

#### **TABLE OF CONTENTS**

2 —	A I	BioArctic
_	About	DIOAICH

Solid scientific competence

#### 4 — The year in brief

An eventful year

#### 6 — CEO Gunilla Osswald

A very successful year that created a good basis for the future

#### 8 — Goal & Strategy

Strategy for sustainable growth

#### 11 — Patents

A strong patent portfolio

#### 12 — Research & Development

Groundbreaking discoveries

#### 14 — Project portfolio

An innovative project portfolio

#### 18 — Therapy areas

Therapy areas with high medical needs

#### 22 — Clinical benefits

Conversations with Alzheimer experts

#### 24 — Market overview

A market with great potential

#### 26 — Sustainability

We contribute with research and development of the highest quality

#### 28 — Human resources

We encourage curiosity and innovation

#### 31 — Organization

Innovation drive and strategic partnerships

#### 32 — The share

The BioArctic share

#### 36 — Board of directors

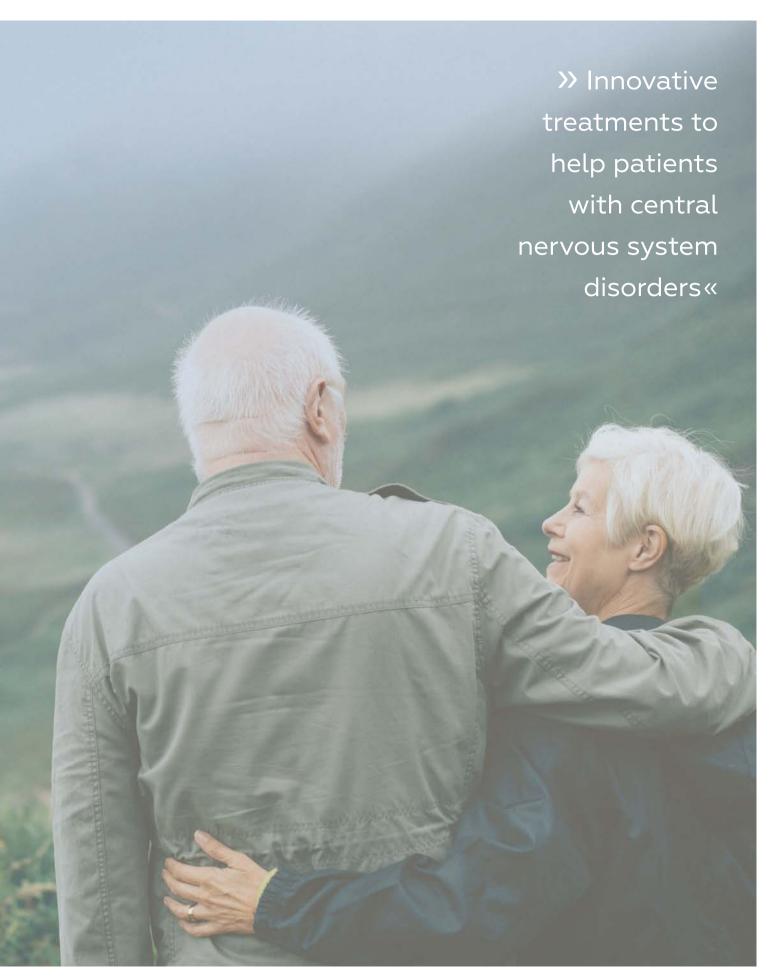
#### 38 — Management

#### 40 — Board of directors' report

#### 48 — Corporate governance report

- 56 Financial statements
- 65 Notes to financial statements
- 87 Assurance of the Board of directors and CEO
- 88 Auditor's report
- 92 Notice of Annual General Meeting
- 93 Glossary





## SOLID SCIENTIFIC COMPETENCE

BioArctic's success is built on solid scientific competence. Our goal is to improve the quality of life for patients with central nervous system disorders. BioArctic is a research intensive biopharma company that creates value by developing treatments in three areas with high unmet medical needs.



BIOARCTIC DEVELOPS ENTIRELY new types of treatments with the ambition to stop or slow down the disease progression in patients with Alzheimer's disease and Parkinson's disease. Today the patients have access only to symptomatic treatments.

The company also develops an innovative treatment concept for complete spinal cord injuries. The goal in all research areas is to develop efficient treatments that significantly improve the patients' quality of life.

#### **OUR VISION**

BioArctic's vision is to become a world-leading Swedish biopharma company within research, development and sales of innovative and effective biological drugs for patients with neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease, and innovative and effective treatments for complete spinal cord injuries. To achieve this vision BioArctic focuses on its core business and encourages a strong culture of curiosity and innovation among its staff and partners. In addition, BioArctic aims to be an attractive and leading collaboration partner in the company's research areas for research groups in academia, the pharma industry and health care.

#### **OUR STRENGTHS**

#### **Groundbreaking discoveries**

BioArctic was founded in 2003 by Professor Lars Lannfelt and Associate Professor Pär Gellerfors to develop important and groundbreaking discoveries made by Professor Lannfelt concerning Alzheimer's disease. These discoveries – the Swedish mutation and the Arctic mutation – have attracted much attention internationally and explain the central role of amyloid beta in Alzheimer's disease, which has led to the development of new treatment strategies.

#### Patented technology

BioArctic has developed a patented technology that has proven successful in the development of the company's first drug candidate, the antibody BAN2401, for Alzheimer's disease. The technology is now also used in developing drugs for other diseases of the central nervous system such as Parkinson's disease (BioArctic's antibody BAN0805) and also for related diagnostics and technology.

#### Innovative project portfolio

The project portfolio consists of differentiated first generation disease modifying drug candidates for neurodegenerative diseases, related diagnostics and technology, and a new treatment concept for complete spinal cord injuries.

#### High scientific competence

The organization possesses the knowledge base required for conducting cutting-edge research in the area of neuro-degenerative diseases. Our employees are highly educated and have robust experience from developing drugs.

#### Strategic collaborations

Collaboration with leading academic research groups at universities is of great importance to BioArctic, and so is collaboration with our strategically important global partners in the Alzheimer projects (Eisai) and the Parkinson projects (AbbVie). The project portfolio is an attractive combination of fully financed projects run in partnership with global pharma companies and innovative in-house projects with great market and outlicensing potential.

#### **External validation**

Over the years a number of the company's projects have received grant funding from Vinnova and the EU's research and development program, Horizon 2020. The grants have been of great financial importance to BioArctic and also constitute an important external quality label.

#### Strong patent portfolio

BioArctic has an active patent strategy covering all major drug markets, including the US, EU, Japan and China.

#### Efficient and flexible organization

Our laboratories and offices are located in central Stockholm, where approximately 50 people are working, demonstrating commitment and ability to deliver results with high quality. In order to run an efficient operation with a relatively small organization BioArctic hires key consultants for specific assignments and for tasks in areas of expertise that we lack or only require from time to time.

## AN EVENTFUL YEAR

2018 has been a successful year. In Alzheimer's disease we reported positive results from the Phase 2b study with BAN2401 and we are looking forward to the next clinical study. In Parkinson's disease we outlicensed the antibody BAN0805 to our collaboration partner AbbVie, who is responsible for and prepares the clinical program. The spinal cord injury project we are running in-house. We can now include patients from countries other than Sweden and we continue the recruitment into the next panel in the combined Phase 1/2 study with SC0806.

**Gunilla Osswald** CEO, BioArctic AB



#### Alzheimer's disease

In July, positive 18-month results from the Phase 2b study with BAN2401 in 856 patients with early Alzheimer's disease were reported. This is the first late-stage study demonstrating effects on cognition as well as reduction in accumulated amyloid beta in the brain with good tolerability. In October, data were presented that further support the positive effect of BAN2401 in all subgroups of early Alzheimer patients. Observations supportive of disease modifying effects were also seen on biomarkers of neurodegeneration in CSF. BioArctic's partner Eisai was discussing the next step in the development of BAN2401 with regulatory authorities and is preparing for further studies.

In August, BioArctic obtained exclusive rights to develop potential antibody treatments (ADI801) for Alzheimer's disease. This concerns a totally new target protein from a research project previously jointly owned with Eisai.

#### Parkinson's disease

In November, AbbVie gave notice to exercise its option to license BioArctic's product portfolio of disease modifying antibodies to alpha-synuclein for Parkinson's disease and other potential indications. AbbVie's inlicensing of the portfolio triggered a milestone payment of MUSD 50. AbbVie will finance and drive the clinical development of BANO805, now under the designation ABBV-0805.

BioArctic's concept patent for the company's treatment strategy for disease modifying treatment of Parkinson's disease was granted in October in Europe.



We are pleased to present this year's SwedenBIO Award to BioArctic. Hopefully the company's research will give patients access to disease modifying treatments for Alzheimer's and Parkinson's diseases, creating value also for their families and for the society.«

Jonas Ekstrand, CEO of SwedenBIO

#### Complete spinal cord injuries

In February, BioArctic was granted patent protection in the US for a method for treatment of patients with complete spinal cord injury.

In March, patent protection was granted in Japan for the company's medical device for treatment of patients with complete spinal cord injury and in October, patent protection was granted also in the EU.

In April, the inclusion of patients with complete spinal cord injury in the first panel of the ongoing Phase 1/2 study with \$C0806 was completed.

During the year, BioArctic received approval from regulatory authorities and ethical committees to include patients from Estonia, Norway and Finland in the ongoing clinical study. Preparations have been made for the start of the next panel.

#### **Diagnostics and biomarkers**

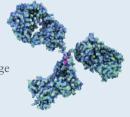
- In September, BioArctic extended the research collaboration with Uppsala University concerning further development of technologies for antibody based imaging (PET) of the brain in Alzheimer patients.
- The same month, BioArctic entered into a research collaboration with Brain Biomarker Solutions in Gothenburg AB concerning the development of new diagnostics for Alzheimer's disease.
- In November, BioArctic announced that the company has obtained a grant from the EU's Horizon 2020 for participation in a European research consortium for better diagnostic tools and biomarkers for Parkinson's disease.

#### FINANCIAL OVERVIEW

	2018	2017
Net revenues, MSEK	714.0	140.7
Operating profit, MSEK	488.8	19.3
Profit for the year, MSEK	381.6	15.2
Cash flow from operating activities, MSEK	-200.1	-135.3
Equity/asset ratio, %	73.1	55.8
Return on equity, %	46.1	4.3
Earning per share, SEK	4.33	0.22
Equity per share, SEK	11.56	7.22
Cash flow from operating activities per share, SEK	-2.27	-1.99
Share price at December 31, SEK	82.00	26.00

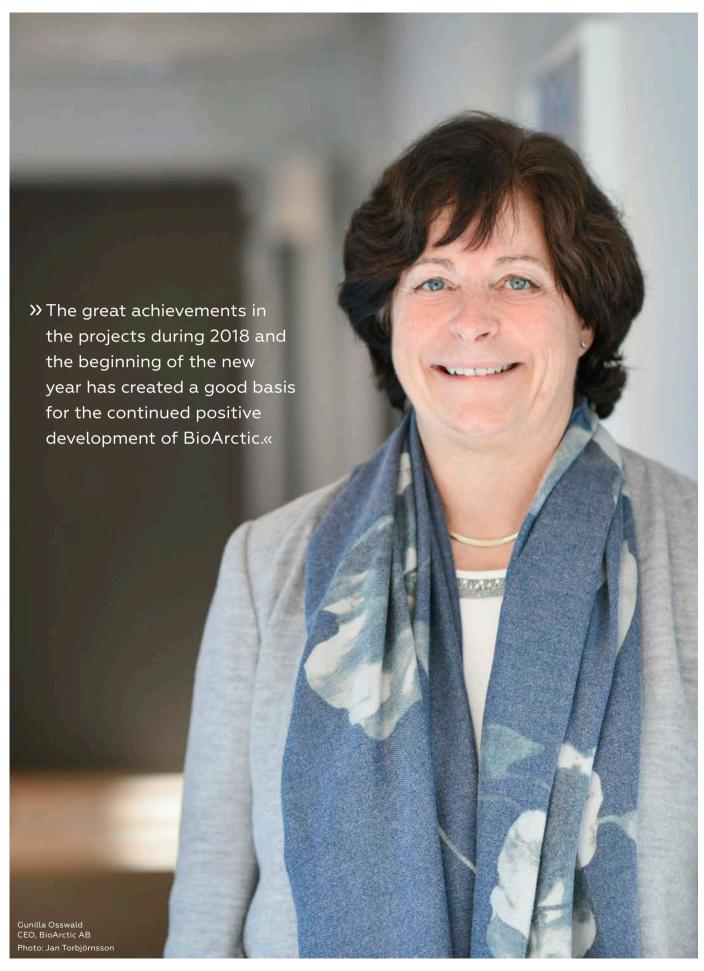
#### **BBB technology**

In May, BioArctic extended the research collaboration with Uppsala University concerning technologies for increased passage over the blood-brain barrier.



An antibody – a protein used by the body's immune system to detect and destroy foreign substances.

Photo: Shutterstock



## A very successful year that created a good basis for the future

LOOKING BACK AT the past year, I am amazed that so much can happen is such a short time. 2018 was an exciting and successful year with three especially important events. The new year has continued to show important progress for the key projects.

THE MOST IMPORTANT was the positive 18-month results from the Phase 2b study with BAN2401 in 856 patients with early Alzheimer's disease. This is the first study in late clinical phase that demonstrates a potential disease modifying effect on clinical function as well as clearance of amyloid beta in the brain, and effect on neurodegenerative biomarkers. BAN2401 showed a good tolerability. The data support the positive effect of BAN2401 in all subgroups of early Alzheimer patients. BAN2401 is a unique antibody that, in a large clinical study, has demonstrated clinical effect and pronounced reduction of amyloid beta in the brain as well as effects on neurodegenerative biomarkers. BAN2401 binds selectively to the toxic soluble aggregated forms of amyloid beta in the brain, so called protofibrils, which are believed to be an important cause of the the disease. The results indicate that the binding profile of the antibody is important. Our partner Eisai has discussed the next stage in the development of BAN2401 with regulatory authorities. In March 2019, Eisai announced that they have initiated the confirmatory Phase 3 study with BAN2401 in early Alzheimer patients.

THE SECOND POSITIVE event was the outlicensing of BioArctic's portfolio of antibodies for alpha-synuclein for disease modifying treatment of Parkinson's disease and other potential indications, to our partner AbbVie. The licensing triggered a milestone payment of MUSD 50. AbbVie will continue to develop BANO805, now with the designation ABBV-0805. In February 2019 the US Food and Drug Administration, FDA, approved the application for the initiation of the first clinical study

with ABBV-0805. The clinical Phase I study started in March 2019.

THE THIRD EVENT was the completion of the inclusion of patients in the first of BioArctic's three panels in the ongoing Phase 1/2 study with \$C0806 for the treatment of complete spinal cord injury. During the year, we received approvals to include patients from Estonia, Finland and Norway in the study. A safety evaluation of all patients in the first panel has been performed, supporting the start of the next panel. The Phase 2 part of the study has started and the first patient was treated with \$C0806 in February 2019. An interim analysis of the first panel concerning efficacy and safety is planned for the first half of 2020, at the latest.

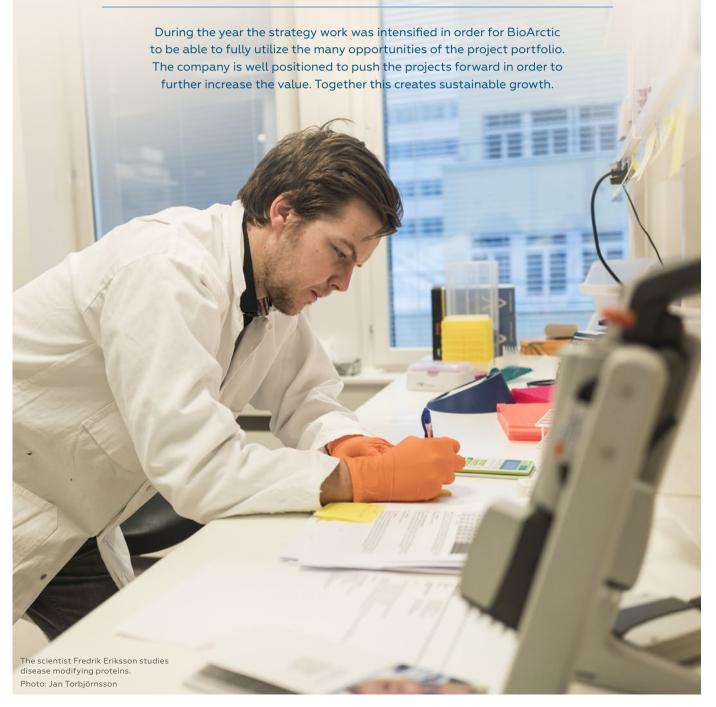
THE COMPANY'S EARLY stage projects developed well during the year. BioArctic obtained exclusive rights to develop a potential antibody treatment (AD1801) for Alzheimer's disease. This concerns a totally new target protein from a research project previously jointly owned with Eisai. During the year, BioArctic extended research collaborations with universities concerning biomarkers and technologies for increased passage across the bloodbrain barrier.

THE PROGRESS IN the projects has created a very good basis for the continued positive development for BioArctic. I am proud to lead this innovative company and happy to be able to continue our work to improve the quality of life for patients with central nervous system disorders.

**Gunilla Osswald** CEO, BioArctic AB

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## STRATEGY FOR SUSTAINABLE GROWTH



OUR GOAL IS to improve the quality of life for patients with central nervous system disorders. BioArctic develops innovative disease modifying treatments based on antibodies (immunotherapy) for neurodegenerative diseases, i.e. diseases where the nervous system atrophies.

We run projects in three treatment areas where effective treatments are lacking today. Our projects are in various phases: from early research phase to late clinical phase. The costly clinical studies in Alzheimer's disease and Parkinson's disease are financed by BioArctic's strategic partners. Together this contributes to a robust portfolio.

#### Competitive project portfolio

BioArctic focuses on building a unique and competitive portfolio of product candidates, diagnostics and technology in the company's indication areas. This is done partly through internal research and development, and partly through research collaborations with strategic partners in the form of research groups at universities, in pharma companies, and in the health care sector. Our strategy is to outlicense certain commercial rights to global pharma and biopharma companies at an appropriate time. For more information on the Project portfolio, see pp. 14–17.

#### **BIOARCTIC'S STRATEGIC TARGET AREAS**

#### 1 — Continue

Continue focusing on the partnership projects and on driving/intensifying the in-house projects with great outlicensing and market potential

#### What happened in 2018?

- Positive Phase 2b study results with BAN2401 in patients with early Alzheimer's disease and continued focus on the clinical development program
- Continued focus on delivery of project activities in Parkinson's disease within the current collaboration agreement with AbbVie
- Preparations of the IND application for BAN0805, that is an application for initiation of clinical studies in the US
- The recruitment of patients with complete spinal cord injury to the first panel in the Phase 1/2 study with SC0806 was completed
- The recruitment to the next panel was initiated, to which also patients from Estonia, Norway and Finland can be included

#### 2 — Develop

Develop projects further, up to the optimal point in time for partnership or exit, in order to maximize return on investment

#### What happened in 2018?

 Outlicensing of the portfolio of disease modifying antibodies to alpha-synuclein to AbbVie for Parkinson's disease and other potential indications

#### 3 — Expand

Expand the portfolio with new targets, indications for orphan drugs, new projects and diagnostics

#### What happened in 2018?

- Preclinical evaluation of BAN2401 for Down's syndrome with dementia and cognitive disorder
- Exclusive rights to the development of the antibody AD1801 (in research phase) for Alzheimer's disease obtained

#### 4 - Invest

Invest in:

- technologies; antibodies, blood-brain barrier, diagnostics and biomarkers
- attracting/retaining employees
- preparing market activities in the Nordic region

#### What happened in 2018?

- Extended collaborations with Uppsala University concerning technologies for antibody-based PET for Alzheimer's disease and increased passage across the blood-brain barrier
- Research collaboration with Brain Biomarker Solutions in Gothenburg AB concerning the development of new diagnostics and biochemical markers for Alzheimer's disease
- Grant from EU's Horizon 2020 for participation in a European research consortium for better diagnostic tools and biomarkers for Parkinson's disease
- Second place in the Allbright Prize 2018, Gender Equality Prize

#### Collaborations and partnerships

Collaborations with universities are of great importance to BioArctic. The company has ongoing collaborations with leading external research groups at a number of universities. For more information, see the section Organization on page 31.

An important part of BioArctic's strategy is the signing of research and licensing agreements with leading pharma and biopharma companies in order to utilize their competence in drug development, manufacturing and commercialization. BioArctic has entered into a number of such agreements, with the Japanese pharma company Eisai and the American biopharma company AbbVie, among others. These strategic partnerships with leading global companies confirm that BioArctic's research is of very high quality.

In the future BioArctic may enter into additional agreements with leading life science companies that can contribute financing and research and development competence for the product candidates, manufacturing and marketing competence, and contribute geographic coverage and other resources.

#### Eisai

In Alzheimer's disease, BioArctic collaborates with Eisai since 2005. BioArctic has entered into three research agreements and two license agreements concerning the antibodies BAN2401 (2007) and BAN2401 back-up (2015).

BioArctic has granted Eisai a global and exclusive license for research, development and commercialization of drugs using the antibodies for the treatment of Alzheimer's disease. Eisai is responsible for the clinical development, applications for marketing authorization and commercialization of the products. BioArctic retains the right to market the licensed products in the Nordic countries and the rights to the antibodies for treatment of indications other than Alzheimer's disease.

