentiate lecanemab step by step.”

What challenges do you see in a potential launch of lecanemab in the Nordic region?

“The major challenge lies in changing how Alzheimer patients are diagnosed and cared for today to how it ought to look in conjunction with the introduction of drugs that slow the progress of the disease and are to be administered at an early stage of the disease, which requires specific diagnostics, and additionally the capacity for infusions and monitoring of treatment results and side effects. A national plan is needed that helps health care with structuring and prioritizing, and financing is needed in order to implement all this regionally.”



” A national plan is needed that helps health care with structuring and prioritizing.

*A new organization to bring lecanemab to patients*

## Sven Eriksson, Head of Medical Affairs

**You were recruited to BioArctic from your role as Medical Lead Alzheimer's Disease at Biogen, and previously had similar roles at Roche, Novartis, Medivir, and Isofol. What experiences did you bring to BioArctic?**

“First and foremost, many years of experience in introducing drugs in the Nordic market. What's different at BioArctic is the chance to do this in a researcher-driven environment where the researchers who produced the molecule and know every data point from the first experiment in mice to our Phase 3 data are working right next to us in the effort. For those of us who work with Medical Affairs, and for the daily scientific dialogue with physicians and researchers around the Nordic region, this is a unique opportunity. My experiences from launches in both large and small companies is an asset, since it is important that we work with the same meticulousness as the larger companies but benefit from the flexibility and rapid decision-making from the smaller company.”

**You are responsible for building up BioArctic's Medical Affairs unit in the Nordic region. How is that going?**

“It is a tremendously exciting process, and we are now in the midst of recruiting medical advisers around the Nordic region. Our medical advisers will have a very important role in building up the network of key opinion leaders, communicating science, and building up understanding both internally and externally around the challenges healthcare faces in the introduction of a new drug. We are meeting with a great deal of interest from individuals with lengthy experience in the industry, and who see that BioArctic is an exciting company where they have the opportunity to be part of a unique launch.”



**What are the main opportunities and challenges in a potential launch of a new drug for Alzheimer's disease?**

“The main opportunity is being part of helping patients with Alzheimer's disease get access to better treatment alternatives. There have been no new drugs launched for these patients in the past 20 years, which is an awfully long time. Alzheimer's disease is a widespread but also fatal disease that currently lacks alternatives for slowing its progress, and we hope we can be part of changing this. The challenges lie in partnering with healthcare to ensure that infrastructure, diagnostics, and monitoring are in place so that the right patients can be safely treated after an approval.”

” The main opportunity is to be involved and contribute to patients with Alzheimer's disease gaining access to better treatment options.

# Employees and values

Clear values, a leadership model, and an objective of improving lives for patients with neurodegenerative diseases unites BioArctic's employees in their daily activities. Research based on the employees' specialist skills within brain diseases are the basis for BioArctic's successful development. Our employees' commitment and desire to promote our vision are BioArctic's main assets.

Much has happened in the area of employees and BioArctic's organization over the past year. The positive results from the Clarity AD Phase 3 study with lecanemab in patients with early Alzheimer's disease is a milestone for BioArctic, and it means that the company has developed from being a dedicated research and development organization into a company that is now establishing a commercial organization to market and sell a drug for Alzheimer's disease. During the year, the company also expanded its project portfolio with new projects in diseases such as Parkinson's disease and Gaucher disease. This has meant an increase in the number of employees from 49 at the end of the previous year to 61 at the end of 2022. This is an increase of 24 percent, which is positive but also a challenge for a smaller organization. Important issues during the year have been building the BioArctic of the future and employing people with specific skills in key functions alongside research such as Market Access, Public Affairs, Marketing, and Medical Affairs. A major effort to establish BioArctic with operations in other Nordic countries also commenced during the year. BioArctic has successfully continued to anchor its core value initiatives and leadership throughout the organization, which makes a clear difference in



its daily work. The work co-workers do encourages continued development by offering them opportunities for new areas of responsibility, expanded partnership possibilities among various project constellations, and new work tasks. Employees are routinely surveyed so as to respond to and make use of their opinions and ideas. This year's surveys were oriented on the psychosocial work environment, well-being, and satisfaction. Several measurement values in the surveys have risen further from already high levels since the positive results from Clarity AD were presented in September, and it was clear that employee satisfaction in the workplace had rated very highly.

The commonly-occurring Net Promoter Score (NPS) scale is oriented on whether the employee would recommend their employer to a friend. The outcome was strengthened markedly after the positive Clarity AD results to 82 (68 in the previous measurement) on a scale from -100 to 100 which, based on the assessment of key figures, ranks as world-class.

The surveys of the psychosocial work environment showed that by and large, employees feel that they have a good work-life balance, that their work situation is enjoyable and stimulating, and that their workplace is both mentally and physically healthy. Moreover, the survey showed that no employees

*Employees and values*

had experienced sexual harassment or victimization at the workplace, and no employees felt they had been discriminated against at the workplace.

In 2023, BioArctic will continue conducting and following up on work environment issues through recurrent employee surveys and push the efforts to develop employee skills further while planning for recurring leadership forums, a project manager training course and Swedish lessons for employees who cannot speak the language.

**Respect, commitment, collaboration and responsibility**

The company's values – Respect, Commitment, Collaboration and Responsibility, which were developed together with BioArctic employees – are the foundation of a shared corporate culture and support for employees in their daily activities. The keyword respect calls attention to the need for active listening and consideration, valuing everyone equally, acting selflessly and following the agreed-upon rules of the game. Engagement reflects the importance of drive and enthusiasm in ourselves and others, finding new ways to think and working creatively and flexibly. Collaboration requires open communication, generosity, humility, clear feedback and shared objectives. Focus on responsibility increases the possibilities of high-quality deliveries on time so that joint projects can be pursued in an optimal manner.

**Leadership founded on shared values**

At BioArctic, value-driven management based on self-leadership, individual-based leadership, and project leadership has taken firm root. Self-leadership is used by all co-workers, both employees and consultants. It is marked by independently taking responsibility for clear communication and high-quality deliveries. Individual-based leadership is exercised by the company's managers and includes responsibility for allocating work and assigning the right resource and competence to projects. Successful project leadership requires project managers to deliver on time, with the right quality, and within budget using a solution-oriented approach.

One focus at BioArctic is facilitating an inclusive work

environment with good competence development. BioArctic makes significant investments in project managers and puts its projects in focus. During the year, the company initiated a project manager training course in several blocks; the first block was conducted in November with nearly 30 percent of employees. Two additional blocks of the training course will be conducted in the spring and autumn of 2023.

Two management forums can be mentioned as examples of the development initiatives that BioArctic carried out during the year, with a focus on change management, recruitment training for managers and language lessons for employees whose native language is not Swedish.

A good work environment is also given priority. During the year, several meetings were held and two safety inspection

tours were conducted by the company's occupational health and safety group.

**Strong partnerships increase the conditions for success**

BioArctic's distinct core values and leadership model have enabled the company to successfully establish and deepen its partnerships with external research groups and global pharma companies. The company's principles of collaboration are built on the belief in the importance of unifying around a vision and common goals, of creating and developing a joint work structure, of cultivating and retaining mutual trust and always acting as one team. This optimizes the possibilities of a relationship in which everyone involved can get the best out of the partnership.

**LEADERSHIP**

1. Self-leadership
2. Individual-based leadership
3. Project leadership

**VALUES**

1. Respect
2. Commitment
3. Collaboration
4. Responsibility

**COLLABORATION PRINCIPLES**

1. Unite around one vision and shared goals
2. Create and develop a shared structure
3. Cultivate and retain mutual trust
4. Act as one team
5. Always strive for "happy-happy"

*From an employee perspective*

# Seeking solutions to the difficult questions of research

Almost ten years ago, Fredrik Eriksson began as a researcher at BioArctic, coming directly from the laboratory in academia (Uppsala University, and prior to that Karolinska Institutet) where he conducted research in immunology. His role has developed during his time at BioArctic, and he now works as Principal Scientist with responsibility for pursuing the company's latest project in Parkinson's disease, PD-BT2238. This is one of the advantages he sees in working with research in the business world: that there are clear career ladders and good opportunities for advancement.

**In late 2022, BioArctic expanded its Parkinson's portfolio with the PD-BT2238 development project. What is that?**

"PD-BT2238 is an antibody that binds highly selectively to alpha-synuclein oligomers – which are considered the harmful forms – without recognizing the harmless monomer forms. By linking our Brain Transporter technology to an alpha-synuclein antibody, we are aiming at bringing more of the active compound into the brain, thereby achieving better treatment efficacy. In turn, this could also mean that the dosage can be decreased if more of the compound ends up in the right place to begin with, and we thereby hope to minimize potential side effects. In this project, we're currently manufacturing the antibody, characterizing the binding and testing in efficacy models. In a year, we hope to have produced data in Parkinson's models that indicate increased exposure in the brain."

**As fields of research, Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis (ALS) have long been described as difficult and challenging. How do you motivate people to not give up on finding viable treatments?**

"That's the best part about it, it's a challenge. Moreover, ALS and Parkinson are even more difficult than Alzheimer's disease

since the disease pathology is largely intracellular, which means inside the cells instead of outside. So you have to find ways of getting the antibodies across the blood-brain barrier, which was a major challenge in Alzheimer's disease, and – very likely in addition – getting these into the cell for the best effect. But I am driven by finding solutions to challenges.

"Another major challenge in Parkinson's disease and ALS is the lack of good biomarkers – the tools for detecting and diagnosing the disease – and that applies to the entire field of research."

**After the failure of several major drug projects in the late stages, in the autumn of 2022 you obtained positive results with lecanemab with high statistically significant efficacy on the reduction of clinical decline. What have you learned from lecanemab that you could apply in Parkinson research and other areas?**

"Previously there were many failures in the Alzheimer field, and primarily our results indicate that there are differences between various antibodies, and each antibody is unique. Not all antibody projects fail because some other project did it, and the main lesson is not to give up hope when competitors get negative results. The field should learn this as well."





**You have worked at BioArctic for more than ten years, first as a scientist, then as a senior scientist, and now as Principal Scientist. How have your tasks changed over the years?**

“For the first few years, I was in the lab 90 percent of the time working on one project. For people who want to develop, BioArctic has a clear career ladder where they can grow in their role. So, over the last few years, I have had more and more overall responsibility, and now I work as a project manager with administrative and budget responsibilities while working on several projects in parallel.”

**Previously, you conducted research at Uppsala University and Karolinska Institutet. What would you say are the biggest differences in researching in academia and at a company?**

“Of course there are clearer deadlines, more clear-cut goals, and better resources in industry, but not the same scope for action as in academia. Personally, it's reassuring to know that you have a job for the long term.”

**Could you describe how the company has changed over the last ten years?**

“Naturally, the company has gotten bigger. There were 20 of us working at the company when I started, and now we are around 70 employees. We also have more resources now and have become more high tech, with really good machinery. We can invest more in research today, and even farm out some parts of the research to contract labs.”

**How would you describe BioArctic as an employer?**

“There's a good atmosphere here at the workplace, and the sky is the limit – there is an openness for bringing up new ideas. For example, I was part of planning our entry into ALS since there were similarities with the research we had already been conducting, and it's exciting to be part of a project from the start. In general, it's a great working environment. There is also a clear career ladder, and as an employee you always have opportunities for advancement. It's a really stimulating environment where you can have room to shine.”

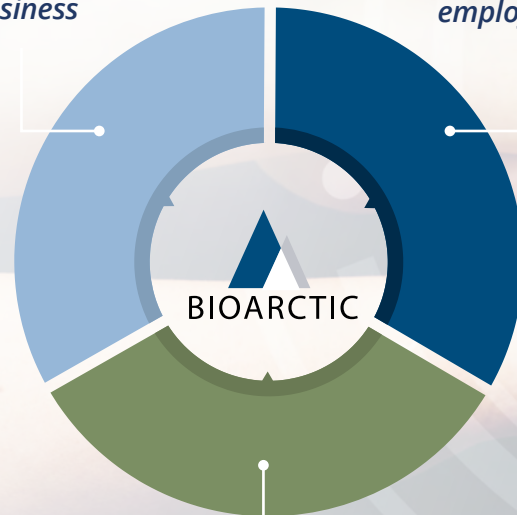


# BioArctic's sustainability initiatives

Based on the UN Sustainable Development Goals, BioArctic's sustainability initiatives are divided into three areas: business, employees, and use of resources.

Sustainable  
*business*

Sustainable  
*employeeship*



Sustainable  
*use of resources*

## BioArctic's sustainability governance

BioArctic's Board of Directors bears overall responsibility for sustainability initiatives and for compliance with regulations and guidelines. This responsibility has been delegated to operating management, which both pursues practical sustainability initiatives and reports back on the results of these initiatives to the Board of Directors.

The practical work is governed by the shared sustainability policy. Regulations and guidelines encompass all employees at all levels in the operation. Alongside our own employees, BioArctic expects our customers, suppliers, and business partners to comply with standards in their own operations, and that these standards are equivalent to those that are included in BioArctic's sustainability policy and Code of Conduct.

*BioArctic's sustainability initiatives*

## BioArctic's key contribution to global sustainability is innovation

Neurodegenerative disorders are among the most fatal and most costly for society. BioArctic's innovation through its research, specialization, and broad network enables more people to live longer and healthier lives together with their families. In addition to the company's core operation itself enabling a better society, the perspective of sustainability is integrated into every part of the operation.

Developing new drugs for severe diseases requires large investments. When entire fields of research must be pushed forward, it almost always happens through united efforts. Researchers around the world, from both academia and business, must collaborate while large amounts of know-how in the areas of production, safety, ethics, regulatory issues, and much more is required.

For over 20 years, BioArctic has built up its own specialist expertise in the development of drugs for neurodegenerative diseases, and contributed to a dynamic international network of skills that together are pushing the field forward.

The success of the innovation behind lecanemab for early Alzheimer's disease confirms the strength of BioArctic's approach. Continued successful development of the core operation will lead to even more people having many more healthy years. Helping patients to healthier lives creates possibilities for society to free up valuable resources. At the same time as BioArctic focuses on its core operation of enabling a better society, the company pursues sustainability initiatives based on the UN's Sustainable Development Goals, which can be divided into three areas: Sustainable business, sustainable employeeship, and sustainable use of resources.

### Sustainable business that promotes continued innovation

In order to create projects that in future could help patients with major medical needs, BioArctic is continually engaged in ensuring that its project portfolio is balanced and innovative, and is efficiently reaching the market and patients.

Strong long-term partnerships with research teams and other pharma companies ensure that BioArctic has access to the latest research and technology in developing new products. By working in accordance with a business model where the partners cover the cost of more expensive trials in late phases, BioArctic creates financial stability and can reinvest in research and development in new projects, which in turn could lead to new innovations and future partnerships with pharma companies.

BioArctic also works in accordance with good business ethics, transparency, and requirements from government authorities regardless of whether the work is being performed internally or together with external partners. Similarly, there are well-defined procedures for quality assurance that comply with strictly regulated drug development

### Sustainable employeeship that promotes job satisfaction and commitment

BioArctic is actively engaged in promoting job satisfaction in the workplace and employee commitment in its operation. The goal is to promote, through joint effort, overall innovation and the company's ability to develop drugs to improve the lives of patients and their families.

To guarantee market-based terms of employment, BioArctic works to offer its employees competitive salaries, benefits, and career opportunities. Moreover, it is important that all employees have access to a healthy physical and psychosocial work environment. BioArctic ensures that all employees work under safe, healthy conditions and that there is a sound balance



*BioArctic's sustainability initiatives*

between work and private life.

The company also aims to encourage and promote competence development for its employees. By offering education, training, and mentor programs, BioArctic ensures that its employees have the tools they need to grow and develop within the organization. To encourage a healthy life among its employees, BioArctic supports a healthy lifestyle. This includes, for example, access to training and health-promoting programs that can help employees achieve good health and a balance between work and leisure. BioArctic also has zero tolerance toward all forms of harassment and discrimination, and actively promotes diversity and equality within the organization.

**Sustainable use of resources at every stage**

BioArctic works to ensure that resources are used as efficiently as possible. For example, the company develops biological drugs, and since these have less of an impact on the environment and nature than chemical drugs, BioArctic promotes more sustainable use of pharmaceuticals. Moreover, optimal consumption of resources is a central part of BioArctic's sustainability initiatives, in which the company continually aims to reduce waste and energy consumption. BioArctic also recycles whatever can be recycled, and prioritizes sustainable alternatives as regards energy consumption. To reduce the climate impact from travel, BioArctic has chosen to be selective as regards which meetings require a physical presence, and the company aims to ensure coordinated and sustainable travel for its employees. All employees are encouraged to routinely submit suggestions for sustainable solutions, which makes sustainability a natural part of the corporate culture.

Finally, BioArctic expects sustainability initiatives from its suppliers. Apart from requirements that must be met in certain cases for Good Manufacturing Practice (GMP), BioArctic aims to choose those suppliers that also prioritize sustainability. By being clear about the expectations of its suppliers, BioArctic is part of driving development toward a more sustainable future.

POLICY	PURPOSE	OWNER
Health and safety policy	Maintain good physical and psychosocial work environment for the company's employees.	Group management
Ethical animal policy	Provide the company's employees with guidance in the principles of animal ethics in studies that involve laboratory animals.	Research division
Sustainability policy	Set up short- and long-term goals to drive, support, and develop the company's sustainability initiatives at all levels, with a focus on sustainable employment, sustainable use of resources, and sustainable business.	Group management
Information security policy	Minimize operational risks linked to information that concerns people, procedures, and systems with a potential adverse impact on the company.	Group management
Diversity and equality policy	Actively counteract discrimination and promote equal rights and opportunities regardless of: Gender, gender identity or expression, ethnic affiliation, religion or other expression of faith, disability, sexual orientation, or age.	HR
Rehabilitation policy	Help sick and injured employees recover the best functionality possible, and conditions for a normal working life.	HR
Code of Conduct	Provide BioArctic's employees with guidance based on the company's core values – respect, commitment, collaboration, and responsibility – in their daily work	Group management
Whistleblower policy	Maintain an open business climate, a high level of business ethics, and always see opportunities for improvement.	Legal

# BioArctic's scientific advances are protected by **strong patents**

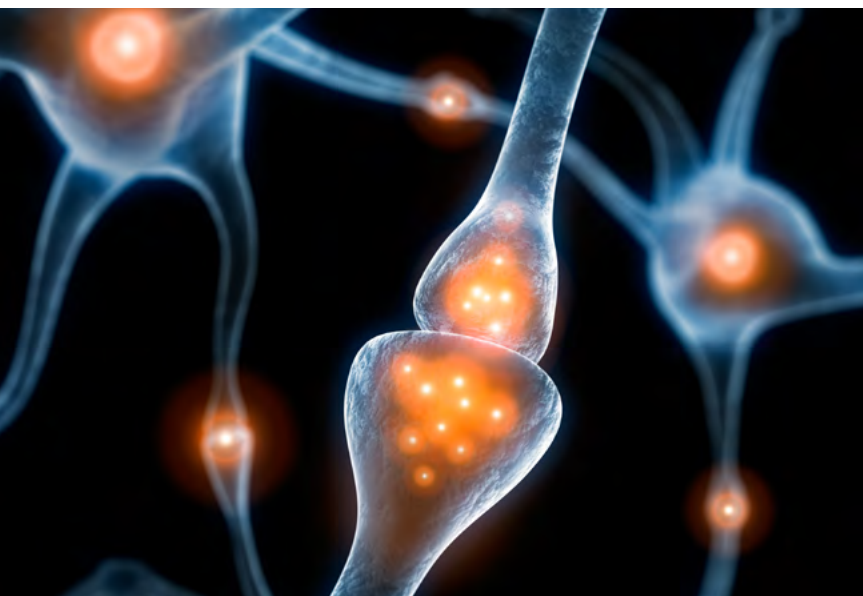
Strong patents are a prerequisite for successfully commercializing the scientific advances that BioArctic is delivering. Using an active patent strategy, the company has successfully established broad intellectual property protection for use and production of lecanemab and its other drug candidates in all major geographical markets including the US, the EU, Japan and China. As of December 31, 2022, the patent portfolio encompasses 13 patent families with more than 240 patents granted and over 70 patent applications pending.

BioArctic's antibody drug for the treatment of early Alzheimer's disease, lecanemab, has patent protection that runs through 2032, including patent term extensions in territories where they are available. The drug candidate BAN0805, which is being developed for the treatment of Parkinson's disease, is under patent protection until 2046, including patent term extensions in territories where they are available. Alongside the patent protection for lecanemab and BAN0805, these drug candidates can obtain data and market exclusivity

for 12 years in the US and for 10 to 11 years in Europe, provided that the compounds obtain market approval.

BioArctic has also a number of ongoing patent applications for its Brain Transporter technology, a technology developed in-house with the potential to facilitate transport of drug compounds across the blood-brain barrier.

The company's most important published patent families as of December 31, 2022 are shown in the table below.



Patent family	Area	Status and market	Protection until
AD II	Alzheimer's disease – concept	Granted: USA, Canada, Australia	June 2025
AD III	Alzheimer's disease – compound 1 Specific protection for lecanemab	Granted: USA, Canada, Europe, Japan, China as well as other countries	March 2027/2032 <sup>1</sup>
AD IV	Alzheimer's disease – compound 2 Specific protection for BAN2401 back-up	Granted: US, Europe, Japan, China as well as other countries	July 2035/2040 <sup>1</sup>
PD V	Parkinson's disease – concept	Granted: USA, Europe, Japan	July 2029
PD VII	Parkinson's disease – compound Specific protection for BAN0805	Granted: USA, Europe, Japan, China, Australia as well as other countries	March 2031/2036 <sup>1</sup>
PD XXV	Specific protection for BAN0805	Granted: US Pending: Europe, China, Japan, and other countries	June 2041/2046

1) Assuming a five-year patent extension is granted where available.

# BioArctic as an investment

## Market introduction of lecanemab initiated

After a successful Phase 3 study in early Alzheimer's disease and an approval under the accelerated approval pathway in the US, the market introduction of lecanemab has now begun. Applications for complete approval have been submitted in the US, the EU, Japan, and China with the ambition of being able to offer larger numbers of patients a disease-modifying treatment of early Alzheimer's disease. BioArctic is entitled to remuneration on global sales except in the Nordic region, where the company has the right to sell the product in partnership with Eisai.

## Potential for the treatment of Alzheimer's disease in the pre-symptomatic stage

A comprehensive Phase 3 study with lecanemab, AHEAD 3-45, is under way to evaluate the possibilities of preventing the development of Alzheimer's disease among people who have not yet manifested any clinical symptoms but have intermediate or elevated levels of amyloid in the brain. In addition, a more user-friendly, subcutaneous formulation of lecanemab is being developed. Both these initiatives, in combination with the positive development of blood biomarkers, have the potential to further increase the use of this treatment and create even more benefit for patients, their families, and society as a whole.

## A project portfolio standing on several pillars

BioArctic's research platform is based on groundbreaking science for the development of disease-modifying treatments for a range of neurodegenerative diseases with significant medical needs. The company is also developing Brain Transporter, a unique technology to improve the uptake of biological drugs in the brain. The company is pursuing a large number of drug projects, five of which are being combined with the BT technology. The broad project portfolio provides opportunities for creating significant value for both patients and shareholders.

## BioArctic's world-class research continually opens new doors

BioArctic's researchers continue to make scientific discoveries and advances that could result in new drug projects. In the past year, the company announced two projects aimed at improving the treatment of two neurodegenerative diseases: amyotrophic lateral sclerosis (ALS) and Gaucher disease.

## Drug project against Parkinson's disease being prepared for Phase 2

BioArctic's broad portfolio of antibodies against alpha-synuclein has the potential to revolutionize the treatment of Parkinson's disease. One of these antibodies has displayed excellent properties in a Phase 1 study, and the continued clinical development program is now being designed.

## Demonstrated capacity to attract and partner with global pharma companies

BioArctic's groundbreaking research, patented technology and capacity for developing disease-modifying drug candidates has facilitated broad collaboration with global pharma companies that has generated revenue of approximately SEK 2 bn to date.

## Strong financial position

Significant revenue from collaboration agreements with global pharma companies brought BioArctic's cash balances to MSEK 805 at the end of 2022. The company's strong financial position creates flexibility and facilitates robust efforts in existing and new projects.

## Successful leadership model and highly skilled employees

BioArctic is a business driven by science, with extensive expertise and experience in brain diseases where the aim is to slow down or, in the future, stop disease progression. The company's skilled employees possess a vast specialist expertise in research and drug development. BioArctic's focus on leadership development and continual initiatives in its corporate culture are important contributions to the company's success.

# The journey continues

BioArctic's employees, in close collaboration with leading academic research groups, have enabled scientific breakthroughs in the treatment of neurodegenerative diseases. The company has built a broad and well-diversified project portfolio with the potential to improve life for a range of patient populations and thus for their families as well. The success of lecanemab in 2022 is just the beginning of a long and exciting journey.

## Broad portfolio with potential to generate significant values

With a groundbreaking drug against early Alzheimer's disease on the threshold of a potential global launch and a diversity of projects in various development phases, conditions are excellent for creating value for patients, their families, and society as a whole. This makes BioArctic an attractive company to partners, investors, and employees. Opportunities for further value-increasing milestones await – especially for lecanemab, which is now being evaluated as a potential preventive treatment for Alzheimer's disease while the development of a more user-friendly subcutaneous form of administration continues.

In Parkinson's disease, efforts are under way to define

the continued development strategy for drug candidate BAN0805, BioArctic's most advanced alpha-synuclein project. Preparations for Phase 2 have begun while the possibility of pursuing the project further together with a commercial partner is being investigated.

## Two new projects announced in 2022

During the past year, new projects were announced that are focused on ALS and Gaucher disease, two severe neurodegenerative diseases with enormous need for efficacious treatments. BioArctic has commenced projects in both fields that are being combined with the company's Brain Transporter technology

in order to improve the passage of drug compounds into the brain. It is believed that the potential in the technology could facilitate the development of more internal projects, but could also be of use to other pharma companies as part of future licensing agreements.

It is in the nature of innovative research and development that the likelihood of success and the time frame for future value-creating events are difficult to predict, but the graphic on the following page is an attempt at illustrating how the continued journey could take shape.

The journey continues





# Risks and risk management

Risk exposure and risk management are a natural part of business operations. Risks are something that could impact BioArctic's operations negatively, but managed correctly could also add value to the company. The focus is on identifying and preventing risks, as well as preparing action plans that could help limit any damage if an undesirable event should occur.

## RISKS

One condition for a company's successful operation and development is a clear, well-supported strategy that is routinely monitored and evaluated. Moreover, a company's ability to achieve established goals is impacted by the routine efforts to identify and prevent risks. A risk is defined as the greater or lesser probability of the occurrence of a harmful event that could impact the company's ability to reach its established goals. Risks are a natural part of all business operations, and they must be handled effectively by the organization. Several times a year, BioArctic conducts an integrated risk assessment in which risks that could impact the company's possibility of achieving its goals are identified and assessed.

## RISK MANAGEMENT

Risk management is intended to prepare for, prevent and limit the effects of events that could negatively impact operations. BioArctic's management has identified possible events and scenarios that could negatively impact the company's operations. These events are being evaluated and compiled into a net list of the risks deemed to be the most relevant. For each risk, measures intended to counter, limit, control and manage the risk are being identified. The risk owners are the members of management who routinely work on identifying, managing and preventing risks, both over the long term and in their daily operations. The risks are evaluated and managed on a quarterly basis in the

management team as well as annually in the Audit Committee, which prepares Group-level risks for the Board.

### Control and follow-up

BioArctic conducts routine checks in its operations, and reviews and updates the company's instructions and work processes. The outcome of the controls are reported, and form a part of the routine risk management process.

### Insurance

BioArctic has insurance protection that is revised annually. The insurance covers property including research equipment and cooling facilities, and there is also operation insurance. In addition there is liability insurance for company, Board members and senior executives.

### Crisis management

BioArctic has well-documented crisis management plans with the objective of minimizing negative impact in situations not covered by normal procedural descriptions.

## OPERATIONAL AND STRATEGIC RISKS

### (A) Negative outcome in the project portfolio

Research and development of drugs is associated with a high level of risk, in the sense that major financial resources are invested in a project that perhaps will never lead to a finished



*Risks and risk management*

drug. A large portion of the total number of research projects being conducted in the field are discontinued during the process, since the drug candidates produced either cannot demonstrate the intended effect or turn out to have unacceptable side effects. BioArctic works continually on planning and preparations ahead of various scenarios and possible outcomes. BioArctic strives for a well-differentiated and well-compiled project portfolio with projects in various phases of development.

**(A 1) Overall portfolio strategy**

BioArctic operates in a complex area of research: disorders of the central nervous system. The company's success is affected by strategic decisions regarding future project priorities, positioning and market strategy.

**(A 2) Outlicensed projects conducted by partners**

In Alzheimer's disease, BioArctic has signed research and license agreements concerning its antibodies (lecanemab and lecanemab back-up) with Eisai, which means that Eisai covers the costs of the clinical studies, which has reduced BioArctic's financial risk exposure significantly. The two studies in BioArctic's research portfolio that have come the furthest are lecanemab for Alzheimer's disease, which in the autumn of 2022 demonstrated positive results in the pivotal Clarity AD Phase 3 study, and the ongoing AHEAD 3-45 Phase 3 study with lecanemab for individuals with pre-symptomatic Alzheimer's disease. A significant portion of the value of BioArctic is linked to the outcomes of these studies. The fact that lecanemab obtained accelerated approval in the US and that Eisai has applied for full approval in the US as well as submitting a marketing authorization application in Japan, China and the EU have all substantially reduced the risk in the outlicensed project portfolio.

**(A 3) Projects conducted in-house and under own development**

BioArctic has a broad research portfolio in the field of CNS. The company conducts in-house research on disorders of the central nervous system, and is developing the Brain Transporter technology. The BAN0805 project in Parkinson's

disease, which BioArctic reclaimed after the partnership with AbbVie was ended, has shown results from the completed Phase 1 study that support further development of the antibody in Phase 2. The drug projects being conducted in-house, except for BAN0805, are in earlier phases, smaller in scope and with lower financial risk exposure.

**(B) Impact of outcomes among competitors**

BioArctic operates in areas of research with significant medical need as well as large patient populations. Competition in these areas is significant, and competitors could develop, market, and sell drugs with greater efficacy that are safer and/or priced lower than BioArctic's or its partners'. For the company, assessing the risks that exist in the respective research areas and routinely monitoring and evaluating changes in the respective markets is of great importance. BioArctic is affected by how competitors in the market perform, and whether they capture market share with their products or reach the market faster than BioArctic or its partners. The development in competing pharma companies and biotech companies conducting research in the same therapy fields could impact BioArctic negatively as a result of negative study outcomes, a deteriorating competitive situation and/or a negative view in the business environment of companies conducting operations in the same areas of research. BioArctic routinely monitors competitors and developments in the industry in BioArctic's niche areas. The company generates its own data to indicate differentiation from competitors, primarily by pointing out differences and more favorable efficacy and/or better side effect profiles. A clear communication strategy with various scenarios based on the outcome of competitors' studies is routinely produced to reduce the risk of a negative impact on the brand and the valuation of the company.

**(C) External events outside the company's control**

An uncontrollable event is something that impacts the business environment in general that BioArctic could have difficulties protecting itself against. Examples of external events

that could have significant impact on the world and thus on BioArctic's operations are pandemics, war, natural catastrophes or widespread terrorism.

**(D) IT and information security risks, and risks of hacking**

Hacking into the company's IT security could lead to unauthorized access to critical data and/or loss of sensitive data, which could have the consequence of making company secrets available to unauthorized persons. The risks are routinely managed through reviews of IT security, clear rules and routines for how information is shared, perimeter security, controls and training.

**(E) Longer outages in operation-critical systems**

An outage in operation-critical systems could result in disruptions to operating activities and impact routine reporting. To manage the risk of outages, routine checks are conducted and stringent requirements are imposed for redundancy. Clear contingency plans and supplementary security storage through offsite server rooms have been implemented.

**(F) Partner-related risks**

A significant part of BioArctic's operations and business model is entering into licensing and collaboration agreements with pharma and biopharma companies to develop and sell potential products. BioArctic is highly dependent on partners who are significantly larger than BioArctic, and there is a risk that agreements that have been signed could be canceled. Differences of opinion and conflicts could also arise among BioArctic's partners or licensees as regards the conditions of agreements in force, such as the interpretation of clinical data, achievement of milestone payments, interpretation of financial remuneration and rights, or ownership rights of patents and similar rights developed as part of these partnerships.

**(G) Patents, intangible assets and government decisions**

BioArctic's success depends largely on the company's ability to receive and maintain protection of the intangible assets attributable to its products. The conditions for patented discoveries

*Risks and risk management*

in the field of drugs and biotech are generally difficult to assess and encompass complex legal and scientific issues. There is no guarantee that BioArctic can receive and maintain patents for its products or its technologies. Even if a patent is issued, it can be subject to appeal, declared invalid or circumvented, which could limit BioArctic's ability to prevent competitors from marketing similar products and reduce the period during which BioArctic has patent protection for its products or technologies. BioArctic and its partners are subject to decisions by government agencies such as in relation to the permits necessary to conduct clinical studies and to commercialize drugs as well as changes to regulations that could take place in areas such as pricing, discounting drugs or changes in circumstances for drug prescriptions.

**(H) Product liability and insurance**

BioArctic's operations entail product liability, which is unavoidable in conjunction with research and development, preclinical studies, clinical studies, production, marketing and sales of drugs. Even if BioArctic deems existing insurance protection to be sufficient, the scope and amount of compensation under this insurance protection is limited. There is therefore no guarantee that BioArctic will be fully compensated for any damage under its existing insurance protection. Nor can it be guaranteed what impact the requirements of product liability or other requirements will have on BioArctic's operations and financial position.

**(I) Employee risks**

BioArctic is dependent to a great extent on key persons to facilitate high-quality research and drug development and thus an attractive future project portfolio. The ability to recruit and retain qualified employees is of extreme importance to ensure the level of competence in the company. BioArctic therefore has a focus on leadership, collaboration policies, and core values as well as issues of diversity and equality, and strives to offer an attractive and sustainable

workplace where good health and a proper work environment are fundamental. The company's goal is to offer competitive conditions and remuneration in order to attract and retain competence.

**(J) Climate, sustainability and environmental risks**

BioArctic's ambition is to conduct research of the highest quality that promotes sustainable and innovative solutions to society's health challenges. The company strives to be a responsible business partner and employer that complies with environmental and work environment legislation and works actively with sustainability topics. Environmental risks regarding the handling of disposable items and hazardous waste such as chemical waste and biological hazardous waste are continuously evaluated. The operations are conducted in compliance with the permits issued to BioArctic by the government agencies concerned.

**(K) Internal and external regulatory risks**

For BioArctic, compliance with laws and other regulations is of great importance, as is conducting operations in accordance with sound business ethics in which corruption and bribery are not accepted. Violations or neglect concerning issues in these areas could damage the company's reputation and result in both sanctions and fines. For preventive purposes, BioArctic has prepared a number of policies that have been implemented in operations, a procedure for internal controls and a quality assurance organization that works to ensure clear procedures and documentation as regards compliance with operation-specific regulations. For BioArctic, ethical and moral positions are important in its daily operations. The company's actions as regards ethics, morals, security and integrity characterize its corporate culture and thus how the company conducts its operations.

**(L) Risk of errors in financial reporting**

BioArctic routinely updates its risk analysis to ensure correct financial reporting. Management and the Board of Directors make decisions annually on which risks are essential to monitor in order to ensure proper internal control in financial reporting. A more detailed description of BioArctic's work on internal control can be found in the Corporate Governance Report on pages 108-120.



## Risks and risk management

RISK	DESCRIPTION OF RISK	MANAGEMENT
A	Negative outcome in the project portfolio divided into:	
(A 1)	Overall portfolio strategy	The risk is managed using a well-differentiated and well-balanced project portfolio focused on central nervous system disorders. The company routinely evaluates various business opportunities to strengthen the potential of its project portfolio.
A 2	Outlicensed projects conducted by partners	Broad data collection, continual review of the projects and routine contact with external partners.
A 3	Earlier projects conducted in-house and under own development	Broad data collection, continual review of the projects. Scenario analyses and routine evaluation in pace with the progress of the projects.
B	Impact of outcomes among competitors	Business intelligence. Generation of own data to demonstrate differentiation from competitors. Market analysis. Communication management.
C	External events outside the company's control	Business intelligence, crisis plans, a clearly defined crisis organization and crisis management exercises as well as clear communication, both internally and externally.
D	IT and information security risks, and risks of hacking	Preventive work and checks. High level of awareness concerning security issues.
E	Longer outages in operation-critical systems	Routine checks, high level as regards redundancy. Contingency plans and safety stockpiling.
F	Partner-related risks	Clear documentation of agreements and close dialogue. Routine evaluation and monitoring.

RISK	DESCRIPTION OF RISK	MANAGEMENT
G	Patents, intangible assets and government decisions	Well-documented patent strategy and in-house patent counsel. Routine monitoring of developments in the intellectual property field.
H	Product responsibilities and insurance	Routine reviews of the company's insurance protection and ensuring that the company complies with existing regulations and documentation requirements as regards product liability.
I	Employee risks	Actively engaged in leadership and maintaining a positive corporate culture. Succession plans prepared and critical roles/functions identified. Work to remain an attractive employer.
J	Climate, sustainability and environmental risks	BioArctic's operations have a limited impact on the climate and the environment. The company works actively with increased recycling of plastic, paper, glass and metal. Handling and transport of hazardous waste takes place with credited parties. Operations are conducted in accordance with existing permits and regulations, and with a focus on sustainability.
K	Internal and external regulatory risks	BioArctic has a structure for internal controls and has an external audit function of the internal controls. The company also has a Code of Conduct that is approved and signed by all employees, which among other things distances the company from corruption and bribery.
L	Risk of errors in financial reporting	Checks have been implemented to ensure correct reporting. Routine checks of identified areas, and monitoring.

# Board of Directors' report

*The Board of Directors and the Chief Executive Officer of BioArctic AB (publ), corporate registration number 556601-2679, hereby submit the Annual Report and consolidated financial statements for the 2022 financial year.*

## OPERATIONS AND STRATEGY

BioArctic AB (publ), based in Stockholm, Sweden, is as of December 31, 2022 the Parent Company in the BioArctic Group, which also includes the dormant subsidiary LPB Sweden AB. The wholly owned subsidiaries BioArctic Denmark ApS, BioArctic Norway A/S, and BioArctic Finland Oy have also been included since the first quarter of 2023.

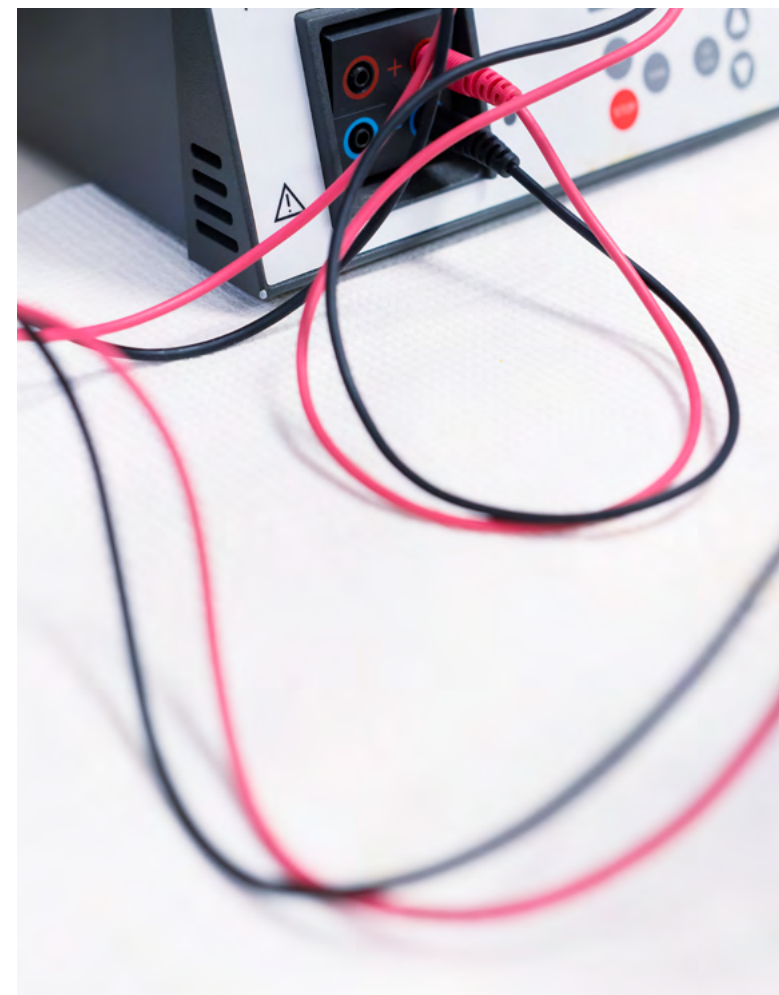
BioArctic AB is a research-based biopharma company focusing on drug treatments for neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease and ALS. The company is also developing a blood-brain barrier technology to facilitate the passage of biological drugs into the brain. BioArctic focuses on innovative treatments in areas with high unmet medical needs. The company was founded in 2003 based on research from Uppsala University, Sweden, and Karolinska Institutet, Sweden. The project portfolio is a combination of fully funded projects pursued in partnership with the Japanese pharma company Eisai and innovative in-house projects with significant market and outlicensing potential. BioArctic's B share has been listed on Nasdaq Stockholm since the autumn of 2017, and since January 2023 has been admitted to trading on the Large Cap list (ticker: BIOA B).

BioArctic's vision is to create drugs through research that improve the lives of patients with serious diseases, and to become a world leading, innovative biopharma company in neurodegenerative diseases. Our work is based on groundbreaking scientific discoveries, and the company's researchers collaborate with strategic partners such as research groups at universities and major pharma companies. BioArctic will be a pharma company that develops, markets, and sells disease-modifying drugs against neurodegenerative diseases that

are difficult to treat. The company has scientific excellence and extensive experience in developing drugs from idea to market. Under BioArctic's business model, the company pursues research and project development at an early stage in-house and then, at an appropriate juncture, licenses commercial rights and late stage development to global pharma companies.

## Alzheimer's disease

In the field of treatments for Alzheimer's disease, BioArctic has been collaborating since 2005 with Eisai, who has signed research partnership agreements and licensing agreements regarding the antibodies lecanemab and lecanemab backup. Eisai conducts and funds the clinical trials, which means BioArctic incurs no costs for them and thereby assumes no financial risk. In the autumn of 2022, Eisai communicated positive results from Clarity AD, the global confirmatory Phase 3 study with lecanemab in patients with early Alzheimer's disease, and the study achieved both the primary endpoint and all secondary endpoints with high statistical significance. In early 2023, Eisai submitted application for full approval in the US as well as marketing authorization applications in Japan and the EU. An application in China has begun as well. If the applications are approved, lecanemab has the potential to become one of the world's first drugs to slow the progress of Alzheimer's disease. Two open-label extension studies with lecanemab are in progress: one linked to a Phase 2b study and one linked to the Clarity AD Phase 3 study. In addition, a Phase 3 study (AHEAD 3-45) is in progress for persons who have not yet developed symptoms of Alzheimer's disease but have intermediate or elevated amyloid levels in the brain.



BioArctic is also conducting research into generating new antibodies intended for treatment of Alzheimer's disease with the goal of slowing or stopping disease progression with innovative molecules that have different mechanisms of action. In addition to the projects being carried out as part of the partnership with Eisai, BioArctic has four additional antibody projects against Alzheimer's disease in its project portfolio, all of which are in the research or preclinical phase. One of these four projects is BAN1503, an antibody project against shorter, truncated forms of amyloid-beta that appear early on in the course of the disease and have a pronounced ability to aggregate and create harmful forms that could cause Alzheimer's disease. The AD-BT2802 and AD-BT2803 drug projects are two antibody projects against Alzheimer's disease that are being combined with our blood-brain barrier technology – Brain Transporter, or BT – to facilitate uptake of antibodies in the brain. BioArctic is also working to develop new methods that could improve diagnostics and the evaluation of treatments for the company's projects in Alzheimer's disease and Parkinson's disease. BioArctic is pursuing a number of projects in partnership with external commercial and academic partners.

#### Parkinson's disease

BioArctic had been collaborating with AbbVie in the field of treatments for Parkinson's disease since 2016. In the spring of 2022, AbbVie informed BioArctic that it had taken a strategic decision to terminate the collaboration around BioArctic's alpha-synuclein project portfolio. BioArctic has reclaimed the projects from AbbVie with the ambition of pursuing them further in-house, or signing new partnership agreements. The objective of the project portfolio is to develop disease-modifying treatments for Parkinson's disease, Lewy body dementia and multiple system atrophy. AbbVie and BioArctic have presented data that supports the continued development of the antibody in Phase 2 with one dose per month.

#### Amyotrophic lateral sclerosis (ALS)

The ND3014 and ND-BT3814 drug projects are oriented 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.

#### Other indications

BioArctic's goal is to improve the treatments of a number of neurodegenerative diseases. The company's scientists are working systematically on solving the major challenges around the

diseases of the brain. BioArctic's knowledge of how to develop antibodies against misfolded proteins can be used against several diseases, and the company conducts a number of early research projects to evaluate the possibility of producing new treatments for various neurodegenerative disorders. The antibody lecanemab is in the pre-clinical phase as a potential treatment of cognitive impairment and dementia in conjunction with Down's syndrome and with traumatic brain injuries. The area of application for drug candidate BAN0805 could be expanded to include diseases such as Lewy body dementia and multiple system atrophy. In late 2022, BioArctic announced that a new project had been initiated that focuses on enzyme



replacement treatment for Gaucher disease in combination with the company's Brain Transporter technology.

### Brain Transporter technology

The blood-brain barrier controls the passage of substances between the blood stream and the brain. It protects the brain from harmful substances, but at the same time it can make the delivery of drugs to the brain more difficult. BioArctic is now developing a second generation of this technology, which has already demonstrated a robust increase in antibodies and improved exposure in the brain. The technology is now being used in five early-stage projects: two in Alzheimer's disease (AD-BT2802 and AD-BT2803), one in Parkinson's disease (PD-BT2238), one in ALS (ND-BT3814), and one in Gaucher disease (GD-BT6822). The technology has significant potential



for many different treatments of various diseases of the brain. BioArctic and Uppsala University have together received research grant from Vinnova for research in the blood-brain barrier project.

At the end of 2022, BioArctic was granted a new patent in the US for fifteen years on technology for the transportation of drugs across the blood-brain barrier.

### PROJECT PORTFOLIO

BioArctic has a well-balanced, competitive portfolio consisting of unique product candidates and a technology for facilitating the passage of drugs across the blood-brain barrier. All projects in the portfolio are focused on disorders of the central nervous system. BioArctic's project portfolio is in various stages – from the early research phase to the late clinical, to regulatory phases and since the first quarter 2023 also on the market in the US.

At December 31, 2022, the portfolio comprised:

- A drug candidate in the regulatory phase: lecanemab for early Alzheimer's disease (Clarity AD)
- Two drug candidates in the clinical phase: lecanemab for individuals who have not yet developed Alzheimer's disease but have elevated amyloid levels in the brain (AHEAD 3-45, Phase 3) and BAN0805 for Parkinson's disease (between Phases 1 and 2).
- Two projects in the preclinical phase: lecanemab for indications such as Down's syndrome with dementia and lecanemab backup for Alzheimer's disease
- Ten projects in the research phase: four projects for Alzheimer's disease (BAN1503, AD2603, AD-BT2802, AD-BT2803); three projects for Parkinson's disease (PD1601, PD1602, PD-BT2238); two projects for ALS (ND3014, ND-BT3814); and one project for Gaucher disease (GD-BT6822); biomarkers and diagnostics to support BioArctic's own research in for Alzheimer's disease and Parkinson's disease; and a blood-brain barrier technology for increased uptake of antibodies and other biological drugs in the brain.

### PARTNERSHIPS, COLLABORATION AND MAJOR AGREEMENTS

An important part of BioArctic's strategy is partnership and licensing agreements with leading pharma and biopharma companies. In addition to financial compensation, BioArctic benefits from the companies' competence in developing, manufacturing and commercializing drugs. BioArctic has signed and has several ongoing agreements with the global Japanese pharma company Eisai. Strategic partnerships with leading global companies are confirmation of the high degree of standard in BioArctic's research. BioArctic's objective is to sign more agreements that could contribute further funding, as well as competence in research and development for product candidates in the preclinical and clinical phase, competence in manufacturing and marketing, geographical breadth and other resources.

Collaborations with universities are of great importance to BioArctic as well. The company currently collaborates with leading researchers at a number of universities.

### Eisai

In 2005, BioArctic inaugurated its first research collaboration with Eisai. BioArctic has granted the use of a global and exclusive license to Eisai for research, development and commercialization of drugs that use the antibodies lecanemab and lecanemab backup for the treatment of Alzheimer's disease. Eisai is on a global basis responsible for the clinical development, applications for market approval and commercialization of the future products. BioArctic holds the rights to commercialize the licensed antibodies in the Nordic region together with Eisai, and the rights to treatment of indications other than Alzheimer's disease. The company has signed a number of agreements with Eisai totaling a potential value of MEUR 222 plus royalty payments. As of December 31, 2022, up to MEUR 136 in potential milestone payments remained to be received from Eisai, of which MEUR 35 was recognized as revenue in the first quarter of 2023. Milestone payments of up to MEUR 101 is remaining. In 2022, MSEK 161.5 in milestone payments and MSEK 8.3 from the collaboration agreement with Eisai were recognized as revenue.

## AbbVie

BioArctic had been collaborating with AbbVie in the field of Parkinson's disease since 2016, when a research agreement was signed that included products such as the antibody BAN0805. Over the course of the contract, BioArctic received MUS\$ 130. In the spring of 2022, AbbVie terminated the collaboration and in the third quarter an agreement was signed with AbbVie on the handover of the projects back to BioArctic. As part of the agreement, AbbVie has the right to receive a low single-digit percentage in royalties on global sales from BioArctic if any of the projects reach the market. As a result of the agreement being signed, no further payments will accrue to BioArctic. In 2022, MSEK 58.5 was recognized as revenue.

## Research grants

In 2019, BioArctic was awarded research grants totaling MSEK 5 from Vinnova for continued research in the blood-brain barrier technology project in collaboration with Uppsala University. From 2019 up until 2022, BioArctic received the entire grant divided into yearly payments. In 2022, MSEK 1.1 from the Vinnova grant was recognized as revenue.

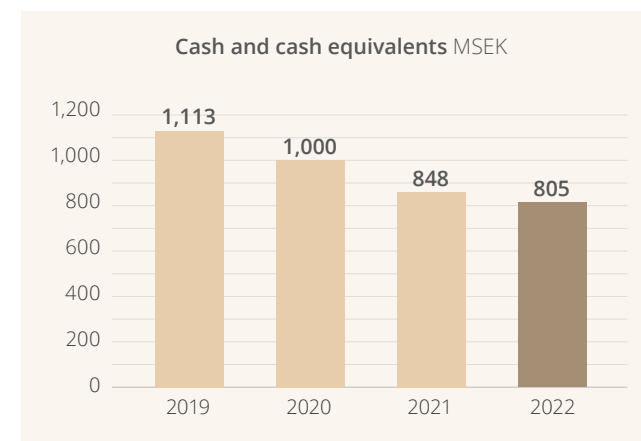
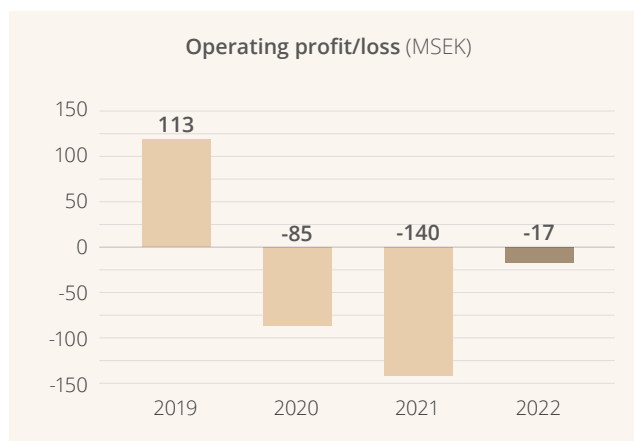
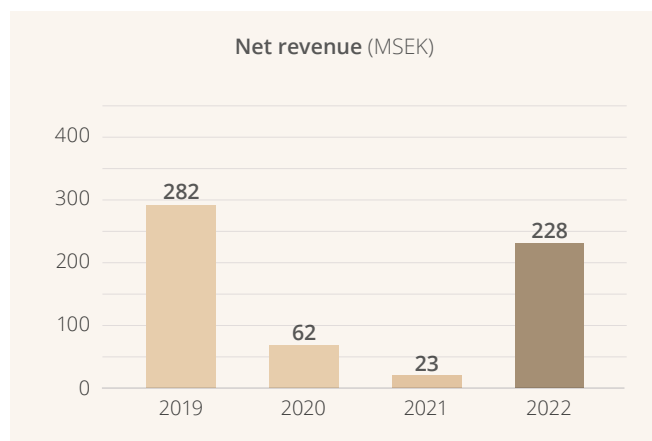
## REVENUE AND OPERATING PROFIT

The company's income consists of milestone payments, remuneration from research agreements and research grants. Owing to the character of the operations, major fluctuations may arise in revenue between different periods, since income from milestone payments are recognized at certain points in time when performance obligations have been fulfilled.

Net revenue for the 2022 financial year totaled MSEK 228.3 (23.1). The increase in revenue year-on-year is attributable primarily to the milestone payment of MEUR 161.5 (15) that BioArctic received from its partner Eisai in conjunction with the US Food and Drug Administration's acceptance of the biologics license application for lecanemab under an accelerated approval pathway. Additionally, the final settlement of the Parkinson's project was completed, which generated MSEK 47.9 in revenue. For the full-year period, a total of MSEK 58.5 (8.5) was recognized as revenue from the collaboration agreement with AbbVie. Other operating income pertaining to research grants and operational currency exchange gains totaled MSEK 1.6 (3.5). Total revenue during the financial year thus increased to MSEK 229.9 (26.7).

Total operating costs were MSEK 247.3 (166.4). The increase is attributable to higher costs for in-house projects as well as the expansion of the marketing organization. External project costs totaled MSEK 74.3 (55.1). Other external costs increased slightly during the year to MSEK 33.0 (24.9). Personnel costs increased to MSEK 115.7 (72.5). The higher amount is attributable to the increase in the number of employees, and that the company's higher share price resulted in the value of warrants – on which the social security contributions are calculated – raising the costs of the employee stock option program. Depreciation of assets totaled MSEK 14.6 (13.1). Other operating costs totaled MSEK 9.7 (0.9) and consisted of realized operational exchange rate losses. Operating loss during the year totaled MSEK -17.4 (-139.7). The improvement year-on-year is due primarily to the milestone payment from Eisai and the settlement from the Parkinson's program.

The Group's net financial items for 2022 totaled MSEK 6.3 (-0.8). Financial income consisted of interest income and financial exchange rate gains, and financial costs consisted primarily of interest on lease liabilities. Loss before tax was MSEK -11.2 (-140.5).





Tax for the year totaled MSEK 0.0 (20.7), which corresponds to an effective tax rate of 0.1 percent (14.7). Loss for the year totaled MSEK -11.2 (-119.8), corresponding to SEK -0.13 per share (-1.36) before and after dilution in 2022.

#### EXCHANGE RATE FLUCTUATIONS

BioArctic is a Swedish company and reports its financial position and its earnings in Swedish kronor (SEK). BioArctic's revenue currently consists essentially of remuneration from partnership and licensing agreements with Eisai, in which payments are received in EUR. BioArctic purchases continuous services in currencies other than SEK, primarily EUR, USD and GBP. The flows of currencies other than SEK in conjunction with the purchase and sale of goods and services are subject to transaction exposure.

BioArctic also reconciles the company's currency exports during the year in order to balance the company's commitments.

#### FLUCTUATIONS CONCERNING REVENUE GENERATION

In 2022, BioArctic did not have any drugs that were commercialized or sold in the market. 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 submission of applications to regulatory authorities,

approval and sales milestones. Owing to the character of BioArctic's revenue, these revenue streams arise unevenly over time throughout the financial year and between quarters, since revenue is governed by the advances made in the projects. See the diagram below for a visualization of how the revenue stream has historically been divided by financial year.

#### BALANCE SHEET AND FINANCIAL POSITION

BioArctic's balance sheet total at 31 December 2022 was MSEK 858.3 (897.7).

##### Non-current assets

BioArctic's non-current assets totaled MSEK 23.5 (17.0). These assets consisted primarily of laboratory equipment and improvement fees on other parties' property. BioArctic's right-of-use assets totaled MSEK 11.7 (16.8). The decrease of MSEK 5.1 is attributable largely to amortizations, which are related primarily to the lease for the main office. The company's financial assets totaled MSEK 1.6 (1.6) and consisted primarily of deposits on leases. The company has no intangible fixed assets. Since BioArctic's own projects are in the early research phase, they do not meet all the conditions for capitalizing R&D expenses and have therefore been expensed in their entirety.

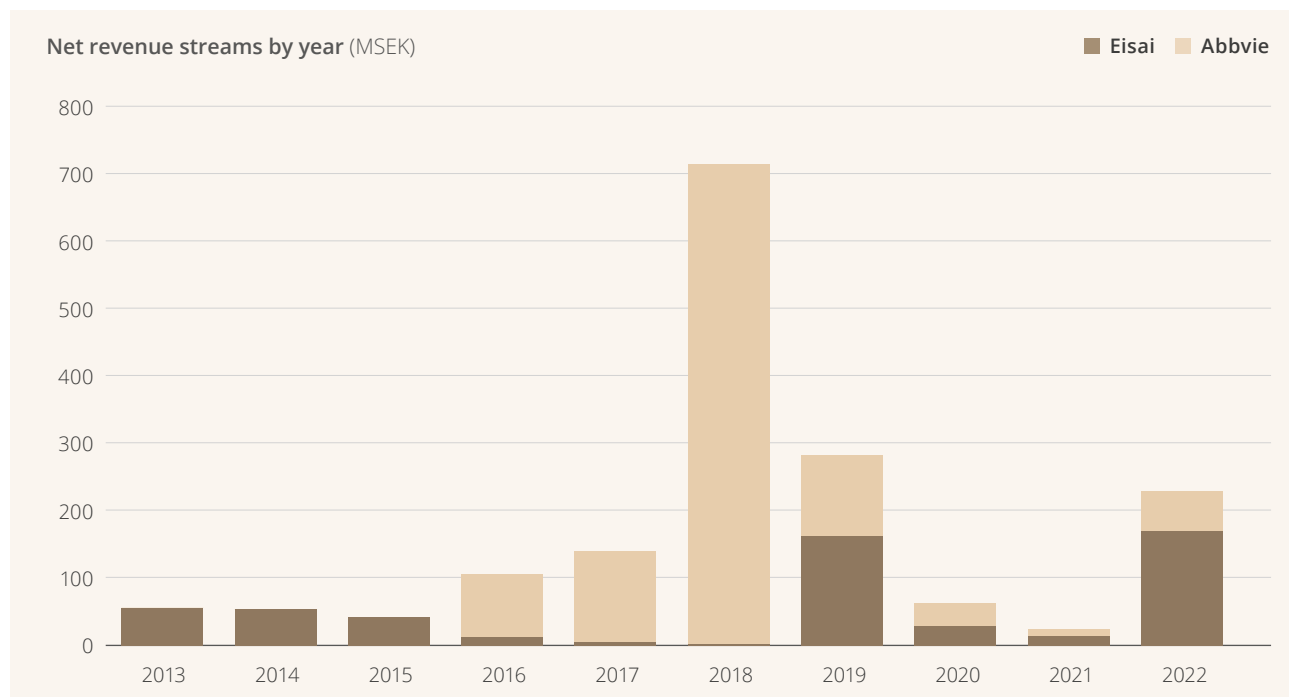
##### Current assets

Current assets in BioArctic consist of current receivables as well as cash and cash equivalents. The company's cash and cash equivalents at year end totaled MSEK 805.4 (848.4).

In order to neutralize currency exposure, a certain amount of liquidity is placed in foreign currencies. This leads to effects in the report in connection with revaluation of currencies at the current exchange rate, which is recognized in operating profit and in finance income and costs.

##### Investments

Investments for the year totaled MSEK 12.8 (4.4) and pertained primarily to laboratory equipment.