The total value of the agreements can amount to MEUR 218 and in addition there are high single digit royalty payments. So far BioArctic has received approximately MEUR 47.

#### AbbVie

In 2016, BioArctic and AbbVie entered into a collaboration to develop and commercialize BioArctic's portfolio of antibodies to pathological forms of alpha-synuclein for the treatment of Parkinson's disease and other potential indications.

In late 2018, BioArctic outlicensed its portfolio of disease modifying antibodies to alpha-synuclein for Parkinson's disease and other potential indications to AbbVie. This triggered a milestone payment of MUSD 50 to BioArctic, which was received in February 2019. BioArctic has previously received MUSD 80. The total value of the license deal can amount to MUSD 755, plus tiered royalties.

BAN0805, a disease modifying treatment for Parkinson's disease, is the antibody to alpha-synuclein that has progressed furthest in development. AbbVie will finance BAN0805, now designated ABBV-0805. The first clinical study started in March 2019. BioArctic continues the conduct of the ongoing agreed activities and continues to work with the follow-up substances (PD1601 and PD1602) according to the current collaboration agreement.

#### TIMELINE December 2018 AbbVie inlicenses BioArctic's portfolio of disease modifying antibodies to alpha-synuclein for Parkinson's disease and July 2018 other potential indications. Positive results from the Phase 2b study with BAN2401 in early April 2018 Alzheimer's disease. Completed inclusion of patients with complete spinal cord injury in the first panel of the Phase 1/2 study with 2017 SC0806 BioArctic is listed on Nasdag Stockholm Mid Cap 2016 A research agreement in Parkinson's disease between BioArctic and AbbVie is 2015 signed. BioArctic and Eisai sign a new license and research agreement in Alzheimer's disease BioArctic receives an MEUR 6.4 grant from the EU's research and development program Horizon 2020 for SC0806 for complete 2013 spinal cord injury The partner Eisai starts a clinical Phase 2b study with BAN2401 in the US and clinical development of BAN2401 is started in Japan. BioArctic receives a grant from Vinnova for the clinical development of SC0806 for complete spinal cord iniurv. 2010 SC0806 for complete spinal cord injury gets orphan drug status in the EU. The clinical development of 2008 BAN2401 starts. BioArctic enters into a license agreement with Swenora Biotech AB. 2007 The first US patent for Alzheimer's disease is approved. A license agreement concerning BAN2401 for the treatment of Alzheimer's disease is signed BioArctic moves into its own premises in Stockholm. 2005 The first research collaboration agreement with Eisai is signed concerning treatment of Alzheimer's disease. Uppsala universitet Holding AB invests in BioArctic. Karolinska Institutet Innovations AB invests in BioArctic (the holding was later transferred to Karolinska Development AB). 2003 BioArctic is founded by Lars Lannfelt and Pär Gellerfors The discovery of the Arctic mutation is published. 2000 Patent application for the discovery of the Arctic mutation is filed in the US. 1992 Professor Lars Lannfelt and his coworkers discover the Swedish mutation which leads to early development of Alzheimer's disease.

## A STRONG PATENT PORTFOLIO

BioArctic has an active patent strategy covering all major drug markets, including the US, EU, Japan and China. At the end of 2018, the company owned 12 patent families comprising more than 200 granted patents and 55 pending patent applications. The patents cover properties, molecular structures and areas of use for the company's drug and product candidates and technology related to the research and development of the drug and product candidates.

AS AN EXAMPLE, PATENTS related to BioArctic's leading candidates in the three major indications, i.e. BAN2401, BAN0805 and \$C0806, have expected expiry dates in 2032, 2036 and 2032, respectively, including applicable patent term extensions for BAN2401 and BAN0805. Furthermore, the company's patent portfolio provides strong protection for diagnostic methods and the company's blood-brain barrier technology.

BioArctic also has extensive know-how relating to the development of antibodies that bind selectively to oligomer/protofibril forms of misfolded proteins. In addition, the company's disease modifying biological drugs (BAN2401 and BAN0805) are expected to have data and market exclusivity for 12 years in the USA and 10-11 years in Europe. BioArctic's orphan drug \$C0806 is expected to have regulatory exclusivity for 7 years in the US and for 10 years in Europe.

A compilation, as of December 31, 2018, of BioArctic's main and published patent families is shown in the table below.

Patent family	Area	Status and market	Protection to
AD I	Alzheimer's disease – concept 1	<b>Granted:</b> USA, Canada, Japan, Australia	July 2021
AD II	Alzheimer's disease – concept 2	<b>Granted:</b> USA, Europe <sup>1</sup> , Canada, Australia	June 2025
AD III	Alzheimer's disease – substance 1 Specific protection for BAN2401	<b>Granted:</b> USA, Canada, Europe, Japan, China, as well as other countries	March 2027 (2032 with patent extension) <sup>2</sup>
AD IV	Alzheimer's disease – substance 2 Specific protection for BAN2401 back-up	Granted: USA Pending: Europe, Japan, China, as well as several other countries	July 2035 (2040 with patent extension) <sup>2</sup>
PD V	Parkinson's disease – concept	Granted: USA, Europe, Japan	July 2029
PD VII	Parkinson's disease – substance Specific protection for BAN0805	Granted: USA, Europe, Japan, China, Australia, as well as other countries Pending: Canada	March 2031 (2036 with patent extension) <sup>2</sup>
SP X	Spinal Cord – method and mould The patents in this patent family are licensed from Swenora Biotech AB	<b>Granted:</b> Australia, Canada, Japan <b>Pending:</b> USA, Europe	March 2027
SP XI	Spinal cord – specific – device	<b>Granted:</b> USA, Europe, Japan, China, Australia <b>Pending:</b> Canada	December 2032

<sup>1)</sup> The concept patent in Europe was revoked after opposition, but the decision has been appealed by BioArctic.

The appeal was filed during 2017 and is pending at the European Patent Office's Boards of Appeal.

<sup>2)</sup> Assuming that a five year's patent extension is granted where available.

### GROUNDBREAKING DISCOVERIES

Our ambition is to develop new innovative treatment strategies that help people with diseases in the central nervous system. This is our most important role and our way to create value for patients and society.

#### **Technology**

#### Neurodegenerative diseases

The key molecular event in Alzheimer's disease and Parkinson's disease is believed to be abnormal protein misfolding and aggregation. The spreading of soluble aggregates leads to neuronal dysfunction, cell death, brain damage and disease symptoms. Each neurodegenerative disease is characterized by a unique aggregated protein. Characteristic for Alzheimer's disease is amyloid beta  $(A\beta)$ , while alpha-synuclein  $(\alpha$ -synuclein) is the signature protein for Parkinson's disease. BioArctic's disease modifying treatment strategy is to eliminate toxic aggregated forms (oligomers/protofibrils) of these proteins in the brain by means of the company's selective antibodies.

#### Alzheimer's disease

The amyloid beta peptide  $(A\beta)$  is the main constituent in the plaques found in the brains of Alzheimer patients. Genetic findings strongly point to  $A\beta$  as the disease-initiating molecule. The monomer form of  $A\beta$  is misfolded and forms both insoluble aggregates (fibrils and amyloid plaques) and soluble forms (oligomers and protofibrils). Research has shown that oligomers and protofibrils of  $A\beta$  are the main toxic forms in Alzheimer's disease.

The drug candidate BAN2401 selectively binds to the soluble, toxic aggregates of A $\beta$  and neutralizes and eliminates them. BAN2401's unique profile is highly selective for A $\beta$  oligomers/protofibrils and binds more than 1,000 times stronger to these than to A $\beta$  monomers and 10-15 times stronger than to A $\beta$  fibrils.

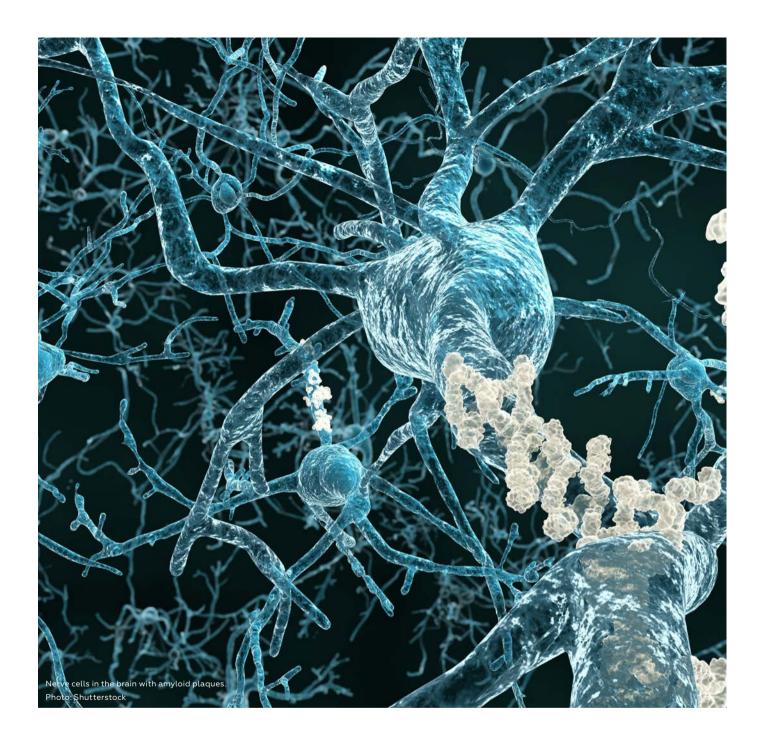
During the year, results from a clinical Phase 2b study in  $8\,56$  patients with early Alzheimer's disease were reported. The

results showed consistent, dose-dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints and biomarkers as well as good tolerability.

#### Parkinson's disease

Patients with Parkinson's disease suffer from extensive loss of nerve cells in the part of the brain that is associated with motor function. In these nerve cells there are so-called Lewy bodies consisting of accumulated misfolded α-synuclein, which is associated with nerve cell loss. The aggregates of  $\alpha$ -synuclein can also be released from the cells and transfer to nearby cells, whereby the disease can spread from one brain area to another. Research has shown that mutations in the α-synuclein gene lead to Parkinson's disease. Some of these mutations are conducive to the formation of large soluble aggregates of oligomers or protofibrils which further aggregate to Lewy bodies. Whereas the insoluble α-synuclein aggregates do not seem to confer cellular damage, numerous studies have demonstrated that soluble oligomers/protofibrils have pronounced neurotoxic effects. Targeting oligomers and protofibrils of α-synuclein should thus be a possible strategy for early treatment of Parkinson's disease.

BioArctic's drug candidate BANO 805 is a monoclonal antibody that selectively targets oligomers/protofibrils of  $\alpha$ -synuclein. BANO 805 binds only weakly to the monomeric forms of the protein, allowing selective targeting of brain oligomers/protofibrils. In preclinical studies BANO 805 has been shown to decrease the levels of  $\alpha$ -synuclein protofibrils, decrease motor symptoms and double the life span in a mouse model for Parkinson's disease.



#### Complete spinal cord injuries

sco806 is BioArctic's product candidate for patients with chronic complete spinal cord injuries. sco806 is a degradable implant with channels for nerve grafts from peripheral nerves and the growth factor FGFI. The product is a combination of a medical device (the implant) and a drug (FGFI). The implant provides a sustained release of FGFI. The channels in the implant are designed to guide axon growth from white to grey matter in the spinal cord, which is a precondition for nerve regeneration. The treatment is based on a surgical procedure where the scar tissue in the injured part of the spinal cord is removed and replaced with sco806 including nerve grafts from the patient's legs (the sural nerve). The growth factor

FGFI has two functions, to stimulate the growth of axons and also to inhibit gliosis (formation of scar tissue). The nerve grafts that are inserted into the channels of the implant have the function to create an environment that stimulates regeneration of axons and to create contact. The surgery is followed by 18 months of rehabilitation through intensive training in a robotic system to support muscle rebuilding in the part of the body affected by paralysis. In preclinical studies, BioArctic has demonstrated nerve regeneration, transfer of electrical impulses and some return of motor function in animals after treatment with \$co806. A clinical Phase 1/2 study of \$co806 is in progress.

# AN INNOVATIVE PROJECT PORTFOLIO

BioArctic develops disease modifying treatments for neurodegenerative diseases like Alzheimer's disease and Parkinson's disease, diagnostic methods for neurodegenerative diseases and related technology, and a treatment concept for complete spinal cord injuries.



#### Alzheimer's disease

Among BioArctic's five projects for disease modifying treatment of patients with early Alzheimer's disease, BAN2401 is the one that has advanced furthest.

BioArctic's drug candidate BAN2401 aims to halt or slow down the continuous cognitive decline in Alzheimer patients. BAN2401 is a monoclonal antibody that selectively binds and eliminates oligomers/protofibrils of A $\beta$ , which are considered to be the toxic forms in Alzheimer's disease. The Japanese pharma company Eisai has obtained the global rights to develop, manufacture and market BAN2401 for the treatment of Alzheimer's disease. BioArctic retains the right to market BAN2401 in the Nordic countries.

Eisai is responsible for the clinical development of BAN2401. During the year, the 18-month results from a Phase 2b study with 856 early Alzheimer patients in the US, Canada, EU, Japan and South Korea were reported. The results showed dose-dependent, clinically meaningful, and statistically significant effects on several clinical endpoints and biomarkers in combination with a good tolerability profile. This is the first study in late clinical phase that demonstrates potential disease modifying effect on cognition and biomarkers with good tolerability. Eisai has discussed the next step in the development of BAN2401 with regulatory authorities and is preparing a confirmatory Phase 3 study.

BioArctic has also developed a new antibody, BAN2401 back-up, and entered into a license agreement with Eisai concerning the new antibody. Eisai is driving this project forward.

In collaboration with Eisai, BioArctic has identified a totally new target protein, enabling the development of new treatments for Alzheimer's disease. During the year a deal was closed giving BioArctic exclusive rights to use the results from the collaboration to develop potential antibody treatments for Alzheimer's disease. The project AD1801 is in research phase.

BioArctic also runs two other early Alzheimer projects in-house, ADI502 and ADI503, with other innovative targets. Both projects are in research phase.

#### Other types of dementia

Aβ-plaques can also be found in patients who suffer from certain other types of dementia, such as dementia in patients with Down's syndrome and traumatic brain injuries. BioArctic considers such indications to be interesting for treatment with BAN2401, which may result in new business opportunities in the future.

BioArctic holds the rights to BAN2401 for other indications than Alzheimer's disease, including dementia indications with neurodegeneration not caused by Alzheimer's disease

(Alzheimer related diseases). Laboratory studies have therefore been started in order to clarify the character of the pathological changes in the brain tissue of patients with Down's syndrome with dementia and the possible relevance of starting clinical treatment studies with BAN2401.

#### Parkinson's disease

The drug candidate BANO805 is a monoclonal antibody that selectively binds and eliminates oligomers and protofibrils of  $\alpha$ -synuclein and aims to halt or slow down the disease progression in patients with Parkinson's disease. The treatment concept is based on innovative research at Uppsala University in collaboration with BioArctic.

BioArctic has entered into a strategic collaboration with the biopharma company AbbVie concerning the continued development of BioArctic's Parkinson projects. The collaboration agreement, closed in 2016, gave AbbVie an option to obtain a license to the portfolio of α-synuclein antibodies. In November 2018, AbbVie gave notice to exercise the option. AbbVie will conduct clinical development of BANO805, now designated ABBV-0805. The first clinical Phase 1 study started in March 2019. BioArctic continues to develop the follow-up substances (PD1601 and PD1602) within the framework of the collaboration with AbbVie.

Other potential indications for BANO805/ABBV-0805 include dementia with Lewy bodies and multiple system atrophy (MSA), which, like Parkinson's disease, have an α-synuclein pathology.

#### Diagnostics, biomarkers and technology

Alzheimer's and Parkinson's diseases are currently diagnosed through clinical investigations, biochemical markers in spinal cord fluid and brain imaging. There is a lack of biomarkers that mirror disease progression and treatment effect.

During the year, BioArctic signed a research agreement with Brain Biomarker Solutions in Gothenburg AB. The research collaboration is aimed at developing new and improved diagnostic methods for Alzheimer's disease by identifying and measuring new biomarkers in spinal cord fluid and blood. The goal is to be able to better and more accurately diagnose the disease and to enable a more precise measuring of the disease progression and to follow the effect of new drugs targeting the amyloid pathology. This constitutes a very great need for the pharma industry in order to develop new drugs.

BioArctic develops PET ligands selectively targeting oligomers/protofibrils in collaboration with Uppsala University. During the year, an extended research agreement was signed with the Department of Public Health and Caring Sciences,



Molecular Geriatrics, concerning technologies for antibody based PET diagnostics.

Within the Parkinson field, the development of diagnostic methods based on BioArctic's antibodies is part of the collaboration with AbbVie.

During the year, BioArctic obtained a grant from the EU's research and innovation program Horizon 2020 for participation in a European research consortium with the task of working for research in collaboration between the pharma industry and European universities. It is also the task of the consortium to educate the next generation of researchers and to encourage entrepreneurship in the area of diagnostics of neurodegenerative diseases such as Parkinson's disease. The consortium consists of approx. ten parties from the pharma industry and academic institutions. The educational part falls within the scope of Marie Sklodowska-Curie's education initiative "Innovative Training Networks, PET Imaging of Alpha-Synuclein Fibril Formation".

BioArctic has obtained financial support for a postgraduate studentship linked to Uppsala University. In this way, we contribute to the education of young researchers, at the same time as we can get access to a technology that can lead to better diagnostic tools and biomarkers with PET ligands for  $\alpha$ -synuclein.

#### Technology for increased passage across the blood-brain barrier

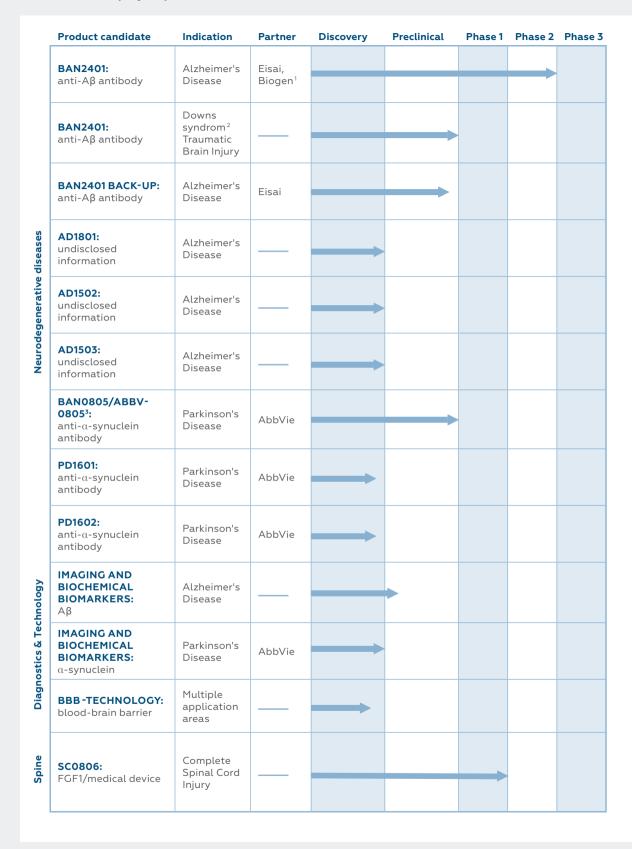
The blood-brain barrier controls the exchange of substances between the blood and the brain. The barrier protects the brain from toxins and other pathogens, but it also makes it difficult to deliver therapeutic agents to the brain. In collaboration with Uppsala University, BioArctic develops technologies that facilitate the passage of antibodies across the blood-brain barrier. During the year, the company signed an extended research collaboration agreement with the Department of Pharmaceutical Biosciences.

#### Treatment of complete spinal cord injuries

sco806 is BioArctic's treatment concept for patients with complete spinal cord injuries. The project is in-licensed from Swenora Biotech AB and is based on research at Karolinska Institutet and Karolinska University Hospital. sco806 is a biologically degradable implant with channels for nerve grafts and the growth factor FGF1. BioArctic's treatment for complete spinal cord injuries (sco806) has received orphan drug designation in the EU/EES as well as in the US.

BioArctic is currently conducting a clinical Phase 1/2 study with \$CO806. The inclusion of Swedish patients to the first of three panels in the study was completed in April 2018. During the year, BioArctic gained approval from regulatory authorities and ethics committees in Estonia, Finland and Norway to include patients from these countries in the study. At the end of the year, the recruitment of patients from Estonia was in progress. The patients receive treatment with \$CO806 at Karolinska University Hospital in Stockholm. The following rehabilitation initially takes place in Sweden and then continues at specialist clinics in the respective home country. A safety evaluation of all patients in the first panel has been performed and supported the start of the next panel. An interim analysis of the first panel concerning efficacy and safety is planned for the first half of 2020 at the latest.

#### BioArctic's project portfolio at December 31, 2018



<sup>1)</sup> Partner with Eisai on BAN2401 for treatment of Alzheimer's disease. Eisai partnered with Biogen on BAN2401 in 2014.

<sup>2)</sup> Down's syndrome with dementia and cognitive impairment.
3) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805.

# THERAPY AREAS WITH HIGH MEDICAL NEEDS

BioArctic develops new innovative treatments based on antibodies (a form of immunotherapy) for neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease. The company has also developed an innovative treatment for complete spinal cord injuries.

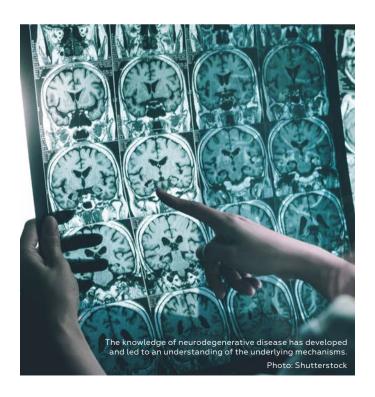
COMMON TO ALL these therapy areas is that there are great medical needs that are not met by the treatments currently available on the market. For Alzheimer's disease and Parkinson's disease there are several symptomatic treatments, i.e. drugs that alleviate the symptoms of the diseases, but no disease modifying treatments that can stop or delay the disease progression and influence the underlying disease pathology. For chronic complete spinal cord injuries there is no effective treatment after the acute phase.

#### **Neurodegenerative diseases**

Neurodegenerative diseases affect the lives of millions of people and constitute a growing health challenge for societies, with rapidly rising costs. Neurodegenerative diseases are conditions in which cells in the brain degenerate and die. These cells do not regenerate, so damage to the nervous system is disastrous. Normally the neurodegenerative processes begin long before any symptoms appear. Today there are no cures or effective treatments that can halt or change the progression of the diseases. The currently available treatments can only influence the symptoms short term.

In recent years the knowledge of neurodegenerative diseases has developed and led to an understanding of the underlying mechanisms. The key factors are today believed to be protein misfolding and spreading of toxic soluble protein aggregates that lead to neuronal

dysfunction, cell death and disease symptoms. BioArctic's treatment strategy is to reduce or eliminate these toxic proteins. In this way, the disease can be halted or given a slower progression.





#### Alzheimer's disease

Alzheimer's disease is estimated to be the cause of more than 60 percent of all cases of dementia with onset in adulthood. The disease is characterized by death of neurons in the brain causing a progressive deterioration of memory and cognitive skills, such as intellectual ability, language, recognition and learning ability. The disease can also lead to personality changes and psychiatric symptoms such as apathy, depression, disorientation, paranoia, aggressiveness, and motor symptoms such as stiffness, akinesia and impaired responsiveness. A patient with far advanced Alzheimer's disease often requires extensive nursing, as the disease affects the patient's ability to care for oneself and handle everyday situations. The disease thus impairs the quality of life for the patients as well as for their families. The great demand for nursing also means great costs for society.

The manifesting disease can be divided into different stages: mild, moderate and severe Alzheimer's disease. Patients with mild Alzheimer's disease can experience memory problems, confusion, personality changes and depression. The moderate form of Alzheimer's disease is characterized by aphasia, impaired judgement and increased memory loss. In severe Alzheimer's disease the patient often exhibits serious cognitive and motor symptoms.

Alzheimer's disease and other dementia conditions are preceded by an early phase (prodromal) where the patient exhibits mild impairments of memory and other cognitive skills. In Alzheimer's disease significantly elevated levels of amyloid beta can be detected in the brain with positron emission tomography (PET) already at the prodromal stage of the disease. A disease modifying treatment should preferably be started as early as possible, before the deterioration of the brain has progressed too far.



#### Parkinson's disease

Parkinson's disease is a progressive disease of the nervous system that is associated with decreased levels of dopamine in the brain. Tremor, decreased locomotion and stiffness are the most common clinical signs of the disease. Other common symptoms are dementia, depression and sleeping difficulties.

As the second most common neurodegenerative disease after Alzheimer's disease, Parkinson's disease affects a large number of individuals and their families. Many who fall ill in

Parkinson's disease are still at working age, with considerable financial consequences for the individual and society. There is currently no disease modifying treatment for Parkinson's disease that can halt or delay the disease progression. This means that the condition of patients with Parkinson's disease will gradually deteriorate and that the disease will eventually limit the patients' possibilities to work and live a normal and independent life.

#### Spinal cord injuries

Spinal cord injuries are usually caused by traumatic events resulting in partial or complete paralysis. The extent of paralysis depends on where the damage occurs: in the neck, thoracic spine or lumbar spine. A complete spinal cord injury is defined as an injury where the patient can accomplish no voluntary movement or have any sensory feedback below the injury. A spinal cord injury causes degeneration of the nerve fibers below the site of the injury as nerve cells do not regenerate. Patients suffering from a complete spinal cord injury may, in addition to paralysis suffer from other serious symptoms, including neuropathic pain, bowel and bladder incontinence, sensory loss, pressure sores, infertility and sexual dysfunction. Increasing stability, restoring bowel and bladder control, reducing pain or enabling sexual functionality would constitute a major improvement of the patient's quality of life.

Complete spinal cord injuries are more common among younger persons and more common in males, as a result of, among other things, a more active and risky lifestyle and working environment. Patients with complete spinal cord injuries require life-long therapy and care, which means high costs for the health care system. A treatment that could reduce the paralysis or improve some functions would be a significant step forward, not only for the patients and their families, but also for society from a cost perspective. Currently no effective treatments are available for chronic complete spinal cord injuries.





#### Other types of dementia

Other types of dementia, such as dementia and cognitive impairment in patients with Down's syndrome and dementia in persons suffering traumatic brain injuries, are potential future indications for the drug candidates that BioArctic is currently developing for Alzheimer's disease. Some 5-6 million individuals around the world are estimated to have Down's syndrome. The development of dementia in Down's syndrome often appears already at the age of 40-50 and is preceded, as in Alzheimer's disease, by an increased amount of amyloid in the brain that can be seen in PET examinations.



# Positive results with BAN2401 in line with the amyloid hypothesis

Professor Dennis J. Selkoe at Harvard Medical School and Brigham and Women's Hospital in Boston is a renowned authority on Alzheimer's disease and has made ground-breaking contributions to the current scientific knowledge regarding the biochemical mechanisms of the disease development. We asked him to comment on the significance of the recent Phase 2b trial, which demonstrated consistent dose-dependent effects of BioArctic's drug candidate BAN2401 on several clinical endpoints, as well as on PET and other biomarkers.

»I AM VERY IMPRESSED by the rational, well-grounded scientific approach that BioArctic and Eisai have taken," says Professor Selkoe. "Overall, the results of the study suggest that BAN2401 robustly cleared amyloid plaques and led to clinically meaningful and statistically significant slower decline of cognitive function.«

In the early 1990s, Professor Selkoe formulated the so-called amyloid hypothesis regarding the development of Alzheimer's disease. According to this theory, the neurodegeneration in Alzheimer's disease is caused by accumulation of amyloid beta-peptide (A $\beta$ ), the protein that BAN2401 is targeting.

**"OVER THE YEARS** a wealth of scientific evidence has accrued in support of the amyloid hypothesis. But the final proof is, of course, testing in humans, and the results from this large clinical trial with an anti-A $\beta$  antibody in over 800 patients lend strong new support for the theory.«

Professor Selkoe is also convinced that it is the smaller soluble aggregates of the  $A\beta$  protein, the oligomers/protofibrils, that are the real culprits in the neuronal dysfunction of Alzheimer's disease.

»THERE IS MUCH evidence suggesting that it is not the amyloid plaques themselves that cause injury to the brain, but rather the soluble oligomers/protofibrils. As BAN2401 is highly selective for Aβ oligomers/protofibrils but has low binding to the other forms of the protein, the trial results also support the view that the oligomers/protofibrils are the right target for a disease modifying treatment in Alzheimer's disease.«

Finally, Professor Selkoe is keen to stress that we must not forget the social and human aspects of this research.

»THERE IS AN urgent need for a treatment that can slow or arrest the development of Alzheimer's disease, and the results suggest that BAN2401 may be doing that. In my role as a clinician this is the kind of agent I would recommend to my patients and their families.«

»IT'S EXCITING THAT BioArctic is addressing this urgent human need. For many other severe diseases, for example infectious and cardiovascular diseases, effective treatments have already been found, helping us to live longer lives. But living longer also means that we have become more likely to be affected by disorders prevalent among the elderly, like Alzheimer's disease, with tragic consequences. The kind of work that BioArctic is doing is therefore of great social and human importance and must go forward as fast as possible!«

Photo of Professor Dennis J. Selkoe: Susan R. Symonds



### New and better drugs and tools are needed to help patients and their families

BioArctic's goal is to improve the quality of life for patients with central nervous system disorders. But what is missing today? We asked Jan Marcusson, Professor and Chief Physician at the Department of Clinical and Experimental Medicine at Linköping University, Sweden.

Professor Marcusson first of all points to the need for more powerful medicines for the treatment of these diseases.

»THE DRUGS AVAILABLE today are not good enough to really help the patients and their families. There are no disease modifying drugs, neither for Alzheimer's disease, nor for Parkinson's disease, just medicines that can deal with the symptoms short term.«

Jan Marcusson believes that several different types of drugs will be needed in the future in order to achieve an optimal disease modifying treatment for Alzheimer's disease.

»WE PROBABLY NEED different treatment principles and combination treatments in order to tailor the treatment for each individual patient. Therefore, it is positive that BioArctic has a promising pipeline, but also that there are other pharma companies with product candidates under development. Hopefully various products will complement each other well in the future.«

But Professor Marcusson says that it is more than just new drugs that is needed. There is also a need for more efficient tools for diagnosing neurodegenerative diseases.

»TODAY ALZHEIMER'S DISEASE is diagnosed in primary care primarily by means of tests of memory and mind functions. If the patient is referred to a specialized memory clinic also spinal fluid samples and imaging may be used.«

»FOR EARLY DETECTION of all who may be on their way to developing the disease we would need simple biological tests, for instance blood tests, that can signal an incipient disease process. When we hopefully get access to new efficient drugs that can impact the disease progression it also becomes even more important to be able to identify the patients at an early stage, maybe even before they develop symptoms.«

Professor Marcusson means that BioArctic has an important role to play in this development.

»I AM INCREDIBLY grateful that there are companies that want to focus on developing these new tools. A smaller company like BioArctic, which unlike the big pharma giants can focus fully on this area, and also has close connections to academic research can make great contributions towards enabling patients and their families who are affected by these devastating diseases to get better help in the future.«

Photo of Professor Jan Marcusson: Nils Petter Nilsson

## A MARKET WITH GREAT POTENTIAL

Common to all BioArctic's therapy areas is the fact that there currently are high medical needs that cannot be met by the treatments available on the market. There is also a great need for better and more specific diagnostic methods enabling correct diagnosis at an early stage and earlier treatment, and for monitoring the treatment effect. Future disease modifying treatments will be used earlier in the disease process, which will lead to an increased potential in a market with an aging population.

50

2018

A normal

brain

#### Alzheimer's disease

The demographic development with an aging population and increasing life expectancy has led to a dramatic increase in the incidence of diseases that affect the elderly, such as various forms of dementia. Some 50 million people worldwide suffer from some form of dementia and the global costs for dementia in 2018 was estimated to approximately USD 1000 billion<sup>1</sup>. The costs are in part attributable to drugs and medical care related to the dementia diseases as such, but the majority of the costs are indirect costs for assisted living and similar.

In 2030 approximately 75 million people are expected to suffer from some form of dementia disease and the care costs for these persons are expected to rise to about USD 2,000 billion<sup>2</sup>. If no effective disease modifying treatments that can halt or delay the disease progression are developed and made available to the patients, the estimated number of persons with dementia diseases is expected to reach approximately 152 million before 20503.

Alzheimer's disease accounts for approximately 60-80 percent of all diagnosed dementias4. It is estimated that approximately 30 million people worldwide suffer from Alzheimer's disease today and the number is expected to triple in 30 years. According to data compiled by GlobalData some 13 million patients suffer from Alzheimer's disease in the nine biggest markets<sup>5</sup> - China, the US, India, Japan and EU-5 (France, Germany, Italy, Spain and the UK).

The treatments for Alzheimer's disease currently on the market are used to alleviate the symptoms, but they cannot halt or slow down the disease progression.

#### 13 million >60% of all dementia diseases are the estimated number of nationts diagnosed as Alzheimer's disease in the nine biggest markets: China. the US, India, Japan and EU-5. 152 50 million people are estimated to suffer from some form of dementia disease. The figure is expected to rise to 152 million by 2050. 2030E 2050F THIS IS HOW THE ALZHEIMER BRAIN LOOKS Images from the PET center, Uppsala University Hospital, Sweden. Amyloid deposits visualized with C11-PIB

The brain of a

person with only

mild pathological changes

An Alzheimer

brain

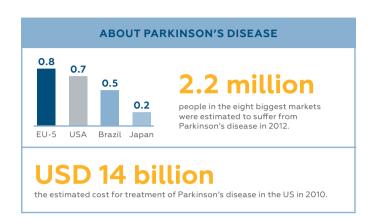
**ABOUT ALZHEIMER'S DISEASE** 

<sup>1) 3)</sup> World Alzheimer Report - Alzheimer's Disease International 2018.

<sup>2)</sup> World Alzheimer Report - Alzheimer's Disease International 2015.

<sup>-4)</sup> Alzheimer's Association. 2018 Alzheimer's Disease Facts and Figures. Alzheimers Dement 2018: 14(3):367-429.

<sup>5)</sup> The information from Global Data is derived from Global Data's market report concerning Alzheimer's disease.



Future disease modifying treatments will be used earlier in the course of the disease, and will not compete directly with existing symptomatic treatments.

Other types of dementia, such as dementia and cognitive impairment in patients with Down's syndrome and dementia in persons who have suffered traumatic brain injuries, are potential future indications for the drug candidates that BioArctic is developing for Alzheimer's disease. Approximately 5-6 million people worldwide with Down's syndrome<sup>1</sup> are at great risk for developing dementia already at age 40-50.

#### Parkinson's disease

Parkinson's disease is the second most common neurodegenerative disease. Compared to Alzheimer's disease it affects a younger patient group, which means that many who fall ill are still at working age, with considerable financial consequences for the individual and society.

From 1990 to 2015 the prevalence of Parkinson's disease has doubled. In 2015 it was estimated that 6.2 million people suffered from Parkinson's disease worldwide<sup>2</sup>. This number is expected to increase to 12.9 million by 2040<sup>3</sup>. In 2012 2.2 million people suffered from Parkinson's disease in the eight biggest markets for the disease – the US, Brazil, Japan and EU-5<sup>4</sup>. The US has the highest prevalence (0.7 million) followed by Brazil (0.5 million). In EU-5 the number is estimated to 0.8 million<sup>5</sup>.

There are currently no estimates of the global public costs for Parkinson's disease. An estimate regarding the US alone calculated the direct and indirect costs linked to treatment of Parkinson's disease in 2010 to USD 14 billion, a figure expected to double to USD 28 billion by 2040<sup>6</sup>. Direct costs

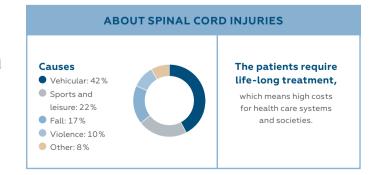
associated with Parkinson's disease include patient care, medication and care costs. Indirect costs include the stress on the care giver and the patient's lost productivity.

The treatments for Parkinson's disease that are currently on the market are focused on relieving the motor symptoms, but these drugs cannot stop or slow down the progression of the disease. There is currently no disease modifying treatment for Parkinson's disease. As in Alzheimer's disease, there is extensive research in progress aimed at identifying earlier stages of the disease where disease modifying treatments can be initiated when such treatments become available.

#### Spinal cord injuries

A spinal cord injury occurs when a trauma or a disease damages the spinal cord and results in partial or total paralysis. The annual incidence of spinal cord injuries worldwide has been estimated to 22 cases per million people. The number of patients with spinal cord injuries varies between 12.7 and 44.3 per million inhabitants depending on country. Some 40 percent of these patients are estimated to have complete spinal cord injuries, some 2.5 million live with paralysis. Complete spinal cord injuries are more common among younger persons, primarily men injured in accidents.

Repairing a permanently injured spinal cord has constituted an enormous challenge. The acute treatment of spinal cord injuries has improved during the last decades, but there is still no effective treatment for chronic complete spinal cord injuries. The poor prognosis in combination with the lack of effective treatments to restore functions has caused society to focus on offering basic and essential care services. The patients require life-long treatment and care, which means high costs for health care systems and societies. The life time cost for a patient is estimated to approximately MUSD 3 9.



- 6) Kowal et al., 2013
  - 7) Datamonitor, Stakeholder Opinions: Spinal Cord Injury, 2010.
  - 8) NSCISC Annual Statistics report 2010. 9) Krueger et al., 2013.

Ref; Lancet Vol 388, ISSUE 10053, p 1545-1602, 2016. Global burden of Disease 2015 Disease and injury incidence and prevalence collaborators. DOI: https://doi. org/10.1016/S0140.6736(16)31678-6.

<sup>2) 3)</sup> Dorsey and Bloem, JAMA Neurology 2018;75:9-10.

<sup>4) 5)</sup> The information from GlobalData is derived from GlobalData's market report concerning Parkinson's disease.

# WE CONTRIBUTE WITH RESEARCH AND DEVELOPMENT OF THE HIGHEST QUALITY

BioArctic operates in areas with high medical needs. The company's long-term value development is dependent on high scientific competence and innovation ability in areas that constitute some of the major global health challenges.



TO PERFORM RESPONSIBLE research, comply with our code of conduct, invest in quality systems and work environment, and attract and retain competent and committed employees is the core of BioArctic's approach to sustainable development.

#### Our role in society

Our ambition is to conduct research of the highest quality that contributes sustainable and innovative solutions to the health challenges of society. Society requires that BioArctic performs an efficient, ethical and thorough research work in the development of our drugs and treatments. We take the safety measures and make responsible decisions as required by law and authorities. We actively follow changes regarding ethical issues in connection with new science and new technologies, and the potential risks for patients participating in clinical trials. In order to protect the environment we take measures to prevent environmental impact from our own operations. Taking responsibility is one of our core values and also at the heart of our long-term business strategy and our daily work.

#### **Code of conduct**

We want to achieve an added value for BioArctic's stakeholders without compromising our responsibility for the environment, work environment and society. Ethical, social and environmental responsibility is an integral part of BioArctic's daily operations and should contribute to sustainable development of the company that benefits all stakeholders long-term. As part of the work with sustainability, we ensure that the contents of the code of conduct are kept up to date and are implemented in the operations.

#### Work environment

Work environment management at BioArctic should be long-term and preventive and be seen as a natural part of the operations, of the decisions we make and of what we do. BioArctic follows a continuous systematic work environment management with regular studies of the work environment and with follow-up on measures decided. BioArctic also performs an annual follow-up and evaluation of the systematic work environment management of the past year. The work environment should be such that the risks for ill health and accidents are minimized and enabling well-being and development opportunities for the employees.

#### Sustainable employeeship

It is BioArctic's ambition to offer a work environment that promotes health and well-being and a healthy balance between work and private life.

#### **Quality management**

BioArctic's operations are strictly regulated and in addition there are very high demands for quality in everything that we do. This mean that we in addition to complying with laws and regulations always must challenge ourselves and continue to strive for the best quality possible. During the year, we have expanded our resources for quality management and focused on upgrading the system for quality control, among other things. During the year, BioArctic was audited by one of our collaboration partners with good result.

#### Demands on suppliers and partners

BioArctic puts high demands regarding sustainability, code of conduct and quality on our suppliers and partners. There are regulations requiring us to perform regular audits to ensure that our suppliers are compliant with the pharma industry's quality system and Good Manufacturing Practice (GMP). During 2018, BioArctic has regularly audited the company's most important suppliers according to a predetermined plan.

#### **GDPR**

The company has taken the measures required to meet the demands of the new European General Data Protection Regulation (GDPR) which came into effect in May 2018.

#### **BIOARCTIC'S OPERATIONS ARE CHARACTERIZED BY**

We are firmly committed to being a leader in research and innovation in the company's therapeutic focus areas and consequently to upholding a high ethical level and integrity in all that we do. We apply our scientific expertise and innovation capacity to some of the greatest global health challenges, such as Alzheimer's disease and Parkinson's disease.

We also take on the challenge of solving the acute need for an innovative and effective treatment for complete spinal cord injury.

We promote a business that is characterized by openness, creativity and respect for the equal value of human beings.

## WE ENCOURAGE CURIOSITY AND INNOVATION

In order to achieve BioArctic's vision we focus on our core operations and encourage a strong culture of curiosity and innovation. Our employees, consultants and partners represent diversity and create a workplace with an international and dynamic environment.



OUR CORE VALUES				
Science driven	Respect	Commitment	Teamwork	Responsibility
We are driven by our desire to understand the diseases in order to be able to develop new treatment strategies	We act respectfully	We are highly engaged in everything we do	We collaborate to achieve our common goals	We deliver high quality science

OUR EMPLOYEES' COMMITMENT and willingness to contribute to our vision is BioArctic's foremost asset. We want our employees to reach their full potential and therefore the individual development plans include a combination of the company's goals and individual goals. We encourage continued development by offering employees new areas of responsibility and tasks in the projects.

#### Employeeship is characterized by our core values

We want everyone to live our core values, which means that all take responsibility and assume ownership for their tasks, including a responsibility for the positive development of the entire company and for achieving its vision. In order to succeed we collaborate across project and function borders and we feel a strong commitment to developing new types of effective drugs that can enable an improved quality of life for the patients. The employeeship at BioArctic is also characterized by a respectful conduct in all parts, which is evaluated in the performance reviews.