### Equity and liabilities

Equity as of December 31, 2022 totaled MSEK 786.2 (788.7). Equity per share outstanding totaled SEK 8.92 (8.96). The equity/asset ratio at December 31 was 91.6 percent (87.9). Lease liabilities of MSEK 10.0 (15.9) are related to right-of-use assets. No loans had been taken out as of December 31, 2022, and the Group has no other credit or facilities, which means the Group had a positive net cash balance of MSEK 795.3 (832.5) at year-end.

### CASH FLOW

The Group's cash flow from operating activities before changes in working capital increased during the year, totaling MSEK -56.6 (-135.4). Cash flow from operating activities after changes in working capital totaled MSEK -31.6 (-140.5). The main reason for the increase for the full year is related to the Eisai milestone payment amounting to MSEK 161.5.

Cash flow from investing activities during the year totaled MSEK -12.8 (-4.4) and were mainly related to laboratory equipment.

Cash flow from financing activities during the year totaled MSEK -2.8 (-7.4) and pertained primarily to amortization of lease liabilities.

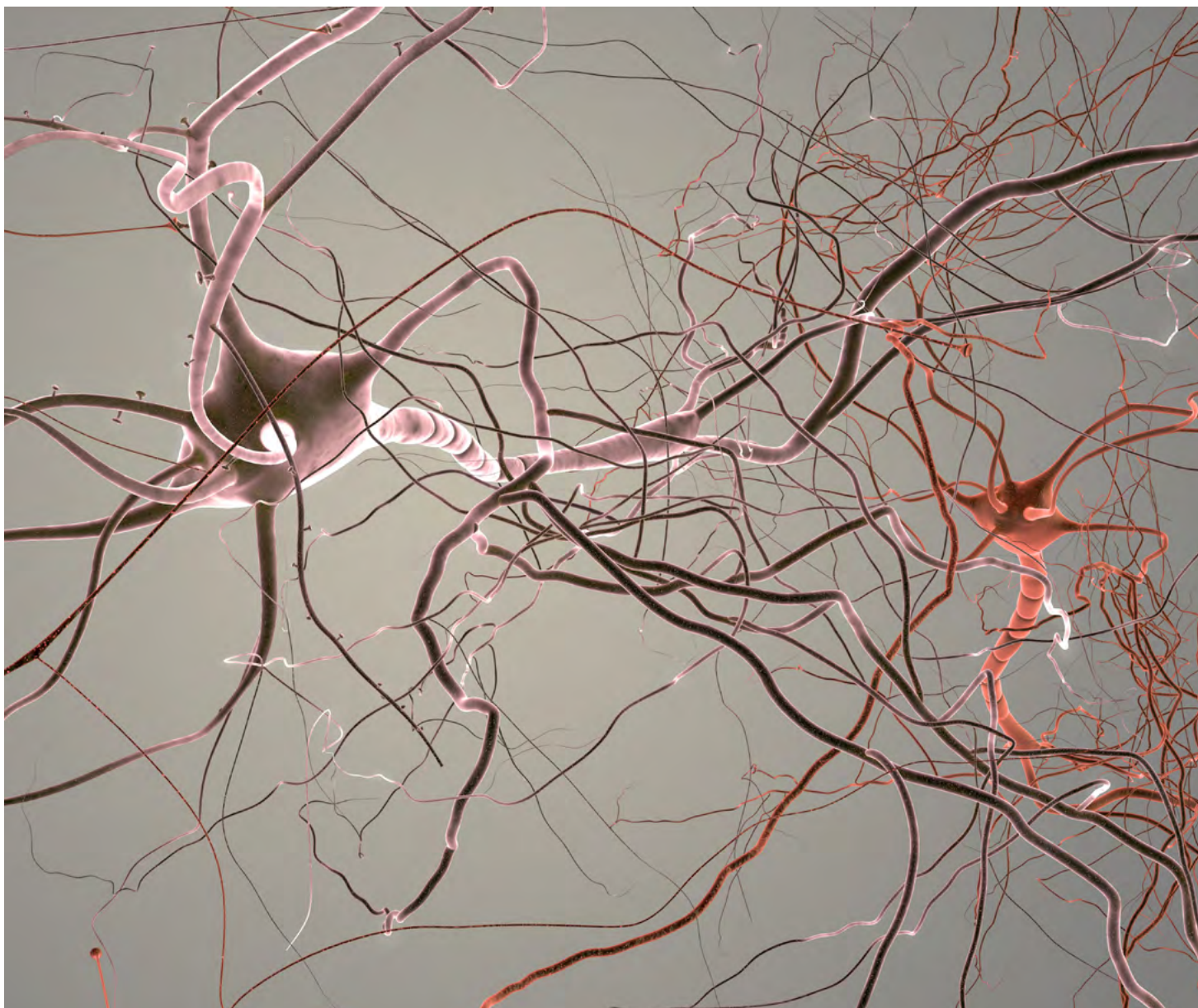
Cash flow for the year totaled MSEK -47.2 (-152.3). The improvement year-on-year is attributable to better operating profit, but was offset by increased investments.

### PARENT COMPANY

BioArctic AB (publ), based in Stockholm, Sweden, is the Parent Company in the BioArctic Group. All Group operations are conducted in the Parent Company. The Parent Company's profit for financial year 2022 totaled MSEK -11.5 (-45.7).

### GROUP

The BioArctic Group as of December 31, 2022 includes the parent company, BioArctic AB (publ) and the dormant subsidiary LPB Sweden AB. The wholly owned subsidiaries BioArctic Denmark ApS, BioArctic Norway A/S, and BioArctic Finland



Oy have also been included in the BioArctic Group since the first quarter of 2023. The companies have been formed to prepare for potential commercialization and sales in the Nordic region.

#### EMPLOYEES

As of December 31, 2022, BioArctic had 61 employees (49). The average number of employees at BioArctic during the year was 57 (46), all of whom are employed in Sweden at the company's head office in Stockholm. Gender equality is part of BioArctic's diversity efforts. In 2022, 37 employees (30) – 61 percent – were women and 24 employees

(19) – 39 percent – were men. Of the total number of employees, 79 percent (82) worked in research and development.

BioArctic contracts with external companies to a great extent to perform such tasks as the production of pharmaceutical substances. In order to conduct efficient operations with a relatively small organization, BioArctic also hires consultants in key roles for specific assignments and for work tasks in areas of competence that the company lacks or has only periodic need of. In total, the number of full-time employees and consultants employed at the end of 2022 was 68 (60). BioArctic strives to offer competitive salaries and benefits, and applies an individually adjusted wage structure adapted to the local market. BioArctic's

ambition is to offer a work environment that promotes health and well-being and a sound balance between work and private life.

#### RISKS AND UNCERTAINTIES

BioArctic's operation, like all business operations, is associated with risks. Risks are something that could impact BioArctic's operations negatively, but managed correctly could also add value to the company. The goal of the Group's risk management is to identify, prevent, measure, control, and limit the risks in its operation.

BioArctic's operational and business environment risks consist primarily of risks related to research and development, clinical trials, and dependence on key individuals.

A detailed description of risk exposure and risk management is provided on pages 49-52. The financial risks are described in Note 3.

#### Impact of the war in Ukraine on the Group

Russia's invasion of Ukraine is a tragedy, above all for the people located in the war zone or who have been forced to flee. There is uncertainty around how the war will unfold, and how great its short- and long-term impact on the world economy will be. BioArctic is carefully monitoring the course of events in our business environment and is currently of the opinion that the invasion does not have any direct impact on its operation.

#### Impact of the prevailing macroeconomic situation on the Group

The macroeconomic situation in the world is marked by rising interest rates and inflation. All income in BioArctic is linked to the development of the euro, which creates a risk of currency fluctuations. BioArctic does not have any loans raised and the impact from the macrofactors listed above is limited as a result of the orientation of its operations.

#### Impact of COVID-19 on the Group

BioArctic had no disruptions to its operations in 2022 as a consequence of COVID-19 and the pandemic. Our approach to COVID-19 has been to closely monitor the course of events

## Events during financial year 2022

- Lecanemab displayed positive results in the Clarity AD confirmatory Phase 3 study in early Alzheimer's disease, and achieved both primary and all secondary endpoints with high statistical significance. Detailed results were presented at the CTAD conference and simultaneously published in the New England Journal of Medicine
- The FDA accepted the Biologics License Application and granted priority review of lecanemab for treatment of early Alzheimer's disease under the accelerated approval pathway
- Eisai commenced submission of lecanemab data in Japan for preliminary review, with the objective of obtaining faster regulatory market approval
- A modeling study published in the scientific journal *Neurology and Therapy* indicated that lecanemab could delay progression to Alzheimer's dementia by several years
- AbbVie took a strategic business decision to terminate its collaboration with BioArctic regarding the alpha-synuclein projects for Parkinson's disease
- A further compound patent for BAN0805 was granted in the US, which is valid until 2041, with a possible extension until 2046
- BioArctic expanded its alpha-synuclein project portfolio with the PD-BT2238 project, which combines a selective antibody against alpha-synuclein with the company's Brain Transporter technology
- BioArctic was granted a new patent in the US on technology for the transportation of drugs across the blood-brain barrier
- BioArctic initiated a new project that focuses on enzyme replacement treatment for Gaucher disease in combination with the company's Brain Transporter technology

in the business environment and to apply clear internal guidelines to ensure as safe a work environment as possible for all employees.

#### GUIDELINES FOR REMUNERATION TO SENIOR EXECUTIVES

For a detailed description of applicable guidelines regarding remuneration and other terms of employment for the CEO and other senior executives, refer to pages 108-120 and to Note 7.

Ahead of the 2022 Annual General Meeting, the Board of Directors reviewed the guidelines for remuneration to senior executives that were adopted by the 2020 AGM and found that the guidelines ought to be adapted to the company's existing and future milestone-related rewards programs. In brief, the changes to the guidelines adopted by the Annual General Meeting mean that remuneration in accordance with existing and future milestone-related rewards programs will not be included in the guidelines on the share of variable remuneration in relation to fixed salary and that certain clarifications will be made.

No changes to the policies for remuneration and other terms of employment for Group Management have been proposed ahead of the 2023 Annual General Meeting.

#### LONG-TERM INCENTIVE PROGRAM

BioArctic has a long-term incentive program (the 2019/2028 program) in the form of an employee stock option program intended for the company's senior executives, researchers and other staff, for more information see page 124. The purpose of the incentive program is to encourage broad share ownership among BioArctic's employees, facilitate recruitment, retain skilled employees and increase employee motivation and fulfillment of targets.

#### REWARDS PROGRAMS

BioArctic has during 2022 had two rewards programs linked to the company's Alzheimer's project, of which one program remains during 2023. The rewards programs cover all permanent employees excluding the founders but including the CEO.

Variable remuneration is paid when the company achieves certain goals linked to the clinical research study and regulatory milestones. Refer also to Note 7.

#### ENVIRONMENT, SUSTAINABILITY AND SOCIAL RESPONSIBILITY

BioArctic's clearest and most important contribution to a globally sustainable future lies in innovation and the development of safe and effective drugs against disorders of the central nervous system. As part of its sustainability efforts, BioArctic conducts high-quality research that promotes sustainable and innovative solutions to society's health challenges. BioArctic endeavors to integrate economic and social sustainability at all levels of its operations, to continually improve the company's procedures, quality assurance systems and work environment,

and to take action to prevent the environmental impact of its own operations. The operations BioArctic conducts are characterized by transparency, creativity and respect for the equal worth of all. The company's work with its partners promotes sustainable development and value creation. BioArctic has identified goals with a clear link to the company's operations in three main areas: sustainable employeeship, sustainable use of resources and sustainable business.

BioArctic is a responsible business partner and employer, and complies with environmental and work environment legislation. In addition, BioArctic has internal policies that encompass guidelines for the environment and the work environment. Pharmaceutical research is conducted in BioArctic's offices in Stockholm. The operations comply with the permits



issued to BioArctic by the government agencies concerned. For example, the company has permits from the Swedish Work Environment Authority (Sv. Arbetsmiljöverket) regarding the use of chemicals, and the Swedish Board of Agriculture (Sv. Jordbruksverket) regarding the import and use of biological tissues in the company's laboratory. In accordance with Swedish environmental legislation, BioArctic is registered with the Stockholm County Administrative Board (Sv. Länsstyrelsen) to conduct its operations. BioArctic is not involved in any environmental disputes. No workplace accidents were reported to Arbetsmiljöverket in 2022.

BioArctic contracts only manufacturers of drugs (antibodies) whose facilities are certified in accordance with the relevant legislation. The same applies to procurement of services from contract research organizations (CROs), i.e. services procured by specialized subcontractors within the pharmaceutical industry.

#### SHARE CAPITAL AND OWNERSHIP

BioArctic's B share (BIOA B) was listed on Nasdaq Stockholm Mid Cap. The market value at year-end totaled SEK 24 billion (10.5). BioArctic's B share rose 128 percent during the year. The share capital at year-end totaled SEK 1,762,632 spread over 88,131,571 shares, of which 14,399,996 were unlisted A shares and 73,731,575 were listed B shares. The number of B shares in the company increased by 71,586 as a result of subscription of shares by participants in the 2019/2028 employee stock option program. The A share has ten votes per share while the B share has one vote per share. The quotient value per share is SEK 0.02. At the end of 2022, BioArctic had 14,840 shareholders (9,816). BioArctic's ten largest shareholders owned shares corresponding to 75.7 percent of the capital and 90.2 percent of the votes. The Board members in the company owned a total of 48,794,523 A shares and B shares (52,365,824) in BioArctic, while company management owned 233,118 B shares (217,041) excluding those owned by Lars Lannfelt, which are counted among Board member shares. In

total, the holdings of the Board and management correspond to 55.6 percent (59.8) of shares outstanding. BioArctic's A shares are owned by Demban AB and Ackelsta AB, which are in turn owned by the founders of BioArctic. Demban AB (Lars Lannfelt) owned 49.3 percent of the votes and 33.5 percent of the capital, and Ackelsta AB (Pär Gellerfors) owned 32.6 percent of the votes and 21.7 percent of the capital.

#### EVENTS AFTER THE BALANCE SHEET DATE

For key events after the balance sheet date, refer to Note 30.

#### FUTURE PROSPECTS

In BioArctic's opinion, the operating expenses for financial year January–December 2023 will total MSEK 330–380, compared with the outcome for 2022 which totaled MSEK 247, and the average operating expense level per year over the last three years of approximately MSEK 188. The build-up of the commercial organization prior to the potential launch of lecanemab, and costs for the expanded and more advanced in-house project portfolio, explain the expected higher level of costs for 2023. Apart from an expected operating expense level, BioArctic makes no financial forecasts regarding its future performance. The company enjoys a strong financial position and has a business model in which its revenue and earnings are primarily based on revenue from research and licensing agreements the company has signed. The company's liquidity facilitates continued development of the projects covered by strategic collaboration agreements as well as financing of the company's own less costly projects. All of BioArctic's focus therapeutic areas, such as Alzheimer's disease, Parkinson's disease and research into ALS and other neurodegenerative diseases are areas that currently lack effective treatments and have great market potential. The company's ambition is to generate the drugs of the future that improve life for people with disorders of the central nervous system. The company's cash holdings remain strong, which creates possibilities for the continued exciting development of BioArctic.

#### DIVIDEND POLICY AND DIVIDEND

Since BioArctic had no product sales in 2022, the company's revenue and earnings primarily consisted of revenue of a non-recurring character in accordance with the research and licensing agreements the company has signed. BioArctic will continue to focus on further developing and expanding the company's project portfolio. It is the intent of the Board not to propose any dividend to shareholders until the company generates long-term and sustainable profitability. Any future dividends and the size thereof will be established based on an assessment of the company's long-term growth, earnings trends and capital requirements, taking into account goals and strategies that have been set at any given time. To the extent a dividend has been proposed, it must have been given proper consideration and based on the above grounds for assessment. The Board proposes that no dividend be paid for financial year 2022.

#### APPROPRIATION OF PROFITS

The Board proposes that the consolidated income statement and balance sheet be presented to the Annual General Meeting on June 1, 2023 for adoption and that the profit for the year as well as the retained profits in the Parent Company be carried forward.

At the disposal of the Annual General Meeting:	(SEK)
Share premium reserve	566,001,132
Retained earnings	229,548,497
Profit/loss for the year	-11,471,996
<b>Total</b>	<b>784,077,634</b>

# Five-year summary

<i>Amounts in MSEK</i>	2022	2021	2020	2019	2018 <sup>1)</sup>
<b>Income statement</b>					
Net revenue	228.3	23.1	62.3	281.8	714.0
Other operating income	1.6	3.5	3.6	14.8	16.3
Expenses	-247.3	-166.4	-151.0	-184.1	-241.4
Operating profit/loss	-17.4	-139.7	-85.0	112.5	488.8
Profit/loss for the year	-11.2	-119.8	-68.5	88.6	381.6
Operating margin, %	neg	neg	neg	39.9	68.5
<b>Balance sheet</b>					
Non-current assets	37.5	35.9	42.0	39.0	11.0
Current assets excl. cash and cash equivalents	15.5	13.4	8.4	31.6	464.8
Cash and cash equivalents	805.4	848.4	999.9	1,112.8	917.3
Equity	786.2	788.7	907.3	974.6	1,017.7
Deferred tax liabilities	—	—	20.7	38.7	32.5
Current liabilities	70.9	101.3	108.7	149.2	342.8
<b>Cash flow</b>					
From operating activities	-31.6	-140.5	-92.3	327.2	-200.1
From investing activities	-12.8	-4.4	-12.5	-3.3	-3.1
From financing activities	-2.8	-7.4	-6.6	-138.5	—
Cash flow for the year	-47.2	-152.3	-111.5	185.4	-203.1
<b>Key ratios</b>					
Equity/asset ratio, %	91.6	87.9	86.4	82.4	73.1
Return on equity, %	-1.4	-14.1	-7.3	8.9	46.1
<b>Data per share, SEK</b>					
Earnings per share, before and after dilution	-0.13	-1.36	-0.78	1.00	4.33
Equity per share	8.92	8.96	10.30	11.07	11.56
Cash flow from operating activities per share	0.36	-1.60	-1.05	3.72	-2.27
Share price at December 31 <sup>1)</sup>	272.00	119.20	95.40	94.90	82.00

<sup>1)</sup> IFRS 16 was not applied in 2018. Its impact on earnings was marginal.

# Financial statements >





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## Consolidated income statement

Amounts in kSEK	Note	2022	2021
<b>Operating income</b>			
Net revenue	5	228,291	23,146
Other operating income	6	1,570	3,542
<b>Total operating income</b>		<b>229,861</b>	<b>26,688</b>
<b>Operating expenses</b>			
Project expenses		-74,326	-55,067
Other external expenses	8	-33,015	-24,852
Personnel expenses	7	-115,650	-72,499
Depreciations of tangible assets	14	-14,633	-13,107
Other operating expenses	10	-9,679	-885
<b>Total operating expenses</b>		<b>-247,303</b>	<b>-166,411</b>
<b>Operating loss</b>		<b>-17,442</b>	<b>-139,723</b>
<b>Profit/loss from financial items</b>			
Interest income and similar items	11	7,025	194
Interest expenses and similar items	11	-751	-984
<b>Loss after financial items</b>		<b>-11,168</b>	<b>-140,512</b>
Tax	12	-11	20,723
<b>Loss for the year</b>		<b>-11,179</b>	<b>-119,789</b>
Loss for the year attributable to owners of the Parent Company		-11,179	-119,789
<b>Earnings per share</b>			
Basic and diluted earnings per share, SEK	13	-0.13	-1.36

## Consolidated statement of comprehensive income

Amounts in kSEK	Note	2022	2021
Loss for the year		-11,179	-119,789
Other comprehensive income		-	-
<b>Comprehensive income for the year attributable to owners of the Parent Company</b>		<b>-11,179</b>	<b>-119,789</b>

## Consolidated balance sheet

Amounts in kSEK	Note	Dec. 31, 2022	Dec. 31, 2021
<b>ASSETS</b>			
Tangible assets	14	23,531	16,963
Right-of-use assets	14	11,733	16,785
Deferred tax assets	12	596	608
Other non-current financial assets	16	1,606	1,588
<b>Total non-current assets</b>		<b>37,466</b>	<b>35,944</b>
Trade receivables		-	2,839
Current tax assets	12	1,216	1,557
Other current receivables	17, 18	6,740	4,648
Prepaid expenses and accrued income	19	7,498	4,337
Cash and cash equivalents	17, 20	805,386	848,405
<b>Total current assets</b>		<b>820,841</b>	<b>861,786</b>
<b>TOTAL ASSETS</b>		<b>858,307</b>	<b>897,730</b>
<b>EQUITY AND LIABILITIES</b>			
Share capital	21	1,763	1,761
Reserves		958	958
Other contributed capital		566,001	560,018
Retained earnings		217,520	225,939
<b>Total equity</b>		<b>786,241</b>	<b>788,676</b>
Non-current lease liabilities	24	1,182	7,785
<b>Total non-current liabilities</b>		<b>1,182</b>	<b>7,785</b>
Current lease liabilities	24	8,857	8,092
Accounts payable	17	21,491	11,818
Current tax liabilities	12	-	-
Other current liabilities		5,427	3,919
Accrued expenses and prepaid income	17, 26	35,108	77,438
<b>Total current liabilities</b>		<b>70,883</b>	<b>101,268</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>858,307</b>	<b>897,730</b>

## Consolidated statement of change in equity

Amounts in kSEK	Note	Share capital	Reserves	Other contributed capital	Retained earnings incl. profit for the year	Total equity
<b>Opening balance at January 1, 2021</b>		1,761	958	560,018	344,562	907,299
Correction of opening balance					-402	-402
Loss for the year		-	-	-	-119,789	-119,789
Other comprehensive income		-	-	-	-	-
<b>Consolidated comprehensive income</b>		0	0	0	-119,789	-119,789
Share-based remuneration	7	-	-	-	1,568	1,568
<b>Closing balance at December 31, 2021</b>		1,761	958	560,018	225,939	788,676
<b>Opening balance at January 1, 2022</b>		1,761	958	560,018	225,939	788,676
Profit/loss for the year		-	-	-	-11,179	-11,179
Other comprehensive income		-	-	-	-	-
<b>Consolidated comprehensive income</b>		0	0	0	-11,179	-11,179
New share issue through exercise of employee stock options		1	-	5,983	-	5,985
Share-based remuneration	7	-	-	-	2,760	2,760
<b>Closing balance at December 31, 2022</b>		1,763	958	566,001	217,520	786,241

## Consolidated cash flow statement

Amounts in kSEK	Note	2022	2021
Operating loss		-17,442	-139,723
Adjustment for non-cash items	28	-41,234	5,230
Interest received		2,535	388
Interest paid		-751	-984
Income tax paid		340	-309
<b>Cash flow from operating activities before change in working capital</b>		<b>-56,552</b>	<b>-135,397</b>
Increase (-) / Decrease (+) in operating receivables		-2,414	-5,122
Increase (+) / Decrease (-) in operating liabilities		27,328	62
<b>Cash flow from operating activities</b>		<b>-31,638</b>	<b>-140,457</b>
Investments in tangible assets	14	-12,746	-4,386
Change in non-current financial assets		-18	-27
<b>Cash flow from investing activities</b>		<b>-12,763</b>	<b>-4,412</b>
Amortization of liability		-8,793	-7,389
Proceeds from new share issue through exercise of employee stock options		5,985	-
<b>Cash flow from financing activities</b>		<b>-2,808</b>	<b>-7,389</b>
<b>Cash flow for the year</b>		<b>-47,209</b>	<b>-152,257</b>
Cash and cash equivalents at January 1		848,405	999,940
Exchange rate differences in cash and cash equivalents		4,190	723
<b>Cash and cash equivalents at December 31</b>	20	<b>805,386</b>	<b>848,405</b>

## Parent Company income statement

Amounts in kSEK	Note	2022	2021
<b>Operating income</b>			
Net revenue	5	228,291	23,146
Other operating income	6	1,570	3,542
<b>Total operating income</b>		<b>229,861</b>	<b>26,688</b>
<b>Operating expenses</b>			
Project expenses		-74,326	-55,067
Other external expenses	8.9	-41,956	-33,223
Personnel expenses	7	-115,650	-72,499
Depreciations of tangible assets	14	-6,621	-5,605
Other operating expenses	10	-9,679	-885
<b>Total operating expenses</b>		<b>-248,233</b>	<b>167,279</b>
<b>Operating loss</b>		<b>-18,371</b>	<b>-140,591</b>
<b>Profit/loss from financial items</b>			
Interest income and similar items	11	7,025	194
Interest expenses and similar items	11	-191	-145
<b>Loss after financial items</b>		<b>-11,537</b>	<b>-140,542</b>
<b>Appropriations</b>			
Reversal of tax allocation reserve		-	94,809
<b>Loss before tax</b>		<b>-11,537</b>	<b>-45,734</b>
Tax	12	65	63
<b>Loss for the year</b>		<b>-11,472</b>	<b>-45,670</b>

There are no items in the Parent Company recognized as other comprehensive income, thus comprehensive income conforms to profit for the year.

## Parent Company balance sheet

Amounts in kSEK	Note	Dec. 31, 2022	Dec. 31, 2021
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Tangible assets</i>			
Leasehold improvements	14	3,153	1,569
Equipment	14	20,379	15,394
		<b>23,531</b>	<b>16,963</b>
<i>Financial assets</i>			
Shares in subsidiaries	15	50	50
Other non-current financial assets	16	1,606	1,588
Deferred tax assets	12	453	388
		<b>2,109</b>	<b>2,026</b>
<b>Total non-current assets</b>		<b>25,641</b>	<b>18,989</b>
<b>Current assets</b>			
<i>Short-term receivables</i>			
Trade receivables	17	-	2,839
Current tax assets	12	1,216	1,557
Other current receivables	18	6,740	4,648
Prepaid expenses and accrued income	19	9,886	6,310
		<b>17,842</b>	<b>15,353</b>
<b>Cash and bank balances</b>	20	<b>805,342</b>	<b>848,359</b>
<b>Total current assets</b>		<b>823,184</b>	<b>863,713</b>
<b>TOTAL ASSETS</b>		<b>848,825</b>	<b>882,702</b>

## Parent Company balance sheet *cont.*

Amounts in kSEK	Note	Dec. 31, 2022	Dec. 31, 2021
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	21	1,763	1,761
Statutory reserve		958	958
		<b>2,721</b>	<b>2,719</b>
<i>Non-restricted equity</i>			
Share premium reserve	22	566,001	560,018
Retained earnings		229,548	272,459
Profit/loss for the year		-11,472	-45,670
		<b>784,078</b>	<b>786,807</b>
<b>Total equity</b>		<b>786,798</b>	<b>789,526</b>
<b>Current liabilities</b>			
Accounts payable	17	21,491	11,818
Current tax liabilities	12	-	-
Other current liabilities		5,427	3,919
Accrued expenses and prepaid income	26	<b>35,108</b>	<b>77,438</b>
<b>Total current liabilities</b>		<b>62,026</b>	<b>93,176</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>848,825</b>	<b>882,702</b>

## Parent Company statement of change in equity

Amounts in kSEK	Note	Restricted equity		Non-restricted equity		Total equity
		Share capital	Statutory reserve	Share premium reserve	Other non-restricted	
Opening balance at January 1, 2021		1,761	958	560,018	270,892	833,629
<b>Comprehensive income</b>						
Profit/loss for the year		-	-	-	-45,670	-45,670
<b>Total comprehensive income</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>-45,670</b>	<b>-45,670</b>
<b>Transactions with shareholders</b>						
Share-based remuneration	7	-	-	-	1,568	1,568
<b>Total transactions with shareholders</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>1,568</b>	<b>1,568</b>
Closing balance at December 31, 2021		1,761	958	560,018	226,789	789,526
Opening balance at January 1, 2022		1,761	958	560,018	226,789	789,526
<b>Comprehensive income</b>						
Loss for the year		-	-	-	-11,472	-11,472
<b>Total comprehensive income</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>-11,472</b>	<b>-11,472</b>
<b>Transactions with shareholders</b>						
New share issue through exercise of employee stock options		1	-	5,983	-	5,985
Share-based remuneration	7	-	-	-	2,760	2,760
<b>Total transactions with shareholders</b>		<b>1</b>	<b>0</b>	<b>5,983</b>	<b>2,760</b>	<b>8,744</b>
Closing balance at December 31, 2022		1,763	958	566,001	218,077	786,798



## Parent Company cash flow statement

Amounts in kSEK	Note	2022	2021
Operating loss		-18,371	-140,591
Adjustment for non-cash items	28	-49,241	-2,272
Interest received		2,535	194
Interest paid		-191	-145
Income tax paid		340	-210
<b>Cash flow from operating activities before change in working capital</b>		<b>-64,928</b>	<b>-143,025</b>
Increase (-) / Decrease (+) in operating receivables		-2,829	-3,914
Increase (+) / Decrease (-) in operating liabilities		27,328	-1,099
<b>Cash flow from operating activities</b>		<b>-40,429</b>	<b>-148,038</b>
Investments in tangible assets	14	-12,746	-4,386
Change in non-current financial assets		-18	-27
<b>Cash flow from investing activities</b>		<b>-12,763</b>	<b>-4,412</b>
New share issue through exercise of employee stock options		5,985	-
<b>Cash flow from financing activities</b>		<b>5,985</b>	<b>-</b>
<b>Cash flow for the year</b>		<b>-47,207</b>	<b>-152,450</b>
Cash and cash equivalents at January 1		848,359	999,892
Exchange rate differences in cash and cash equivalents		4,190	917
<b>Cash and cash equivalents at December 31</b>	20	<b>805,342</b>	<b>848,359</b>

# Notes to financial statements



## NOTE 1 General information

BioArctic AB (publ), corporate identity number 556601-2679, is the Parent Company in a Group focused on neurodegenerative disorders. The company has leading competence in research and development of innovative biological drugs, such as antibodies, that address high unmet medical needs.

The shares of BioArctic AB have been listed on Nasdaq Large Cap since January 2, 2023.

The Group's business is conducted in the Parent Company. BioArctic is a limited liability company with its registered office at Warfvinges väg 35, SE-112 51 Stockholm, Sweden.

The annual accounts and consolidated financial statements were approved by the Board of Directors on April 26, 2023 and have been submitted for ratification at the Annual General Meeting on June 1, 2023.

## NOTE 2 Summary of significant accounting policies

The main accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated. The Group applied the modified retrospective approach in the transition to IFRS 16. This means that the comparison figures for 2018 on page 62 have not been restated.