#### BioArctic's three leaderships

BioArctic's operations are science-driven with great focus on the projects. In order to run the operations in an optimal way we have defined three types of leadership. The individual-based leadership is the leadership executed by line managers, with the development of the individual in focus. Project leadership is the leadership that project managers use to run the projects. The third type of leadership is self-leadership, which all employees



#### **OUR VISION**

To become a world-leading Swedish biopharma company within research, development and sales of innovative and effective biological drugs for patients with neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease, and innovative and effective treatments for complete spinal cord injuries.

and managers use to drive themselves and their tasks. Self-leadership is characterized by taking own responsibility, result orientation and focus on solutions. In all three types of leadership we strive for sustainable leadership. Sustainable leadership means that we offer stimulating and developing work assignments, encourage well-being and work for a healthy balance between work and leisure time.

#### BioArctic's specialist career

As a complement to BioArctic's different types of leadership we have during the year initiated and defined a specialist career with three levels: Scientist, Senior Scientist and Principal Scientist. The specialist career should be seen as an alternative to the traditional managerial career and as a way for BioArctic to encourage continuous competence development.

#### Competence development and knowledge exchange

The employees' ability to contribute their expertise is crucial to the success of BioArctic. We value everyone's competence and accumulated experience. We encourage continuous competence development and initiatives for increased knowledge and regular exchange of scientific knowledge. We annually arrange an internal research conference aimed at stimulating increased exchange of ideas and knowledge between the projects. We also arrange internal seminars in the research areas where we are active and invite external lecturers with specialist competence in relevant areas.

#### Safe and secure working environment

Our working environment should be a safe and secure one where all coworkers develop and feel committed. As a part of the company's systematic environment management work we continuously perform physical safety inspections with focus on laboratory and office environment. Each quarter we perform pulse measurements related to the psychosocial work environment. The annual performance reviews and regular follow-up meetings have a number of focus areas, including working environment factors, core values and well-being.

#### **Diversity**

BioArctic's point of departure is that all coworkers and applicants shall be treated equally. Each person has the same value and possibilities, regardless of background and individual differences. In interaction these differences increase the power of development and change and become an asset for the organization. Our diversity work means to not discriminate, but to value and manage diversity. At BioArctic there is zero tolerance of all forms of harassment. A system for whistleblowers has been established and all employees have been informed about this.

Diversity means variation and scope of people, thoughts and opinions – a mix of gender, transgender identity or expression, ethnicity, religion or other creed, disability, sexual orientation and age.

#### **Equality**

Of BioArctic's total number of employees at the end of the year, 31 (25) persons, 60 (60) percent were women and 40 (40) percent were men. In the management team 50 (33) percent were women and 50 (67) percent were men. In management positions 50 (33) percent were women and 50 (67) percent were men.

The Allbright Foundation presents an annual prize to the Swedish listed company that has made the best progress in the area of gender equality during the past year. BioArctic was honored with a shared second place in the 2018 Allbright Award.

The jury statement read: BioArctic is prized primarily for a workplace that gives men and women the same career opportunities, according to the employees themselves.

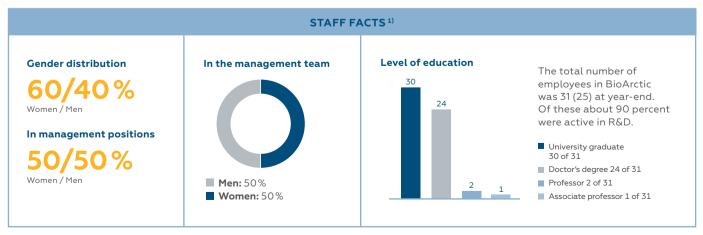
#### Recruitment

2018 was a successful year for BioArctic, which has meant that the company is expanding. During the year a number of new employees were recruited and new consultants contracted.

BioArctic continuously works to develop and improve the recruitment process, in parallel with strengthening the company's attractiveness as an employer. It is essential to attract the best persons in the competence areas for which the company has a need.



ALLBRIGHTPRISET 2018
Bioarctic



<sup>1)</sup> All figures are calculated on the total number of employees, 31 persons, at December 31, 2018. Contracted consultants corresponded to 10 (12) full-time positions at year-end, but are not included in the above statistics.

## INNOVATION DRIVE AND STRATEGIC PARTNERSHIPS

BioArctic's success and long-term value development is dependent on high scientific quality in our research and an effective and flexible organization.

BIOARCTIC IS ORGANIZED to have the necessary know-ledge and competences that an innovative biopharma company in world-class needs. The organization consists of highly educated, research-oriented employees and consultants with extensive experience of drug development. The management team has more than 200 years of combined experience, the majority from research and development departments at big pharma companies. The company's staff is well educated and includes 24 scientists with a doctoral degree, which means that some 75 percent of the employees have a doctor's degree in relevant research areas.

» BioArctic's proprietary technology, committed and competent employees, collaborations with leading academic research groups and strategic partnerships with global pharma companies have made it possible to develop innovative treatments based on antibodies (immunotherapy) for neurodegenerative diseases.«

#### **Extensive expertise and experience**

BioArctic has the internal knowledge base needed to conduct cutting edge research in neurodegenerative diseases. Our coworkers are educated at renowned universities, including Uppsala University, Karolinska Institutet, KTH Royal Institute of Technology, Stockholm University, Linköping University, Lund University, Umeå University and Université Pierre et Marie Curie, Paris, Harvard Medical School, Boston and Rockefeller University, New York, among others.

BioArctic's board and management team are well composed groups with competence and experience from leading academic positions as well as extensive industry and business background. Read more in the sections Board of directors and Management, pp. 36–39.

#### Strategic scientific collaborations

BioArctic has extensive collaborations with leading external research groups at Uppsala University, Karolinska Institutet, Karolinska University Hospital, University of Gothenburg, Linköping University and Lund University. The company also has extensive strategic collaborations with strong research partners like Eisai and AbbVie.

#### Efficient and flexible organization

BioArctic also engages external partners for pharmacology, toxicology, process development and production of drug substances, and for the conduct of clinical trials.

### THE BIOARCTIC SHARE

BioArctic's market capitalization amounted to SEK 7.2 billion (2.3) at the end of the year. The share price has had a positive development and increased by 215 percent over the year.

#### Trading and market capitalization

BioArctic's B-share (BIOA B) has been listed on Nasdaq Stockholm since October 12, 2017. The introductory price was SEK 24.00. BioArctic is included in the Mid-Cap segment and is classified as a company in the health care business. The capital acquisition in connection with the listing contributes to giving BioArctic the opportunity to pursue the business strategy to build a research portfolio with a number of innovative projects that can be outlicensed to global pharma companies at a suitable point in time.

At the end of 2018, the market capitalization was SEK 7.2 billion (2.3). The price of the BioArctic share was SEK 82.00 (26.00) on the last day of trading in December 2018. BioArctic's B-share had its highest price of SEK 172.00 on July 24, whereas it recorded its lowest price of SEK 20.40 in March and April.

#### Share capital and number of shares

At the end of the year the share capital amounted to SEK 1,761,200 spread over 88,059,985 shares; 14,399,996 of which are unlisted A-shares and 73,659,989 are B-shares. 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.

#### Share turnover

In 2018 a total of 77.5 (11.6) million B-shares were traded for a value of MSEK 7,012 (301). On average 912,436 (211,586) BioArctic's B-shares were traded per day.

#### **Dividend policy**

BioArctic's revenue and profit are mainly based on income of non-recurring character under the license and collaboration agreements that the company has entered into. BioArctic will continue focusing on developing and expanding the company's project portfolio. The available financial resources and the reported result should

therefore generally be reinvested in the operations to finance BioArctic's long-term strategy.

Any future dividends and the size thereof will be determined based on the company's long-term growth, earnings trend and capital requirements, taking into account the current objectives and strategies. Dividends shall, in so far as dividends are proposed, be well-balanced with respect to the goals, scope and risks of the operations.

#### Dividend

The board of directors proposes to the Annual General Meeting a dividend of SEK 1.50, a total of approximately MSEK 132.

The Board has concluded that the capital supply is secure and the company's financial resources are sufficient to finance its projects and programs as planned without additional share issue.

#### **Ownership structure**

At the end of 2018 BioArctic had 8,221 (2,398) shareholders. Swedish owners accounted for 88 percent of the capital and 95 percent of the votes. BioArctic's foreign institutional investors, primarily in Europe and the US, accounted for 12 percent of the capital and 5 percent of the votes. BioArctic's A-shares are owned by Demban AB and Ackelsta AB, companies owned by the founders of BioArctic.

#### Information to shareholders

BioArctic informs its shareholders and the outside world through multiple channels. Information made public in press releases, interim reports and annuals reviews are published at the company's website www.bioarctic.com. Material from the presentations of the interim reports is also available for downloading from the website by journalists, investors, analysts and other interested parties. BioArctic's website is the main channel for the annual report, therefore the annual report is not sent to shareholders who have not explicitly requested this.

#### Distribution of Swedish/foreign ownership at December 31, 20181)



Foreign shareholders 11.86 %

#### 1) Source: Euroclear Sweden AB.

#### Ownership distribution by geography at December 31, 2018<sup>1)</sup>



Rest of the world 0.22 %

#### Ownership categories at December 31, 2018 1)

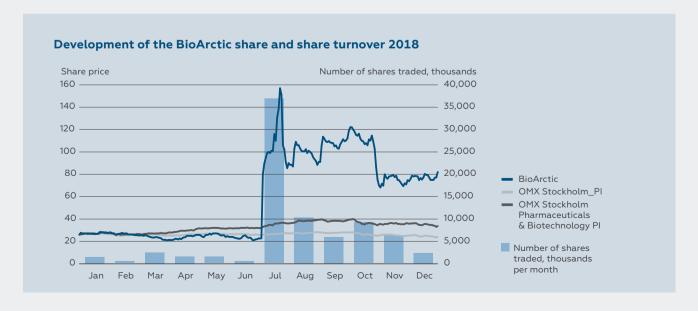


• Legal entities (Sweden): 61.17 %

Funds and institutions (Sweden): 22.32 %

Foreign shareholders: 11.86 %

Private individuals (Sweden): 4.65 %



#### Distribution of the share at December 31, 2018<sup>1)</sup>

Number of shares	Number of shareholders	A-shares	B-shares	Total number of shares (%)
1 – 500	6,778	-	936,967	1.06
501 – 1,000	711	-	601,038	0.68
1,001 - 5,000	545	-	1,209,470	1.37
5,001 – 10,000	66	-	501,256	0.57
10,001 - 50,000	71	-	1,682,588	1.91
50,001 –	50	14,399,996	68,728,670	94.40
Totals at 31 Dec 2018	8,221	14,399,996	73,659,989	100.00

<sup>1)</sup> Source: Euroclear Sweden AB.

#### The ten largest shareholders according to Euroclear Sweden AB at December 31, 2018

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	8,639,998	22,848,159	35.76	50.19
Ackelsta AB	5,759,998	15,232,989	23.84	33.46
AP3 (3rd Swedish National Pension Fund)	-	4,107,414	4.66	1.89
AP4 (4th Swedish National Pension Fund)	-	3,500,000	3.97	1.61
Skandinaviska Enskilda Banken S.a., W8imy	-	3,231,581	3.67	1.48
Öresund, Investment AB	-	2,250,000	2.56	1.03
Handelsbanken Fonder	-	1,977,150	2.25	0.91
Unionen-Svenska	-	1,763,000	2.00	0.81
SEB Investment Management	-	1,649,531	1.87	0.76
Gladiator	-	1,458,478	1.66	0.67
10 Largest shareholders	14,399,996	58,018,302	82.24	92.81
Other shareholders	-	15,641,687	17.76	7.19
Total	14,399,996	73,659,989	100.00	100.00

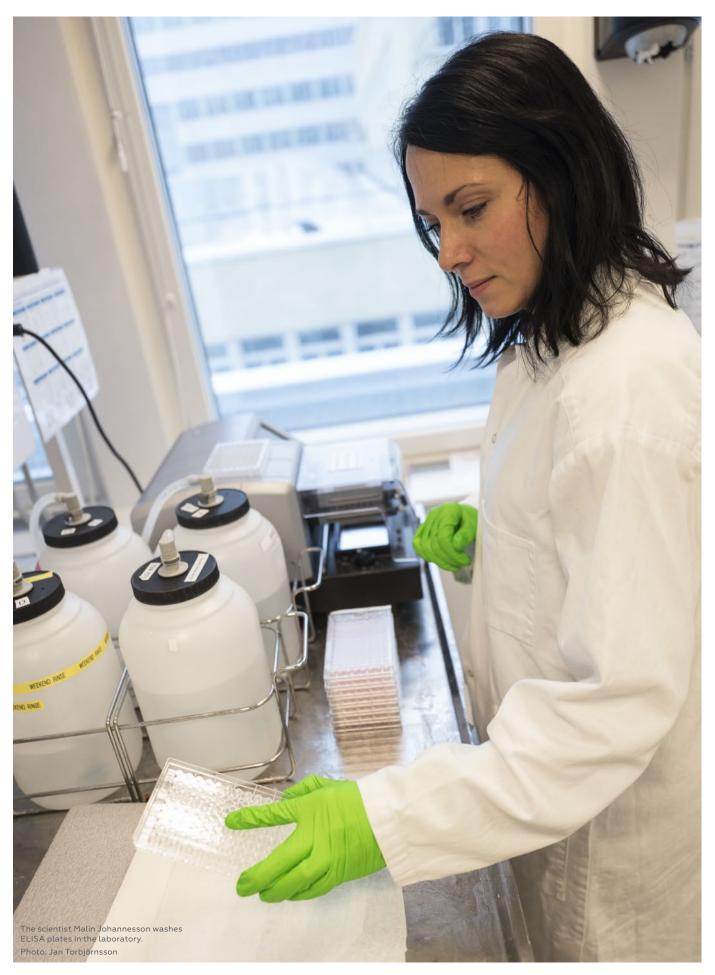
#### Financial calendar

2019 May 9 Interim Report January – March
May 9 Annual General Meeting
July 11 Interim Report January - June
October 24 Interim Report January
- September

2020 February 6 Full Year Report 2019
(preliminary date)

#### Analysts continuously monitoring BioArctic

Carnegie, Erik Hultgård, erik.hultgard@carnegie.se DNB (Den Norske Bank), Patrik Ling, patrik.ling@dnb.se Rx Securities, Joseph Hedden, joseph@rxsecurities.com



### **BOARD OF DIRECTORS**



#### Wenche Rolfsen Chairman of the board since September 2017; board member since 2016, chairman of the Remuneration Committee

Wenche Rolfsen has 30 years' experience in senior positions in preclinical research and development at Pharmacia. She was responsible for the early clinical organization at Quintiles Europe and CEO of Quintiles Scandinavia for a total of 11 years. She also has extensive experience from board positions in listed companies and is a member of the board of Swedish Match AB and Recipharm AB, among others

**Born:** 1952

**Education:** Pharmacist, Doctor of pharmacy (pharmacognosy), Adjunct Professor at Uppsala University,

Background: Head of pharmacology at Pharmacia & Upjohn; VP clinical trials Quintiles Europe, CEO of Scandinavian Quintile's organization

Other current assignments: Chairman of InDex Pharmaceuticals Holding AB and InDex Pharmaceuticals AB; board member of Swedish Match AB, Recipharm AB and InDex Diagnostics AB, and CEO and board member of Rolfsen Consulting AB. Partner in Serendipity Partners

#### Prior assignments (past five years):

Chairman of Aprea Therapeutics AB, Denator AB and Aprea Personal AB; board member of Smartfish AB, Moberg Pharma AB, TFS Trial Form Support International AB, Apotek Produktion & Laboratorier AB and Stiftelsen Industrifonden

**Holdings:** 19,200 B-shares and call options entitling to the acquisition of 27,270 B-shares

Independent in relation to BioArctic, its senior management and major shareholders



# Ivar Verner Deputy chairman since 2017, board member since 2010, chairman of the Audit Committee

Ivar Verner is former authorized public accountant, partner and chairman of the board of Grant Thornton Sweden AB

Born: 1947

**Education:** Master of Business Administration, Stockholm School of Economics, Sweden

**Background:** Former authorized public accountant, partner and chairman of Grant Thornton Sweden AB

Other current assignments: Chairman of Erlandsons Brygga AB, Centrum Fastigheter i Norrtälje AB, Norrländska Gruppbostäder Holding AB, Tegnér & Son AB, Firren AB and Valsättra Exploaterings AB. Board member of Förvaltningsaktiebolaget Kanalen, Verner & Partners AB and Valsättra Tomter AB

Prior assignments (past five years): Chairman of Rejlers AB (publ), Wel-

come Hotel i Sverige AB, Constrera AB and SpineMedical AB. Board member of Forex Bank AB and Svenska Vårdfastigheter AB

**Holdings:** 72,500 B-shares through Förvaltningsaktiebolaget Kanalen AB and call options entitling to the acquisition of 27,270 B-shares

Independent in relation to BioArctic, its senior management and major shareholders



# Hans Ekelund Board member since 2014, member of the Audit Committee and the Remuneration Committee

Hans Ekelund has an MBA from Stockholm School of Economics. He has had a number of assignments as board member and has previously been CFO of Ratos

Born: 1948

**Education:** Master of Business Administration, Stockholm School of Economics, Sweden

**Background:** Previously CFO of Ratos and a number of assignments as board member

Other current assignments: Chairman of Connect Öst (non-profit organization) and board member of Ekarna Invest AB

Prior assignments (past five years):

Chairman of Minimarket Stockholm AB and deputy board member of Wave Impact Heat Management AB. Board member of SpineMedical Sverige AB and SpineMedical AB

Holdings: 42,500 B-shares through Ekarna Invest AB and call options entitling to the acquisition of 27,270 B-shares

Independent in relation to BioArctic, its senior management and major shareholders



#### Pär Gellerfors Board member since 2003

Pär Gellerfors is together with Lars Lannfelt founder of BioArctic. Pär Gellerfors is Associate Professor of Biochemistry at Stockholm University. He is also co-founder of HemeBiotech/ Zymenex A/S and has held several board memberships

Born: 1947

Education: Bachelor degree in chemistry at Stockholm University 1967; PhD in chemistry at Stockholm University 1977; Associate Professor of Biochemistry at Stockholm University 1983, Sweden

Background: One of the founders of BioArctic in 2003, CEO from 2003 to 2013 and Senior Vice President Business Strategy and co-opted member of the management team until September 1, 2018. More than 30 years' experience of drug and business development from Pharmacia and biotech companies. Co-founder of HemeBiotech/ Zymenex A/S

Other current assignments: CEO and board member of Swenora Biotech AB, board member of Ackelsta AB, LPB Sweden AB and deputy board member of Otwomed AB

Prior assignments (past five years):

CEO and board member of SpineMedical Sverige AB and SpineMedical AB and board member of LPB Sweden Holding AB

**Holdings:** 5,759,998 A-shares and 15,232,989 B-shares through Ackelsta ΔΒ

Not independent in relation to BioArctic, its senior management and in relation to major shareholders



#### Lars Lannfelt Board member since 2003, Chairman of the Research Committee

Lars Lannfelt is founder of BioArctic with Pär Gellerfors. Lannfelt is Senior Vice President for University Collaborations and co-opted member of the Management team. He is also Senior Professor at Uppsala University and member of the Royal Swedish Academy of Sciences

Born: 1949

Education: Medical degree 1978; specialist in psychiatry 1987; doctoral thesis at Karolinska Institutet 1990; Associate Professor of Neurogenetics at Neurogenetics in geriatrics 2000, Sweden

Background: Professor of Geriatrics at Uppsala University 2001; Senior Professor at Uppsala University 2016 and member of the Royal Swedish Academy of Sciences since 2004. Founder of BioArctic in 2003, chairman of the board 2003 – September 2017, board member from September 2017 and a number of assignments and roles in the company

Other current assignments: Board member of Demban AB and LPB Sweden AB

# Prior assignments (past five years):

Board member of Demban Förvaltning AB, SpineMedical Sverige AB, SpineMedical AB and LPB Sweden Holding AB

**Holdings:** 8,639,998 A-shares and 22,848,159 B-shares through Demban AB

Not independent in relation to BioArctic, its senior management and in relation to major shareholders



#### Mikael Smedeby Board member since May 2018

Mikael Smedeby is a lawyer and board member of Advokatfirman Lindahl, Uppsala, where he has been active since 1997 and in leading positions since 2010. For several years Mikael Smedeby has been ranked as "leading" in life sciences in Sweden by Practical Law Company and listed in Who's WhoLegal Life Science 2018

Born: 1968

**Education:** Master of Laws, Uppsala University, Sweden

Background: Active as a lawyer since 1994, with Advokatfirman Lindahl since 1997, member of the Swedish Bar Association since 1999. Since 2010, leading positions at Advokatfirman Lindahl, as managing partner and chairman, among others. Special experience in corporate law, mergers and acquisitions, financing and licensing, with many clients in the life sciences sector. Member of BioArctic's board of directors 2014 – June 2017, extensive experience of board work in companies outside life sciences

Other current assignments: Chairman of the board in Hanza Holding AB, Coeli Holding AB, Salléngruppen AB. Board member of Uppsala Innovation Centre AB, Disruptive Materials AB and Motion Display Scandinavia AB

Prior assignments (past five years): – Holdings: 10,000 B-shares and call options entitling to the acquisition of 27,270 B-shares

Not independent in relation to BioArctic and the company's senior executives as a result of Advokatfirman Lindahl's assignment as advisors to BioArctic



# Eugen Steiner Board member since 2017, member of the Audit Committee and the Remuneration Committee

Dr. Eugen Steiner is an investor and a life-science veteran. For more than 30 years, he has led several life-science companies across various geographies and stages of development. He has been with the venture capital firm Healthcap since 1997, serving as Venture Partner. He earned his M.D. and Ph.D. degrees from Karolinska Institutet

Born: 1954

Education: Medical doctor, Ph.D. in clinical pharmacology at Karolinska Institutet Sweden

Background: Over 30 years' experience of leading life science companies. Prior to that Dr. Steiner was a physician at Karolinska Hospital (Huddinge) and researcher at Karolinska Institutet. Venture partner to HealthCap since 1997 and CEO of several companies in which HealthCap has invested. Extensive experience from board positions in Sweden, Norway, the UK and the US

Other current assignments: Board member of Apotek Produktion & Laboratorier AB, Inbox Capital AB, Karolinska Institutet Holding AB, Karolinska Institutet Innovations AB, Stiftelsen Forska!Sverige, Stockholm School of Entrepreneurship and Setraco AB. Deputy board member of Doctrin AB

#### Prior assignments (past five years):

CEO of Glionova AB, CEO and chairman of NVC Holding AB and chairman of Biostratum Inc., LTB4 Sweden AB, CC10 Sweden AB, Globen Ögonklinik AB and PanSyn Sweden AB. Board member of Alba Therapeutics Inc., Hanza Holding AB, MD International AB, and Nephrogenes Inc.

Holdings: 40,000 B-shares through Setraco AB and call options entitling to the acquisition of 27,270 B-shares

Independent in relation to BioArctic, its senior management and major shareholders

#### Information and holdings:

Information and holdings in BioArctic AB at December 31, 2018.

### **MANAGEMENT**



#### Gunilla Osswald Chief Executive Officer

In the current position since 2014, employed since 2013. More than 30 years' experience from drug development. Successfully brought projects from pre-clinical and clinical development to regulatory approval and market introduction as well as managed in- and outlicensing of drug projects. Leading positions at Astra/AstraZeneca during 1985-2013, including Vice President with the responsibility of the product portfolio in neurodegenerative diseases

Born: 1961 Education: Pharmacist 1983 and Ph.D. in biopharmacy and pharmacokinetics at Uppsala University 1984, Sweden Other current assignments: Board member of PledPharma AB (publ) and SpineMedical AB and deputy board member of LPB Sweden AB Prior assignments (past five years): Board member of SF Process Development AB, SpineMedical Sverige AB and LPB Sweden Holding AB **Holdings:** 12,800 B-shares and call options entitling to the acquisition of 87,270 B-shares



#### Jan Mattsson Vice President Finance,

Chief Financial Officer
In the current position since
2017. More than 30 years'
experience in business and
administration, including CFO
for Sefina Finance AB, Allenex
AB, Argnor Wireless Ventures
AB, Logitall AB and Investment AB Kinnevik

Born: 1960
Education: MBA, University of Orebro 1984, Sweden
Other current assignments: – Prior assignments (past five years): Board member of Sefina Svensk Pantbelåning AB and Humidus AB
Holdings: 15,000 B-shares (privately and through the company Almsäter Interim Management AB) and call options entitling to the acquisition of 27,270 B-shares



#### Gunilla Andersson\* Senior Director HR

In the current position since January 2019. Contracted since 2014 for HR. The first two years for various HR related assignments and from 2016 for the role as HR Director. Nearly 30 years' experience as HR consultant and HR manager from educational organizations and pharmaceutical companies like Pharmacia and Novartis among others. For the past 17 years, she has managed her own consulting company focusing on HR, leadership and recruitment

Born: 1961
Education: B.Sc. Human
Resource Development and
Labour Relations from Lund
University 1990, Sweden
Other current assignments: –
Prior assignments (past five
years): –
Holdings: –



#### Christina Astrén Eriksson Director IR and Communications

Contracted since 2015 and for investor relations since 2017. More than 30 years' experience in communications, including communications director at Pfizer, AstraZeneca, Wyeth and Pharmacia and interim IR & communications manager at Orexo AB (publ)

Born: 1959
Education: Graduate from
Stockholm School of Journalism, Stockholm University
1984; Graduate from the
Institute of Higher Education in
Marketing Communication and
Advertising (IHR), Stockholm
University, 1988, Sweden
Other current assignments: –
Prior assignments (past five
years): –

Holdings: 25,000 B-shares (through the company C Astrén AB)



#### Hans Basun Vice President Clinical Development, Chief Medical Officer

In the current position since 2007. More than 20 years' experience from the pharmaceutical industry in leading position in clinical research at Astra Arcus/AstraZeneca. Background as Senior Consultant at Huddinge University Hospital and Uppsala University Hospital, Sweden

Born: 1949 Education: Medical degree and residency in psychiatry and geriatrics, Associate Professor at Karolinska Institutet and Adjunct Professor at Uppsala University

Other current assignments: Deputy board member of SpineMedical AB

Prior assignments (past five years): –

Holdings: 20,823 B-shares and call options entitling to the acquisition of 27,270 B-shares



#### Johanna Fälting Vice President Translational Science & Pharmacology In the current position since

January 2018, employed since 2012. 18 years' experience of neuroscience/pharmacology, translational science and development in the global pharma and biotech industry

#### Born: 1972

Education: Ph.D. in Physiology, Stockholm University 2001; Licentiate degree in physiology, Stockholm University 1997; Master's degree in biology, Stockholm University, 1995, Sweden

Other current assignments: Deputy board member of Biozoul AB

#### Prior assignments (past five vears): -

Holdings: 10,000 B-shares and call options entitling to the acquisition of 27,270 B-shares



#### Lars Lannfelt\*\* Senior Vice President **University Collaborations**

Co-opted member of the Management team. In the current position since September 2018. Founder of BioArctic with Pär Gellerfors in 2003. Board member and a number of assignments and roles in the company since then. More than 35 years' experience from research in Alzheimer's disease and other neurodegenerative diseases. Professor of Geriatrics at Uppsala University 2001; Senior Professor at Uppsala University 2016 and member of the Royal Swedish Academy of Sciences since 2004

## Born: 1949

Education: Medical degree 1978; specialist in psychiatry 1987; doctoral thesis at Karolinska Institutet 1990; Associate Professor of Neurogenetics at Karolinska Institutet 1993: specialist in geriatrics 2000, Sweden

# Other current assignments:

Board member of BioArctic AB, Demban AB and LPB Sweden AB

# Prior assignments (past

five years): Board member of Demban Förvaltning AB, SpineMedical Sverige AB, SpineMedical AB and LPB Sweden Holding AB Holdings: 8,639,998 A-shares and 22,848,159 B-shares through Demban AB



#### Mikael Moge Vice President Chemistry, Manufacturing & Control and Protein Chemistry

In the current position since January 2018, employed since 2012. 20 years' experience from drug development and 15 years of experience as research and development manager within process development and GMP manufacturing. Previously section manager at Process R&D at AstraZeneca

#### Born: 1967

Education: Master of Engineering chemical engineering, KTH Royal Institute of Technology 1992, Ph.D. of Science organi chemistry, KTH 1997, Stockholm, Sweden

# Other current assignments: -Prior assignments (past five

Holdings: Call options entitling to the acquisition of 6.825 B-shares



#### Christer Möller Vice President Pre-Clinical **Development, Chief Scientific** Officer

In the current position since 2006. 20 years' experience from developing protein drugs from idea to clinical trials including leading positions at small biotech/pharma companies; Zymenex A/S among others. In addition, comprehensive academic experience having pursued research projects concerning growth factors and preclinical research in diabetes

#### Born: 1959

Education: B.Sc. in Biology Stockholm University 1983; Ph.D. in Medical Science, Karolinska Institutet 1992, Sweden

#### Other current assignments: -Prior assignments (past five years): -

Holdings: 16,500 B-shares and call options entitling to the acquisition of 27,270



#### Nora Sjödin Vice President Regulatory Affairs

In the current position since January 2018, employed since 2017. 25 years' experience from leading positions in global Regulatory Affairs in companies such as AstraZeneca, NDA Regulatory Service and Pharmalink. The extensive regulatory affairs experience includes regulatory matters from early development projects to approved pharmaceuticals on the market

#### Born: 1957

Education: General Nursing, SRN, 1978, B.Sc. 1982, Sweden Other current assignments: Prior assignments (past five vears): -Holdings: -

# Changes in the management team:

- Gunilla Andersson joined the management team effective January 1, 2019.
- \*\* Lars Lannfelt co-opted member of the management team effective September 1, 2018. Before that date, Pär Gellerfors was co-opted member of the management team until September 1, 2018

#### Information and holdings:

Information and holdings in BioArctic AB at December 31, 2018.

# Board of directors' report

The Board of Directors and the Chief Executive Officer of BioArctic AB (publ), corporate identity number 556601-2679, hereby submit the Annual Report and consolidated financial statements for the fiscal year January 1 – December 31, 2018.

#### **OPERATIONS**

BioArctic AB (publ) based in Stockholm, Sweden, is the parent company in the BioArctic Group, which also includes the dormant subsidiaries SpineMedical AB and LPB Sweden AB. BioArctic was founded in 2003 based on innovative research at Uppsala University. BioArctic is a research based biopharma company focusing on disease modifying treatments and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. The company also develops a treatment for complete spinal cord injury. The company focuses on new types of treatments in areas with high unmet medical needs.

BioArctic has high scientific competence and experience in developing drugs from idea to market. Collaborations with universities are of great importance to the company together with the strategically important global partners in the Alzheimer and Parkinson projects. BioArctic conducts its own clinical development in the field of complete spinal cord injury, a project partly funded by the EU's research and development program Horizon 2020. Through long-term collaboration agreements with global pharmaceutical companies, BioArctic has demonstrated its skills and ability to deliver innovative drug projects.

In the treatment area Alzheimer's disease, BioArctic has collaborated with Eisai since 2005. BioArctic has entered into a total of three research collaboration agreements and two license agreements relating to the antibodies BAN2401 and BAN2401 back-up. The total value of these agreements may amount to MEUR 218 in addition to royalties. So far, approximately MEUR 47 has been received. In the treatment area Parkinson's disease, BioArctic has collaborated with AbbVie since 2016, when a research collaboration agreement was concluded including, among other things, the antibody BAN0805. AbbVie then obtained the right to acquire a license to develop and commercialize the antibodies. The total aggregated value of the agreement may amount to MUSD 755 and in addition royalty payments may be received. BioArctic has received a one-time payment of MUSD 80. In November AbbVie exercised its option to license BioArctic's portfolio of antibodies targeting alpha-synuclein for Parkinson's disease and other potential indications. The license became effective after clearance by the U.S. Federal Trade Commission (FTC) in December

and triggered a milestone payment of MUSD 50. AbbVie will finance and conduct the clinical development of BAN0805, now ABBV-0805.

The project portfolio is a combination of fully funded projects run in partnership with global pharma companies and innovative in-house projects with significant market and outlicensing potential.

BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (BIOA B).

#### **ORGANISATION**

The average number of employees in BioArctic during the year amounted to 29 (26). At December 31, 2018 the number of employees is 31 (25). Of these employees 19 (15) are women. About 90 (95) percent of the total number of employees are active in research and development.

BioArctic, to a great extent, utilizes external companies e.g. for the production of drug substances and the conduct of clinical trials. In order to run an efficient operation with a relatively small organization BioArctic hires key consultants for specific assignments and for tasks in areas of expertise that the company lacks or only requires from time to time.

BioArctic strives to offer competitive salaries and benefits and applies individual salaries adapted to the local labor market. BioArctic's ambition is to offer a work environment that promotes health and well-being and a healthy work/life balance.

#### PROJECT PORTFOLIO

BioArctic's project portfolio at December 31, 2018:

- Two projects in clinical phase: BAN2401 for Alzheimer's disease and SC0806 for patients with complete spinal cord injury.
- Three drug projects in preclinical phase: BAN2401 for Down's syndrome with dementia and traumatic brain injury, BAN2401 back-up for Alzheimer's disease, and BAN0805/ ABBV-0805 for Parkinson's disease, and biomarker and diagnostics projects for Alzheimer's disease.
- Three projects in research phase for Alzheimer's disease (AD1801, AD1502 and AD1503).
- Two projects in research phase for Parkinson's disease (PD1601, PD1602) as well as biomarker and diagnostics projects for Parkinson's disease.
- One blood-brain barrier technology project.

#### **MAJOR AGREEMENTS**

#### Eisai

Since 2005, BioArctic has a long-term collaboration with Eisai in the area of Alzheimer's disease. Within the framework of the collaboration, BioArctic and Eisai have entered into several agreements, including the development and commercialization agreement concerning the antibody BAN2401 entered into in 2007 and a similar agreement concerning BAN2401 back-up entered into in 2015. BioArctic has granted Eisai a global and exclusive license concerning research, development and commercialization of drugs using the antibodies for the treatment of Alzheimer's disease. Eisai is responsible for the clinical development, applications for market approval and commercialization of the products. BioArctic retains the rights to market and sell the licensed products in the Nordic countries and the rights to the antibodies for the treatment of other indications than Alzheimer's disease.

#### **AbbVie**

In September 2016, BioArctic and AbbVie entered into a research and license agreement concerning the development and commercialization of BioArctic's antibodies to alpha-synuclein for the treatment of Parkinson's disease and other potential indications and related diagnostics.

In November 2018, AbbVie exercised its option for the license for further development and commercialization of products containing BioArctic's antibody BAN0805 and other antibodies discovered or developed within the framework of the research collaboration.

BioArctic has the primary responsibility for the preclinical development work and AbbVie is responsible for the clinical development.

### Swenora Biotech AB

The commercialization of SC0806, BioArctic's product for treatment of patients with complete spinal cord injury, is governed by a license agreement from September 2008 between the company and Swenora Biotech AB. Under the agreement BioArctic has obtained a global exclusive right to developing, marketing and selling the technology and the product that may be suitable to commercialize, based on the results from the clinical development. BioArctic has financed the preclinical development and pays for the clinical development of the project, partly funded by the EU's Horizon 2020. BioArctic has made a one-time payment to Swenora Biotech AB in connection with reaching a regulatory milestone. The payments totaled MSEK 0.8. If the project develops positively BioArctic

will make milestone payments to Swenora Biotech AB when development-related and regulatory milestones are achieved, and royalty on future sales.

# The EU's research and development program Horizon 2020

For the clinical development of SC0806 BioArctic and its partners have received a grant from the EU program Horizon 2020 (Grant Agreement No. 643853) from the European Commission amounting to a maximum of MEUR 6.4. So far MEUR 4.2 has been paid. BioArctic is the project coordinator and coordinates the work and the reporting of results to Horizon 2020 for the six parties included in the project, in addition to BioArctic Karolinska University Hospital and rehabilitation clinics in Sweden, Estonia, Finland and Norway. Since August 2017, patients treated with SC0806 in the ongoing Phase 1/2 study are offered 12 months' additional treatment in an extension study.

# KEY EVENTS DURING THE FINANCIAL YEAR Corporate governance

At the Annual General Meeting, Mikael Smedeby was elected board member. The other members were re-elected. Professor Lars Lannfelt, who together with Pär Gellerfors founded BioArctic, resumed his employment at September 1. Associate Professor Pär Gellerfors left his employment in the company on September 1, but remains a board member.

#### Alzheimer's disease

Eisai presented the 18 months analysis of the Phase 2b-study with BAN2401 in 856 patients with early Alzheimer's disease at the AAIC® conference in Chicago on July 25 and at the CTAD conference in Barcelona on October 25. The results demonstrated consistent dose-dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints as well as dose-dependent and significant effects also on biomarkers including amyloid-PET and was well tolerated. This is the first study in late clinical phase that demonstrates a disease modifying effect on clinical function as well as a reduced aggregation of amyloid beta in the brain and an effect on neurodegenerative biomarkers. An open-label extension study, without placebo control, with continued BAN2401 treatment with the highest study dose for the participants in the Phase 2b study was started at the end of the year. BioArctic's partner Eisai was discussing the next stage in the development of BAN2401 with regulatory authorities and is preparing for the continued clinical program.

In August 2018, BioArctic obtained exclusive rights to develop antibody treatments for Alzheimer's disease from a research project previously jointly owned with Eisai. The partner Eisai retained the rights to develop small molecule treatment from this research project with a different target than those in the projects BAN2401 and BAN2401 back-up.

#### Parkinson's disease

In November AbbVie exercised its option to license BioArctic's antibody portfolio targetting alpha-synuclein for Parkinson's disease and other potential indications. The license was acquired after clearance by the U.S. competition authority in December and triggered a milestone payment of MUSD 50. AbbVie will progress and finance the clinical development of BAN0805, now known as ABBV-0805. The first clinical study is planned to start in 2019.

During the year, BioArctic received approval for a concept patent Europe for the company's strategy for disease modifying treatment of Parkinson's disease.

### Complete spinal cord injury

In April the inclusion of patients with complete spinal cord injury to the first of three panels of BioArctic's ongoing clinical Phase 1/2 study with SC0806 was completed. The study is approved by the regulatory authorities and ethics committees in Sweden, Estonia, Norway and Finland. Recruiting of patients for the next panel has been on-going. An interim analysis of the first panel regarding efficacy and safety is planned no later than the first half of 2020.

BioArctic gained patent protection in the US for a method for treatment of complete spinal cord injury. The company also received patent approval in Japan and the EU for a medical device which is one of the components of the product candidate SC0806.

### Diagnostics and technology

BioArctic expanded the research collaboration with Uppsala University concerning the further development of technologies for antibody-based imaging (PET) of the brain in Alzheimer patients, and for better passage across the blood-brain barrier.

The company entered into a research agreement with Brain Biomarker Solutions in Gothenburg AB concerning the development of new diagnostics for Alzheimer's disease.

At the end of the year BioArctic obtained a grant from the EU's Horizon 2020 for participation in a European research consortium for better diagnostic tools and biomarkers for Parkinson's disease.

## Five-year summary

Amounts in MSEK	2018	2017	2016	2015	20141)
Income statement					
Net revenues	714.0	140.7	105.6	41.6	53.7
Other operating income	16.3	19.0	39.1	7.6	1.0
Expenses	-241.4	-140.5	-69.8	-44.3	-47.7
Operating profit	488.8	19.3	74.6	4.8	6.9
Profit for the year	381.6	15.2	57.6	3.7	6.8
Operating margin, %	68.5	13.7	70.7	11.7	12.9
Balance sheet					
Non-current assets	11.0	10.0	8.5	12.7	13.0
Current assets	464.8	20.1	7.0	4.6	8.5
Cash and cash equivalents	917.3	1 110.4	692.5	113.8	132.8
Equity	1,017.7	636.1	60.8	108.3	104.6
Deferred tax liabilities	32.5	5.5	4.1	-	1.4
Current liabilities	342.8	498.9	643.1	22.8	48.4
Cash flow					
From operating activities	-200.1	-135.3	675.1	-16.4	-24.2
From investing activities	-3.1	-2.8	-3.0	-2.3	-1.3
From financing activities	-	560.2	-105.1	-	-
Cash flow for the year	-203.1	422.1	567.1	-18.7	-25.5
Key ratio					
Equity/asset ratio, %	73.1	55.8	8.6	82.6	67.7
Return on equity, %	46.1	4.3	68.1	3.5	6.7
Data per share, SEK					
Earning per share	4.33	0.22	0.91	0.06	0.11
Equity per share	11.56	7.22	0.96	1.72	1.66
Cash flow from operating activities per share	-2.27	-1.99	10.71	-0.26	-0.38
Share price at 31 December 2)	82.00	26.00	-	-	-

<sup>&</sup>lt;sup>1)</sup> Fiscal years 2014 have been recalculated to IFRS.

# FINANCIAL DEVELOPMENT Revenues

Net revenues amounted to MSEK 714.0 (140.7), which was an increase by MSEK 573.3 compared to the previous year. The increase is attributable to the MSEK 448.6 (MUSD 50) milestone payment from AbbVie and the increased activity in the Parkinson program.

Other operating income primarily relates to research grants and exchange rate gains and amounted to MSEK 16.3 (19.0) in 2018. The reason for the decrease during 2018 is due to reduced reported income from research grants and lower positive operational exchange rate gains than in 2017.

# Operating expenses and operating profit

Operating expenses amounted to MSEK 241.4 (140.5). Project costs amounted to MSEK 145.4 (63.6) and the increase during the year is explained by increased project costs, mainly attributable to the Parkinson program, but also to other projects in the portfolio. Other external expenses decreased by MSEK 4.3 to MSEK 31.9 and the decrease is due to costs in 2017 relating to the listing on Nasdaq Stockholm. Personnel costs increased to MSEK 57.0 (32.9), largely explained by a provision for variable remuneration based on achieved targets in the Parkinson program, but also by an increase in the number of employees. Other operating expenses amounted to MSEK 5.0 (5.7), consisting of realized operational exchange rate losses.

<sup>&</sup>lt;sup>2)</sup> The company was listed in October 2017, so no observable share price exists before the listing.

Operating profit for the year amounted to MSEK 488.8 (19.3), which was an increase by MSEK 469.5. As described above, the increase was mainly attributable to the MSEK 448.6 (MUSD 50) milestone payment from AbbVie which was recognized as revenue in its entirety in 2018.