### BASIS OF PREPARATION

The consolidated financial statements have been prepared in accordance with the Swedish Annual Accounts Act, RFR 1 Supplementary accounting rules for groups, the International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU. The income statement is classified

according to nature of expenses.

The Group's financial statements have been prepared based on historical costs, which means that assets and liabilities are recognized at these values and, where appropriate, certain financial instruments are measured at fair value. The financial statements have been prepared on the assumption that the Group pursues its operation in accordance with the going concern principle, which entails the premise that the Group will be able to settle its debts as they mature. To confirm the assumption of a going concern in preparing the financial reports, the Group has taken the following specific factors into account:

- The Group's liquidity is deemed to remain stable
- The Group does not have any external loan financing
- The Group's financial position is good, with a high debt/equity ratio of 91.6 percent
- As of December 31, 2022, up to MEUR 136 in milestone payments remained to be received from Eisai. Apart from the milestone payments, royalty payments are due to BioArctic based on the global sales of lecanemab, which have the potential to provide significant revenue.
- Management prepares an annual budget and long-term strategy plans, including an assessment of the Group's cash-flow needs, and continues to monitor actual outcome against budget and strategy plans throughout the reporting period.

Based on these factors, management is of the opinion that the Group has and will continue to have adequate resources to continue its operations for the foreseeable future. The financial statements have also been prepared with the application of the accrual basis of accounting.

The functional currency of the Parent Company, including all its subsidiaries, and the reporting currency of the Group is the Swedish krona (SEK). All amounts are indicated in thousands of Swedish kronor (kSEK) unless otherwise indicated.

Amounts in parentheses refer to the previous year. Negative figures are either expenses or payments (cash flow).

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. Furthermore, the Board of Directors and company management are required to make certain assessments in applying the company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in note 4.

### CLIMATE-RELATED ISSUES

The material assumptions, assessments, and estimations that form the basis of preparation for the report are deemed not to have been substantially impacted by climate-related issues. As of the balance-sheet date, management has not identified any material risks to the Group that originate from climate change and could adversely affect the Group's financial reports.

### NEW AND AMENDED STANDARDS FROM 2022

A number of new standards, amendments and interpretations of existing standards entered force during the financial year. These have had no material effect on the Group's financial statements.

### NEW AND AMENDED STANDARDS FROM 2023 ONWARD

A number of new standards and changes to interpretations of existing standards will enter force for financial years beginning after January 1, 2023, that were not applied in advance in preparing the Group's financial statements. New and amended standards with future application are deemed to have no material effect on the Group's financial statements.

### CONSOLIDATION

Subsidiaries are all companies over which the Group has a controlling interest. The Group controls a company when the

*Note 2, cont.*

Group is exposed to, or has rights to, variable returns from its holdings in the company and has the ability to influence those returns through its power in the company. Subsidiaries are included in the consolidated financial statements as of the date controlling interest was transferred to the Group. They are deconsolidated from the date that control ceases.

The Group applies the acquisition method to account for business combinations. The purchase price for the acquisition of a subsidiary comprises the fair value of the assets transferred, liabilities incurred to the former owners of the company acquired and the shares issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration arrangement. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. Acquisition costs are expensed as they are incurred.

Inter-company transactions, balances and unrealized gains on transactions between Group companies are eliminated. Gains and losses resulting from inter-company transactions and which are recognized among assets are also eliminated. The accounting policies for subsidiaries have been changed where necessary to ensure consistent application of Group policies.

**SEGMENT REPORTING**

An operating segment is a part of the Group that conducts operations from which revenue can be generated and incurs costs, and for which independent financial information is available.

The highest executive decision-maker in the Group monitors operations at the aggregate level, which means the operations constitute the same segment and no separate segment information is therefore presented. The Board of Directors

has been identified as the highest executive decision-maker in the Group.

**FOREIGN CURRENCY TRANSLATION****Functional and reporting currency**

Items included in the financial statements for the different units in the Group are measured in the currency used in the financial environment where the respective companies primarily operate (functional currency). The consolidated financial statements use Swedish kronor (SEK), which is the Parent Company's functional and reporting currency.

**Transactions and balances**

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year-end exchange rates are generally recognized in profit or loss.

**REVENUE**

The Group's revenue consists primarily of revenue from licensing and collaboration agreements. In assessing whether revenue is to be recognized, the Group follows a five-step process:

1. Identify the agreement with the customer
2. Identify the performance obligations
3. Establish the transaction price
4. Allocate the transaction price to the performance obligations
5. Recognize the revenue at the point in time the performance obligation is fulfilled

**Licensing and collaboration agreements**

Revenue from licensing and collaboration agreements can consist of remuneration from research agreements, milestone

payments, non-recurring and licensing remuneration and royalties. In addition, BioArctic may have contractual rights to remuneration for costs incurred. The transaction price is established based on what the Group expects to receive from each agreement in exchange for transfer of the goods or services agreed on. The revenue is recognized either at a given point in time or over time when (or if) the Group fulfills its performance obligations by transferring the goods or services promised to the customer.

The Group recognizes a contract liability when it has received the payment obtained regarding its unfulfilled performance obligations and recognizes these amounts as deferred income in the balance sheet. In the same way, if the Group fulfills a performance obligation before compensation is received, it recognizes either accrued income or a receivable in the balance sheet, depending on if any aspect other than time determines when remuneration falls due.

*Research collaborations (remuneration from research agreements)*

Revenue recognition reflects earnings under the specific terms of the agreement and is applied individually to each transaction. The revenue is recognized over time based on the fulfillment of the performance obligations. The Group measures the course of events toward complete fulfillment by continually evaluating the degree of completion based on costs incurred in the research collaborations.

*Milestone payments*

The performance obligations for milestones achieved are recognized as revenue at a given point in time. Revenue for milestone payments consists of a transaction price agreed on in advance.

*Non-recurring and licensing remuneration*

Non-recurring remuneration upon signing of an agreement is normally without a repayment obligation and is recognized

*Note 2, cont.*

at a given point in time. It normally pertains to the right to develop, register, market and sell BioArctic's patented products within a given geographical area and within a given indication. Non-recurring remuneration can also consist of remuneration for technology or transfer of knowledge to the partner, or consist of remuneration for the right to acquire a license in the future.

*Royalty income*

Royalty income normally arises continually when distributors recognize sales. This recognition occurs in the same period as the sales.

*Remuneration for costs incurred and sale of products*

Remuneration for costs incurred (i.e. costs invoiced onward to the customer) is recognized in the period when it arises. Revenue from sales of products is recognized at the point in time when control transfers to the customer.

**Other operating income**

In addition to government grants, the Group also has other operating income in the form of currency exchange gains of an operational nature and gains from the divestment of tangible assets.

**GOVERNMENT GRANTS**

The Group's government grants are recognized as other operating income.

*Government grants*

Revenue from government grants is recognized as revenue when it is reasonably certain that the Group will fulfill the conditions associated with the grant, and the government grant will be received. Grants received before the terms for recognizing it as revenue are fulfilled are recognized as liabilities.

**EXPENSES, FINANCIAL ITEMS AND TAXES****Project expenses**

Project costs pertain to direct external costs for BioArctic's research and drug development in preclinical and clinical studies as well as regulatory operations. Costs attributable to development projects are recognized as intangible assets when all the following criteria are met:

1. It is technically feasible for the company to complete the intangible asset so that it will be available for use or sale.
2. The company intends to complete the intangible asset and use or sell it.
3. The company has the potential to use or sell the intangible asset.
4. The company can demonstrate how the intangible asset will generate probable economic benefits.
5. There are adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
6. The company can reliably estimate the expenditures attributable to the intangible asset during its development.

Development costs that have been expensed cannot be recognized as an asset in subsequent periods. BioArctic has no expenditures that fulfill all the criteria, and all research and development costs have therefore been expensed. The external projects are owned by our partners, and BioArctic has no costs for the clinical programs.

**Other external expenses**

Operating expenses that do not belong to project expenses and pertain primarily to costs for offices and external services are recognized as other external expenses.

**Remuneration to employees***Contractual remuneration*

BioArctic had two rewards programs during 2022 (for 2023 one program remains) that covers all permanent employees,

which means there is a variable remuneration component that can be paid out in conjunction with the fulfillment of targets in addition to the fixed remuneration. Refer to the information provided in Note 7. The variable remuneration is not pensionable. BioArctic has no agreements covering post-employment benefits.

*Defined-contribution pension plans*

The Group's pension plans are defined-contribution, and pertain to the fees the company pays to the plan or to the insurance company and the return on capital the fees generate. Consequently, the employee bears the actual risk (that the payment will be lower than expected) and the investment risk (that the assets invested will be insufficient to generate the expected payments). The Group has no defined-benefit pension plans.

*Share-based remuneration*

BioArctic has a share-based remuneration program, settled in the form of equity instruments, for its employees. The program runs over 5.5 years and requires the employee to remain in their employment for the term of the program. When the employee receives share-based remuneration, the fair value of the employees' services is determined at the fair value of the equity instrument allotted. The fair value is calculated at the time of allotment using the Black & Scholes model. The fair value of the warrants allotted is recognized as a personnel expense with a corresponding increase in retained earnings, and spread over the vesting period based on the best possible estimate of the number of share warrants expected to be vested. The effect of amended estimates for the number of share warrants vested is recognized in the period in question.

Social security contributions attributable to share-based instruments for employees as remuneration for services purchased are expensed across the vesting period. The provision is based on fair value of the warrants and remeasured at every reporting date based on an estimate of the fees that could be

*Note 2, cont.*

paid when the instruments are redeemed.

**Other operating expenses**

Currency exchange losses of an operational nature and losses in connection with divestment of tangible assets are recognized as other operating costs.

**Financial income**

Financial income pertains to interest income on bank funds and receivables, as well as dividend income where applicable and positive foreign exchange differences on financial items. Financial income is recognized in the period to which it pertains.

**Financial expenses**

Financial expenses pertain to interest and other costs arising in conjunction with borrowing, and are recognized in profit or loss in the period to which they pertain. Negative foreign exchange differences on financial items and negative interest on cash and cash equivalents are also included in financial expenses.

**Taxes**

Tax for the period consists of current tax and deferred tax. Taxes are recognized in profit or loss, except when the underlying transaction is recognized in other comprehensive income or directly against equity, when the associated tax effect is also reported on this line.

Current tax is the estimated tax on the taxable earnings for the period. Taxable earnings differ from recognized earnings by having been adjusted for non-taxable and non-deductible items. Current tax is tax to be paid or received as regards the current year, adjusted for any current tax attributable to earlier periods.

Foreign tax held is recognized in the balance sheet to the

extent it is deemed it can be settled against Swedish corporate tax.

Deferred income tax is recognized using the balance sheet method, which means that deferred tax liabilities are recognized in the balance sheet for all temporary differences arising between the carrying amount and taxable value of assets and liabilities. If the temporary difference arose upon the initial recognition of assets and liabilities constituting an asset acquisition, on the other hand, the deferred tax is not recognized. Deferred tax assets regarding deductible temporary differences and loss carry forwards are only recognized to the extent it is likely that the amount can be utilized against future taxable surplus. Deferred tax is determined in accordance with statutory tax rates that have been enacted or substantially enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

**RESEARCH AND DEVELOPMENT / INTANGIBLE ASSETS**

An intangible asset is recognized in the balance sheet when it is likely that the future economic advantages that can be attributed to the asset will fall to the Group, and when the value of the asset can be reliably calculated. Expenditures regarding development are capitalized and recognized in the balance sheet as intangible assets if the criteria for recognition in the balance sheet under IAS 38 Intangible assets are met. There are no expenditures in the Group that meet the criteria for being recognized as an asset.

**TANGIBLE ASSETS**

Tangible assets are recognized at cost less accumulated depreciation and write-downs. The cost includes expenditures that are directly attributable to the acquisition of the asset. Subsequent costs are included in the asset's carrying amount or recognized as a separate asset only when it is likely that

future economic benefits associated with the item will fall to the Group and the cost of the item can be measured reliably. The useful life for inventory and equipment is deemed to be five years. Leasehold improvements are written-off based on the estimated useful life.

Right-of-use assets (leases) reported separately in the balance sheet are described in Note 14.

**LEASED ASSETS****The Group as lessee**

An agreement is assessed as to whether or not it is a lease. A lease is defined as "an agreement that transfers the right of use of the underlying asset for a given period in exchange for remuneration." The agreements are assessed as to whether they fulfill the three criteria below in order to be considered as meeting the definition of a lease:

1. The agreement contains an identified asset
2. The Group has the right to all the material economic advantages arising through use of the identified asset throughout the entire lease period
3. The Group has the right to control the use of the identified asset throughout the entire lease period

*Measurement and recognition of leases as lessee*

At the beginning of the lease, a right-of-use asset and a lease liability are recognized in the balance sheet. The right-of-use asset is measured at cost, which covers the sum that the leasing liability was originally measured at as well as any initial direct or indirect expenditures associated with the right-of-use asset. The depreciation of the right-of-use asset is linear over the assessed useful life. Any need for impairment of the right of use is assessed when there is an indication of a decrease in value.

At the beginning of the lease, the lease liability is measured at the current value of the lease liabilities that are unpaid at

*Note 2, cont.*

that point in time. Lease fees are discounted using the lease's implicit interest rate, if it can easily be determined, or the Group's incremental borrowing rate. Lease fees included in the measurement of the lease liability include fixed fees, variable index- or price-based lease fees, amounts that are expected to be disbursed in accordance with residual value guarantees and payments for warrants that are deemed to have been exercised. After the start date, the lease liability is reduced by lease payments divided between amortization and financial expenses.

In conjunction with changes to leases, the lease liability is remeasured and the carrying amount of the right-of-use asset is adjusted accordingly. In the event the carrying amount of the right-of-use asset is adjusted downward to zero, the remeasurement is recognized in profit or loss.

Right-of-use assets and lease liabilities are recognized separately in the balance sheet.

**FINANCIAL INSTRUMENTS**

A financial instrument is any form of agreement that gives rise to a financial asset or financial liability. Financial assets in the balance sheet pertain to trade receivables and other receivables as well as cash and cash equivalents. Financial liabilities pertain to accounts payable, lease liabilities and contractual accrued expenses. The Group holds no derivatives.

Financial assets and financial liabilities are recognized when the Group becomes party to an agreement as regards the contractual terms and conditions of the financial instrument. Financial assets are removed from the balance sheet when the contractual rights regarding the financial asset expire, or when the financial asset and all significant risks and benefits are transferred. A financial liability is removed from the balance sheet when it is extinguished (i.e. when it is completed, annulled or expires).

Financial assets and liabilities are initially measured at fair value. Financial assets and liabilities are classified under the categories of amortized cost, fair value via profit or loss and fair value via other comprehensive income. During the periods included in the financial statements, all financial assets or liabilities are categorized as amortized cost. Financial assets classified under amortized cost are measured after initial recognition at amortized cost using the effective interest rate method. No discounts are applied if the effect of the discount is insignificant.

Financial assets and liabilities are offset and the net amount reported in the balance sheet when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously.

**TRADE RECEIVABLES**

Trade receivables are reported net after reserves for expected credit losses. The expected duration of trade receivables is short, which is why the value is recognized at a nominal amount without discounts using the amortized cost method. The Group uses a simplified method for recognizing trade and other receivables as well as contract assets, and recognizes expected credit losses for the remaining duration. In this calculation, the Group uses its historical experience, external indicators and forward-looking information to estimate the expected credit losses. The amount reserved is recognized over profit or loss.

**CASH AND CASH EQUIVALENTS**

Cash and cash equivalents include cash on hand, bank balances and, where appropriate, other current investments with a due date within three months. Cash and cash equivalents are recognized at the nominal amount.

**ACCOUNTS PAYABLE**

These amounts represent liabilities for goods and services provided to the Group that are unpaid prior to the end of financial year. Trade payables are categorized as other financial liabilities. Since trade payables have a short expected duration, the value is recognized at the nominal amount.

**EQUITY**

Share capital represents the nominal value of shares issued. Transaction costs directly attributable to the issue of new shares or warrants are shown in equity as a deduction, net of tax, from the proceeds. Retained earnings comprise profit carried forward and share-based remuneration to employees for the current and previous financial years.

Share premium reserve is recognized as other contributed capital and statutory reserves are recognized as reserves.

**CASH FLOW STATEMENT**

Cash flow from operating activities is prepared using the indirect method, whereby profit or loss is adjusted with transactions of a non-cash nature and items of income or expense associated with investing and/or financing cash flows.

**ALTERNATIVE PERFORMANCE MEASURES**

The Group applies ESMA guidelines for alternative performance measures. In accordance with these guidelines, the Group's alternative performance measures are defined in Note 32. The Group applies alternative performance measures since the company believes they provide valuable supplementary information to management and investors, as they are central to understanding and evaluating the Group's operations.

*Note 2, cont.***PARENT COMPANY ACCOUNTING POLICIES**

The Parent Company complies with the Swedish Annual Accounts Act and the recommendation of the Financial Reporting Council, RFR 2 Accounting for legal entities. The application of RFR 2 means that in the annual report for the legal entity, the Parent Company applies all IFRS and opinions approved by the EU to the extent possible as part of the Annual Accounts Act and the Pension Obligations Vesting Act, and taking into account the connection between reporting and taxation. The recommendation indicates which exceptions from and additions to IFRS can be made.

Consequently, the Parent Company applies the principles presented in Note 2 of the consolidated financial statements, with the exceptions indicated below. The principles have been consistently applied to all the years presented, unless otherwise stated. Assets, provisions and liabilities have been measured at cost unless otherwise stated.

**Presentation formats**

The income statement and balance sheet follow the presentation format indicated in the Annual Accounts Act. This entails certain differences compared with the consolidated financial statements – for example, sub-items under equity have different designations.

**Shares and participations in subsidiaries**

Shares and participations in subsidiaries are recognized at cost, less any impairments.

**Deferred income tax**

Amounts allocated to untaxed reserves constitute taxable temporary differences. Owing to the connection between reporting and taxation, however, the deferred tax liability on untaxed reserves in a legal entity is reported as part of the untaxed reserves. Appropriations of profits in profit or loss are also reported including deferred tax.

**Leases**

Lease fees are expensed on a linear basis over the term of the lease. No right of use or lease liability is recognized in the balance sheet.



## NOTE 3 Financial risk management

### FINANCIAL RISK FACTORS

Through its operations, the Group is exposed to various financial risks. The overall goal of financial risk management is to minimize the risks of negative impact on the Group's earnings.

#### Foreign exchange risk

Foreign exchange risk pertains to the risk of impact on the Group's earnings and financial position as a consequence of changes in exchange rates. The Group has no loans in foreign currencies, and is therefore not exposed to any foreign exchange risk in connection with borrowing. Purchases and revenue in foreign currencies give rise to transaction exposure. Purchases in foreign currencies are primarily in EUR, USD, GBP and CHF. Purchases for 2022 totaled kEUR 1,833 (851), kUSD 1,572 (675), kGBP 501 (474) and kCHF 194 (99). Revenue in foreign currencies for 2022 totaled kEUR 15,793 (1,451). The table below shows the material balance sheet items in foreign currencies that the Group had as of December 31, 2022 and what impact a 10-percent change in the net amount in GBP, USD, EUR and CHF would have on earnings. Purchases in foreign currencies were higher in 2022 compared with previous years, which is attributable to an increase in the scope of the operation.

#### Interest rate risk

The Group has significant holdings in banks that are impacted by interest rate levels, which means that the Group is exposed to interest rate risk on its cash and cash equivalents. At December 31, 2022, the Group had cash and cash equivalents of kSEK 805,386 (848,405). A change of 0.5 percentage points in the interest rate would entail an annual impact on earnings of kSEK 4,027 (4,242) before tax and kSEK 3,197 (3,368) after tax. As of December 31, 2022 the Group had no external loan financing, and thus has no interest rate risk for such commitments.

#### Amounts in kSEK per Dec. 31, 2022

Currency	Trade receivables	Cash and cash equivalents	Accounts payable	Net per currency	10%	Before tax	After tax
CHF	0	1,850	0	1,850	+/-	185	147
EUR	0	14,974	-908	14,066	+/-	1,407	1,117
GBP	0	5,800	-286	5,514	+/-	551	438
USD	0	12,429	-2,967	9,462	+/-	946	751
<b>Total</b>	<b>0</b>	<b>35,053</b>	<b>-4,161</b>	<b>30,892</b>	<b>+/-</b>	<b>3,089</b>	<b>2,453</b>

#### Amounts in kSEK per Dec. 31, 2021

Currency	Trade receivables	Cash and cash equivalents	Accounts payable	Net per currency	10%	Before tax	After tax
CHF	0	5	0	5	+/-	0	0
EUR	278	2,517	-2,018	777	+/-	78	62
GBP	0	3,705	0	3,705	+/-	370	294
USD	0	3,505	-1,562	1,943	+/-	194	154
<b>Total</b>	<b>278</b>	<b>9,732</b>	<b>-3,580</b>	<b>6,430</b>	<b>+/-</b>	<b>643</b>	<b>511</b>

#### Financing risk

BioArctic's financial position is strong, since the company has no external loan financing and has a positive net cash balance. The access to capital is impacted by several different factors, including the performance of current research and development projects as well as partnership and licensing agreements. The point in time and scope of further financing needs depend not only on how milestone payments fall due, but also on whether the Group succeeds in signing new collaboration agreements and on market reception of potential future products. It is vital that the Group's partners continue to collaborate with BioArctic, since future revenue is currently dependent on these partnerships. General access

to credit and BioArctic's creditworthiness also impact the financing risk.

#### Liquidity risk

Liquidity risk (i.e. the risk that the Group does not have sufficient cash funds to meet the needs of operating activities) is deemed to be low over the short and medium term, since the Group has a positive net cash balance and thereby good access to cash and cash equivalents. Group Management actively monitors the liquidity situation to call attention to liquidity risks in a timely manner. The Group has no financial investments apart from bank balances.

*Note 3, cont.***Credit risk**

Credit risk is the risk that a counterparty does not fulfill an obligation toward the company. BioArctic's credit risk is low, since the Group does not have any external loan financing and thereby does not run any credit risk for bank loans it has signed. The Group also has limited credit exposure in relation to customers, including outstanding receivables. The Group has a significant amount of cash and cash holdings with the Group's banks, but the counterparty risk is deemed to be very low.

**OPERATIONAL AND STRATEGIC RISKS**

Refer to the "Risks and risk management" section in the Board of Directors' Report for a description of the most important operational and strategic risks. The risks that the Group has identified are related to outcomes in outlicensed projects being conducted by partners, and projects being conducted in-house. In addition, there are risks in the overall portfolio strategy, risks related to partners, impact from competitors, events beyond the company's control such as pandemics, government decisions, IT and information security risks, product responsibility and insurances, patent protection and employee risks as well as climate, sustainability and environmental risks.

**SENSITIVITY ANALYSIS**

Sensitivity analyses have been prepared concerning foreign exchange risk and interest rate risk as described above.

**CAPITAL MANAGEMENT**

The Group's objective as regards capital management is to safeguard its ability to continue as a going concern, so that it can continue to generate returns for shareholders and benefits for other stakeholders. An optimal capital structure promotes keeping the costs of capital down. To maintain or adjust the capital structure, the Group can issue new shares, or alternately pay a dividend to its shareholders.

**NOTE 4 Significant accounting estimates and judgments**

To prepare financial statements in accordance with IFRS, Group Management and the Board of Directors must make assessments and assumptions. These impact recognized asset and liability items, and revenue and expense items as well as other information submitted. The assessments are based on experiences and assumptions that Group Management and the Board deem to be reasonable under the prevailing circumstances. Actual outcome may then differ from these assessments if other conditions emerge. The assessments that are most material to the preparation of the consolidated and Parent Company financial statements are described below.

*Revenue from research collaborations*

Recognition of revenue from research collaborations is based on the degree of completion as regards fulfillment of performance obligations. These performance obligations may change as a result of certain sub-operations being terminated while others may need to be added or reworked. This could lead to changes in the amount assessed against complete fulfillment of the performance obligation, which could entail an adjustment of revenue. The Group reviews all projects on a quarterly basis to ensure that revenue is based on a course of events toward a complete fulfillment of the performance obligations. For further information, refer to Note 5.

*Impact of COVID-19 on BioArctic*

BioArctic had no disruptions to its operations in 2022 as a consequence of COVID-19 and the pandemic. Our approach to COVID-19 has been to closely monitor the course of events in the business environment and to apply clear internal guidelines so as to ensure the safest working environment possible for all employees. The company's revenue and costs for the year were only marginally impacted by the pandemic.

**NOTE 5** Net revenue

Revenue for 2022 includes MSEK 58.5 (8.5) that was recognized in deferred income at the start of the financial year. The table shows the distribution of revenue by geographic market and how the revenue is recognized.

Amounts in kSEK	Group		Parent Company	
	2022	2021	2022	2021
<b>Net revenue by geographic market</b>				
Europe (Ireland)	58,478	8,466	58,478	8,466
Asia (Japan)	169,813	14,681	169,813	14,681
<b>Total net revenue</b>	<b>228,291</b>	<b>23,146</b>	<b>228,291</b>	<b>23,146</b>
<b>Net revenue by type</b>				
Milestone payments, recognized at a given point in time	161,460	-	161,460	-
Income from research agreements, recognized over time	66,831	23,146	66,831	23,146
<b>Total net revenue</b>	<b>228,291</b>	<b>23,146</b>	<b>228,291</b>	<b>23,146</b>

For the financial year, two individual customers represented more than 10 percent each of revenues. For the 2021 financial year as well, two individual customers represented more than 10 percent of revenues.

Essentially, BioArctic's net revenue consists of revenue from research collaboration in Alzheimer's disease with Eisai and the now-concluded partnership with AbbVie in Parkinson's disease. For milestone payments, fixed payments can be received at an amount determined in advance based on contractual milestones. In 2022, BioArctic received and recognized in profit a milestone payment from Eisai of MSEK 161.5

(MEUR 15) in conjunction with the US Food and Drug Administration's acceptance of the biologics license application for lecanemab under an accelerated approval pathway.

BioArctic had been collaborating with AbbVie in the field of Parkinson's disease since 2016, when a research agreement was signed that included products such as the antibody BAN0805. In the spring of 2022, AbbVie chose to terminate the collaboration for strategic reasons, and in the third

quarter, an agreement was signed with AbbVie on the handover of the projects back to BioArctic. Under the collaboration agreement with AbbVie pertaining to BAN0805, BioArctic received an initial payment of MSEK 701.6 (MUSD 80) in the third quarter of 2016, of which MSEK 70.4 was recognized as non-recurring remuneration in 2016. The remainder of the payment was accrued based on costs incurred up through the end of the project, which took place in the third quarter of 2022. In 2022, MSEK 58.5 was recognized as income, of which MSEK 47.9 as a nonrecurring effect in conjunction with the conclusion of the project. As of 31 December 2022, the entire preliminary payment of MSEK 701.6 (MUSD 80) for the research collaboration agreement with AbbVie had been recognized as income over time. The Group did not have any prepaid income as of 31 December 2022.

**NOTE 6** Other operating income

Amounts in kSEK	Group		Parent Company	
	2022	2021	2022	2021
Operational foreign exchange gains	175	1,016	175	1,016
EU grants	-	847	-	847
Vinnova grants	1,141	1,670	1,141	1,670
Costs invoiced onward	254	-	254	-
Other items	-	9	-	9
<b>Total other operating income</b>	<b>1,570</b>	<b>3,542</b>	<b>1,570</b>	<b>3,542</b>

**NOTE 7** Employees**Remuneration to CEO and senior executives**

CEO Gunilla Osswald received remuneration of kSEK 5,346 as fixed annual salary in 2022, which included benefits and amendments pertaining to annual leave owed. Over and beyond that, there is an additional pension provision of 35 percent. The CEO is covered by the rewards program covering all employees; see below. In 2022, the CEO had variable remuneration of up to 35 percent of annual salary. Between the company and the CEO, there is a notice period of 12 months by the company and 6 months by the CEO. Upon termination by the Company, the company has the right to relieve the employee during the notice period.

Company management comprises ten senior executives. Senior executives except the CEO receive normal market remuneration and individually negotiated premiums for service pension or alternately premiums under the terms of the company's pension plan. All other employees receive market salaries, and premiums are allocated to the occupational pension in accordance with the terms of the company's pension plan. All employees have a contractual mutual notice period of three months or alternately in accordance with the Employment Protection Act. Severance pay is not applied. For non-executive Board members, fees have been paid pursuant to the resolutions of the Annual General Meeting.

BioArctic has one rewards program covering all permanent employees. One condition for receiving variable remuneration is that the employee has been employed for more than six months at the time when the goal that forms the basis for payment of variable remuneration is reached. The goals are linked to milestones achieved under the research program for Alzheimer's disease. The potential variable remuneration to the employee amounts to one month's salary per milestone. The variable remuneration is not pensionable.

*Share-based remuneration to employees*

The 2019/2028 employee stock option program covers at most 1,000,000 employee stock options. To facilitate the company's delivery of shares under the 2019/2028 employee stock option program, the AGM resolved on a private placement of a maximum of 1,000,000 warrants.

The maximum dilution effect of the 2019/2028 employee stock option program is estimated to be 1.1 percent of share capital and 0.5 percent of the voting rights in the company (calculated based on the number of existing shares in the company), provided that all employee stock options are fully exercised. The employee stock options can be exercised for subscription of shares at the earliest three years after allocation.

On the balance sheet date (December 31, 2022), 845,000 employee stock options had been allocated. Of these, 260,000 employee stock options were allocated in 2022. The total number of warrants forfeited on December 31, 2022 was 10,000, and the number of warrants redeemed was 71,586, which means that 763,414 employee stock options were thus outstanding at the end of the year. The allocation of employee stock options yields a dilution effect corresponding to 693,414 shares (or 0.8 per cent) at the end of the period. However, these options are not included in the calculation of earnings per share after dilution since the company is reporting negative earnings. The program extends over five years and six months from the point in time of allocation for the respective employees. The warrants grant participants the right to acquire 60 percent of the allocated share rights after three years, a further 20 percent after four years and the remaining 20 percent after five years, provided that the participant remains employed in the Group.

**Guidelines for remuneration to senior executives**

The guidelines cover the Chief Executive Officer, the Executive Vice President (if applicable) and the individuals

who are members of executive management at any given time. To the extent that the Board members of the company perform work for BioArctic alongside their Board assignments, these guidelines will also apply to any remuneration paid to the Board member for such work.