# Profit for the year and earnings per share

Net financial items amounted to MSEK 0.8 (0.4) in 2018. Profit before tax amounted to MSEK 489.6 (19.7). The tax expense for the year was MSEK 108.0 (4.5) and the effective tax rate was 22.1% (23.0). Profit for the year amounted to MSEK 381.6 (15.2) in 2018 and earnings per share before and after dilution amounted to SEK 4.33 (0.22).

# Financial position

BioArctic's balance sheet total at December 31, 2018 amounted to MSEK 1,393.0 (1,140.4). The equity amounted to MSEK 1,017.7 (636.1) at December 31, 2018. This corresponds to equity per outstanding share of SEK 11.56 (7.22) before and after dilution. The equity/assets ratio has increased from 55.8 percent at December 31, 2017 to 73.1 percent at December 31, 2018. There were no loans as of December 31, 2018 and no loans have been taken since this date. The Group has no other credit facility or loan commitments.

The MUSD 50 milestone payment for the licensing of the Parkinson portfolio to AbbVie was recognized as revenue in its entirety and was paid to BioArctic in February 2019.

#### Cash flow

Cash flow from operating activities in 2018 amounted to MSEK -200.1 (-135.3). The decrease in cash flow compared to the preceding year is related to the increased activity primarily in the Parkinson program.

The cash flow from investment activities during the year amounted to MSEK -3.1 (-2.8). The investments in tangible fixed assets for the year amounted to MSEK 4.3 (3.4) and were mainly related to scientific instruments.

The cash flow from financing activities during the year amounted to MSEK 0.0 (560.2). The cash flow in 2017 was derived from the fundraising that took place during 2017.

Cash flow for the year amounted to MSEK -203.1 (422.1) and the Group's cash and cash equivalents at December 31, 2018 amounted to MSEK 917.3 (1,110.4).

# **ENVIRONMENTAL WORK AND WORK ENVIRONMENT**

BioArctic is a responsible business partner and employer and adheres to environmental and health and safety legislation. In addition, the company has internal policies that include

guidelines for the environment and the work environment. Pharmaceutical research is conducted in BioArctic's premises in Stockholm. The activities are conducted in accordance with the permits granted to BioArctic by the relevant authorities. For example, the company has permits from the Swedish Work Environment Authority concerning the use of chemicals and from the Swedish Board of Agriculture concerning the import and use of tissues in the company's laboratory. In accordance with Swedish environmental legislation BioArctic is registered with the County Administrative Board to conduct its activities. BioArctic is not involved in any environmental dispute. No working place accidents were reported to the Swedish Work Environment Authority in 2018.

BioArctic only contracts manufacturers of drugs (antibodies) whose plants are certified in accordance with the relevant legislation. The same applies to the procurement of services from so-called CROs (Contract Research Organizations).

During the year BioArctic continuously reviewed the company's processes and systems to ensure that they are working in order to prevent inappropriate exercise of power. In November BioArctic was honored with a shared second place in the Allbright Prize 2018. The prize is awarded annually by the Allbright Foundation to the Swedish listed company that has made the best progress in the area of gender equality during the past year.

### IT SECURITY

The importance of protecting the company's information makes IT security a high priority in BioArctic. The company's IT policy includes guidelines for use, data storage and communication. All data are copied and handled according to defined security and back-up procedures. Computers and programs are secured by means of local hardware encryption. BioArctic also continuously works to strengthen the employees' safety awareness in handling both hardware and software. The company has taken all measures necessary for meeting the requirements of the new European data protection regulation, GDPR, which came into effect in May 2018.

# RISKS AND UNCERTAINTY FACTORS

Company management makes assumptions, judgments and estimates that affect the content of the financial statements. Actual results may differ from these assumptions and estimates, as is also stated in the accounting principles. The objective of the Group's risk management is to identify, measure, control and limit the risks of the business.

The risks can be divided into external, internal and financial risks. For the financial risks, see also Note 4.

#### External risks

#### Market

BioArctic's success and long-term value development is dependent on a high scientific quality of research and the ability to assess the risks involved in the operations and in the market where BioArctic operates and has control over factors that can be influenced. If competitors win market share with their products or competing research projects achieve better effect and reaches the market faster than BioArctic's products, the future value of BioArctic's project and product portfolio may be lower than initially expected.

# Projects and products

Research and drug development up to market approval is a risky process requiring much capital. The majority of the projects that are started will never reach market approval. Crucial for the future of BioArctic is the company's ability to develop new drug and product candidates, enter into partnerships and successfully bring own projects to market introduction and sales.

Even if BioArctic's project and product portfolio gain regulatory approvals there are also other factors that decide if the company's product achieves commercial success. Factors like effect, price, side-effects, treatment options, among others, affect the possibilities to gain acceptance among doctors, patients and client organizations, and so does the choice of sales and marketing strategies.

#### Regulatory decisions

BioArctic is exposed to regulatory decisions like necessary approvals for conducting clinical trials and commercializing the drugs, and changes in the rules for pricing and reimbursement of drugs or changed conditions for a given prescription.

### Competition and commercial success

BioArctic operates in a large and attractive medical area, thus there is significant competition and competitors may develop, market and sell drugs that are more effective, safer and lower priced than BioArctics' products. The pharma industry is very competitive and there is a risk that the current product margins cannot be maintained. A number of BioArctic's major competitors develop and market drugs for the same diseases that BioArctic targets. Competitors may also have higher manufacturing and distribution capacity as well as more sales and marketing opportunities than BioArctic or BioArctic's partners.

#### Internal risks

### Research and development

Research and development of drugs is associated with high risk as great financial resources are invested in a product that may never become a finished medical product. Many projects are discontinued during the process as the substances developed either cannot demonstrate intended effect or turn out to have too great negative side-effects. Other competing pharma and biotech companies conducting research in the same therapy area may cause BioArctic's research projects to appear less attractive to complete and cause them to be discontinued at an earlier stage.

### Product liability and insurances

BioArctic's operations involve product liability, which is unavoidable in connection with research and development, preclinical studies, clinical trials, production, marketing and sales of drugs. Even if BioArctic finds the current insurance protection sufficient, the extent of the insurance protection and the compensation amount is limited. There is thus no guarantee that BioArctic will receive full compensation for any damages under the existing insurance coverage. It cannot be guaranteed that a suitable insurance coverage can be obtained at acceptable cost, or that such insurance coverage can be obtained at all. Nor can any guarantees be made as to which impact product liability claims or other claims may have on BioArctic's operations or financial position.

## **Production**

BioArctic has no in-house manufacturing, which means that the company relies on subcontractors for the production of products and drugs and for production for projects in preclinical and clinical phase. Relevant substance must be produced in sufficient quantity and of sufficient quality. There is a risk that BioArctic cannot meet its production needs at a reasonable cost at a given point in time.

#### Patent protection

BioArctic's future success to a large extent depends on the company's ability to gain and retain protection for the intellectual property rights related to BioArctic's products. The conditions for gaining patent protection for inventions in the pharma and biotech area are generally difficult to assess and involve complex legal and scientific issues. There is no guarantee that BioArctic can gain and retain patents for its products or technologies. Even when patents are granted they can be disputed, declared invalid or circumvented, which may limit BioArctic's ability to prevent competitors from marketing similar products

and decrease the time under which BioArctic has patent protection for its future products.

# Collaboration agreements

A significant component of BioArctic's operations and market strategy is to enter into collaboration agreements with pharma and biotech companies for the development and sales of potential products. Disagreements and conflicts may occur between BioArctic's partners or counterparts concerning the terms of existing agreements, e.g. the interpretation of clinical data, the achievement of milestone payments, interpretations of financial remuneration for or the ownership to patents and similar rights that have been developed within the framework of these collaborations. Currently BioArctic is to a large extent dependent on partners that are significantly bigger than BioArctic.

# Clinical trials, safety and efficacy criteria

Before a new product in the form of a drug substance can be introduced on the market it must be demonstrated that it complies with the stringent standards for safety and efficacy established by the authorities in the countries where the drug is planned to be marketed. The process for regulatory approval normally requires extensive preclinical and clinical studies that are very costly and time consuming. The U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other regulatory authorities may delay, limit or simply deny granting market authorization for one or more causes, if a drug substance is not safe or effective, among others. If BioArctic does not succeed in getting approval of their current or future drug candidates, it will not be possible to market and sell them. Any shortcomings or delays in the implementation of preclinical or clinical trials will delay and thereby reduce BioArctic's ability to generate revenue from the commercialization of these drug candidates, which may have considerable negative financial effects for BioArctic.

### Dependence on key personnel

BioArctic is to a great extent dependent on key personnel. The ability to recruit and retain qualified personnel is of outmost importance to ensure the competence level in the company.

# Financial risks

### Currency risk

BioArctic has a relatively large commitment in foreign currency. This is hedged by keeping liquidity in the currencies where there is an exposure. To fully maintain this at any given point in time is complicated, thus it cannot be ruled out that there may be an extra foreign currency exposure at times.

### Counterparty risk

BioArctic only collaborates with creditworthy counterparts, which is important as the company has only a few counterparties that generate revenue.

### Liquidity and refinancing risk

BioArctic has very good liquidity but not yet any products on the market generating revenue from sales or royalties. At the time when the company intends to carry out a refinancing there may be uncertainties concerning market conditions and internal conditions for a refinancing.

#### KEY EVENTS AFTER THE END OF THE FINANCIAL YEAR

- On February 4 BioArctic announced that Eisai will initiate a single Phase 3 confirmatory study with BAN2401 for early Alzheimer's disease in the first quarter of 2019. The study was initiated in March.
- In February the U.S. Food and Drug Administration (FDA) approved the Investigational New Drug Application for ABBV-0805, previously called BAN0805, for Parkinson's disease. The Phase 1 study with ABBV-0805 started in March.
- BioArctic's product candidate SC0806 for patients with complete spinal cord injuries has progressed into the Phase 2 part of the Phase 1/2 study.

### **FUTURE PROSPECTS**

The capital acquisition in connection with the listing contributes to giving BioArctic the opportunity to continue developing and working with the projects covered by the big and strategic collaboration agreements, and to run the company's in-house projects. All three areas; Alzheimer's disease, Parkinson's disease and complete spinal cord injuries, are areas where effective treatments are lacking today.

2018 was a successful year that has created a good basis for the future. BioArctic's partner Eisai reported positive results from the Phase 2b study with BAN2401 for the treatment of early Alzheimer's disease and a single confirmatory Phase 3 study is initiated. AbbVie has licensed BioArctic's portfolio of antibodies to alpha-synuclein for disease modifying treatment of Parkinson's disease and other potential indications. AbbVie will finance and run the clinical development of BAN0805, now called ABBV-0805. All in all, this gives the company further external validation and we are looking forward with confidence to the future of these collaborations.

# **GUIDELINES FOR REMUNERATION TO SENIOR EXECUTIVES**

The company shall offer company management market level compensation that makes it possible to recruit and retain senior

executives. The compensation to company management shall consist of fixed salary, customary employment benefits and pension. Variable compensation can also be paid.

The fixed salary shall take into account the individual's responsibilities and experience, and be reviewed annually. The division between fixed salary and any variable remuneration shall be proportional to the executive's responsibility and authority. The variable remuneration shall always be limited to a predetermined maximum amount and be linked to predetermined and measurable criteria and designed to achieve greater community of interest between the executive and the company's shareholders. The earning period or alternatively the time from entering into the agreement until a share may be acquired shall not be less than three years in share and share price related incentive programs. The terms for variable remuneration shall be designed so that the board, under particularly difficult circumstances, has the possibility to restrict or refuse to give out variable remuneration if this is deemed to be unreasonable and inconsistent with the company's responsibility to the shareholders. For variable remuneration it is possible to restrict or refuse to pay variable remuneration if the board considers that this is justified for other reasons.

Pension terms shall be in accordance with market practice for corresponding positions and be based on defined contribution solutions.

Fixed salary during the period of notice and severance pay shall together not exceed an amount corresponding to the fixed salary for two years.

Executives who hold a position as board member or deputy board member shall not receive a special board fee for this.

The board is allowed to deviate from these guidelines in individual cases should there be special reasons for doing so.

Information on the guidelines for remuneration adopted at the Annual General Meeting 2018 and other principles for terms of employment concerning senior executives is given in Note 8.

### PARENT COMPANY

BioArctic AB (publ) based in Stockholm, Sweden is the parent company of the BioArctic Group. All the Group's operations are conducted in the parent company. The parent company's net profit amounted to MSEK 285.8 (10.4) for the financial year 2018.

# **BIOARCTIC'S SHARE AND OWNERSHIP**

BioArctic's B-share (BIOA B) is listed on Nasdaq Stockholm Mid Cap. The market value at the end of 2018 was SEK 7.2 billion (2.3). During 2018 BioArctic's share saw a positive development of 215 percent. The BioArctic B-share reached

its highest level of SEK 172.00 on July 24, whereas it recorded its lowest price of SEK 20.40 in March and April. BioArctic's share price was SEK 82.00 (26.00) on the last trading day in December 2018.

At the end of 2018 BioArctic had 8,221 (2,398) share-holders. Swedish owners represented 88.1% of the capital and 95.2% of the votes. Main owners are Demban AB (Lars Lannfelt) with 50.2% of the votes and 35.8% of the capital and Ackelsta AB (Pär Gellerfors) with 33.5% of the votes and 23.8% of the capital.

#### DIVIDEND

The board of directors proposes to the 2019 Annual General Meeting that a dividend of SEK 1.50 per share, a total of approximately MSEK 132, shall be paid.

The board has concluded that the company's finances are sufficient to finance its projects and programs as planned without additional share issue.

### PROPOSED APPROPRIATION OF PROFIT

The following funds are at the disposal of the Annual General Meeting:

Amount in SEK	December 31, 2018
Share premium reserve	560,017,974
Retained earnings	53,944,488
Profit for the year	285,759,413
Total	899,721,875

The board proposes that the above profits of SEK 899,721,875 are appropriated with SEK 132,089,978 paid as dividend to shareholders and SEK 767,631,898 carried forward.

As regards the Group's and Parent company's result and position in general, see the following income statement and balance sheet with accompanying notes.

# Corporate governance report

#### **GENERAL**

BioArctic AB (publ) is a Swedish public limited liability company, corporate identity number 556601-2679, with its registered office in Stockholm, Sweden. BioArctic's B-share (BIOA B) is listed on Nasdaq Stockholm Mid Cap since October 12, 2017.

Corporate governance refers to the rules and decision-making hierarchies that contribute to the efficient and controlled management of the operations of a company, with the aim of meeting the owners' demands for return on invested capital. Corporate governance in Sweden has traditionally been regulated by law. In addition, the industry's self-regulatory bodies have continuously presented various provisions concerning corporate governance. Companies listed on a regulated market shall apply the Swedish Code of Corporate Governance ("the Code") issued by the Swedish Corporate Governance Board. More information on the Code is available at www.bolagsstyrning.se.

After the listing on Nasdaq Stockholm the Swedish Companies Act, BioArctic's articles of association, Nasdaq Stockholm's rules for issuers, the Code and other applicable laws and regulations form the basis for corporate governance within BioArctic. Also internal regulations and instructions affect BioArctic's corporate governance, e.g. the rules of procedure of the board, instructions for the CEO (Chief Executive Officer), instructions for financial reporting and other policy documents within the Group.

BioArctic aims for a high standard by clarity and simplicity in the management system and the governing documents. Governance, management and control of BioArctic is divided between 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. Through increased openness and transparency a good insight into the company's activities is provided, which contributes to effective governance.

# **BIOARCTIC'S APPLICATION OF THE CODE**

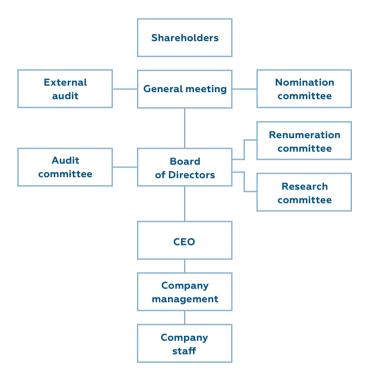
No deviation from the Code has occurred during the year.

# COMPLIANCE WITH STOCK EXCHANGE REGULATIONS AND GOOD PRACTICES ON THE STOCK MARKET

BioArctic has not been subject to any decision of the Nasdaq Stockholm disciplinary board or any statement by the Swedish Securities Council.

### CORPORATE GOVERNANCE STRUCTURE

The following figure gives an overview of BioArctic's corporate governance structure.



#### SHAREHOLDERS

BioArctic's B-share (BIOA B) is noted on Nasdaq Stockholm. At December 31, 2018 the share capital in BioArctic amounted to SEK 1,761,199.70 divided into 14,399,996 series A-shares (number of votes: 10) and 73,659,989 series B-shares (number of votes: 1), each with a quotient value of SEK 0.02. The number of shareholders at the end of the year was 8,221 (2,398). (Source: Euroclear Sweden AB).

At December 31, 2018 the following shareholders had a holding in BioArctic representing at least one tenth of the voting power of all shares in the company:

Shareholder	Share of votes in BioArctic
Demban AB (controlled by board member Lars Lannfelt)	50.2%
Ackelsta AB (controlled by board member Pär Gellerfors)	33.5%

For further information on BioArctic's share and ownership structure, see the section The BioArctic share on pp. 32–34.

#### **GENERAL MEETING**

The shareholders' influence in the company is exercised at the General Meeting, which is the company's highest decision-making body. Shareholders who wish to participate in the proceedings at the meeting must be registered in the share register kept by Euroclear Sweden AB five weekdays before the General Meeting, and notify the company not later than the date specified in the notice of the meeting. This day must not be a Sunday, another public holiday, Saturday, Midsummer's Eve, Christmas Eve or New Year's Eve, and may not fall earlier than the fifth weekday before the meeting.

At the company's Annual General Meeting income statements and balance sheets are adopted, the board and auditors are elected, remunerations are determined and other statutory issues or matters prescribed by the Code are resolved. At the meeting there are opportunities for shareholders to ask questions to the board of directors, management and auditors. BioArctic's articles of association contain no restrictions on how many votes each shareholder can cast at a general meeting. Nor do the articles of association contain any specific provisions relating to the appointment or dismissal of board members or the amending of the articles of association.

The notice to attend a general meeting shall be published in the Swedish National Gazette (Sw. Post- och Inrikes Tidningar) and on the company's website. At the time of the notice, information relating to the notice shall be advertised in Svenska Dagbladet. Notice of an Annual General Meeting or Extraordinary General Meeting where amendment of the articles of association will be processed shall be issued not earlier than six (6) and not later than four (4) weeks prior to the meeting. Notice of other extraordinary general meeting shall be issued not earlier than six (6) and not later than three (3) weeks prior to the meeting. The minutes of the meeting shall be available on the company's website no later than two weeks after the meeting.

# Annual General Meeting May 15, 2018

The Annual General Meeting was held on May 15, 2018 in Stockholm. At the Annual General Meeting the following matters were treated:

- Presentation of the annual accounts and the auditors' report, and the consolidated accounts and the Group auditors' report
- Adoption of the income statement and balance sheet, and the Group income statement and Group balance sheet
- Decision of appropriation of company profits according to the adopted balance sheet
- Decision on the discharge of liability to the board and the CEO

- Determination of the number of board members and the number of auditors and deputy auditors
- Determination of remuneration to the board of directors and the auditor
- Election of board members
- Election of auditor
- Decision on the establishment of a nomination committee and guidelines for the work of the nomination committee
- Decision on guidelines for remuneration to senior executives

The minutes and other documentation from this general meeting are available at the company's website www.bioarctic.com

### **ANNUAL GENERAL MEETING 2019**

The Annual General Meeting 2019 will be held on May 9, 2019 at 5.00 p.m. at Grant Thornton Sweden AB, Sveavägen 20 in Stockholm.

#### NOMINATION COMMITTEE

According to the resolution at the Annual General Meeting in BioArctic on May 15, 2018 the members of the nomination committee for the 2019 Annual General Meeting shall be appointed by the chairman of the board by contacting the three largest shareholders according to Euroclear Sweden AB's transcription of the share register as of September 30, 2018 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.

At September 30, 2018 the three largest shareholders were Demban AB, Ackelsta AB and the Fourth Swedish National Pension Fund. The latter, however, has chosen to give up its seat on the nomination committee. Thus the Third Swedish National Pension Fund, which is the company's fourth largest owner (according to Euroclear Sweden AB), have been consulted and accepted a seat on the nomination committee.

The composition of the nomination committee shall be announced on the company's website no later than six months prior to the Annual General Meeting. The nomination committee represents the company' shareholders and shall prepare and submit proposals to the Annual General Meeting for decisions on the election of chairman of the board, deputy chairman (if any), and other board members, fees for the chairman and the other board members, and possible remuneration for committee work, the election of and fees to the auditor and deputy auditor (if applicable), resolution on the principles for appointing the nomination committee, and election of the chairman of the meeting.

The nomination committee for the Annual General Meeting 2019 consists of Margareta Öhrvall (Demban AB), Claes Andersson (Ackelsta AB) and Gunnar Blix (the Third Swedish National Pension Fund). The nomination committee appoints a chairman from among its members, and Gunnar Blix has been appointed. All shareholders have been given the opportunity to present proposals for board members for further evaluation in the context of the committee's work. The nomination committee has had 3 (1) meetings as well as informal contacts.