The guidelines adopted at the 2022 Annual General Meeting are applicable to remuneration that is contracted, and to changes that are made to previously contracted remuneration. The guidelines also cover remuneration that is paid out under the company's existing milestone-based incentive plan. Transfer of securities and granting of rights to the future acquisition of securities from BioArctic are equally considered remuneration.

The guidelines do not cover remuneration resolved on by the General Meeting (e.g. share-based incentive programs). The General Meeting can decide, outside and independently of these guidelines, on share-based and similar remuneration. The 2019 Annual General Meeting resolved to introduce an employee stock option program intended for company management, researchers, and other personnel. Executives who hold posts as members or deputy members of the board of directors of the Group company will not receive separate Board fees for this.

*Overview of previously adopted guidelines*

Ahead of the 2022 Annual General Meeting, the Board of Directors reviewed the guidelines for remuneration to senior executives that were adopted by the 2020 Annual General Meeting. The Board found that the guidelines needed to be adapted to BioArctic's existing and future milestone-based rewards program.

In brief, the changes to the guidelines mean that remuneration in accordance with existing and future milestone-related rewards programs will not be included in the guidelines on the

*Note 7, cont.*

share of variable remuneration in relation to fixed salary. The guidelines adopted will remain in force until the 2026 Annual General Meeting at the longest.

*How the guidelines promote BioArctic's business strategy, long-term interests and sustainability*

BioArctic AB is a Swedish research-based biopharma company focusing on disease-modifying treatments for neurodegenerative disorders such as Alzheimer's disease, Parkinson's disease, and ALS. BioArctic focuses on innovative treatments in areas with high unmet medical needs. BioArctic has a balanced, competitive portfolio consisting of unique product candidates, as well as advanced technology for facilitating the passage of drugs across the blood-brain barrier. The project portfolio is a combination of fully funded projects pursued in partnership with global pharma companies and innovative in-house projects with significant market and outlicensing potential.

BioArctic's vision is to generate innovative drugs that improve the life for patients with disorders of the central nervous system. Our work is based on groundbreaking scientific discoveries, and the company's researchers collaborate with strategic partners such as research groups at universities and major pharma companies. BioArctic has a great deal of scientific competence and years of experience in developing drugs from idea to market. BioArctic's business model involves initially pursuing project development in-house and, once the project has reached a phase of development requiring more resources or competence, entering research collaborations and signing collaboration agreements or outlicensing certain commercial rights to global pharma companies.

Successful implementation of BioArctic's strategy and safeguarding of the company's long-term interests presupposes that BioArctic can recruit and retain management with the competence and capacity to achieve the goals that have been set. This requires BioArctic to be able to offer competitive remuneration. These guidelines promote the BioArctic's

business strategy, long-term interests and sustainability by providing the company with the possibility of offering competitive remuneration to senior executives.

*Forms of remuneration*

BioArctic's remuneration system must be market-based and competitive. Remuneration can be paid out in the form of fixed salary, variable remuneration, pensions and other benefits.

**Fixed salary**

Fixed salary will be individual for each executive and based on the executive's position, responsibility, competence, experience and performance. The senior executive can be offered the possibility of a salary exchange between fixed salary and pension and other benefits, respectively, on condition that it is cost-neutral for the company.

**Variable remuneration**

Variable remuneration will be related to the outcome of BioArctic's goals and strategies and based on predefined and measurable criteria designed to promote long-term value creation. The share of total remuneration that comprises variable remuneration may vary depending on position. At most, however, variable remuneration – except for remuneration under the company's milestone-based rewards program – can correspond to 50 percent of the senior executive's annual fixed salary. Variable remuneration must be non-pensionable to the extent it does not otherwise follow from compulsory provisions in collective bargaining agreements. The Board of Directors must have the opportunity in accordance with either law or agreement and the limitations that follow therefrom to recall variable remuneration that was erroneously paid out. For 2022, the CEO and the other senior executives had the right to variable remuneration between 20 and 35 percent of their annual salaries.

BioArctic has a milestone-based rewards program in Alzheimer's disease that is linked to regulatory milestones, and to milestones that are based on future potential sales. A

previously determined amount will be disbursed if and when BioArctic achieves certain pre-defined regulatory milestones, and milestones that are based on future potential sales. The achievement of such milestones is typically associated with significant uncertainty. Variable remuneration under the milestone-based rewards program is disbursed – to the extent it is paid – on an irregular basis in pace with the milestones being achieved. Moreover, remuneration of this kind can be expected to display highly significant variation from one year to another. The design of and uncertainty around the milestone-based rewards programs justify the fact that existing and future programs of a similar design are not covered by the guidelines on the proportion of the variable remuneration in relation to fixed salary.

*Criteria for payment of variable remuneration*

The criteria that form the basis for payment of variable remuneration, with the exception of the company's milestone-based rewards program, are to be established yearly by the Board of Directors for the purpose of ensuring that the criteria are in line with BioArctic's current business strategy and earnings targets. The criteria may be individual or shared, financial or non-financial, and must be designed to promote BioArctic's business strategy, sustainability strategy and long-term interests. The criteria can, for example, be linked to: BioArctic achieving certain goals as part of its clinical tests, BioArctic initiating or concluding a certain step or achieving a certain research result as part of its drug development, BioArctic initiating research collaboration with a certain partner, or BioArctic signing a certain agreement. The criteria can also be linked to the employee themselves, for example, the person needing to have worked for BioArctic for a certain period of time. Variable remuneration under milestone-based rewards programs must be linked to pre-defined milestones in BioArctic's development projects or achieving the commercialization of the company's drug candidates.

The period that forms the basis for assessing whether or not the criteria have been met must total at least one year,

**Note 7, cont.**

with the exception of the milestone-based rewards program where payments are based on the achievement of pre-defined milestones. The extent to which the criteria have been met will be assessed once the measurement period has concluded.

Assessment of whether financial criteria have been met will be based on the release of the latest financial information by BioArctic. The Board will decide on payment of any variable remuneration after preparation in the Remuneration Committee.

**Pension benefits**

Pension benefits must be defined-contribution to the extent the executive is not covered by defined-benefit pension under compulsory provisions in collective bargaining agreements.

At most, pension premiums for defined-contribution pensions can correspond to 40 percent of the senior executive's annual fixed salary.

**Other benefits**

Other benefits can include a company car, occupational health services, life and health insurance and other similar benefits. Other benefits will comprise a smaller share of total remuneration and at most can correspond to 10 percent of the senior executive's annual fixed salary.

**Consultancy fees**

Consultancy fees must be market-based. To the extent consulting service are performed by a Board member of BioArctic, the Board member concerned does not have the right to take part in the preparation by the Board (or the Remuneration Committee) of questions concerning remuneration for the consulting services in question.

**Salary and conditions of employment for employees**

In order to assess the reasonableness of the guidelines, the Board of Directors took salaries and conditions of employment for BioArctic's employees into consideration when preparing the

proposal for these guidelines. With that, the Board studied information pertaining to the employees' total remuneration, the forms this remuneration took, how remuneration levels have changed over time and the rate at which they changed.

**Notice period and severance pay**

As regards the CEO, the notice period upon termination by BioArctic will be a maximum of twelve months, while the notice period upon resignation by the CEO will be a maximum of six months.

As regards senior executives other than the CEO, the notice period upon termination by BioArctic will be a minimum of three months and a maximum of twelve months, while the notice period upon resignation by the senior executive will be a minimum of three months and a maximum of six months, if not otherwise prescribed by law.

Severance pay can be paid to senior executives upon termination by BioArctic. Total fixed salary during the notice period and severance pay will not exceed an amount corresponding to two years of the fixed salary.

Remuneration may be paid for a commitment to restriction of competition. Remuneration of this type will compensate for any potential loss of income and will only be paid to the extent that the former senior executive does not have the right to severance pay. At most, the remuneration can total 60 percent of the senior executive's fixed salary upon termination, if nothing else follows from compulsory provisions in collective bargaining agreements. Remuneration of this type can be paid out during the period the commitment to restriction of competition is in effect, which can be a maximum of 12 months after the termination of employment, with the possibility of deduction against other income from services or in accordance with consultancy agreements.

**The decision-making process for establishing, reviewing and implementing the guidelines**

The Board of Directors has established a Remuneration Committee, which has been tasked with preparing the

Board's decisions on issues concerning remuneration policies, remuneration and other conditions of employment for company management; monitoring and evaluating programs both ongoing and concluded during the year for variable remuneration to company management; and monitoring and evaluating application of the guidelines for remuneration to senior executives that the General Meeting is to resolve on, as well as remuneration structures and remuneration levels in effect at BioArctic. The tasks of the Committee also include preparing Board decisions on proposals for guidelines for remuneration to senior executives.

The Board of Directors will draw up proposals for new guidelines in the event substantial changes to the guidelines are needed, though at least once every four years. The Board of Directors will present the proposal for resolution at the AGM. The guidelines will remain in effect until new guidelines have been adopted by the General Meeting.

In order to avoid conflicts of interest, senior executives will not be present at the Board of Directors' handling of and decisions on issues related to remuneration to the extent they are impacted by these issues.

**Departures from the guidelines**

The Board of Directors may decide to temporarily depart from the guidelines if in an individual case there are particular reasons to do so and a departure is necessary in order to serve BioArctic's long-term interests and sustainability or to ensure the company's financial stability.

Particular reasons could, for example, consist of a departure being deemed necessary in order to recruit or retain key persons, or in connection with extraordinary circumstances such as BioArctic achieving a certain desired result in a shorter time than planned, BioArctic successfully signing a certain agreement in a shorter time and on better terms than predicted, or BioArctic increasing in value or increasing its sales or profits to a greater extent than forecast.

## Note 7, cont.

## AVERAGE NUMBER OF EMPLOYEES

Number	Group		Parent Company	
	2022	2021	2022	2021
Women	34	28	34	28
Men	21	17	21	17
<b>Total</b>	<b>55</b>	<b>46</b>	<b>55</b>	<b>46</b>

## BOARD MEMBERS AND SENIOR EXECUTIVES

Number	2022		2021	
	Balance sheet date	Of whom women	Balance sheet date	Of whom women
<b>BioArctic AB</b>				
Board members	8	2	8	2
CEO and other senior executives <sup>1</sup>	9	4	9	4

1) Lars Lannfelt is a member of both the Board of Directors and the management group, but is reported in the table above only in the Board of Directors so as to avoid double counting.

## SALARIES, REMUNERATION AND SOCIAL SECURITY CONTRIBUTIONS

Amounts in kSEK	Group		Parent Company	
	2022	2021	2022	2021
<b>Salaries and remuneration</b>				
Board of Directors, CEO and other senior executives <sup>1</sup>	28,516	23,510	28,516	23,510
(of which, variable)	(3,849)	(2,585)	(3,849)	(2,585)
Other employees	42,184	26,442	42,184	26,442
<b>Total salaries and remuneration</b>	<b>70,700</b>	<b>49,952</b>	<b>70,700</b>	<b>49,952</b>
<b>Social security contributions <sup>2</sup></b>				
Pension costs	11,313	8,614	11,313	8,614
(of which Board of Directors, CEO and other senior executives)	(5,222)	(4,250)	(5,222)	(4,250)
<b>Total salaries, remuneration and social security contributions</b>	<b>111,364</b>	<b>70,767</b>	<b>111,364</b>	<b>70,767</b>

1) This amount for 2022 includes invoiced fees of kSEK 64 (2,097).

2) The primary reason for the increase is that the company's share price, and thereby the value of the warrants on which social security contributions are calculated, has increased the social security contributions for the employee stock option program.

The company has no outstanding pension obligations.

## Note 7, cont.

## REMUNERATION AND OTHER BENEFITS, 2022

Amounts in kSEK	Fixed salary/ Fees	Variable remunera- tion	Pension	Share- based remu- neration	Total
<b>Board of Directors</b>					
Wenche Rolfsen (chairman)	696	-	-	-	696
Lars Lannfelt <sup>1</sup>	2,015	-	435	-	2,450
Pär Gellerfors	321	-	-	-	321
Eugen Steiner	350	-	-	-	350
Ivar Verner	400	-	-	-	400
Mikael Smedeby	310	-	-	-	310
Håkan Englund	250	-	-	-	250
Lotta Ljungqvist <sup>3</sup>	293	-	-	-	293
<b>Senior executives</b>					
CEO Gunilla Osswald	5,346	1,418	1,434	531	8,730
Other senior executives (8 persons) <sup>1,4</sup>	13,552	2,431	3,352	602	19,937
<b>Total remuneration and other benefits</b>	<b>23,534</b>	<b>3,849</b>	<b>5,222</b>	<b>1,133</b>	<b>33,737</b>

## REMUNERATION AND OTHER BENEFITS, 2021

Amounts in kSEK	Fixed salary/ Fees	Variable remunera- tion	Pension	Share- based remu- neration	Total
<b>Board of Directors</b>					
Wenche Rolfsen (chairman)	626	-	-	-	626
Lars Lannfelt <sup>1,5</sup>	1,975	-	606	-	2,581
Pär Gellerfors	366	-	-	-	366
Eugen Steiner	350	-	-	-	350
Ivar Verner	400	-	-	-	400
Hans Ekelund <sup>2</sup>	116	-	-	-	116
Mikael Smedeby	315	-	-	-	315
Håkan Englund	250	-	-	-	250
Lotta Ljungqvist <sup>3</sup>	169	-	-	-	169
<b>Senior executives</b>					
CEO Gunilla Osswald	3,182	891	1,059	277	5,409
Other senior executives (8 persons) <sup>1,4</sup>	12,457	1,694	2,584	443	17,178
<b>Total remuneration and other benefits</b>	<b>20,206</b>	<b>2,584</b>	<b>4,250</b>	<b>720</b>	<b>27,760</b>

1) Lars Lannfelt is active in the company and is employed at 100% of full-time service. Lars is part of the management group but is reported in the Board of Directors only in the table above so as not to be double-counted.

2) Hans Ekelund was a Board member until May 6, 2021.

3) Lotta Ljungqvist has been a Board member since May 6, 2021.

4) The amount does not include any invoiced fees (kSEK 1,915).

5) Of kSEK 606 in pension costs, kSEK 212 is attributable to 2020.



*Note 7, cont.*

## 2019/2028 STOCK WARRANT PROGRAM

	Number of warrants
Outstanding as of January 1, 2021	540,000
Granted	40,000
Forfeit/Redeemed/Due	-
<b>Outstanding as of December 31, 2021</b>	<b>580,000</b>
Outstanding as of January 1, 2022	580,000
Granted	260,000
Forfeit	-5,000
Redeemed	-71,586
Due	-
<b>Outstanding as of December 31, 2022</b>	<b>763,414</b>
Redeemable as of December 31, 2021	0
<b>Redeemable as of December 31, 2022</b>	<b>398,414</b>

The Black & Scholes model was used to calculate the exercise price. The volatility used in calculating the value of the warrants was established based on a comparison with similar companies, and has been set at 40 per cent. During the period, an interest rate corresponding to a five-year government bond was used, and no dividend has been assumed. Apart from the above, no other assumptions have been taken into account when calculating the fair value. The 71,586 warrants that were redeemed in 2022 originate from allocation 1, and the average subscription price was SEK 83.60. In 2022, kSEK 2,760 (1,568) was recorded as personnel expenses.

Allocation	Grant date	Vesting period concludes	Weighted average remaining contract period	Number of warrants granted	Share price at allocation date, SEK	Fair value per warrant at allocation date, SEK	Exercise price, SEK
Allocation 1	Sep. 11, 2019	Sep. 11, 2024	2.2 years	435,000	62.90	17.20	83.60
Allocation 2	Sep. 11, 2019	Sep. 11, 2024	2.2 years	25,000	62.90	17.46	82.46
Allocation 3	Dec. 1, 2019	Dec. 1, 2024	2.4 years	20,000	98.00	47.14	67.75
Allocation 4	Feb. 3, 2020	Feb. 3, 2025	2.6 years	5,000	86.90	26.14	105.37
Allocation 5	Apr. 4, 2020	Apr. 4, 2025	2.8 years	25,000	67.15	26.62	60.19
Allocation 6	Dec. 7, 2020	Dec. 7, 2025	3.4 years	35,000	94.20	34.01	94.19
Allocation 7	Jan. 15, 2020	Jan. 15, 2026	3.5 years	10,000	100.30	35.74	101.76
Allocation 8	Aug. 15, 2021	Aug. 15, 2026	4.1 years	30,000	135.80	52.74	124.80
Allocation 9	Jan. 10, 2022	Jan. 10, 2027	4.5 years	170,000	109.20	33.5	129.82
Allocation 10	Apr. 25, 2022	Apr. 25, 2027	4.8 years	20,000	80.80	19.73	113.34
Allocation 11	Nov. 1, 2022	Nov. 1, 2027	5.3 years	70,000	232.60	99.57	161.71
<b>Total allocated as of December 31, 2022</b>				<b>845,000</b>			

**NOTE 8** Remuneration to the auditors

Amounts in kSEK	Group		Parent Company	
	2022	2021	2022	2021
<b>Grant Thornton</b>				
Audit engagement	550	521	550	521
Audit services in addition to audit engagement	110	110	110	110
Tax advisory service	104	53	104	53
Other services	152	22	152	22
<b>Total remuneration to Grant Thornton</b>	<b>916</b>	<b>706</b>	<b>916</b>	<b>706</b>

Audit assignment refers to the review of the Annual Report and the accounts, as well as of the administration by the Board of Directors and the CEO, and to other work tasks that it is the business of the company's auditor to perform as well as consultancy or other assistance occasioned by observations in conjunction with such reviews or the performance of other such work tasks.

Audit services in addition to audit engagement pertain primarily to a general audit of interim financial statements.

Tax advisory service includes consultancy on income tax and VAT.

Other services pertain to consultancy not attributable to any of the categories of service named above.

**NOTE 9** Commitments**LEASE COMMITMENTS**

The Group applies IFRS 16 Leases, which means that leases are recognized in the balance sheet as a right-of-use asset and a lease liability. Operating leases for 2022 pertain only to the Parent Company and to rent for office premises and lease payments for company cars under non-cancelable operating leases where the remaining term of the lease is between 1 and 3 years.

**EXPENSED MINIMUM LEASE PAYMENTS**

Amounts in kSEK	<i>Parent Company</i>	
	2022	2021
Lease fees, premises	10,211	8,814
Lease fees, vehicles	1,297	1,115
<b>Total</b>	<b>11,509</b>	<b>9,929</b>

**FUTURE MINIMUM LEASE PAYMENTS FOR NON-CANCELABLE OPERATING LEASES**

Amounts in kSEK	<i>Parent Company</i>	
	2022	2021
Within one year	10,433	10,290
Later than one year but not later than five years	413	8,248
Later than five years	-	-
<b>Total</b>	<b>10,846</b>	<b>18,538</b>

**OTHER COMMITMENTS**

BioArctic has undertaken to conduct research operations to reach predefined milestones. The commitments that were current as of December 31, 2021 were settled in 2022. The Group does not have any prepaid income as of 31 December 2022.

**NOTE 10** Other operating expenses

Amounts in kSEK	<i>Group</i>		<i>Parent Company</i>	
	2022	2021	2022	2021
Loss on disposal of property, plant and equipment	-	8	-	8
Operational foreign exchange losses	9,679	877	9,679	877
<b>Total other operating costs</b>	<b>9,679</b>	<b>885</b>	<b>9,679</b>	<b>885</b>

**NOTE 11** Finance income and expenses

Amounts in kSEK	<i>Group</i>		<i>Parent Company</i>	
	2022	2021	2022	2021
Interest charged	2,535	-	2,535	-
Foreign exchange gains	4,490	194	4,490	194
<b>Total financial income</b>	<b>7,025</b>	<b>194</b>	<b>7,025</b>	<b>194</b>
Non-current lease liabilities	-559	-838	-	-
Financial expenses	-191	-145	-191	-145
<b>Total financial expenses</b>	<b>-751</b>	<b>-984</b>	<b>-191</b>	<b>-145</b>
<b>Total financial income and expenses</b>	<b>6,274</b>	<b>-790</b>	<b>6,834</b>	<b>49</b>

**NOTE 12** Tax

Amounts in kSEK	Group		Parent Company	
	2022	2021	2022	2021
Current tax	-	-	-	-
Deferred tax	-11	20,723	65	63
<b>Total tax on profit for the year</b>	<b>-11</b>	<b>20,723</b>	<b>65</b>	<b>63</b>

**RECONCILIATION OF EFFECTIVE TAX**

In the table below, reported tax is reconciled against tax based on the Swedish tax rate of 20.6% (20.6%).

**RECONCILIATION OF EFFECTIVE TAX**

Amounts in kSEK	Group		Parent Company	
	2022	2021	2022	2021
Loss before tax	-11,168	-140,512	-11,537	-45,734
Tax under applicable tax rate, 20.6% (20.6%)	2,301	28,946	2,377	9,421
Non-deductible expenses	-313	-150	-313	-150
Standard income on tax allocation reserve	-	-94	-	-94
Adjustment, tax allocation reserve reversal	-	-	-	-1,013
Revaluation of deferred tax	-	123	-	-
Tax effect on loss carry-forward not capitalized <sup>1</sup>	-1,999	-8,101	-1,999	-8,101
<b>Total tax</b>	<b>-11</b>	<b>20,723</b>	<b>65</b>	<b>63</b>
Effective tax, %	0.1%	14.7%	0.6%	0.1%

<sup>1</sup> Taxable saved loss at year-end 2022 was MSEK 49.0 (39.3).

**CURRENT TAX ASSETS**

Amounts in kSEK	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Current tax assets	1,216	1,557	1,216	1,557
<b>Total current tax assets</b>	<b>1,216</b>	<b>1,557</b>	<b>1,216</b>	<b>1,557</b>

**CURRENT TAX LIABILITIES**

Amounts in kSEK	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Current tax liabilities	-	-	-	-
<b>Total current tax liabilities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

**DEFERRED TAX**

Deferred tax consists of tax items to be settled in the future. The table below specifies deferred tax receivables and tax liabilities regarding temporary differences between the carrying amount of assets and liabilities and their taxable value.

**DEFERRED TAX ON TEMPORARY DIFFERENCES**

Amounts in kSEK	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Leasehold improvements	453	388	453	388
Deferred tax, IFRS 16	143	219	-	-
<b>Total deferred tax assets</b>	<b>596</b>	<b>608</b>	<b>453</b>	<b>388</b>
Tax allocation reserve	-	-	-	-
Accelerated depreciation	-	-	-	-
<b>Total deferred tax liabilities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total net deferred tax</b>	<b>596</b>	<b>608</b>	<b>453</b>	<b>388</b>

Note 12, cont.

#### CHANGE IN DEFERRED TAX

Amounts in kSEK	Group			Parent Company		
	Jan. 1, 2022	Recognized in profit or loss	Dec. 31, 2022	Jan. 1, 2022	Recognized in profit or loss	Dec. 31, 2022
Leasehold improvements	388	65	453	388	65	453
Deferred tax, IFRS 16	219	-76	143	0	-	0
<b>Total deferred tax assets</b>	<b>608</b>	<b>-11</b>	<b>596</b>	<b>388</b>	<b>65</b>	<b>453</b>
Tax allocation reserve	0	-	0	0	-	0
Accelerated depreciation	0	-	0	0	-	0
<b>Total deferred tax liabilities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total net deferred tax</b>	<b>608</b>	<b>-11</b>	<b>596</b>	<b>388</b>	<b>65</b>	<b>453</b>

Amounts in kSEK	Group			Parent Company		
	Jan. 1, 2021	Recognized in profit or loss	Dec. 31, 2021	Jan. 1, 2021	Recognized in profit or loss	Dec. 31, 2021
Leasehold improvements	325	63	388	325	63	388
Deferred tax, IFRS 16	128	92	219	0	-	0
<b>Total deferred tax assets</b>	<b>452</b>	<b>155</b>	<b>608</b>	<b>325</b>	<b>63</b>	<b>388</b>
Tax allocation reserve	-19,958	19,958	0	0	-	0
Accelerated depreciation	-707	707	0	0	-	0
<b>Total deferred tax liabilities</b>	<b>-20,666</b>	<b>20,666</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total net deferred tax</b>	<b>-20,214</b>	<b>20,821</b>	<b>608</b>	<b>325</b>	<b>63</b>	<b>388</b>

#### NOTE 13 Earnings per share and share data

Earnings per share is calculated by dividing earnings for the year attributable to Parent Company shareholders by a weighted average of the number of ordinary shares outstanding during the period. As of the balance-sheet date, 845,000 warrants have been allocated, of which 763,414 warrants are outstanding after deductions for forfeited and exercised warrants. These allocated warrants yield a dilution effect corresponding to 693,414 shares (or 0.8 percent) at the end of the period.

Amounts in kSEK	Group	
	2022	2021
Loss for the year attributable to owners of the Parent Company, kSEK	-11,179	-119,789
Weighted average number of shares outstanding before dilution	88,074,302	88,059,985
Weighted average number of shares outstanding after dilution	88,682,985	88,579,985
<b>Earnings per share before dilution, SEK</b>	<b>-0.13</b>	<b>-1.36</b>
<b>Earnings per share after dilution, SEK <sup>1</sup></b>	<b>-0.13</b>	<b>-1.36</b>
Proposed dividend per share, SEK	0.00	0.00
Number of shares outstanding as of the balance sheet date	88,131,571	88,059,985
Number of warrants outstanding	763,414	580,000

1) No dilution effect since the company reported negative earnings.

**NOTE 14** Tangible assets and right-of-use assets*Group*

Amounts in kSEK	Leasehold improvements	Equipment	Total	Right-of-use assets
Cost at January 1, 2022	4,328	39,769	44,097	38,123
Acquisitions	2,189	11,001	13,190	2,954
Sale/disposal	-	-444	-444	
<b>Cost at December 31, 2022</b>	<b>6,517</b>	<b>50,326</b>	<b>56,843</b>	<b>41,077</b>
Depreciations at January 1, 2021	-2,760	-24,375	-27,135	-21,338
Correction of opening balance				5
Sale/disposal	-	444	444	
Depreciations	-605	-6,017	-6,621	-8,012
<b>Depreciations at December 31, 2022</b>	<b>-3,364</b>	<b>-29,947</b>	<b>-33,311</b>	<b>-29,345</b>
<b>Carrying amount at January 1, 2022</b>	<b>1,569</b>	<b>15,394</b>	<b>16,963</b>	<b>16,785</b>
<b>Carrying amount at December 31, 2022</b>	<b>3,153</b>	<b>20,378</b>	<b>23,531</b>	<b>11,733</b>

*Group*

Amounts in kSEK	Leasehold improvements	Equipment	Total	Right-of-use assets
Cost at January 1, 2021	4,067	35,645	39,712	35,242
Acquisitions	261	4,194	4,456	2,881
Sale/disposal	-	-70	-70	-
<b>Cost at December 31, 2021</b>	<b>4,328</b>	<b>39,769</b>	<b>44,097</b>	<b>38,123</b>
Depreciations at January 1, 2021	-2,176	-19,416	-21,592	-13,423
Sale/disposal	-	62	62	-
Depreciations	-584	-5,021	-5,605	-7,915
<b>Depreciations at December 31, 2021</b>	<b>-2,760</b>	<b>-24,375</b>	<b>-27,135</b>	<b>-21,338</b>
<b>Carrying amount at January 1, 2021</b>	<b>1,891</b>	<b>16,229</b>	<b>18,120</b>	<b>21,820</b>
<b>Carrying amount at December 31, 2021</b>	<b>1,569</b>	<b>15,394</b>	<b>16,963</b>	<b>16,785</b>

## Note 14, cont.

Amounts in kSEK	Parent Company		
	Leasehold improvements	Equipment	Total
Cost at January 1, 2022	4,328	39,769	44,097
Acquisitions	2,189	11,001	13,190
Sale/disposal	-	-444	-444
<b>Cost at December 31, 2022</b>	<b>6,517</b>	<b>50,326</b>	<b>56,843</b>
Depreciations at January 1, 2022	-2,760	-24,375	-27,135
Sale/disposal	-	444	444
Depreciations	-605	-6,017	-6,621
<b>Depreciations at December 31, 2022</b>	<b>-3,364</b>	<b>-29,947</b>	<b>-33,311</b>
Carrying amount at January 1, 2022	1,569	15,394	16,963
<b>Carrying amount at December 31, 2022</b>	<b>3,153</b>	<b>20,378</b>	<b>23,531</b>

Amounts in kSEK	Parent Company		
	Leasehold improvements	Equipment	Total
Cost at January 1, 2021	4,067	35,645	39,712
Acquisitions	261	4,194	4,456
Sale/disposal	-	-70	-70
<b>Cost at December 31, 2021</b>	<b>4,328</b>	<b>39,769</b>	<b>44,097</b>
Depreciations at January 1, 2021	-2,176	-19,416	-21,592
Sale/disposal	-	62	62
Depreciations	-584	-5,021	-5,605
<b>Depreciations at December 31, 2021</b>	<b>-2,760</b>	<b>-24,375</b>	<b>-27,135</b>
Carrying amount at January 1, 2021	1,891	16,229	18,120
<b>Carrying amount at December 31, 2021</b>	<b>1,569</b>	<b>15,394</b>	<b>16,963</b>

## NOTE 15 Shares in subsidiaries

Amounts in kSEK	Parent Company	
	Dec. 31, 2022	Dec. 31, 2021
Opening cost	50	50
Acquisition/Sale	-	-
<b>Closing cost</b>	<b>50</b>	<b>50</b>

## SPECIFICATION OF PARENT COMPANY'S SHARES AND PARTICIPATIONS IN SUBSIDIARIES

Subsidiary/Corp. ID No./Reg. office	Share owned, % <sup>1</sup>	Equity	Profit/loss for the year
LPB Sweden AB, 559035-9112, Stockholm	100%	44	-2

1) Pertains to ownership share of capital, which also corresponds to the proportion of voting rights for the total number of shares.

## NOTE 16 Other non-current financial assets

Amounts in kSEK	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Deposit	1,606	1,588	1,606	1,588
<b>Total other non-current financial assets</b>	<b>1,606</b>	<b>1,588</b>	<b>1,606</b>	<b>1,588</b>

Pertains to deposit for rental contract in the form of restricted cash; refer to Note 27.

**NOTE 17** Overview of financial instruments**CATEGORIES OF FINANCIAL ASSETS AND LIABILITIES**

The Group's financial assets and liabilities are fully attributable to cash and cash equivalents, trade receivables, other current receivables, trade payables and contractual accrued expenses. The Group has no foreign exchange contracts or listed securities.