As a basis for its evaluation of the composition of the board the nomination committee has had access to the evaluation performed by the board and also had the opportunity to meet the board members individually. Based on this evaluation and the opportunity to consider proposals for new board members the nomination committee works out a proposal for the board that will be announced in connection with the notice of the 2019 Annual General Meeting. The auditors are appointed by the Annual General Meeting annually. In the election of auditors the audit committee (consisting of chairman Ivar Verner, Hans Ekelund and Eugen Steiner) supports the nomination committee in the development of proposals. The current auditors, Grant Thornton Sweden AB, were first elected at the 2016 Annual General Meeting.

#### **BOARD OF DIRECTORS**

### The board's tasks and responsibilities

The board of directors is ultimately responsible for BioArctic's organization and the management of the company's operations, which should be conducted in the best interest of the company and all shareholders.

The main tasks of the board include managing strategical issues concerning operations, financing, establishments, growth, result and financial position and continuously monitoring the company's financial situation. The board shall also ensure that there are effective systems for monitoring and control of the company's operations and ensure that BioArctic's information is transparent and accurate, relevant and reliable.

# The board's working practices and work allocation

The board adheres to written rules of procedure that are revised annually and adopted at the inaugural board meeting held in connection with the Annual General Meeting. The rules of procedure govern, among other things, board practices, 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.

Instructions for financial reporting and instructions for the CEO are also determined in connection with the inaugural board meeting.

### Composition of the board of directors

According to BioArctic's articles of association the board shall consist of no less than three (3) and no more than eight (8) members with no deputies. The members are normally elected at the Annual General Meeting for the time up until the next Annual General Meeting, but additional board members can be elected during the year at an Extraordinary General Meeting. The company shall have one or two auditors with or without deputy auditors.

The board consists of seven ordinary members, without deputies: Wenche Rolfsen (chairman), Ivar Verner (deputy chairman), Lars Lannfelt, Pär Gellerfors, Hans Ekelund, Eugen Steiner and Mikael Smedeby. At the Annual General Meeting on May 15, 2018, Mikael Smedeby was elected as a new board member. The chairman, deputy chairman and the other board members were re-elected.

The board considers that Wenche Rolfsen, Ivar Verner, Hans Ekelund and Eugen Steiner are independent to the company as well as to company management and major shareholders. Hans Ekelund is a cousin of Lars Lannfelt's wife. The board considers that this circumstance does not mean that he should not be considered to be independent to the company, its management and major shareholders. Mikael Smedeby is active as a lawyer and partner in Advokatfirman Lindahl KB, which provides ongoing legal advice to BioArctic at market-based rates. He is considered to be dependent in relation to BioArctic and the company's senior executives as a result of Advokatfirman Lindahl's assignment as advisors to BioArctic.

Lars Lannfelt and Pär Gellerfors are the company's main shareholders and own, through their own companies, 35.8 percent of the shares, representing 50.2 percent of the votes; and 23.8 percent of the shares representing 33.5 percent of the votes in the company, respectively. Up to September 1, 2018 Pär Gellerfors was also employed by the company and adjunct in the company' management team. A consultancy agreement regarding support in the area of contracts and patents was signed in December, 2018 between Ackelsta AB, owned by Pär Gellerfors, and BioArctic AB. No payments have been made under this agreement during 2018. From September 1, 2018 Lars Lannfelt is reemployed by the company and adjunct in the company's management team. Lars Lannfelt and Pär Gellerfors are thus not to be considered to be independent to the company, its management and major shareholders.

The board's composition, with members with different backgrounds and broad aggregate experience, means that the board members together have the knowledge required for the work of the board, including issues related to drug development, industry knowledge, strategy and corporate management.

It also means that the company management enjoys good individual support from board members in questions relating e.g. to science, research, contacts with regulatory authorities, law, finance, accounting, communications and organizational development.

The board members' age, educational background, working experience, significant current assignments, year of election and holdings in BioArctic is described in the presentation of the Board of directors on pp. 36–37.

#### Chairman of the board

The role of the chairman is to lead the board of directors' work and to ensure that the work is carried out efficiently, and that the board fulfils its obligations according to the Swedish Companies Act and the rules of procedure of the board. The chairman shall, through contact with the CEO, continuously receive the information needed to be able to monitor the company's position, financial planning and development. The chairman shall also consult with the CEO on strategic matters and verify that the board's decisions are implemented in an effective manner. The chairman is responsible for contacts with the shareholders in ownership matters and for communicating the views of the owners to the board. The chairman does not take part in the operative work in the company, nor is he or she a member of the management team.

#### Remuneration to the board of directors

At the Extraordinary General Meeting on May 15, 2018 the board's remuneration was determined to amount to a total of SEK 1,550,000. The remuneration should be SEK 500,000 to the chairman, SEK 250,000 to the deputy chairman, and SEK 200,000 to each of the other board members not employed by the company. The fees apply for the current term until the next Annual General Meeting. It was further decided that a fee amounting to SEK 100,000 should be paid to the chairman of the audit committee and SEK 60,000 to each other member of the audit committee not employed by the company. Finally a fee amounting to SEK 60,000 should be paid to the chairman of the remuneration committee and SEK 40,000 to each other member of the remuneration committee not employed by the company. No fees are paid for the research committee.

# The board of directors' work during the year

In 2018 the board held 12 (26) meetings, one of which was an inaugural meeting directly adjacent to the Annual General Meeting on May 15, 2018. The minutes taken at these meetings are minutes recording decisions.

The board's regular meetings are prepared by the chairman of the board together with the company's CEO. Prior to each board meeting the board receives a written material as a basis for the issues and decisions that will be addressed at the meeting. At some board meetings one or more representatives from the company management may participate to account for matters within their respective areas. At each regular board meeting an update on the operations and a financial follow-up is given. These reports are compiled by the CEO and the CFO (Chief Financial Officer). During the year also matters relating to the company's strategy, current and potential partners, organization and competence requirements have been discussed. The company's auditor participated in the meeting which dealt with the annual accounts and in meetings dealing with the interim report for the period January - September 2018 and the audit of the company's internal control. In this way the board and the auditor had the opportunity to discuss the operations, accounts and audit work.

#### **Audit committee**

During the year the audit committee consisted of Ivar Verner (chairman), Hans Ekelund, and Eugen Steiner. The audit committee met 4 (6) times.

The board of directors' audit committee shall consist of at least three members, one of whom shall be the chairman, and works according to rules of procedure adopted by the board. The audit committee's role is mainly to monitor the company's financial position, to monitor the effectiveness of the company's internal control, internal audit and risk management, to be informed about the audit of the Annual Report and consolidated financial statements, and to review and monitor the auditor's impartiality and independence.

The audit committee approves any additional missions for the external auditors and makes a review of the additional missions with respect to their independence. The audit committee shall also assist the nomination committee in proposals for resolutions on the election and remuneration of the auditor and continuously meet the company's auditor. All meetings of the audit committee are minuted and the minutes are presented to the board together with an oral report in connection with the board's decision making.

Issues addressed in 2018 include risk analysis, internal and external financial reporting, review of the outcome of the examination of the operations performed by the auditor elected at the Annual General Meeting and issues related to internal control and the authorization manual.

#### Remuneration committee

During the year the remuneration committee consisted of Wenche Rolfsen (chairman), Hans Ekelund and Eugen Steiner. The remuneration committee met 4 times (1).

The board of directors' remuneration committee shall consist of at least three members, one of whom one shall be the chairman. The committee works according to rules of procedure adopted by the board. The remuneration committee's role is primarily to prepare matters regarding remuneration and other terms of employment for the CEO and other senior executives.

The remuneration committee shall also monitor and evaluate ongoing and during the year completed programs for variable remuneration to the company's management and monitor and evaluate the implementation of the guidelines for remuneration to senior executives adopted by the Annual General Meeting. All meetings of the remuneration committee are minuted and the minutes are presented to the board together with an oral report in connection with the board's decision making.

#### Research committee

BioArctic's operations have a strong scientific focus with drug projects in early and late phase. At the board meeting on September 26, 2018 the board of directors decided to establish a research committee with focus on scientific issues. The board of directors' research committee shall consist of at least one (1) member, one of whom shall be the chairman and convener. In addition to the chairman the research committee consists of the CSO (Chief Scientific Officer) as adjunct. Depending on the areas concerned the researchers whose competence is needed for the issues dealt with are called as adjuncts. Also external researchers can participate as needed.

The research committee works according to rules of procedure adopted by the board and have an advisory capacity in relation to the board and the CEO. The research committee's role is primarily to identify and evaluate research areas and disease indications where BioArctic may develop commercially successful products.

During the year the research committee consisted of Lars Lannfelt (chairman). The committee had three meetings. All meetings of the research committee are minuted and the minutes are presented to the board together with an oral report in connection with the board's decision making.

#### Evaluation of the work of the board of directors

In accordance with what is laid down in the rules of procedure for the board of directors, the board continuously evaluates its work through open discussions in the board and through an annual board evaluation. The result of the annual evaluation is submitted to the nomination committee. The nomination committee has also had individual meetings with the board members in order to be able to ask questions about the work of the board.

### Evaluation of the work of the CEO

In accordance with what is laid down in the rules of procedure for the CEO, the board of directors continuously evaluates the work of the CEO through open discussions and an annual evaluation. The board deals specifically with this issue at least once a year, with nobody from the company management present. Regular and systematic assessment forms the basis for the evaluation of the CEO's performance and for a continuous development of the work.

Board member	Independent to the company and its management	Independent to major shareholders	Presence board meetings	Presence audit committee	Presence remuneration committee	Presence research committee
Wenche Rolfsen	Yes	Yes	12 of 12		4 of 4	
Ivar Verner	Yes	Yes	12 of 12	4 of 4		
Hans Ekelund	Yes	Yes	12 of 12	4 of 4	4 of 4	
Pär Gellerfors	No	No	11 of 12			
Lars Lannfelt 1)	No	No	12 of 12			3 of 3
Mikael Smedeby <sup>2)</sup>	No	Yes	6 of 12			
Eugen Steiner	Yes	Yes	12 of 12	4 of 4	4 of 4	

<sup>&</sup>lt;sup>1)</sup> Lars Lannfelt, chairman of the research committee, which was established on September 26, 2018.

<sup>&</sup>lt;sup>2)</sup> Mikael Smedeby, elected board member at the Annual General Meeting on May 15, 2018.

#### **AUDITORS**

The company's auditor, Grant Thornton Sweden AB, was first elected at the Annual General Meeting 2016. The current term is for the period until the end of the Annual General Meeting 2019. Mia Rutenius is the auditor in charge. During the year the company's auditor has, in addition to auditing the company's accounts, also performed a review of the interim reports for the period January – September. As described under "The board of directors' work during the year" the company's auditor has also met the board at the board meeting dealing with the annual accounts and at meetings dealing with the audit of the company's internal control. For information on remuneration to auditors, see Note 9.

#### **CEO AND COMPANY MANAGEMENT**

The CEO's and the senior executives' age, main education, working experience, major current assignments and holdings in BioArctic are shown in the presentation of the Management team on pp. 38–39.

# INTERNAL CONTROL CONCERNING THE FINANCIAL REPORTING

The overall purpose of the internal control is to ensure, to a reasonable degree, that the company's operating strategies and targets are monitored and that the owners' investments are protected. Furthermore, the internal control shall ensure, with reasonable certainty, that the external financial reporting is reliable and prepared in accordance with good accounting practice, that applicable laws and regulations are followed, and that the requirements imposed on listed companies are complied with. The board of directors has the overall responsibility for the internal control.

The Swedish Companies Act and Annual Accounts Act contain requirements which mean that information about the main features of BioArctic's system for internal control and risk management should be part of the company's corporate governance report. The board's responsibility for the internal control is also regulated in the Code. The board shall among other things ensure that BioArctic has good internal control and formal procedures ensuring that established principles for financial reporting and internal control are observed and that there are adequate systems for monitoring and control of the company's operations and the risks associated with the company and its operations.

In order to maintain a good internal control the board has adopted a number of governing documents, e.g. rules of procedure for the board, instructions for the CEO, instructions for financial reporting, a financial policy and an information policy. The board has assessed the need for a special audit function (internal audit) and has come to the conclusion that such a function is not currently justified in BioArctic considering the scope of the operations and the existing internal control structures. The board annually reassesses the need for a separate internal audit function.

Since 2017 the board has established an audit committee whose main tasks among other things include monitoring and quality assurance of the company's financial reporting, continuous contacts with the company's external auditor, to monitor the effectiveness of the company's internal control concerning financial reporting, and to review and monitor the auditor's impartiality and independence. Within the board the audit committee also has the main responsibility for monitoring and managing risks that may affect the company's operations negatively.

The responsibility for ongoing internal control and risk management has been delegated to the company's CEO, who regularly reports to the board in accordance with the established instructions.

The internal control and risk management are controlled and evaluated on an ongoing basis through internal and external audits and evaluations of the company's governing documents. Invoices are for instance reviewed by the purchaser and authorized by another person within the company in accordance with the established authorization manual and year-end procedures are performed in duality, so that all tasks performed are always verified by another person within the company.

In addition to the above described internal control there is also internal operations specific control of data regarding research and development and quality control including a systematic monitoring and evaluation of the company's research and manufacturing work and products.

#### **Control environment**

BioArctic's board adheres to rules of procedure which are adopted annually at the inaugural board meeting. These rules of procedure form the basis for the board's work and for an efficient handling of the risks that relate to the operations.

The framework for BioArctic's internal control consists of the company's policies. BioArctic's policies and other governing documents are expected to create the basis for good internal control.

## Information and communication

Information on BioArctic's governing documents such as policies, guidelines and procedures is given to the persons concerned. All policies and guidelines are updated as needed and reviewed at least every two years and are communicated to employees and other persons concerned. Issues related to financial reporting are also discussed at meetings where relevant working groups meet. For external communications BioArctic follows established policies.

# Follow-up

Within BioArctic the income statement and balance sheet and selected key ratios are followed-up continuously. In addition to the financial follow-up there is also follow-up of the ongoing research projects, the internal control and a risk assessment. The board is given updates and analyses of the financial outcome.

#### Information to the stock market

In accordance with the commitments resulting from being a listed company, BioArctic gives the stock market information on the Group's financial position and development. The information is given in the form of interim reports and an annual report published in Swedish and English. In addition to the financial information BioArctic also publishes other information which BioArctic is obligated to disclose in accordance with stock exchange regulations or applicable legislation, press releases concerning news and events relating to the company and the company's operations, and presentations for shareholders, finance analysts and investors in Sweden as well as abroad. Information that constitutes insider information is handled and published according to the rules in EU's market abuse regulation (MAR). The information that is made public is also published on BioArctic's websites www.bioarctic.se (in Swedish) and www.bioarctic.com (in English).

# **GUIDELINES FOR REMUNERATION TO SENIOR EXECUTIVES**

According to the Swedish Companies Act, the general meeting shall resolve on guidelines for remuneration to the CEO and other senior executives.

Senior executives are those persons who, together with the CEO, form the Group management. Remuneration to senior executives consists of fixed salary, variable remuneration, pensions and other benefits.

At the Annual General Meeting on May 15, 2018 guidelines for remuneration to senior executives were adopted with the following main content.

The company shall offer company management market level compensation that makes it possible to recruit and retain senior executives. The compensation to company management shall consist of fixed salary, customary employment benefits and pension. Variable remuneration can also be paid, but should not exceed an amount corresponding to six monthly salaries.

The fixed salary shall take into account the individual's responsibilities and experience, and be reviewed annually. The division between fixed salary and any variable remuneration shall be proportional to the executive's responsibility and authority. The variable remuneration shall always be limited to a predetermined maximum amount and be linked to predetermined and measurable criteria and designed to achieve greater community of interest between the executive and the company's shareholders. The earning period or alternatively the time from entering into the agreement until a share may be acquired shall not be less than three years in share and share price related incentive programs. The terms for variable remuneration shall be designed so that the board, under particularly difficult economic circumstances, has the possibility to restrict or refuse to give out variable remuneration if this is deemed to be unreasonable and inconsistent with the company's responsibility to the shareholders. For variable remuneration it should be possible to restrict or refuse to pay variable remuneration if the board considers that this is justified for other reasons.

Pension terms shall be in accordance with market practice for corresponding positions and be based on defined contribution solutions.

Fixed salary during the period of notice and severance pay shall together not exceed an amount corresponding to the fixed salary for two years.

Executives who hold a position as board member or deputy board member in a Group company shall not receive a special board fee for this.

The board is allowed to deviate from these guidelines in individual cases should there be special reasons for doing so.

#### Remuneration to the CEO and other senior executives

In 2018 BioArctic's CEO Gunilla Osswald received a fixed compensation amounting to SEK 189,150 per month. Gunilla Osswald furthermore has the right to pension provisions corresponding to 35 percent of the fixed compensation.

The CEO is included in the variable remuneration programs covering all employees in the company. In addition the CEO has the right to a non-pensionable variable remuneration amounting to a maximum of 35 percent of the total fixed compensation in 2018. The target achievement for variable remuneration in 2018 amounted to 100 percent.

Between the company and the CEO there is a notice period of 12 months if the company gives notice of termination and 6 months if the CEO gives notice. For other senior executives the notice period is mutually 3 months, alternatively the notice period set out in the Employment Protection Act (LAS). Severance pay is not applied.

call options if the holder terminates his/her employment or assignment in the company during the duration of the call options.

# Incentive programs

BioArctic has two incentive programs linked to the company's Alzheimer and Parkinson projects, covering all permanent employees (including the CEO). Variable remuneration is paid when the company achieves certain goals linked to the clinical research programs for BAN2401 for Alzheimer's disease and BAN0805 (ABBV-0805) for Parkinson's disease. As the variable remuneration programs are linked to the research programs, the variable remuneration payments may occur irregularly as these goals are reached. Some of these goals are also far in the future. One condition for receiving variable remuneration is that the employee has been permanently employed and that the employment has lasted for at least six months at the time when the goal that is the basis for payment of variable remuneration is reached and that the employee has not given notice at the time of the payment. The potential variable remuneration for the employee amounts to one monthly salary. The variable remuneration is not pensionable.

# Share-based incentive programs and acquisition of shares by board members and senior executives

The company does not have any outstanding share-based incentive program or otherwise any outstanding warrants. However, the company has two incentive programs for the employees (including the CEO and senior executives), see above.

In 2017 the main owners Demban AB and Ackelsta AB issued call options to certain board members and senior executives in the company, including the CEO, concerning a total of 366,795 of the main owners' B-shares in BioArctic. The CEO's holding at the end of the year amounted to 12,800 B-shares and call options entitling to the purchase of 87,270 B-shares. The exercise period (i.e. the period during which the option can be used) runs through June 30, 2020 according to the option agreement. The exercise price for the call options amounts to approximately SEK 26.67 per share. In connection with the issue of the call options the holders have paid an option premium, corresponding to the market value of the options according to the Black & Scholes model, to the main owners. The call options are freely negotiable. However, under the agreement the main owners have the right to repurchase the

# Financial statements

# Consolidated income statement 1)

Amounts in kSEK	Note	2018	2017
Net revenues	6	713,970	140,706
Other operating income	7	16,259	19,044
Total operating income		730,229	159,750
Project expenses		-145,357	-63,641
Other external expenses	9, 10	-31,949	-36,197
Personnel expenses	8	-57,039	-32,936
Depreciations of tangible assets	15	-2,059	-1,993
Other operating expenses	11	-5,031	-5,689
Operating profit		488,794	19,294
Financial income	12	2,171	1,043
Financial expenses	12	-1,371	-647
Profit before tax		489,593	19,690
Income tax	13	-107,991	-4,534
Profit for the year		381,602	15,157
Profit for the year attributable to owners of the parent company		381,602	15,157
Earnings per share			
Earnings per share, SEK	14	4.33	0.22

<sup>&</sup>lt;sup>1)</sup> BioArctic has decided to change to income statement by nature of expense and the comparative periods have been changed accordingly, see Note 2.