Dec. 31, 2022 Amounts in kSEK	Note	Amortized cost	Fair value through profit or loss	Fair value through other comprehen- sive income
<b>Financial assets</b>				
Trade receivables		-		
Other current receivables	18	491	-	-
Cash and cash equivalents	20	805,386	-	-
<b>Total financial assets</b>		<b>805,878</b>	<b>0</b>	<b>0</b>
<b>Financial liabilities</b>				
Accounts payable		-21,491	-	-
Contractual accrued expenses	26	-6,166	-	-
<b>Total financial liabilities</b>		<b>-27,657</b>	<b>0</b>	<b>0</b>
<b>Total financial instruments (assets + / liabilities -)</b>		<b>778,221</b>	<b>0</b>	<b>0</b>

Dec. 31, 2021 Amounts in kSEK	Note	Amortized cost	Fair value through profit or loss	Fair value through other comprehen- sive income
<b>Financial assets</b>				
Trade receivables		2,839		
Other current receivables	18	397	-	-
Cash and cash equivalents	20	848,405	-	-
<b>Total financial assets</b>		<b>851,641</b>	<b>0</b>	<b>0</b>
<b>Financial liabilities</b>				
Accounts payable		-11,818	-	-
Contractual accrued expenses	26	-3,758	-	-
<b>Total financial liabilities</b>		<b>-15,576</b>	<b>0</b>	<b>0</b>
<b>Total financial instruments (assets + / liabilities -)</b>		<b>836,065</b>	<b>0</b>	<b>0</b>

**THE GROUP'S MATURITY STRUCTURE  
FOR UNDISCOUNTED FINANCIAL LIABILITIES**

Amounts in kSEK	2023	2024	2025	2026	2027
Accounts payable	21,491	-	-	-	-
Lease liabilities	10,433	262	151	-	-
Contractual accrued expenses	6,166	-	-	-	-
<b>Total</b>	<b>38,090</b>	<b>262</b>	<b>151</b>	<b>-</b>	<b>-</b>

**NOTE 18** Other current receivables

	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Amounts in kSEK				
VAT receivables	3,853	2,531	3,853	2,531
Tax account	2,395	1,720	2,395	1,720
Other	491	397	491	397
<b>Total other current receivables</b>	<b>6,740</b>	<b>4,648</b>	<b>6,740</b>	<b>4,648</b>

**NOTE 19** Prepaid expenses and accrued income

	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Amounts in kSEK				
Prepaid rent	568	497	2,955	2,470
Other prepaid expenses	6,931	3,841	6,931	3,841
<b>Total prepaid expenses and accrued income</b>	<b>7,498</b>	<b>4,337</b>	<b>9,886</b>	<b>6,310</b>

**NOTE 20** Cash and cash equivalents

	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Amounts in kSEK				
Cash and bank balances	805,386	848,405	805,342	848,359
<b>Total cash and cash equivalents</b>	<b>805,386</b>	<b>848,405</b>	<b>805,342</b>	<b>848,359</b>

**NOTE 21** Share capital

Class of share	Number of shares	Share capital, SEK	Quotient value, SEK	Votes per share	Total votes
A shares	14,399,996	288,000	0.02	10	143,999,960
B shares	73,731,575	1,474,631	0.02	1	73,731,575
<b>Total</b>	<b>88,131,571</b>	<b>1,762,631</b>			<b>217,731,535</b>

## DEVELOPMENT OF SHARE CAPITAL

Year	Event	Number of new shares	Number of A shares	Number of B shares	Total number of shares	Change in share capital, SEK	Total share capital, SEK
2000	Company founded	1,000	1,000	-	1,000	100,000	100,000
2002	Split 1000:1	999,000	1,000,000	-	1,000,000	-	100,000
2002	Split 4:1	3,000,000	4,000,000	-	4,000,000	-	100,000
2002	Reclassification of A shares to B shares	-	3,000,000	1,000,000	4,000,000	-	100,000
2004	Rights issue	133,333	3,133,333	1,000,000	4,133,333	3,333	103,333
2005	Rights issue	66,666	3,199,999	1,000,000	4,199,999	1,667	105,000
2011	Subscription through warrants	4,000	3,199,999	1,004,000	4,203,999	100	105,100
2017	Stock dividend issue	-	3,199,999	1,004,000	4,203,999	1,156,100	1,261,200
2017	Split 15:1	58,855,986	47,999,985	15,060,000	63,059,985	-	1,261,200
2017	Reclassification of A shares to B shares	-	14,399,996	48,659,989	63,059,985	-	1,261,200
2017	Rights issue	25,000,000	14,399,996	73,659,989	88,059,985	500,000	1,761,200
2022	New share issue through exercise of employee stock options	71,586	14,399,996	73,731,575	88,131,571	1,431	1,762,631
		<b>88,131,571</b>				<b>1,762,631</b>	

Regarding changes in equity, refer to the consolidated and Parent Company statements of changes in equity.



## NOTE 22 Proposed appropriation of retained earnings

The Board of Directors proposes that available funds amounting to SEK 784,077,634 be disposed of as follows:

Amounts in SEK	Dec. 31, 2022
Dividend to shareholders	0
Carried forward	784,077,634
<b>Total</b>	<b>784,077,634</b>

## NOTE 23 Untaxed reserves

Amounts in kSEK	Parent Company	
	Dec. 31, 2022	Dec. 31, 2021
Tax allocation reserves	-	-
Accelerated depreciation	-	-
<b>Total untaxed reserves</b>	<b>0</b>	<b>0</b>

## NOTE 24 Lease liabilities

Lease liabilities presented in the balance sheet are allocated as follows:

Amounts in kSEK	Group	
	Dec. 31, 2022	Dec. 31, 2021
Current	8,857	8,092
Non-current	1,182	7,785
<b>Total lease liabilities</b>	<b>10,039</b>	<b>15,878</b>

For 2022, interest paid on leasing totaled SEK 559,479 (838,441). The table below describes the Group's leases based on the type of right of use recognized in the statement of financial position:

Right-of-use assets	Number of right-of-use assets	Interval, duration remaining	Average remaining lease period	Number of contracts with warrants to extend	Number of contracts with warrants to purchase	Number of contracts with variable fees pegged to an index	Number of contracts with warrants to cancel
Office premises	4	1 year	1 year	4	0	4	0
Garage spaces	1	1 year	1 year	1	0	1	0
Employee vehicles	11	0–3 years	1 year	11	11	0	0

### LEASES NOT RECOGNIZED AS LIABILITIES

The Group has chosen not to recognize a lease liability regarding short-term leases (leases with an expected term of 12 months or less) or low-value leases. Payments concerning such leases are expensed on a linear basis. The Group did not have any short-term leases in either 2022 or 2021. Furthermore, the recognition of certain lease fees as lease liabilities is not permitted, which is why they are also routinely expensed.

## NOTE 25

## Reconciliation of liabilities attributable to financing operations

Amounts in kSEK	Lease liabilities
Jan. 1, 2022	15,878
<b>Cash items</b>	
Amortization	-8,793
<b>Non-cash items</b>	
Fair value	
Cost	2,954
Dec. 31, 2022	10,039

Amounts in kSEK	Lease liabilities
Jan. 1, 2021	20,768
<b>Cash items</b>	
Amortization	-7,389
<b>Non-cash items</b>	
Fair value	-
Cost	2,498
Dec. 31, 2021	15,878

## NOTE 26

## Accrued expenses and prepaid income

Amounts in kSEK	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Accrued personnel expenses	30,764	15,229	30,764	15,229
Contractual accrued expenses	6,166	3,758	6,166	3,758
Prepaid income	-	59,119	-	59,119
Other accrued expenses and prepaid income	-1,822	-667	-1,822	-667
<b>Total accrued expenses and prepaid income</b>	<b>35,108</b>	<b>77,438</b>	<b>35,108</b>	<b>77,438</b>

In 2022, SEK 58.5 M (8.5) was recognized as revenue, which included prepaid income at the start of the financial year. No revenue was recognized during the year from fulfilled or partially fulfilled performance obligations from earlier periods.

**NOTE 27** Pledged assets and contingent liabilities**PLEGDED ASSETS**

The pledged assets in the table below were pledged as security for office premises.

Amounts in kSEK	Group		Parent Company	
	Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2022	Dec. 31, 2021
Restricted cash	1,500	1,500	1,500	1,500
Deposit, lease	106	88	106	88
<b>Total pledged assets</b>	<b>1,606</b>	<b>1,588</b>	<b>1,606</b>	<b>1,588</b>

**CONTINGENT LIABILITIES**

The contingent liabilities below have been identified as applying to both the Group and the Parent Company:

- BioArctic has agreed with a former partner that if BAN0805 reaches the market, a payment obligation will arise in relation to the contracting party pertaining to a low single-digit percentage royalty on global sales. This obligation lies far in the future and is time-limited.
- Under the EU research collaborations it has signed, BioArctic has a repayment obligation toward the contracting parties in the event the projects are terminated and the advance payments received exceed the costs incurred. BioArctic also has an obligation to defray the expenses for the medical care needs of patients included in these trials.
- As part of the Swedish state grants received, the company has a repayment obligation if the projects are terminated, or alternately the company does not complete the project in accordance with guidelines, and the project costs incurred do not total the amount disbursed.

All projects are proceeding according to plan, and there are no indications that repayment obligations or other obligations could arise. The same assessment was made in 2020.

**NOTE 28** Disclosures on the cash flow statement**ADJUSTMENT FOR NON-CASH ITEMS**

Amounts in kSEK	Group		Parent Company	
	2022	2021	2022	2021
Depreciations of tangible assets and right-of-use assets	14,184	13,045	6,177	5,543
Profit (-) / loss (+) on disposal of property, plant and equipment	-	-	-	-
Prepaid income	-58,478	-8,466	-58,478	-8,466
Unrealized foreign exchange gains (-) / losses (+)	300	-917	300	-917
Share-based remuneration	2,760	1,568	2,760	1,568
<b>Total adjustment for non-cash items</b>	<b>-41,234</b>	<b>5,230</b>	<b>-49,241</b>	<b>-2,272</b>

**NOTE 29** Transactions with affiliated parties

Board member Pär Gellerfors submitted invoices totaling MSEK 0.1 (0.1) via Acelsta AB for consultant services during the January–December period. All services invoiced to related parties are based on normal market prices.

Apart from the remuneration to Acelsta AB, as well as salaries and Board fees described above, no material transactions have taken place between the Group and related parties. All transactions took place under market conditions.

**NOTE 30** Events after the balance sheet date

- The FDA approved lecanemab (under the name Leqembi) via the accelerated approval pathway for treatment of Alzheimer's disease.
- BioArctic's partner Eisai submitted a supplemental biologics license application to the FDA for full approval of Leqembi for treatment of Alzheimer's disease in the US, and submitted marketing authorization applications in the EU and Japan. The applications in the EU and Japan have been accepted for review, and the application in Japan has been granted a priority review.
- The approval in the US and applications in Japan and the EU gave BioArctic the right to MEUR 35 in milestone payments, which were disbursed in the first quarter of 2023.
- On January 2, 2023, BioArctic was moved to Nasdaq Large Cap.
- The subsidiaries BioArctic Denmark ApS, BioArctic Norway A/S, and BioArctic Finland Oy were formed in the first quarter of 2023.
- BioArctic's Chairman of the Board Wenche Rolfsen informed the Nomination Committee that she would not stand for re-election at the company's Annual General Meeting on June 1, 2023. The Nomination Committee proposed that Eugen Steiner, currently a Board member of BioArctic, succeed Wenche Rolfsen as chairman of the company, and that Ivar Verner continue as Deputy Chairman.
- 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 the election of Cecilia Edström as a new Board member for a mandate period up until the end of the next Annual General Meeting.
- The market authorization application for lecanemab in China was granted priority review by the Chinese National Medical Products Association (NMPA).

- Anders Martin-Löf has been employed as the new Chief Financial Officer. Current CFO Jan Mattsson will remain in the role until Anders Martin-Löf has taken office 1st of May, and will then transition into a newly-established role as Financial Manager.
- The FDA accepted the registration application for full approval and grants priority review for lecanemab for the treatment of Alzheimer's disease. The date when a notification regarding the registration application will be given at the latest, a so-called PDUFA (Prescription Drug User Fee Act) action date has been set as July 6, 2023.

**NOTE 32** Definition and reconciliation of key ratios

Key ratio	Definition
Other income	Income other than net revenue
Operating profit/loss	Result before financial items
Operating margin, %	Operating profit/loss divided by net revenue
Equity per share	Adjusted equity divided by the number of shares at the end of the period
Cash flow from operating activities per share, SEK	Cash flow from operating activities divided by the weighted average number of shares outstanding
Equity/asset ratio, %	Adjusted equity divided by the balance sheet total
Return on equity	Earnings after tax divided by the average adjusted equity

**NOTE 31** Information on purchases and sales within the Group

No purchases or sales occurred within the Group.

*Note 32, cont.*

Amounts in kSEK	2022	2021	2020	2019	2018
Operating margin					
Operating profit/loss	-17,442	-139,723	-85,012	112,538	488,794
Net revenue	228,291	23,146	62,347	281,772	713,970
Operating margin, %	neg	neg	neg	39.9%	68.5%
<b>Basic earnings per share</b>					
Profit/loss for the year	-11,179	-119,789	-68,517	88,468	381,602
Weighted average number of shares outstanding before dilution	88,074,302	88,059,985	88,059,985	88,059,985	88,059,985
Earnings per share before dilution, SEK	-0.13	-1.36	-0.78	1.00	4.33
<b>Diluted earnings per share</b>					
Profit/loss for the year	-11,179	-119,789	-68,517	88,468	381,602
Weighted average number of shares outstanding after dilution	88,682,985	88,579,985	88,177,985	88,059,985	88,059,985
Earnings per share after dilution, SEK	-0.13	-1.36	-0.78	1.00	4.33
<b>Equity per share</b>					
Equity	786,241	788,676	907,299	974,497	1,017,736
Number of shares outstanding	88,131,571	88,059,985	88,059,985	88,059,985	88,059,985
Equity per share	8.92	8.96	10.29	11.07	11.56
<b>Cash flow from operating activities per share</b>					
Cash flow from operating activities	-31,638	-140,457	-92,341	327,165	-200,057
Weighted average number of shares outstanding before dilution	88,074,302	88,059,985	88,059,985	88,059,985	88,059,985
Cash flow from operating activities per share	-0.36	-1.60	-1.05	3.72	-2.27
<b>Equity/asset ratio</b>					
Adjusted equity	786,241	788,676	907,299	974,497	1,017,736
Balance sheet total	858,307	897,730	1,050,313	1,183,332	1,393,042
Equity/asset ratio, %	91.6%	87.9%	86.4%	82.4%	73.1%
<b>Return on equity</b>					
Profit/loss for the year	-11,179	-119,789	-68,517	88,468	381,602
Average adjusted equity	787,459	847,988	940,898	996,116	826,935
Return on equity, %	-1.4%	-14.1%	-7.3%	8.9%	46.1%

# Assurance of the Board of Directors and CEO

The Board of Directors and the CEO hereby assure that the consolidated accounts and annual report were prepared as per the International Financial Reporting Standards (IFRS) as adopted by the EU, and generally accepted accounting principles, respectively, and provide a true and fair view of the development of the Group's and Parent Company's financial position and performance, and that the Board of Directors' report provides a true and fair view of the Group's and parent company's operations, financial position and performance as well as describing material risks and uncertainties faced by the companies that are part of the Group. The income statements and balance sheets of the parent company and the Group are subject to adoption by the Annual General Meeting on June 1, 2023.

STOCKHOLM, APRIL 26, 2023

Wenche Rolfsen  
*Chairman of the Board*

Ivar Verner  
*Deputy Chairman*

Håkan Englund  
*Board member*

Pär Gellerfors  
*Board member*

Lars Lannfelt  
*Board member*

Lotta Ljungqvist  
*Board member*

Mikael Smedeby  
*Board member*

Eugen Steiner  
*Board member*

Gunilla Osswald  
*CEO*

Our audit report was submitted on April 26, 2023  
Grant Thornton Sweden AB

Mia Rutenius  
*Authorized public accountant  
Auditor in charge*

Therese Utengen  
*Authorized public accountant*

# Auditor's report

*To the general meeting of the shareholders of BioArctic AB (publ) corporate identity number 556601-2679*

## REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

### Opinions

We have audited the annual accounts and consolidated accounts of BioArctic AB (publ) for the year 2022. The annual accounts and consolidated accounts of the company are included on pages 53-102 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company as of December 31, 2022 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of December 31, 2022 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014/EU) Article 11.

### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014/EU) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

### Revenue recognition

The Group's reported revenues as at December 31, 2021 is kSEK 26 688, and mainly includes milestone payments and compensations related to research collaborations. The reporting of revenue related to compensations from research collaborations is based on the fulfillment of performance obligations. Performance obligations for milestones achieved are reported as revenue at a point in time. Since the Group's

revenues are of material amount and include significant elements of assessments revenues have been assessed as a key audit matter. For further information on accounting policies for revenue recognition, see note 2 and note 5 in the annual report of BioArctic AB (publ).

Our audit has included the following audit procedures but were not limited to these:

- Understanding and assessment of the company's routines and controls related to revenue recognition,
- Examination of recognised revenue related to research collaborations and milestone payments against agreements and received payments,
- Examination of project accounting, examination of project expenses and examination of the assessments made by management related to percentage of completion and fulfillment of performance obligations in major research collaborations,
- Examination and assessment that applied accounting principles are in accordance with IFRS and whether information disclosed in the annual report is in all material respect sufficient in accordance with the Annual Accounts Act and IFRS.

### Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 2-52 and 108-120. The other information also consists of the remuneration report, which we have had access to prior to the date of this audit report. The Board of Directors and the Managing Director are responsible for this other information.

*Auditor's report*

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

**Responsibilities of the Board of Directors and the Managing Director**

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or mistake.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the

going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

**Auditor's responsibility**

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or mistake, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or mistake and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or mistake, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from

mistake, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.



*Auditor's report*

- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

**REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS****Opinions**

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of BioArctic AB (publ) for the year 2022 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

**Basis for Opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

**Responsibilities of the Board of Directors and the Managing Director**

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the

company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

**Auditor's responsibility**

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the

*Auditor's report*

audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine, and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

#### The auditor's examination of the Esef report Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4 a of the Swedish Securities Market Act (2007:528) for BioArctic AB (publ) for the financial year 2022.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

#### Basis for Opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of BioArctic AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the Esef report in accordance with the Chapter 16, Section 4 a of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies International Standard on Quality Management 1, which requires the firm to design, implement and operate a system of quality management including policies or procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design audit procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a validation that the Esef report has been prepared in a valid XHTML format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report have been marked with iXBRL in accordance with what follows from the Esef regulation.

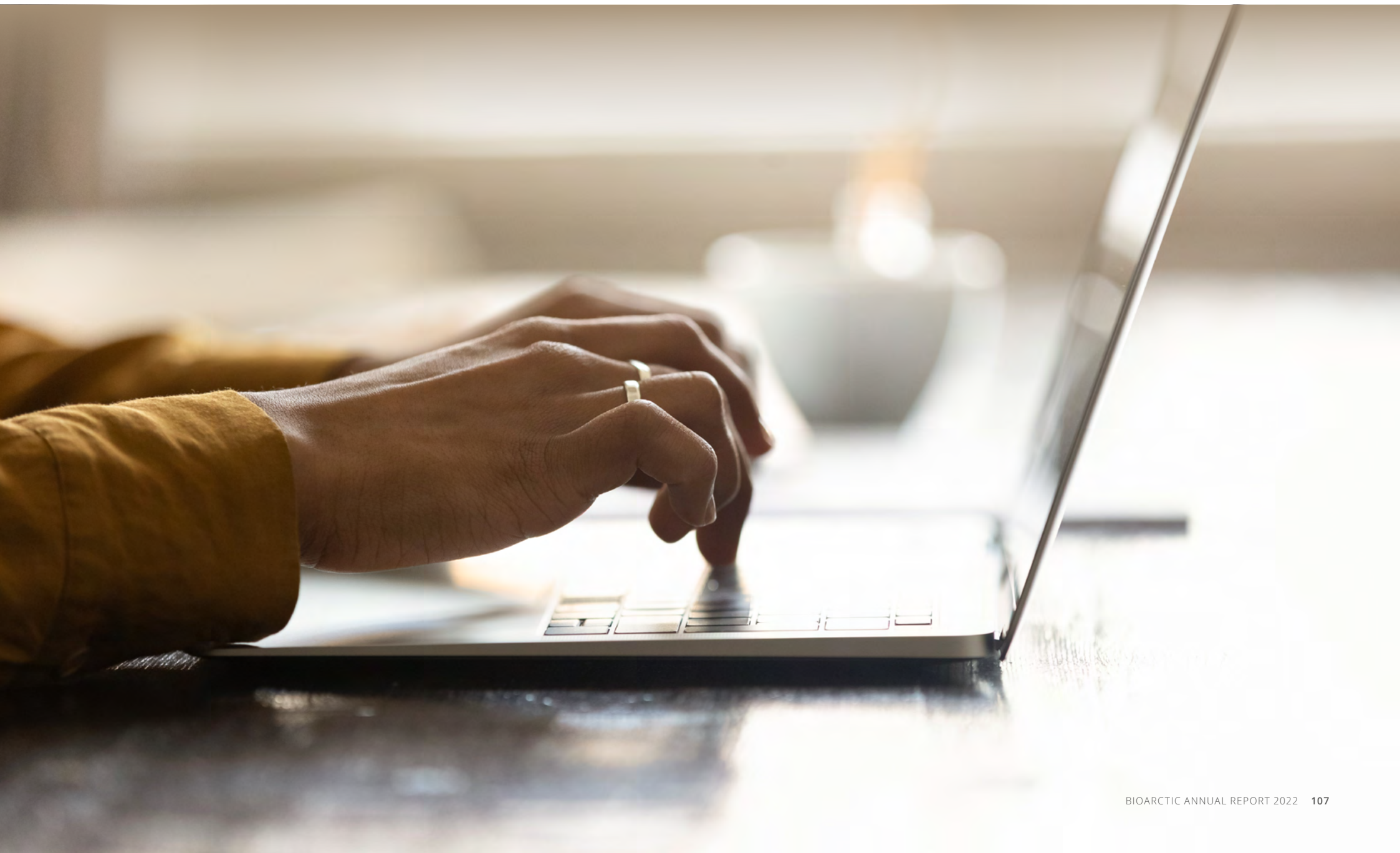
Grant Thornton Sweden AB, Kungsgatan 57 SE 103 94 Stockholm, was appointed auditor of BioArctic AB (publ) by the general meeting of the shareholders on the May 5, 2022 and has been the company's auditor since the June, 22 2016.

Stockholm April 26, 2023

Grant Thornton Sweden AB

Mia Rutenius  
Authorized public accountant  
Auditor in charge

Therese Utengen  
Authorized public accountant



*Comments from the Chairman*

# Groundbreaking research and initiatives for the future

2022 was the most successful year in BioArctic's history, and as Chairman of the Board I am extremely proud of the solid research efforts that form the basis of the positive Phase 3 results for lecanemab in Alzheimer's disease. During the year, the Board made several decisions in order to ensure that BioArctic continues to develop sustainably over the long term, and that the company's research helps address society's challenges by offering patients a better life.

It has been 20 years since BioArctic was founded by Lars Lannfelt and Pär Gellerfors. Together the Board and management have developed the company from a dedicated research and development organization into a company that now establish a commercial organization. The hope is that we in the near future will be able to participate in the work of marketing and selling lecanemab, a recently approved drug for Alzheimer's disease in the USA, also in the Nordics. Research is lengthy and time-consuming work, and I am proud of having been part of enabling the company's fantastic journey. Over the past year, BioArctic has presented groundbreaking research in Alzheimer's disease. The company's research in the field has enabled lecanemab to become the first disease-modifying drug in the world that, in a major clinical program, demonstrated a distinct and significant reduction in degeneration of Alzheimer's disease.

The activities of the Board of Directors of BioArctic over the past year were largely oriented on the company's long-term strategy and on issues of financing. Work has involved comprehensive planning for various scenarios regarding the outcome of the results of the Clarity AD Phase 3 study in Alzheimer's disease. Since BioArctic's research portfolio consists primarily of unique antibody treatments targeted at

the misfolded proteins that form the basis for the emergence of several different neurodegenerative diseases, the outcome had a significant impact not only for lecanemab but also for several other projects in the company's research portfolio. The Board of Directors has thus worked to diversify potential risks in the portfolio by expanding and investing for the future. During the year, decisions were made to intensify research into the company's blood-brain barrier technology. A second generation of this technology has already been shown to cause a robust increase of and improve exposure in the brain to the antibodies, and it is now being used in five preliminary projects in BioArctic's portfolio. Furthermore, a new project has been initiated that focuses on enzyme replacement treatment for Gaucher disease, as well as an additional project in Parkinson's disease, both in combination with the company's Brain Transporter technology. The Board's decision to initiate several more exciting research projects in new areas of disease means a greater rate of investment in the company at the same time as future growth potential is increasing. Additionally, this work involves building up a Nordic sales organization that possesses the specialist competence that an organization needs to commercialize a drug in a new phase in the company's history. One recurring, and increasingly important, area for the



Board is BioArctic's sustainability initiatives and the long-term growth strategy. Efforts have been made to increase transparency for investors and other stakeholders regarding what BioArctic is doing in this field, while the company has begun preparations for compliance with the new laws and expanded reporting requirements that the company is covered by, in pace with the growth of the operation.

On behalf of the Board, I would like to extend our sincerest and warmest thanks to CEO Gunilla Osswald, and BioArctic's employees, for their successes and efforts during the year. I would also like to thank my colleagues on the Board for a constructive and pleasant collaboration, and our shareholders, who support our long-term vision. Since I have declined re-election, the nomination committee has proposed to the general meeting that I hand over the position as chair to Eugen Steiner. It has been an exciting and stimulating year, and I wish BioArctic every success.

Stockholm, April 26, 2023

**Wenche Rolfsen**

*Chairman of the Board*

# Corporate governance

## *Bodies, regulations and governance*

### INTRODUCTION

Active control of risks and a well-functioning corporate culture promote the creation of value for stakeholders. Corporate governance refers to the rules and decision-making hierarchies that efficiently and in a controlled manner promote management and governance as well as the ability to monitor developments within the company.

BioArctic AB, corporate registration number 556601-2679, is a Swedish limited company with its head office in Stockholm. The BioArctic share has been listed on Nasdaq Stockholm Mid Cap since 2017; as of January 2, 2023, the company has been listed on Large Cap. The Corporate Governance Report, which is a part of the company's Board of Directors' report, has been examined by the company's auditor, Grant Thornton Sweden AB, and the results of the examination are presented in their statement on page 121 of this Annual Report.

### GOVERNANCE DOCUMENTS

Corporate governance in BioArctic is controlled by external laws and regulations as well as internal instructions and guidelines.

The external regulations include the relevant laws and ordinances (including the Companies Act, the Annual Accounts Act, the Market Abuse Regulation and IFRS), stock market regulations in the market where the company's shares are admitted for trading (the Nordic Man Market Rulebook for Issuers of Shares), and the Swedish Code of Corporate Governance (the "Code").

Internal regulations include the company's Articles of Association, internal instructions, and guidelines. Examples of internal instructions and guidelines include the Board of

Directors' rules of procedure, formal work plans for the committees and instructions to the CEO. In addition, the Board of Directors of BioArctic has adopted a number of policies and guidelines that control the company's operations, and instructions for financial reporting are documented in the company's finance handbook.

### THE SWEDISH CODE OF CORPORATE GOVERNANCE

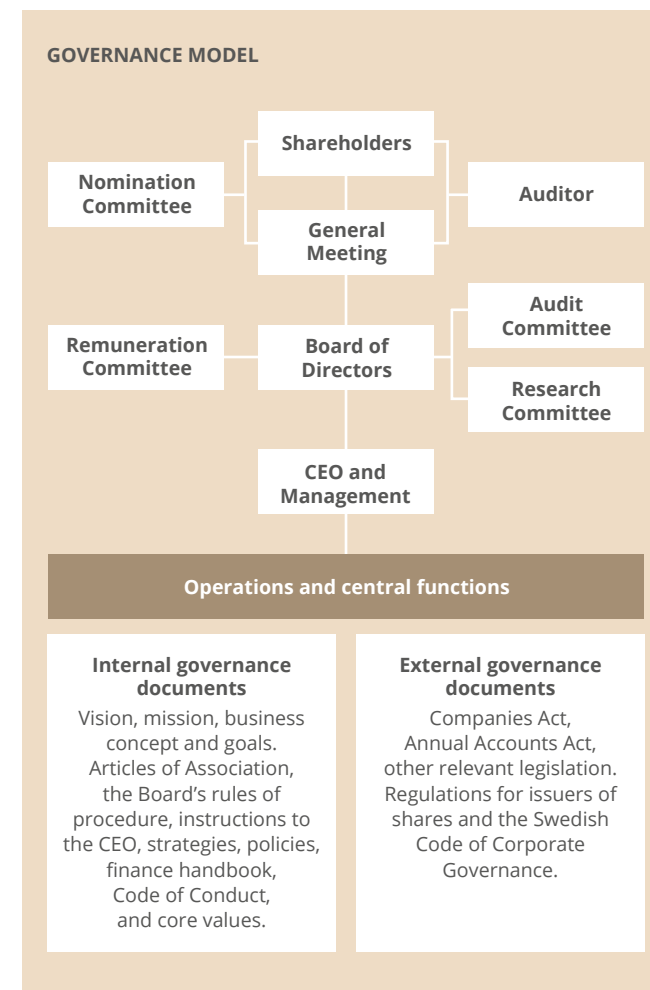
BioArctic applies the Swedish Code of Corporate Governance, and no deviations from the Code occurred during the year. The Company was not subject to any decision of the Nasdaq Stockholm disciplinary board or any statement by the Swedish Securities Council during the year.

### THE GOVERNANCE MODEL

Governance, management and control of BioArctic is exercised by the shareholders through the Annual General Meeting, the Board of Directors, the CEO and the auditors in accordance with the Swedish Companies Act and the Articles of Association.

### SHAREHOLDERS AND SHARES

BioArctic's B share (BIOA B) has been traded in Nasdaq Stockholm since 2017. At December 31, 2022 the share capital in BioArctic amounted to SEK 1,762,631.42 divided into 14,399,996 Class A shares (number of votes: 10) and 73,731,575 Class B shares (number of votes: 1), each with a quotient value of SEK 0.02. The number of shares in the company increased by 71,586 during the fourth quarter of 2022 as a result of subscription of shares by participants in the 2019/2028 employee stock option program. According to ownership data from Monitor by Modular Finance, the



number of shareholders at year-end was 14,840 (9,816) and the ten largest shareholders owned 90.2 percent of the votes and 75.7 percent of the capital in the company. Provided that the attendees of the Annual General Meeting have registered in the prescribed order, each owner will have the right at the AGM to vote for all owned, directly registered, and represented shares.

There are no provisions in BioArctic's Articles of Association that limit the right to transfer shares or how many votes each shareholder can cast at a general meeting.

For further information on BioArctic's share and ownership structure, see the BioArctic share section on pages 122-124 or visit [www.bioarctic.com](http://www.bioarctic.com).

#### GENERAL MEETING

The General Meeting is BioArctic's highest decision-making body, where the stakeholders have the right to pass resolutions on issues affecting the company. The Annual General Meeting

(AGM) is held on a yearly basis, six months after the end of the financial year. At the AGM, the balance sheet and income statement are presented, as well as the consolidated balance sheet and income statement, and resolutions are passed on such matters as appropriation of the Company's earnings, election of Board members and fees to Board members and auditors, and other matters submitted to the AGM in accordance with the law.

The Articles of Association do not contain any specific provisions relating to the amending of the Articles of Association.

#### 2022 Annual General Meeting

The AGM of BioArctic was held on May 5, 2022. Due to the coronavirus pandemic, the AGM was held via a postal voting procedure, which meant that the shareholders did not physically attend the meeting. At the meeting, 66,337,793 votes – corresponding to 75.3 percent of the number of votes in the company – were represented via the voting procedure. The

#### Resolutions at the 2022 AGM included:

- that no dividend would be paid for the 2021 financial year, and that profits at the disposal of the General Meeting would be carried forward
- the discharge of the Board members and CEO from liability for the 2021 financial year
- the re-election of Board members Wenche Rolfsen (chairman), Ivar Verner (deputy chairman), Håkan Englund, Pär Gellerfors, Lars Lannfelt, Lotta Ljungqvist, Mikael Smedeby, and Eugen Steiner
- that total fees determined yearly, including fees for committee work, of SEK 2,660,000 are to be paid to the Board
- the appointment of Grant Thornton Sweden AB as the auditing company, with Mia Rutenius as auditor in charge
- the passing of a resolution on the process for establishing a Nomination Committee and guidelines for the Committee's work
- the passing of a resolution on approval of the remuneration report pertaining to the 2021 financial year
- the passing of a resolution on guidelines for remuneration to senior executives
- the passing of a resolution on authorization for share issues
- the passing of a resolution on the adoption of new Articles of Association

The complete minutes are available on BioArctic's web site.



minutes and other documentation from the General Meeting are available on BioArctic's website, [www.bioarctic.com](http://www.bioarctic.com).

### 2023 ANNUAL GENERAL MEETING

The 2023 AGM will be held on Thursday, June 1, 2023 at Lindhagen Konferens in Stockholm, Sweden. Shareholders registered in the share register maintained by Euroclear Sweden as of May 24, 2023 and who have registered in accordance with the instructions in the notice to attend the AGM will have the right to attend the meeting.

### NOMINATION COMMITTEE

The task of the Nomination Committee is to ensure that the members of the Board of Directors of BioArctic jointly possess the knowledge and experience that are relevant for enabling the satisfactory performance of the company over time. The Nomination Committee presents a proposal to the AGM regarding the number of Board members and the composition of the Board as well as proposals regarding fees to the

Board of Directors, including fees for committee work. The Nomination Committee will also present a proposal concerning the Chairman of the Board and the AGM, as well as the auditors and their remuneration. Under the Code, the Nomination Committee must have at least three members, a majority of which must be independent in relation to the company and Group Management. The basis for the activities of the Committee consists of the annual assessment of the activities of the Board, as well as the company-specific needs in BioArctic. The proposals of the Nomination Committee are presented in the notice to attend the AGM, and a justification for the Nomination Committee's proposals is published on BioArctic's website. All shareholders have the right to present proposals to the Nomination Committee via e-mail to [arsstamma@bioarctic.se](mailto:arsstamma@bioarctic.se).

According to the resolution at the AGM of BioArctic on May 5, 2022, the members of the Nomination Committee for the 2023 AGM shall be appointed ahead of the AGM by Chairman of the Board contacting the three largest shareholders in terms of voting rights according to Euroclear Sweden AB's transcription of the share register as of September 30, 2022 and asking each of them to appoint a member of the Nomination Committee. In the event that any of the three largest shareholders does not wish to appoint a member of the Nomination Committee, further shareholders should be contacted until the Nomination Committee consists of three members.

### The Nomination Committee prior to the 2023 Annual General Meeting

A Nomination Committee was appointed in October 2022. The owners who are included on the Nomination Committee based on the company's ownership structure as of September 30, 2022 are Demban AB, Ackelsta AB and the Fourth AP Fund. The company's Chairman of the Board, Wenche Rolfsen, has been co-opted onto the Nomination Committee. All members have been deemed independent in relation to the company and Group Management. The Nomination Committee has held 2 (2) meetings as well as informal contacts

up until the time for the AGM. No remuneration has been paid for the activities of the Nomination Committee.

### Composition of the Nomination Committee

Name	Representing	Share of votes as of 30 Sep 2022, %
Margareta Öhrvall	Demban AB	50.1
Claes Andersson	Ackelsta AB	33.4
Jannis Kitsakis	The Fourth AP Fund	1.9

### BOARD OF DIRECTORS

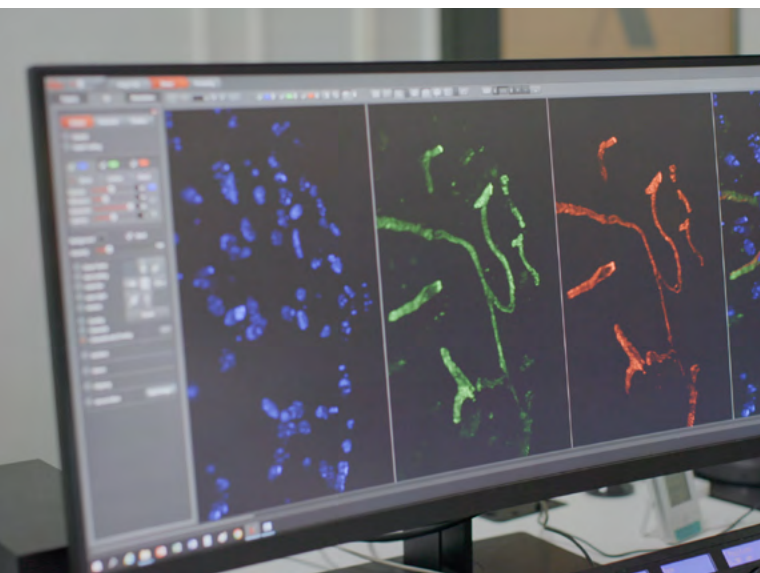
#### Tasks and responsibilities of the Board

The Board of Directors is BioArctic's second highest decision-making body after the General Meeting. The Board has overall responsibility for the suitability of the company's organization, and that operations are carried out in accordance with the Articles of Association, the Companies Act, and other applicable laws and regulations. The Board endeavors to create long-term value for shareholders and other stakeholders, and is responsible together with company management for the overall strategy as well as the company's financing and financial position, and works to ensure the Company has proper risk management and internal control. The tasks of the Board also include issues of reporting, audits, and remuneration.

#### Composition of the Board

Under BioArctic's Articles of Association, the Board shall consist of no less than three and no more than eight ordinary members elected by the General Meeting, with no deputies. The members, who are normally elected annually at the AGM for the period until the close of the next AGM, must provide competence and experience that benefit BioArctic's performance. The Articles of Association do not contain any specific provisions relating to the appointment or dismissal of Board members.

At present, the Board consists of eight regular members with no deputies. All members were re-elected at the AGM on



May 5, 2022. CEO Gunilla Osswald and CFO Jan Mattsson are present at all Board meetings. Jan Mattsson serves as the secretary of the Board. Other senior executives participate as rapporteurs in connection with particular issues. For a summary and presentation of the Board members, see pages 117-118.

### Independence of the Board

Seven of the eight Board members are independent in relation to both the company and its management, and six of the eight Board members are independent in relation to the major shareholders. The company's two founders, Lars Lannfelt and Pär Gellerfors, who are also Board members and primary owners, cannot be considered independent in relation to major shareholders. Lars Lannfelt is employed by the company and is part of the company's management group, and therefore cannot be considered independent in relation to the company and to management. Pär Gellerfors has provided support around contractual issues and patents via Ackelsta AB. Ackelsta AB submitted invoices during the year totaling MSEK 0.1 (0.1) for

### Composition of the Board

Name	Elected	Independent in relation to company and management	Independent in relation to major shareholders	Audit Committee	Remuneration Committee	Board of Directors	Audit Committee	Remuneration Committee
Wenche Rolfsen	2016	Yes	Yes	—	Yes <sup>1</sup>	16/16	—	3/5
Ivar Verner	2010	Yes	Yes	Yes	—	16/16	4/4	—
Håkan Englund	2020	Yes	Yes	—	—	16/16	—	—
Pär Gellerfors	2003	Yes	No	—	Yes <sup>2</sup>	15/16	—	2/5
Lars Lannfelt	2003	No	No	—	—	15/16	—	—
Lotta Ljungqvist	2021	Yes	Yes	—	Yes <sup>3</sup>	15/16	—	5/5
Mikael Smedeby	2018	Yes	Yes	Yes	—	16/16	4/4	—
Eugen Steiner	2017	Yes	Yes	Yes	Yes	16/16	4/4	5/5

1) Resigned from the Committee on August 31, 2022

2) Succeeded Lotta Ljungqvist as member on August 31, 2022

3) Succeeded Wenche Rolfsen as Chairman on August 31, 2022

market-based remuneration of consultant services. BioArctic herewith meets the requirements from Nasdaq Stockholm and the Code regarding the independence of Board members.

### Board activities

The Board will carry out its activities jointly, under leadership of the Chairman. The Board of Directors' rules of procedure are revised annually and adopted at the inaugural Board meeting every year. The rules of procedure govern such aspects as Board functions, work tasks, the decision-making procedure within the company, the Board's meeting agenda, the Chairman's duties and the allocation of responsibilities between the Board and the CEO. The Board also establishes instructions for the Board's committees and the CEO. The Chairman, who is selected by the AGM, has an expanded responsibility for governing and managing the work of the Board and of ensuring that the Board's work is efficiently carried out, that the Board fulfills its commitments in accordance with the Companies Act and the Board's rules of procedure, and that the decisions of the Board are implemented in an

efficient manner. The Chairman is also responsible for conducting an annual Board evaluation, which is also presented to the Nomination Committee.

The Board meets according to a meeting schedule that is established yearly. At each regular Board meeting, an update on the operations and a financial follow-up is given. During the year, matters relating to the company's strategy and future potential opportunities to sell on the Nordic market, as well as the formation of a sales and marketing organization, were also discussed. Development of the company's project portfolio, collaboration with current and potential partners, the organization, financing issues, and competence needs were also addressed.

In 2022, the Board held 16 (15) meetings, one of which was an inaugural meeting in connection with the AGM on May 5, 2022. The minutes taken at these meetings record decisions that have been taken.

### Remuneration to the Board

Fees and other remuneration to the Board members are established at the AGM. At the AGM on May 5, 2022, it was resolved that the total fees to Board members, including committee work, would remain unchanged at SEK 2,660,000 and allocated as follows:

- Fees to Chairman of the Board Wenche Rolfsen totaling SEK 750,000 and fees to Deputy Chairman Ivar Verner totaling SEK 300,000
- For regular Board members not employed by the company (i.e. five members excluding Lars Lannfelt) fees totaling SEK 250,000 each
- Fees in the Audit Committee totaling SEK 100,000 to the Chairman and SEK 60,000 to the other non-executive committee members
- Fees in the Remuneration Committee totaling SEK 60,000 to the Chairman and SEK 40,000 to the other non-executive committee members
- No fees are paid to the Research Committee



## AUDIT COMMITTEE

The primary task of the Audit Committee is to support the Board in its work of fulfilling its financial reporting responsibilities including accounting, audits, internal control, internal audits and risk management. The Audit Committee also routinely ensures contact with the Company's auditor and stays informed and active in decisions concerning financial issues, risks, the company's annual report, quarterly reports and internal control.

The Audit Committee works in accordance with instructions established by the Board of Directors. The company's auditor reports on the orientation and scope of the audit, as well as its views on the company's risks, in the committee meetings. The tasks of the Audit Committee also include establishing guidelines for which services, other than the audit, the company can procure from the company's auditor. All meetings of the Audit Committee are minuted and the minutes are reported in connection with the meetings of the Board.

### *Audit Committee members, 2022–2023*

- Ivar Verner (Chairman)
- Mikael Smedeby (member)
- Eugen Steiner (member)

The Audit Committee met 4 (5) times. The company's auditor participated in two of these meetings.

## REMUNERATION COMMITTEE

The primary task of the Remuneration Committee is to submit proposals to the Board regarding remuneration to the CEO and principles of remuneration and other conditions of employment for management as well as monitoring and evaluating variable remuneration and long-term incentive programs. The Remuneration Committee will monitor and assess application of the guidelines for remuneration to senior executives that the AGM resolved on. The Remuneration Committee works in accordance with a formal work plan established by the Board

of Directors. All meetings of the Remuneration Committee are minuted and the minutes are reported to the Board.

### *Remuneration Committee members, 2022–2023*

- Lotta Ljungqvist (succeeded Wenche Rolfsen as Chairman on August 31, 2022)
- Pär Gellerfors (member) (succeeded Lotta Ljungqvist as member on August 31, 2022)
- Eugen Steiner (member)

The Remuneration Committee met 5 (3) times.

## RESEARCH COMMITTEE

BioArctic's operations have a scientific focus, with drug projects in both early and late phases. The company has a Research Committee that focuses on addressing scientific issues. The Research Committee works according to rules of procedure adopted by the Board and has an advisory capacity in relation to the Board and the CEO. The Research Committee has one ordinary member, with BioArctic's Chief Science Officer (Christer Möller) and Distinguished Scientist Per-Ola Freskgård as co-opted members. In addition, internal and external researchers take part depending on the area being discussed. The role of the Research Committee is primarily to identify and evaluate research areas and disease indications where BioArctic can develop commercially successful products.

### *Research Committee members, 2022–2023*

- Lars Lannfelt (Chairman)

The Research Committee met 8 (8) times.

## AUDITORS

The auditor is appointed by the AGM in accordance with proposals from the Nomination Committee. The auditor is to review BioArctic's annual report and financial statements, as well as the administration of the company. After each financial year, the auditor will submit an Auditor's Report

and a Group Auditor's Report to the AGM. The external audit of the financial statements is to be carried out in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. The company's auditor, Grant Thornton Sweden AB, was first elected at the 2016 Annual General Meeting. The current mandate is for the period up until the end of the 2023 Annual General Meeting, and Mia Rutenius is the auditor in charge. An authorized public accountant, Mia Rutenius is a member of FAR, the association of Swedish professional accountants. Grant Thornton Sweden AB may be responsible for the audit until 2027, or until 2037 if a new procurement is carried out after ten years, before a new auditor is chosen in accordance with the rules in force. Authorized public accountant Mia Rutenius can be the auditor in charge until the 2024 AGM, when in accordance with regulations she will need to rotate her assignments. In addition to the assignment in BioArctic, Mia Rutenius is auditor in charge for among others PION Group AB och Infrea AB. For information on remuneration to auditors, refer to Note 8 in the 2022 Annual Report.

## CEO AND MANAGEMENT GROUP

The Management Group of BioArctic consists of the CEO and nine other individuals, six of whom are men and four women. Management meets twice a month for discussion and decisions concerning the ongoing operations, and hold at least one strategy meeting annually. The members of the Management Group develop the annual business plan, which the Board decides on at the end of the year, and prepare material in their respective areas that is presented to the Board.

For a summary and presentation of the Management Group, see pages 119-120.

## GUIDELINES FOR REMUNERATION TO SENIOR EXECUTIVES

Updated guidelines for remuneration to senior executives were adopted at the AGM on May 5, 2022 and are valid up until the 2026 AGM. One change to the previously adopted guidelines

was made in order to adjust the guidelines to BioArctic's existing and future milestone-related rewards program.

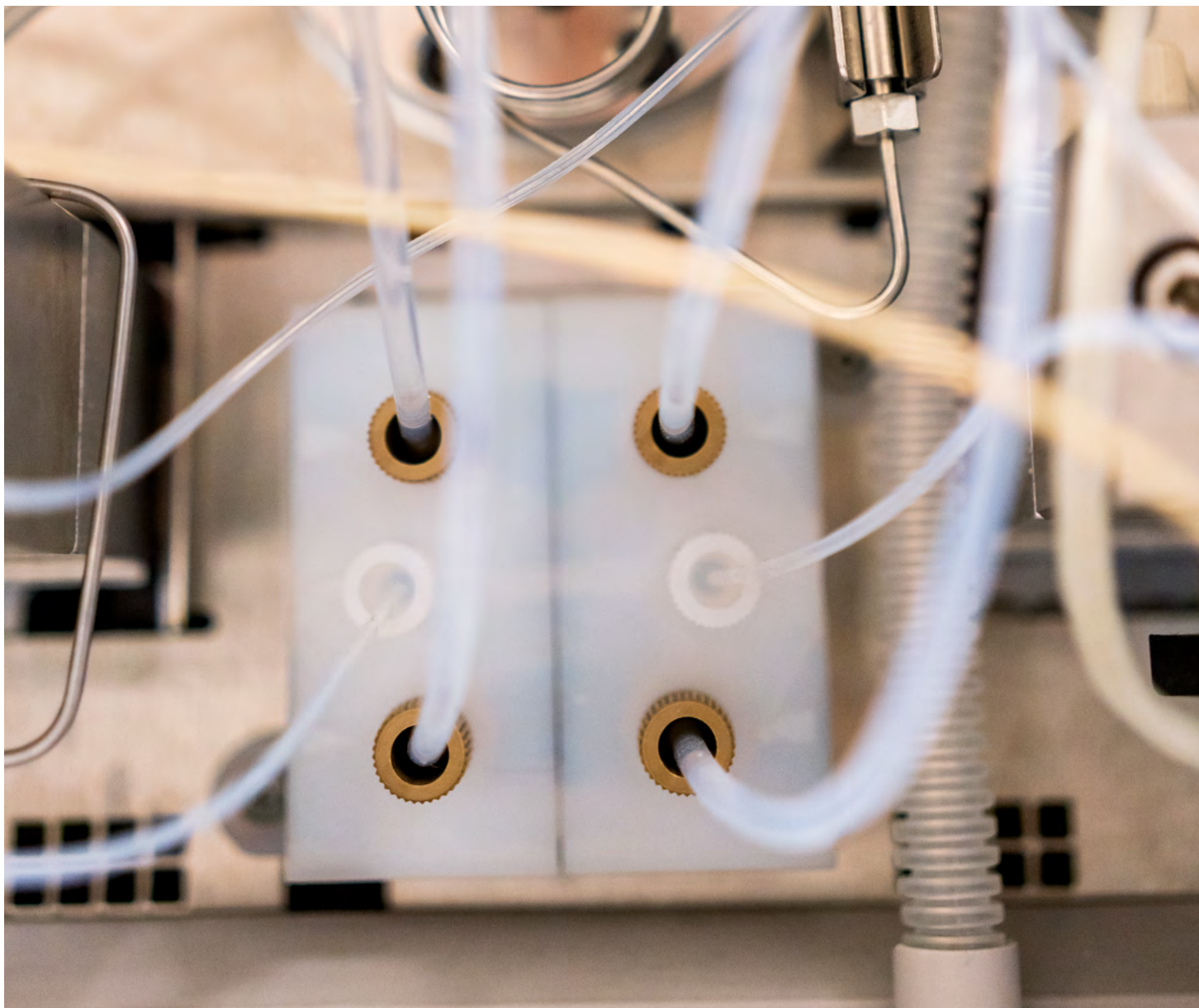
The guidelines cover the CEO as well as the members of company management. The guidelines do not cover remuneration that is to be resolved on by the General Meeting (e.g., fees to Board members or share-based incentive programs). The guidelines will be applied to remuneration that is agreed on – and to changes made to remuneration that was previously agreed on – after the guidelines were adopted by the 2022 AGM. The guidelines also cover remuneration paid out under BioArctic's existing milestone-related incentive programs in accordance with resolutions by the General Meeting. The guidelines govern the decisions on remuneration that are taken by the Remuneration Committee and Board of Directors.

BioArctic's remuneration system must be market-based and competitive. Remuneration can be paid out in the form of fixed salary, variable remuneration, pensions and other benefits. Fixed salary will be individual for each executive and based on the executive's position, responsibility, competence, experience and performance. Variable remuneration will be related to the outcome of BioArctic's goals and strategies and based on pre-defined and measurable criteria designed to promote long-term value creation. The share of total remuneration that comprises variable remuneration may vary depending on position. Short-term variable remuneration is expensed during the financial year and paid out after the AGM has adopted the income statement and balance sheet. The guidelines that were resolved on by the 2022 AGM have been complied with, and all previously decided remuneration that has not yet been paid out is within the framework indicated above.

For the complete guidelines as resolved, refer to Note 7 on pages 84-89.

#### BOARD PROPOSALS FOR NEW GUIDELINES FOR REMUNERATION TO GROUP MANAGEMENT

No changes to the policies for remuneration and other terms of employment for Group Management have been proposed ahead of the 2023 AGM.



# The report of the Board on internal control regarding financial reporting

The objective of internal control is to identify, assess, and manage BioArctic's risks. Using effective risk management, the work can concentrate on the areas that are most important for reducing the Company's total risk exposure.

In accordance with the Companies Act and the Swedish Code of Corporate Governance (the Code), the Board is responsible for the company having well-designed control and functional procedures so that the company's financial reporting, administration and operation are monitored and controlled in a satisfactory manner. The report has been prepared in accordance with the Annual Accounts Act and the Code.

The CEO of BioArctic is ultimately responsible for monitoring whether the work on the company's internal control is being carried out in accordance with the form decided on by the Board of Directors. BioArctic's work on internal control pertaining to financial reporting is led by the CFO. The overall

purpose of the internal control is to ensure, to a reasonable degree, that the company's operating strategies, targets and defined risks are monitored and that the owners' investments are protected. Furthermore, the internal control shall ensure, with reasonable certainty, that external financial reporting is reliable and prepared in accordance with accepted accounting practices in Sweden, that applicable laws and regulations are followed, and that the requirements that are set on listed companies are complied with.

## Framework for internal control

Internal control at BioArctic is based on the Committee of Sponsoring Organizations of the Threadway Commission (COSO) model, the framework of which has been applied to the company's operations and conditions. The framework comprises five components:

- control environment
- risk assessment
- control activities
- information and communication
- monitoring

## Control environment

The control environment constitutes the basis for internal control concerning financial reporting. Clearly defining and

communicating the company's decision-making paths, authority and responsibility in the organization, as well as making governing documents in the form of policies, instructions and manuals available, is important.

The Board of Directors of BioArctic has established a work procedure and rules of procedure for its work and the Board's committee activities. For monitoring and quality assurance of the financial reporting, the Board has inaugurated an Audit Committee. To create a foundation for proper internal control and to maintain a high standard in the company, the Board has adopted a number of fundamental governing documents including rules of procedure for the Board and the CEO, instructions for financial reporting, a finance policy, a Code of Conduct, and an information policy.

In addition to the above-described internal control pertaining to financial reporting, there is also internal, operation-specific control of data regarding research and development and quality control systems, including systematic monitoring and evaluation of the company's research and manufacturing work and products.

## Risk assessment

BioArctic continually evaluates the risks that could lead to errors in the financial reporting in order to ensure proactive management of these risks and proper internal control over risk-taking.



*The report of the Board on internal control regarding financial reporting, cont.*

The Board's Audit Committee takes decisions in which risks are essential to monitor in order to ensure proper internal control in financial reporting. This is done by identifying key procedures in financial administration, project reporting, and company-wide areas, and defining controls for these.

In addition, the Audit Committee conducts an annual risk analysis pertaining to operational and strategic risks. For a more detailed description of risks and risk management, refer to pages 49-52.

#### Control activities

The Company's organization and procedures are designed to manage the risks that the Board deems to be essential for internal control of financial reporting. At BioArctic, the company's control structure consists of an organization with clear roles that facilitate an efficient and suitable allocation of responsibilities as well as specific control activities designed to detect, manage, and proactively prevent risks of errors in the reporting.

Examples of control activities can include decision-making processes in connection with important decisions or investments, as well as routine monitoring and procedures as regards earnings analyses, payments, VAT and tax accounting, spot checks, and reconciliation. The items and key procedures that are linked to the risks identified are routinely subjected to tests by external consultant, who also review the design of the internal controls with regard to quality and efficiency. The results of the tests are reported to the Audit Committee, where they are prepared for presentation to the Board.

#### Information and communication

All of BioArctic's governing documents such as policies, instructions, and procedural descriptions are communicated and are available via a validated electronic document

management system. The finance handbook comprises a governing document that contains guidelines and procedural descriptions for the routine work in the finance department. The finance handbook is routinely updated based on changes to both internal and external requirements. For communication with internal and external parties, there is an information policy that contains guidelines for disseminating information pertaining to internal and external reporting of financial information. The purpose of the policy is to ensure that BioArctic complies correctly and completely with all its disclosure obligations.

#### Monitoring

The internal control work constitutes support for the Board, the Audit Committee and senior management in their work on assessing and evaluating material areas of risk in financial reporting in order to subsequently select suitable initiatives and follow-up actions to ensure reliable financial reporting.

#### Areas of focus during the year

The activities that strengthened internal control during the year include:

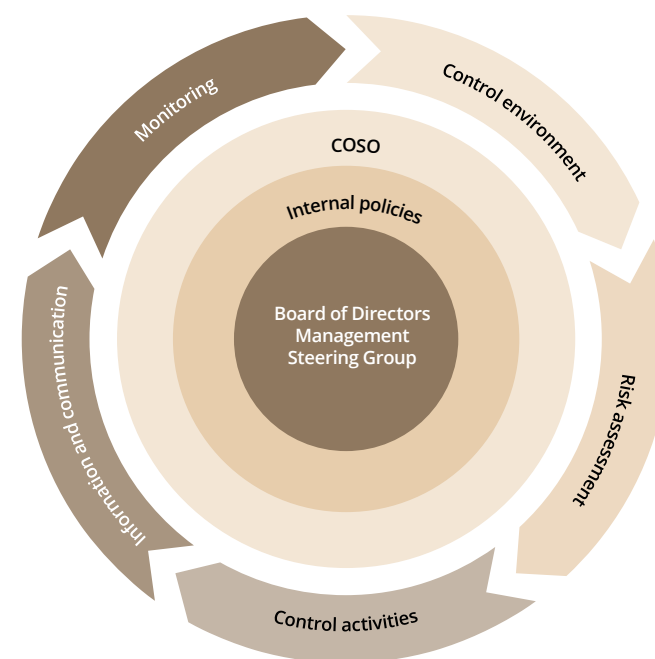
- external reviews of internal controls
- external penetration tests of the company's IT environment
- reviews and updates of BioArctic's internal control descriptions, with regard to quality and efficiency
- annual update of selected governing documents
- preparation of additional procedural descriptions and instructions for the purchasing process

Stockholm, April 26, 2023

*Board of Directors of BioArctic AB*

#### Evaluation of specific review function

BioArctic does not have a specific review function, meaning an internal audit function. BioArctic has a review function performed by an external party that is appointed by the Board. It is the opinion of the Audit Committee and of the Board of Directors that monitoring, documentation, and review of the company's internal control through an external review function fulfills the role of a specific review function.



# Board of Directors



## Wenche Rolfsen

*Chairman*

**Born:** 1952

**Other assignments:** Chairman of InDex Pharmaceuticals Holding AB. Board member of InDex Diagnostics AB; CEO and board member of Rolfsen Consulting AB. Partner in Serendipity Partners.

**Education:** Pharmacist, Doctor of Pharmacy (pharmacognosy), Adjunct Professor at Uppsala University, Sweden.

**Experience and prior assignments:** Head of pharmacology at Pharmacia & Upjohn; VP clinical trials Quintiles Europe, CEO of Quintiles Scandinavia. Chairman of Aprea Therapeutics AB, Denator AB and Aprea Personal AB. Board member of Swedish Match AB, Swedish Orphan Biovitrum AB (SOBI), Recipharm AB, Smartfish AB, Moberg Pharma AB, Apotek Produktion & Laboratorier AB and Stiftelsen Industrifonden.

**Member since:** 2016  
Independent in relation to the company and management, and to major shareholders in the company.

**Total holdings\* in BioArctic:** 36,675 Class B shares.



## Ivar Verner

*Deputy Chairman and Board member*

**Born:** 1947

**Other assignments:** Chairman of Erlandsons Brygga AB, Craft Software Holding AB and Valsattra Exploaterings AB. Board member of Sehlhall Fastigheter AB.

**Education:** Master of Business Administration, Stockholm School of Economics, Sweden.

**Experience and prior assignments:** Chairman of Rejlers AB, Centrum Fastigheter i Norrtälje AB, Tegnér och Son AB, Welcome Hotel i Sverige AB and Grant Thornton Sweden AB. Board member of Forex Bank AB and Svenska Vårdfastigheter AB.

**Member since:** 2010

**Committee membership:** Chairman of the Audit Committee. Independent in relation to the company and management, and to major shareholders in the company.

**Total holdings\* in BioArctic:** 113,770 B shares, privately and through Förvaltningsaktiebolaget Kanalen.



## Håkan Englund

*Board member*

**Born:** 1952

**Other assignments:** Chairman of the board of SecureAppbox AB. Board member of Antrad Medical AB and Prostatype Genomics AB. Owner and CEO of JDS Invest AB, which conducts consultancy operations and invests in listed and unlisted companies.

**Education:** Various courses at Uppsala University in economics and chemistry. Courses in polymer technology at KTH Royal Institute of Technology in Stockholm.

**Experience and prior assignments:** Various executive positions including positions in commercialization at Pharmacia Biotech AB and Phadia AB. More than 30 years of experience in the industry. Former board member of Apoteks-Samariten AB, Olink AB, Sensidose AB, Immuneed AB and Arocell AB.

**Member since:** 2020

Independent in relation to the company and management, and to major shareholders in the company.

**Total holdings\* in BioArctic:** 0 Class B shares.



## Pär Gellerfors

*Board member*

**Born:** 1947

**Other assignments:** Founder and CEO of MPG Medical AB. Board member of Ackelsta AB and LPB Sweden AB.

**Education:** Bachelor degree in chemistry; PhD in chemistry; Associate Professor of Biochemistry. All at Stockholm University, Sweden.

**Experience and prior assignments:** Founder of BioArctic in 2003, former CEO of the company. CEO and board member of Swenora Biotech AB; founder and research director at Zymenex AS; founder and board member of LPB Sweden Holding AB; board member of Sigrid AB.

**Member since:** 2003

**Committee membership:** Remuneration Committee

Independent in relation to the company and company management. Not independent in relation to major shareholders in the company.

**Total holdings\* in BioArctic:** 5,759,988 Class A shares through Ackelsta AB. 13,343,201 Class B shares through Ackelsta AB.

\* Includes holdings by self, closely associated persons, controlled companies or in capital insurance accounts as per March, 31, 2023.

Board of Directors, cont.



### Lars Lannfelt

Board member

**Born:** 1949

**Other assignments:** Board member of Demban AB and LPB Sweden AB.

**Education:** Medical degree (specialist in psychiatry) and doctoral thesis at Karolinska Institutet, Stockholm, Sweden; Associate Professor of Neurogenetics at Karolinska Institutet, specialist in geriatrics.

**Experience and prior assignments:** More than 35 years of experience in research into Alzheimer's disease and other neurodegenerative diseases. Professor of Geriatrics at Uppsala University; member of the Royal Swedish Academy of Sciences. Founder of BioArctic in 2003, Chairman of the Board and a number of assignments and roles in the company.

**Member since:** 2003

Not independent in relation to the company and management, and to major shareholders in the company.

**Total holdings\* in BioArctic:** 8,639,998 Class A shares through Demban AB. 20,885,052 Class B shares through Demban AB.



### Lotta Ljungqvist

Board member

**Born:** 1961

**Other assignments:** Board member of Atlas Antibodies AB, Genovis AB, Arocell AB, NorthXBiologics AB, and BioLamina AB. Chairman of the Royal Swedish Academy of Engineering's (IVA) Division X, Biotechnology, and chairman of SwedenBio.

**Education:** Degree in biochemistry from KTH Royal Institute of Technology in Stockholm, Sweden. Doctorate in biochemical technology.

**Experience and prior assignments:** CEO of Testa Center, Cytiva (formerly GE Healthcare Life Sciences). Executive roles as CEO, head of business area, head of research and project manager for biopharma projects at GE Healthcare Life Sciences, Biovitrum and Pharmacia.

**Member since:** 2021

**Committee membership:** Chairman of the Remuneration Committee. Independent in relation to the company and management, and to major shareholders in the company.

**Total holdings\* in BioArctic:** 3,159 Class B shares.



### Mikael Smedeby

Board member

**Born:** 1968

**Other assignments:** Lawyer and partner at Advokatfirman Lindahl. Chairman of the board of Coeli Holding AB (including subsidiaries) and Sälléngruppen AB (including subsidiaries). Board member of Rarity Bioscience AB. Sirius Fotboll and Smedeby Forvaltning AB.

**Education:** Master of Laws, Uppsala University, Sweden. Reserve officer training at the Swedish Infantry Officers' College and the Swedish Infantry Combat School.

**Experience and prior assignments:** Special experience in corporate law, mergers and acquisitions, financing and licensing. Held executive positions at Advokatfirman Lindahl 2010–2019, including Managing Partner and chairman of the board. Member of the Board of Directors of BioArctic, 2014–2017.

**Member since:** 2018

**Committee membership:** Audit Committee. Independent in relation to the company and management, and to major shareholders in the company.

**Total holdings\* in BioArctic:** 27,270 Class B shares.



### Eugen Steiner

Board member

**Born:** 1954

**Other assignments:** Chairman of the board of Spago Nanomedical AB and Empros Pharma AB. Board member of A3P Biomedical AB, Inbox Capital AB, Epiendo Pharmaceuticals ehf, and Stockholm School of Entrepreneurship. Venture partner in HealthCap.

**Education:** Karolinska Institutet (licensed physician, Doctor of Clinical Pharmacology).

**Experience and prior assignments:** CEO or acting chairman of the board in several life science companies in Sweden, Norway, the UK and the US for more than 35 years. Member of Royal Swedish Academy of Engineering (IVA) and deputy chairman of its Division X, Biotechnology.

**Member since:** 2017

**Committee membership:** Audit Committee and Remuneration Committee. Independent in relation to the company and management, and to major shareholders in the company.

**Total holdings\* in BioArctic:** 75,000 Class B shares.

\* Includes holdings by self, closely associated persons, controlled companies or in capital insurance accounts as per March, 31, 2023.

# Management



**Gunilla Osswald**

*President and CEO of BioArctic AB*

**Born:** 1961

**Employed since:** 2013

**Other assignments:** Board member of Egetis Therapeutics AB.

**Education:** Pharmacist; Ph.D. in biopharmacy and pharmacokinetics at Uppsala University, Sweden.

**Experience and prior assignments:** More than 35 years of experience in drug development. Executive positions at Astra/AstraZeneca, including Vice President responsible for the product portfolio in neurodegenerative diseases. Board member of SP Process Development AB.

**Member of BioArctic Group Management since:** 2013

**Total holdings\* and warrants in BioArctic:** 75,070 Class B shares. Warrants granting acquisition rights to 150,000 Class B shares (2019/2028 program).



**Gunilla Andersson**

*Vice President HR.*

**Born:** 1961

**Employed since:** 2019 (contracted since 2014).

**Other assignments:** Manages her own consulting firm in HR.

**Education:** B.Sc. Human Resource Development and Labor Relations with a specialization in labor rights from Lund University, Sweden.

**Experience and prior assignments:** Over 30 years of experience as HR consultant and HR manager in educational organizations and pharma companies such as Pharmacia and Novartis.

**Member of BioArctic Group Management since:** 2019

**Total holdings\* and warrants in BioArctic:** 0 shares. Warrants granting acquisition rights to 20,000 Class B shares (2019/2028 program).



**Oskar Bosson**

*Vice President Investor Relations & Communications*

**Born:** 1976

**Employed since:** 2020

**Other assignments:** —

**Education:** Engineering degree in molecular biotechnics and bachelor's degree in business administration from Uppsala University.

**Experience and prior assignments:** 20 years of experience globally in communications. Has held senior positions in companies such as Sobi, Ovako and Elekta.

**Member of BioArctic Group Management since:** 2020

**Total holdings\* and warrants in BioArctic:** 4,381 Class B shares. Warrants granting acquisition rights to 20,000 Class B shares (2019/2028 program).



**Johanna Fälting**

*Vice President Head of Research*

**Born:** 1972

**Employed since:** 2012

**Other assignments:** —

**Education:** Ph.D. in Physiology, Stockholm University; Licentiate degree in physiology, Stockholm University; Master's degree in biology, Stockholm University, Sweden.

**Experience and prior assignments:** Over 20 years of experience in drug development in executive positions in R&D, and development in the global pharma and biotech industry.

**Member of BioArctic Group Management since:** 2012

**Total holdings\* and warrants in BioArctic:** 41,855 Class B shares. Warrants granting acquisition rights to 15,500 Class B shares (2019/2028 program).



**Anna-Kajia Grönblad**

*Chief Commercial Officer.*

**Born:** 1968

**Employed since:** 2021 (contracted since 2020)

**Other assignments:** —

**Education:** B.Sc. in business administration from Uppsala University.

**Experience and prior assignments:** More than 25 years of experience in leading commercial roles in the global pharmaceutical industry. Previously CEO for Sanofi AB and General Manager, Nordics & Baltics General Medicines.

**Member of BioArctic Group Management since:** 2021

**Total holdings\* and warrants in BioArctic:** 9,300 B shares, privately and through Saimi AB. Warrants granting acquisition rights to 20,000 Class B shares (2019/2028 program).

\* Includes holdings by self, closely associated persons, controlled companies or in capital insurance accounts as per March 31, 2023.

Management, cont.



### Lars Lannfelt

Senior Vice President  
University Collaborations. Founder of BioArctic in 2003.

**Born:** 1949

**Employed since:** 2016

**Other assignments:** Board member of BioArctic AB, Demban AB and LPB Sweden AB.

**Education:** Medical degree (specialist in psychiatry) and doctoral thesis at Karolinska Institutet, Stockholm, Sweden; Associate Professor of Neurogenetics at Karolinska Institutet, specialist in geriatrics.

**Experience and prior assignments:** More than 35 years of experience in research into Alzheimer's disease and other neurodegenerative diseases. Professor of Geriatrics at Uppsala University; member of the Royal Swedish Academy of Sciences. Founder of BioArctic in 2003, Chairman of the Board and a number of assignments and roles in the company.

**Member of BioArctic Group Management since:** 2003

**Total holdings\* and warrants in BioArctic:** 8,639,998 Class A shares through Demban AB. 22,635,052 Class B shares through Demban AB.



### Jan Mattsson

Vice President Finance,  
Chief Financial Officer.

**Born:** 1960

**Employed since:** 2017

**Other assignments:** —

**Education:** MBA from Örebro University.

**Experience and prior assignments:** More than 30 years of experience in business and administration, including as CFO at Sefina Finance AB, Allenex AB, Argnor Wireless Ventures AB, Logitall AB and Investment AB Kinnevik.

**Member of BioArctic Group Management since:** 2017

**Total holdings\* and warrants in BioArctic:** 23,855 Class B shares, privately and through Almsäter Interim Management AB. Warrants granting acquisition rights to 20,000 Class B shares (2019/2028 program).



### Mikael Moge

Vice President Chemistry,  
Manufacturing & Control

**Born:** 1967

**Employed since:** 2012

**Other assignments:** —

**Education:** Master of Chemical Engineering, KTH Royal Institute of Technology; Ph.D. in organic chemistry, KTH; Stockholm, Sweden.

**Experience and prior assignments:** Over 20 years of experience in drug development and 20 years of experience as R&D director in process development and GMP manufacturing. Former section manager in Process R&D at AstraZeneca.

**Member of BioArctic Group Management since:** 2012

**Total holdings\* and warrants in BioArctic:** 9,470 shares Warrants granting acquisition rights to 19,000 Class B shares (2019/2028 program).



### Christer Möller

Vice President Pre-Clinical Development,  
Chief Scientific Officer

**Born:** 1959

**Employed since:** 2006

**Other assignments:** —

**Education:** B.Sc. in Biology, Stockholm University, Sweden; Ph.D. in Medical Science, Karolinska Institutet, Stockholm, Sweden.

**Experience and prior assignments:** Over 20 years of experience in developing protein drugs from idea to clinical trials including leading positions at small biotech/pharma companies such as Zymenex A/S. In addition, comprehensive academic experience from research projects concerning growth factors and preclinical research in diabetes.

**Member of BioArctic Group Management since:** 2006

**Total holdings\* and warrants in BioArctic:** 52,770 Class B shares. Warrants granting acquisition rights to 21,000 Class B shares (2019/2028 program).



### Tomas Odergren

Chief Medical Officer

**Born:** 1959

**Employed since:** 2019 (contracted since 2016)

**Other assignments:** Senior Clinical Consultant, GKeller Consulting.

**Education:** Medical degree and specialist training in neurology, M.D. from Karolinska Institutet; Pharmaceutical Medicine EUCOR/ECPM certified.

**Experience and prior assignments:** Over 25 years of experience in the pharma industry, in leading positions in clinical research at AstraZeneca and H. Lundbeck. Chief Specialist ICR Neurology H Lundbeck A/S (2015–2017).

**Member of BioArctic Group Management since:** 2020

**Total holdings\* and warrants in BioArctic:** 5,700 Class B shares. Warrants granting acquisition rights to 20,000 Class B shares (2019/2028 program).

\* Includes holdings by self, closely associated persons, controlled companies or in capital insurance accounts as per March 31, 2023.



# Auditor's report on the corporate governance statement

*To the general meeting of the shareholders in BioArctic AB (publ), corporate identity number 556601-2679*

## Engagement and responsibility

It is the board of directors who is responsible for the corporate governance statement for the year 2022 on pages 108–120 and that it has been prepared in accordance with the Annual Accounts Act.

## The scope of the audit

Our examination has been conducted in accordance with FAR's standard Rev 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

## Opinions

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Stockholm April 26, 2023

Grant Thornton Sweden AB

Mia Rutenius  
Authorized public accountant  
Auditor in charge

Therese Utengen  
Authorized public accountant

# The share and shareholders

BioArctic's stock market performance during the year has been very strong, and its market capitalization totaled SEK 24 billion at year-end, which means that the share price during the year increased 128 percent. The number of shareholders in the company also increased year-on-year.

## Trading and market value

The BioArctic share has been traded on Nasdaq Stockholm's Large Cap under the symbol BIOA B since January 2023. In 2022, around 102.9 million (37.8) B shares were traded at an aggregate value of roughly SEK 21.3 billion (4.4). The average daily volume during the year totaled MSEK 83.4 (17.5). The

majority of volume in the share – approximately 50 percent – took place on Nasdaq Stockholm. In addition to trading on the Stockholm stock market, approximately 40 percent of trading took place on the Cboe marketplace, 6 percent in the LSE Group, nearly 4 percent, on Aquis and just over 1 percent in other trading venues.

The market value at year-end was SEK 24 billion (10.5).

## Share performance in 2022

BioArctic's share rose sharply during the year, noting an upswing of 128 percent, and the closing price on 30 December was SEK 272. The highest price paid – SEK 342 – was noted on September 29, 2022, and the lowest price – SEK 66.70 – was noted on May 9, 2022.

## The ten largest shareholders as of December 31, 2022

Owner	Number of A shares (10 votes per share)	Number of B shares (1 vote per share)	Share of capital (%)	Share of 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
The Fourth Swedish National Pension Fund	—	3,713,640	4.2	1.7
Swedbank Robur Fonder	—	3,592,454	4.1	1.7
The Third Swedish National Pension Fund	—	3,297,088	3.7	1.5
Handelsbanken Fonder	—	2,263,611	2.6	1.0
Unionen	—	2,200,000	2.5	1.0
Nordea Fonder	—	1,056,394	1.2	0.5
Investment AB Öresund	—	1,000,000	1.1	0.5
SEB Fonder	—	950,301	1.1	0.4
<b>Total</b>	<b>14,399,996</b>	<b>52,301,741</b>	<b>75.7</b>	<b>90.2</b>



### Share capital

The share capital at year-end totaled SEK 1,762,632 spread over 88,131,571 shares, of which 14,399,996 are unlisted A shares and 73,731,575 are listed B shares. The number of shares in the company increased by 71,586 during the fourth quarter of 2022 as a result of subscription of shares by participants in the 2019/2028 employee stock option program. The A share has ten votes per share while the B share has one vote per share. The quotient value per share is SEK 0.02.

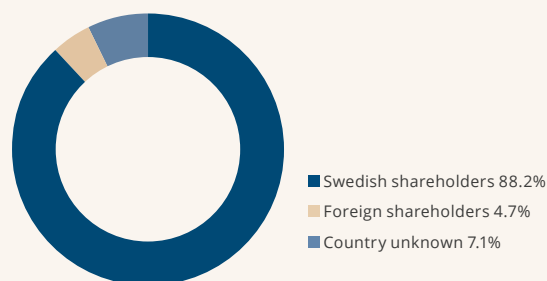
### Ownership structure

At year-end, BioArctic had 14,840 shareholders (9,816). The shareholding in Sweden totaled 88.2 percent of the capital and 95.2 percent of the votes. Of foreign ownership, shareholders in Finland represented 1.2 percent of the capital, shareholders in the US represented 1.0 percent and shareholders in Norway

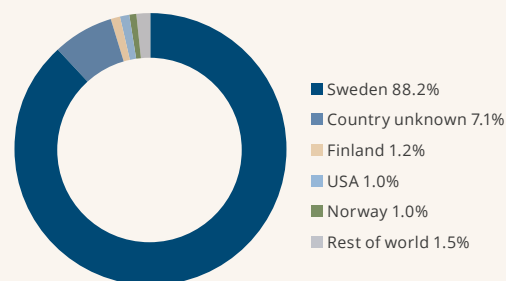
represented 1.0 percent. Owners with unknown geographic domiciles represented 7.1 percent of the capital. The Swedish ownership is dominated by private persons and companies with 67.4 percent of the capital. Funds owned 10.4 percent, and insurance and pension companies owned 8.8 percent of the capital. BioArctic's ten largest shareholders owned shares corresponding to 75.7 percent of the capital and 90.2 percent of the votes. The Board members in the company owned a total of 48,794,523 A shares and B shares (52,365,824) in BioArctic, while company management owned 233,118 B shares (217,041) excluding those owned by Lars Lannfelt, which are counted among Board member shares. In total, the holdings of the Board and management correspond to 55.6 percent (59.8) of shares outstanding. BioArctic's A shares are owned by Demban AB and Ackelsta AB, which are in turn owned by the founders of BioArctic.

BioArctic share data	2022
Number of shares at year-end	88,131,571
Market value at year-end (SEK billion)	24
Price change since listing (%)	584
Number of shareholders	14,840
Share price at year-end (SEK)	272
Year high (SEK)	342
Year low (SEK)	66.70
Share of ownership, capital, 10 largest shareholders (%)	75.7

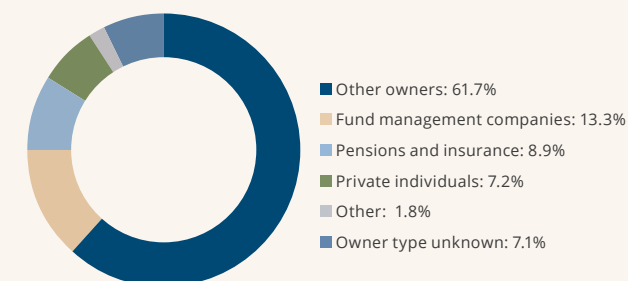
Distribution of Swedish and foreign shareholding at December 31, 2022



Distribution of capital by geography at December 31, 2022



Distribution of capital by ownership category at December 31, 2022



## Share structure at December 31, 2022

Number of shares	Number of share-	A shares	B shares	Shares (%)
1-500	13,349	—	1,122,027	1.3
501-1,000	715	—	580,964	0.7
1,001-5,000	540	—	1,159,689	1.3
5,001-10,000	89	—	650,086	0.7
10,001-50,000	87	—	2,119,549	2.4
50,001-	60	14,399,996	61,792,974	86.5
Size of holding unknown	—	—	6,306,286	7.1
<b>Total, December 31, 2022</b>	<b>14,840</b>	<b>14,399,996</b>	<b>73,731,575</b>	<b>100</b>

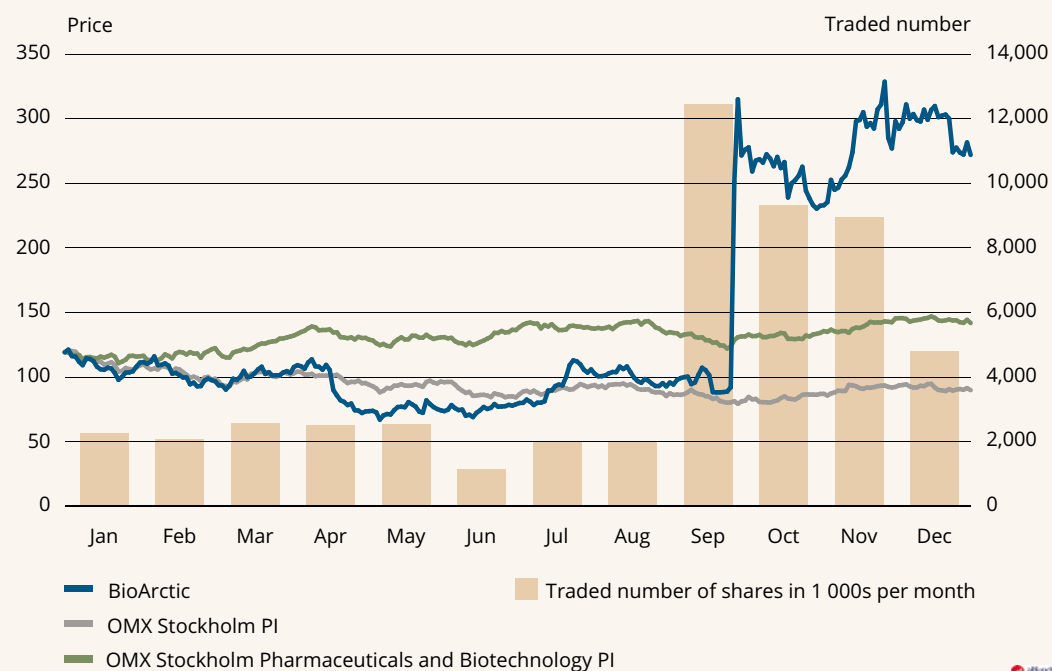
## Dividends and dividend policy

In financial year 2022, BioArctic had no drugs being sold in the market, which meant that the company's revenue and earnings were primarily based on revenue of a non-recurring character from the research and licensing agreements. BioArctic will continue to focus on further developing and expanding the company's project portfolio, which means that available funds and accrued earnings will primarily be reinvested in operations for future initiatives and expansion. It is the intent of the Board not to propose any dividend to shareholders until the company generates long-term sustainable profitability. Any future dividends and the size thereof will be established based on the company's long-term growth, earnings trends and capital requirements, taking into account current goals and strategies. To the extent a dividend is proposed, it will be judged carefully, taking into account the goals, scope and risks of the operations. For the 2023 AGM, the Board has proposed that no dividend be paid out for the 2022 financial year.

## Share-based incentive programs

BioArctic has a long-term incentive program (the 2019/2028 program) in the form of an employee stock option program intended for the company's senior executives, scientists and other staff. The purpose of the incentive program is to encourage broad share ownership among BioArctic's employees, facilitate recruitment, retain skilled employees and increase employee motivation and performance. The program, which is intended for 65 employees in total, includes a total of 1,000,000 warrants. Of these, 845,000 warrants have been awarded. The total number of warrants exercised was 10,000, and the number of options redeemed was 71,586. If the maximum number (i.e. 1,000,000 warrants) are utilized, the dilution will total 1.1 percent of the share capital and 0.5 percent of the voting rights in the company.

Share price trends and volume, BioArctic 2022



# Shareholder information

## BioArctic's web site

BioArctic's web site (bioarctic.se) provides information for investors and other stakeholders who want to expand their knowledge of the company's operation. The web site contains information on the company's operation, vision, mission, business concept, and project portfolio as well as a description of strategy and how BioArctic collaborates with partners. The web site also contains financial information, historical press releases, information on corporate governance, Group management, and the Board of Directors as well as the company's sustainability initiatives. In addition, there is information on the performance of BioArctic's share over time as well as information on the owners of the shares. Furthermore, there is information on the Annual General Meeting as well as a service that makes it possible to subscribe to press releases and financial reports via e-mail.

## Financial information

BioArctic's financial reports – such as quarterly reports and annual reports – are available on the company's web site. The web site also contains an archive of financial reports since 2017, when BioArctic was listed on Nasdaq Stockholm. The financial reports are distributed in digital form only via the web site. Those wishing to do so can choose to subscribe to the financial reports via e-mail using the subscription service found on the web site. In conjunction with its interim reports and year-end reports, BioArctic hosts a teleconference in English where news and results are presented.

## Communication and activities in Investor Relations

In order to increase knowledge of BioArctic's operation, the information that the company disseminates to shareholders,

## Financial calendar

April 26, 2023	Interim Report January–March
June 1, 2023	2023 Annual General Meeting
July 12, 2023	Interim Report April–June
November 8, 2023	Interim Report July – September
February 7, 2024	Year-end Report 2023

investors, and analysts must be open, relevant, and correct.

Investor Relations provides the capital market, investors, shareholders and other stakeholders with relevant information in accordance with applicable legislation, Nasdaq Stockholm regulations, the Swedish Code of Corporate Governance, and BioArctic's information policy. In conjunction with the communication of its quarterly interim reports, BioArctic presents the company and its financial development and hosts teleconferences. Additionally, important events that occur in the company are published through the distribution of press releases. BioArctic endeavors to maintain a high level of accessibility for existing shareholders, potential shareholders, analysts, media, and other stakeholders. The company participates in industry-specific conferences and seminars, and holds regular meetings with investors and analysts.

## Analysts who monitor BioArctic

Carnegie	Erik Hultgård
DNB	Patrik Ling
Nordea	Viktor Sundberg
Redeye	Fredrik Thor
Royal Bank of Canada (RBC)	Zoe Karamanoli
RX Securities	Joseph Heddan

## CONTACT



*Vice President Communications & Investor Relations*

**Oskar Bosson**

Tel: +46 70 410 71 80

oskar.bosson@bioarctic.se

# 2023 Annual General Meeting

The 2023 Annual General Meeting of BioArctic AB (publ) will be held at 4:30 p.m. (CEST) on Thursday, June 1, 2023 at Lindhagen Konferens in Stockholm, Sweden. Registration will begin at 4:00 p.m.

## Registration

Those shareholders registered in the share register maintained by Euroclear Sweden AB as of May 29, 2023, and have reported their intent to participate in the meeting to the company by 5:00 p.m. on May 29 have the right to participate in the AGM. More information will be provided in the notice to attend the Annual General Meeting.

Shareholders whose shares are nominee-registered, in addition to registering their participation in the meeting, must temporarily register their shares in their own name in the share register (voting rights registration) in order to have the right to participate in the meeting. Re-registration must be completed

## IMPORTANT DATES FOR THE 2023 AGM

- May 24 – record date for the 2023 AGM
- May 29 – final registration date for participation in the AGM
- June 1 – admittance to the AGM begins, 4:00 p.m.
- June 1 – the AGM begins, 4:30 p.m.

no later than on May 26 and should be requested from the bank or fund manager well in advance of this date.

## Dividend

Since BioArctic has no product sales, the company's current revenue and earnings primarily consist of revenue of a non-recurring character in accordance with the research and licensing agreements the company has signed. BioArctic will continue to focus on further developing and expanding the company's project portfolio. Available funds and earnings recognized will therefore primarily be reinvested in operations for funding the company's long-term goals and strategy. The Board therefore proposes that no dividend be paid for the 2022 financial year.

## Notice to attend the Annual General Meeting

The notice to attend the Annual General Meeting is issued via an announcement in Post- och Inrikes Tidningar and Svenska Dagbladet, and through being made available on the company's web site. Documents that are to be presented at the Annual General Meeting are made available on the company's web site. They are also sent to shareholders who request it and provide their mailing address.



# Glossary

## A

### 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.

### Alpha-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.

### ALS (*amyotrophic lateral sclerosis*)

A rare and difficult neurodegenerative illness that impacts the body's ability to control muscular activity.

### 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 forms the plaque around brain cells visible in patients with Alzheimer's disease.

### Amyloid PET

A diagnostic imaging method used to identify the presence and prevalence of harmful accumulations of amyloid beta in the brain.

### Amyloid pathology

A condition in which harmful accumulation of amyloid beta is the underlying cause.

### 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.

### Arctic mutation

A mutation in the gene for the amyloid precursor protein (APP) that promotes certain hereditary cases of Alzheimer's disease. Discovered by Professor Lars Lannfelt and his research group, and gave the company its name.

### ARIA-E

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

### ARIA-H

Haemorrhages, usually small and punctate, that occur in patients treated with anti-amyloid monoclonal antibodies for Alzheimer's disease and that also occur in people in the absence of such treatment.

## B

### 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.

### Biological drugs

A drug whose components have been manufactured in or extracted from a living cell (e.g. amyloid beta or alpha-synuclein) that the antibody binds to.

### 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.

## C

### Central nervous system (CNS)

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

### CHMP

The Committee for Medicinal Products for Human Use.

### Clinical studies

Drug trials performed in human subjects.

## D

### 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 a higher dose.

### Double-blind

A method of designing a clinical trial so that both the research subject and staff administering the therapy have no information on whether a drug or a placebo is being administered to the patient.

### Drug candidate

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

## E

### Endpoint

A measurement defined in advance for measuring the effect in a trial.

### Effect variable

The parameter(s) measured to assess the result of a research study.

### EMA

The European Medicines Agency.

## F

### Fast track designation

The 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.

## I

**Immunotherapy**

A form of medical treatment in which the activity of the immune system is deliberately activated or moderated.

**Indication**

A medical condition in conjunction with which the administration of a specific treatment has been approved.

**Interim analysis**

A statistical analysis conducted during an ongoing clinical trial to evaluate preliminary findings.

**Intravenous**

Injection of a drug directly into the blood using a syringe or cannula.

## L

**Lecanemab**

BioArctic's drug candidate for early Alzheimer's disease, which was developed in partnership with the Japanese company Eisai.

**Lewy bodies**

Accumulations of misfolded alpha-synuclein in brain cells. Leads to conditions such as Parkinson's disease and certain dementia-related illnesses.

**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.

## M

**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.

**Mutation**

A change to genetic makeup – DNA – that could give rise to disease.

## N

**Neurodegenerative diseases**

Diseases that entail a gradual breakdown and degeneration in brain and nervous system function.

## O

**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 an active substance.

## P

**PET**

Positron emission tomography is a type of diagnostic method using imaging for medical assessment.

**Phase 1 study**

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

**Phase 2 study**

Studies the safety and efficacy of a drug candidate in a limited number of patients. Later stages of Phase 2 studies can be called Phase 2b, and evaluate the optimal dosage of the drug being studied.

**Phase 3 study**

Confirmatory study of the safety and efficacy of a drug candidate in a large number of patients.

**Placebo-controlled**

A study design in research that entails some of the patients receiving an 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 on humans.

**Product candidate**

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

**Protein**

Complex molecules manufactured by the body, consisting of thousands of atoms, often with a biological function.

**Protofibril**

A harmful aggregation of amyloid beta formed in the brain, which gives rise to Alzheimer's disease, or a harmful aggregation of alpha-synuclein, formed in the brain, that gives rise to Parkinson's disease.

## R

**Randomized study**

A random division of test subjects into predetermined treatment groups or placebo groups in a clinical trial.

**Receptor**

Protein structures that initiate a biochemical chain reaction in the body once activated.

**Research phase**

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

**Royalty**

Remuneration when someone uses or sells a product onward.

## S

**Selective binding**

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

**Subcutaneous treatment**

Treatment where the drug is administered to the patient through an injection under the skin.

## T

**Titration of dose**

Stepwise increase in medication in order to achieve a 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.