# Consolidated statement of comprehensive income

Amounts in kSEK	Note	2018	2017
Profit for the year		381,602	15,157
Other comprehensive income		-	-
Comprehensive income for the year attributable to owners of the parent company		381,602	15,157

# Consolidated balance sheet

Amounts in kSEK	Note	December 31, 2018	December 31, 2017
ASSETS			
Tangible assets	15	9,289	7,093
Other non-current financial assets	17	1,500	2,675
Deferred tax asset	13	189	230
Total non-current assets		10,978	9,997
Other current receivables	18, 19	3,904	4,728
Prepaid expenses and accrued income	18, 20	460,853	15,390
Cash and cash equivalents	18, 21	917,307	1,110,367
Total current assets		1,382,064	1,130,486
TOTAL ASSETS		1,393,042	1,140,483
EQUITY AND LIABILITIES			
Share capital	22	1,761	1,761
Reserves		958	958
Other contributed capital		560,018	560,018
Retained earnings		454,999	73,397
Total equity		1,017,736	636,134
Deferred tax liabilities	13	32,520	5,487
	13		
Total non-current liabilities		32,520	5,487
Account payable	18	14,808	7,586
Current tax liabilities	13	73,339	3,310
Other current liabilities		3,849	1,263
Accrued expenses and prepaid income	18, 25	250,791	486,702
Total current liabilities		342,787	498,862
TOTAL EQUITY AND LIABILITIES		1,393,042	1,140,483

# Consolidated statement of change in equity

Amounts in kSEK	Note	Share capital	Reserves	Other contributed capital	Retained earnings	Total equity
Opening balance at January 1, 2017		105	958	300	59,397	60,760
Profit for the year		-	-	-	15,157	15,157
Other comprehensive income		-	-	-	-	0
Group comprehensive income		105	958	300	74,553	75,916
Stock dividend issue	22	1,156	-	-	-1,156	0
Rights issue	22	500	-	599,500	-	600,000
Expenses for right issuse		-	-	-39,782	-	-39,782
Closing balance at December 31, 2017	,	1,761	958	560,018	73,397	636,134
Opening balance at January 1, 2018		1,761	958	560,018	73,397	636,134
Profit for the year		-	-	-	381,602	381,602
Other comprehensive income		-	-	-	-	0
Group comprehensive income		1,761	958	560,018	454,999	1,017,736
Closing balance at December 31, 2018	3	1,761	958	560,018	454,999	1,017,736

# Consolidated cash flow statement

Amounts in kSEK	Note	2018	2017
Operating profit		488,794	19,294
Adjustment for non-cash items	27	-726,886	-143,453
Interest received		40	65
Interest paid		-1,371	-647
Income tax paid		-10,889	-7,739
Cash flow from operating activities before change in working capital		-250,313	-132,481
Increase (-) / Decrease (+) in operating receivables		3,911	-13,164
Increase (+) / Decrease (-) in operating liabilities		46,345	10,318
Cash flow from operating activities		-200,057	-135,327
Investment in tangible assets	15	-4,255	-3,448
Disposal of tangible assets		-	635
Change in non-current financial assets		1,175	-
Cash flow from investing activities		-3,080	-2,813
Rights issue			560,218
		-	
Cash flow from financing activities		0	560,218
Cash flow for the year		-203,136	422,078
Cash and cash equivalents at January 1		1,110,367	692,530
Exchange rate difference in cash and cash equivalents		10,076	-4,241
Cash and cash equivalents at December 31	21	917,307	1,110,367

# Parent company income statement 1)

Amounts in kSEK	Note	2018	2017
Operating income etc.			
Net revenues	6	713,970	140,706
Other operating income	7	16,259	19,044
Operating income		730,229	159,750
Operating expenses			
Project expenses		-145,357	-63,641
Other external expenses	9, 10	-31,949	-36,197
Personnel expenses	8	-57,039	-32,936
Depreciations of tangible assets	15	-2,059	-1,993
Other operating expenses	11	-5,031	-5,689
Operating profit		488,794	19,294
Profit/loss from financial items			
Financial income	12	2,171	1,043
Financial expenses	12	-1,371	-647
Profit after financial items		489,594	19,690
Appropriations			
Change in tax allocation reserve		-122,603	-4,800
Change in accelerated depreciation		-273	-1,341
Profit before tax		366,718	13,549
Income tax	13	-80,959	-3,183
Profit for the year		285,759	10,367

<sup>&</sup>lt;sup>1)</sup> BioArctic has decided to change to income statement by nature of expense and the comparative periods have been changed accordingly, see Note 2.

There are no items in the parent company recognized as other comprehensive income, thus comprehensive income conforms to the result for the year.

# Parent company balance sheet

Amounts in kSEK	Note	December 31, 2018	December 31, 2017
ASSETS			
Non-current assets			
Tangible assets			
Leasehold improvements	15	993	947
Equipment	15	8,296	6,146
		9,289	7,093
Financial assets			
Shares in subsidiaries	16	100	100
Other non-current financial assets	17	1,500	2,675
Deferred tax asset	13	189	230
		1,789	3,005
Total non-current assets		11,078	10,097
Current assets			
Short term receivables			
Other current receivables	19	3,904	4,728
Prepaid expenses and accrued income	20	460,853	15,390
		464,757	20,119
Cash and cash equivalents	21	917,209	1,110,269
Total current assets		1,381,967	1,130,387
TOTAL ASSETS		1,393,044	1,140,484

# Parent company balance sheet cont.

Amounts in kSEK	Note	December 31, 2018	December 31, 2017
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	22	1,761	1,761
Statutory reserve		958	958
		2,719	2,719
Non-restricted equity			
Share premium reserve	23	560,018	560,018
Retained earnings	23	53,944	43,577
Profit for the year	23	285,759	10,367
		899,722	613,962
Total equity		902,441	616,682
Untaxed reserves	24	147,817	24,941
Current liabilities			
Account payable		14,808	7,586
Current tax liabilities	13	73,339	3,310
Other current liabilities		3,849	1,263
Accrued expenses and prepaid income	25	250,791	486,702
Total current liabilities		342,787	498,861
TOTAL EQUITY AND LIABILITIES		1,393,044	1,140,484

# Parent company statement of change in equity

	-	Restricted	equity	Non-restricted equity		
Amounts in kSEK	Note	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Total equity
Opening balance at January 1, 2017		105	958	300	44,733	46,096
Comprehensive income						
Profit for the year		-	-	-	10,367	10,367
Total comprehensive income		0	0	0	10,367	10,367
Transactions with shareholders'						
Stock dividend issue	22	1,156	-	-	-1,156	0
Rights issue	22	500	-	599,500	-	600,000
Expenses for right issuse		-	-	-39,782	-	-39,782
Total transactions with shareholders'		1,656	0	559,718	-1,156	560,218
Closing balance at December 31, 2017		1,761	958	560,018	53,944	616,682
Opening balance at January 1, 2018		1,761	958	560,018	53,944	616,682
Comprehensive income						
Profit for the year		-	-	-	285,759	285,759
Total comprehensive income		0	0	0	285,759	285,759
Transactions with shareholders'						
Total transactions with shareholders'		0	0	0	0	0
Closing balance at December 31, 2018		1,761	958	560,018	339,704	902,441

# Parent company cash flow statement

Amounts in kSEK	Note	2018	2017
Operating profit		488,794	19,294
Adjustment for non-cash items	27	-726,886	-143,453
Interest received		40	65
Interest paid		-1,371	-647
Income tax paid		-10,889	-7,739
Cash flow from operating activities before change in working capital		-250,312	-132,481
Increase (-) / Decrease (+) in operating receivables		3,911	-13,164
Increase (+) / Decrease (-) in operating liabilities		46,345	10,318
Cash flow from operating activities		-200,056	-135,327
Investment in tangible assets	15	-4,255	-3,448
Disposal of tangible assets		-	635
Change in non-current financial assets		1,175	_
Cash flow from investing activities		-3,080	-2,813
Rights issue		-	560,218
Cash flow from financing activities		0	560,218
Cash flow for the year		-203,136	422,078
Cash and cash equivalents at January 1		1,110,269	692,430
Exchange rate difference in cash and cash equivalents		10,076	-4,241
Cash and cash equivalents at December 31	21	917,209	1,110,269

# Notes to financial statements

## NOTE 1

# **GENERAL INFORMATION**

BioArctic AB, corporate identity no. 556601-2679, is the parent company in a Group focused on diseases in the central nervous system (CNS). The company has leading competence in research and development of innovative biological drugs like antibodies that meet great medical needs.

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 the consolidated accounts have been approved by the board of directors on April 8, 2019 and are submitted for determination at the Annual General Meeting on May 9, 2019.

### NOTE 2

#### **CHANGE OF FORMAT**

BioArctic has decided to change from income statement by function to income statement by nature of expenses. The reason for the change is that management and the board of directors control the operations in this way. The comparative periods have been changed accordingly. The calculation of key ratios has not been affected.

#### NOTE 3

# SUMMARY OF SIGNIFICANT ACCOUNTING PRINCIPLES

The significant accounting principles applied in preparing these consolidated financial statements are described in the following. Unless otherwise stated, these principles have been applied consistently for all the years presented.

# 3.1 BASIS OF PREPARATION OF FINANCIAL STATEMENTS

The consolidated financial statements have been prepared in accordance with the Annual Accounts Act, RFR 1 Supplementary accounting rules for groups, and International Financial reporting Standards (IFRS) and IFRIC interpretations as adopted by the EU at December 31, 2018. The income statement is classified according to nature of expenses, see Note 2.

The Group's financial reports have been prepared based on historical acquisition value, which means that assets and liabilities are reported at these values and where appropriate certain financial instruments are measured at fair value. The functional currency for the parent company, including all its subsidiaries, and the Group's reporting currency, is Swedish kronor (SEK). All amounts are given in thousands of Swedish kronor (kSEK) unless otherwise stated. Amount in brackets

refer to the previous year. Negative numbers are either expenses or payments (cash flow).

Preparing financial statements according to IFRS requires the use of some critical accounting estimates. Further, it is required that the board and management make some assessments in the application of the company's accounting principles. The areas that involve a high degree of assessments, that are complex, or areas where assumptions and estimates are of major importance for the consolidated financial statements are described in Note 5.

#### 3.2 NEW ACCOUNTING PRINCIPLES

IFRS 15 and IFRS 9 are applied from January 1, 2018 and explanations of the effects of this are given below. Other standards, changes or interpretations coming into force for financial years commencing on January 1, 2018 have had no effect on the Group's financial reports.

#### IFRS 15 Revenue from Contracts with Customers

IFRS 15 Revenue from Contracts with Customers regulates the reporting of revenues and came into force on January 1, 2018. IFRS 15 replaces IAS 18 Revenue and IAS11 Construction Contracts as well as the appropriate SIC and IFRIC. According to IFRS the company shall recognize revenue at a point in time or over time as the company meets performance obligations by transferring the promised goods and services to a customer, who thereby obtains control of the asset. Most of BioArctic's revenue from contracts with customers relates to research collaborations and milestone payments. The transition to IFRS 15 means that the revenue is recognized over time, which corresponds to the previous reporting based on degree of completion. BioArctic receives one-time payments from customers which are accounted when the right to compensation has been established. This point in time corresponds to the time when performance obligations are met according to IFRS 15. The amount recognized as revenue is the compensation the company expects to be entitled to in exchange for transferring promised goods and services to a customer. The Group has not identified any differences in reporting at the transition to IFRS 15, neither regarding amounts, nor when in time the revenue is recognized. The transition has only meant increased disclosure requirements.

# IFRS 9 Financial instruments

IFRS 9 Financial instruments replaces IAS 39 Financial instruments: Recognition and Measurement. IFRS 9 comes into force for financial years commencing on January 1, 2018 or later. In principle BioArctic always receives payment from agreements with customers in advance. There are thus no bad debt losses.

# note 3 cont.

Except that the categories of financial assets have been changed, the Group has not identified any differences in reporting in connection with the transition to IFRS 9.

#### 3.3 NEW IFRS STANDARDS FROM 2019 AND LATER

A number of new standards and changes to interpretations and existing standards that will come into effect for financial years starting after January 1, 2019 have not been applied in the preparation of the Group's financial reports. New and changed standards with future application that will affect the financial reports are described below.

#### **IFRS 16 Leases**

IFRS 16 replaces IAS 17 Leases and the appropriate interpretations IFRIC 4, SIC-15 and SIC-27. This standard requires that assets and liabilities attributable to all leasing agreements, with a few exceptions, are recognized in the balance sheet. This reporting is based on the view that an asset is used for a specific period of time and at the same time an obligation arises to pay

for this right. The standard is to be applied for financial years commencing on January 1, 2019 or later. BioArctic has elected to apply the modified retrospective approach. The effect of the application of IFRS 16 will be that BioArctic will account for a right-to-use asset and a leasing liability for office premises and parking lots that currently are accounted for as operational leasing contracts. The company has chosen to apply the relief rules concerning short-term agreements and low-value agreements. The effect of the first application of IFRS 16 from January 1, 2019 is shown below:

- The Group's assets and liabilities will increase with MSEK 31.8 to MSEK 1.424.8
- The equity assets ratio will decrease by 1.7 percentage points from 73.1% to 71.4%

The effect on the Group's balance sheet at the first application of IFRS 16 at January 1, 2019 is shown below:

Amounts in kSEK	Closing balance at December 31, 2018 (IAS 17)	Application of IFRS 16	Opening balance at January 1, 2019 (IFRS 16)
ASSETS			, ,
Tangible assets	9,289	33,282	42,571
Other non-current financial assets	1,500	-	1,500
Deferred tax asset	189	-	189
Total non-current assets	10,978	33,282	44,260
Other current receivables	3,904	-	3,904
Prepaid expenses and accrued income	460,853	-1,531	459,322
Cash and cash equivalents	917,307	-	917,307
Total current assets	1,382,064	-1,531	1,380,533
TOTAL ASSETS	1,393,042	31,751	1,424,793
EQUITY AND LIABILITIES			
Total equity	1,017,736	0	1,017,736
Non-current liabilities	-	25,611	25,611
Deferred tax liabilities	32,520	-	32,520
Total non-current liabilities	32,520	25,611	58,131
Current liabilities	-	6,139	6,139
Other current liabilities	342,787	-	342,787
Total current liabilities	342,787	6,139	348,926
TOTAL EQUITY AND LIABILITIES	1,393,042	31,751	1,424,793

Reconciliation of leasing liabilities according to IFRS 16 against future minimum lease payments in Note 10 is shown below.

#### **Amounts in kSEK**

Commitment for operating leases at December 31, 2018	33,981
Discounting using the Group's incremental borrowing rate of 4.0%	-3,299
Adjustment for extension options or termination clauses	1,069
Lease liability on January 1, 2019	31,751

#### 3.4 CONSOLIDATED FINANCIAL STATEMENT

Subsidiaries are all companies over which the Group exercises a controlling interest. The Group controls a company when it is exposed to or has the right to a variable return on its interest in the company and is able to influence the return through its interest in the company. Subsidiaries are included in the consolidated financial statements as of the date on which the controlling interest is transferred to the Group. They are excluded from the consolidated financial statements as of the date on which the controlling interest seizes to exist.

Acquisition accounting is used to report the Group's acquisitions. The purchase sum for the acquisition of a subsidiary consists of the fair value of the transferred assets, liabilities that the Group incurs to previous owners of the acquired company, and the shares issued by the Group. The purchase amount also includes the fair value of all assets and liabilities resulting from an agreement on conditional consideration. Identifiable assets acquired and liabilities assumed in a business acquisition are initially measured at their fair values at the acquisition date.

Intercompany transactions, balances, income and expenses from transactions between Group companies are eliminated. Gains and losses resulting from intercompany transactions which have been recognized in assets are also eliminated. Where applicable the accounting principles for subsidiaries have been amended to ensure a consistent application of the Group's principles.

# 3.5 SEGMENT REPORTING

An operating segment is a part of the Group that conducts operations from which it can generate income and incur costs and for which independent financial information is available.

The highest executive decision-maker in the Group follows up the operations on aggregated level, which means that the operations constitute one and the same segment and thus no separate segment information is presented. The board of directors is identified as the highest executive decision maker in the Group.

# 3.6 TRANSLATION OF FOREIGN CURRENCY

# 3.6.1 Functional currency and reporting currency

Items included in the financial statements for the different units in the Group are measured using the currency in the financial environment in which the unit mainly operates (functional currency). In the consolidated financial statements Swedish kronor (SEK) is used, as this is the parent company's functional currency and the reporting currency.

### 3.6.2 Transactions and balances

Transactions in foreign currency are translated to functional currency at transaction date exchange rates or at the date of revaluation. Foreign exchange gains and losses arising from the payment of such transactions and at the recalculation of monetary assets and liabilities in foreign currency at the transaction date exchange rate are reported in the income statement.

#### **3.7 REVENUES**

The Group's revenues mainly comprise revenues from license and collaboration agreements. When assessing whether a revenue is to be reported, the group follows a 5-step process:

- 1. Identifying the agreement with a customer
- 2. Identifying performance obligations
- 3. Determining the transaction price
- 4. Allocating the transaction price over the performance obligations
- Reporting revenues at the time of fulfilment of the performance obligation.

# 3.7.1 License and collaboration agreements

Revenue from license and collaboration agreements can consist of payments under research agreements, milestone payments, one-time and license payments as well as royalty revenues. In addition, BioArctic may under the agreement have the right to obtain compensation for costs incurred. The transaction price is determined based on what the Group expects to obtain from each contract in exchange for transfer of the agreed products or services. Revenues are reported either at a point in time or over time, when (or if) the Group fulfils performance obligations by transferring the promised goods and services to the customer.

The Group reports a contractual liability when it has received a payment with respect to unfulfilled performance obligations, and reports these amounts as deferred income in the balance sheet. In like manner, in the event the Group fulfils a performance obligation before consideration is received, the group reports either accrued income or a receivable in the balance sheet, depending on whether any factor other than the time aspect is decisive as to when payment is due.

#### note 3 cont.

# Research collaborations (remuneration under research agreements)

The reporting of revenue reflects accrual according to the specific terms of agreement and is applied to each transaction separately. Revenues are reported over time based on fulfilment of performance obligations. The group measures the course towards complete fulfilment by regularly evaluating the degree of completion based on expenses incurred in the research collaboration projects.

# Milestone payments

Performance obligations for milestones achieved are reported as revenue at a point in time. Revenues in respect of milestone payments comprise a transaction price agreed in advance.

# One-time and license payments

One-time payments at the entering into an agreement normally come without repayment obligation and is reported at a point in time. It normally relates to the right to develop, register, market and sell BioArctic's patented products within a designated geographic area and within a designated indication. One-time payments may also constitute payment for technology or know-how transfers which are to take place to the cooperation partner or may constitute payment for the right to acquire a license in the future.

# Royalty payments

Royalty income normally accrues continuously as distributors report sales. The reporting is made in the same period as the sales.

## Compensation for costs incurred and sales of products

Compensation for costs incurred, i.e. costs that are re-invoiced to the customer, are reported in the period when they are incurred. At the sale of products revenue is reported at the point in time when the control is transferred to the customer.

# 3.7.2 Other operating income

In addition to the public funding described in Note 3.8, the Group also has operating income in the form of foreign exchange gains and gain on disposal of tangible fixed assets.

# 3.8 PUBLIC FUNDING

The group's public funding is reported as Other operating income.

# Public funding

Income from public funding is reported as revenue when it is reasonably likely that the Group will meet the terms associated with the funding and the public funding will be received. Funds received before the conditions for reporting such as revenue have been satisfied is reported as a liability.

# Joint agreements

BioArctic has received public funding for one joint agreement, the EU's Horizon 2020, where BioArctic is the coordinator. In the income statement the Group has reported its share of revenue under this agreement. The part of the public funding received for Horizon 2020 that shall be forwarded to other legal entities is reported as liability until payment is made.

# 3.9 EXPENSES, FINANCIAL ITEMS AND TAXES 3.9.1 Project expenses

Project expenses relate to direct external costs for BioArctic's research and drug development in preclinical and clinical studies and regulatory activities. Expenses attributable to development projects can be reported as intangible assets when all the following criteria are met:

- 1. It is technically possible for the company to finalize the intangible asset so that it can be used or sold.
- 2. The company intends to finalize the intangible asset and use it or sell it.
- 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 is able to reliably calculate the expenditure attributable to the intangible asset during its development.

Development costs that are expensed cannot be reported as assets in coming periods. BioArctic has no expenses that meet all the criteria and all research and development costs have therefore been expensed.

# 3.9.2 Other external expenses

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

# 3.9.3 Remuneration to employees

# Remuneration under agreement

BioArctic has a rewards program covering all permanent employees consisting of a variable part in addition to the fixed remuneration which can be paid when objectives have been reached. See further information under Note 8. The variable remuneration is not pensionable. BioArctic has no agreements including post-employment benefits.

# Defined contribution pension plans

The Group's pension plans are defined contribution plans and concern the contributions the company pays to the plan or an insurance company and the capital return that the contributions give. Consequently it is the employee who carries the actuarial risk (that the remuneration is lower than expected) and investment risk (that the invested assets will be insufficient to give the expected remunerations). The Group has no defined benefit pension plans.

# 3.9.4 Leasing

Leasing agreements are classified at the closing of the agreement either as financial or operational leasing. The Group only has operational leasing agreements. These lease payments are expensed on a straight-line basis over the lease term. Associated costs, such as maintenance and insurance, are expensed as incurred.

# 3.9.5 Other operating expenses

Operational exchange losses and losses on disposal of tangible fixed assets are reported as other operating expenses.

#### 3.9.6 Financial income

Financial income refers to interest on bank deposits and receivables and in applicable cases dividend, and positive exchange rate differences on financial items. Financial income is reported in the period to which it relates.

# 3.9.7 Financial expenses

Financial expenses refer to interest and other expenses that are incurred in connection with borrowings and reported in the income statement in the period to which they relate. Also negative exchange rate differences on financial items and negative interest on cash and cash equivalents are included in financial expenses.

### **3.9.8 Taxes**

The tax expense for the period comprises current and deferred tax. Taxes are reported in the income statement, except when the underlying transaction is reported in other comprehensive income or directly against equity, then the related tax effect is also reported under this item.

Current tax is the tax calculated based on the taxable result for the period. The taxable result differs from the reported result in that it has been adjusted for non-taxable and non-deductible items. Current tax is the tax to be paid or received for the current year, possibly adjusted for current tax relating to previous periods.

In the balance sheet withheld foreign tax is reported to the extent that is expected to be offset against Swedish corporation tax.

Deferred tax is reported using the balance sheet method, which means that deferred tax liabilities are recognized in the balance sheet for all temporary differences arising between the book value and the written-down value of assets and liabilities. If the temporary difference arises on initial recognition of assets and liabilities that constitute an asset acquisition, deferred tax is not recognized. Deferred tax assets relating to deductible temporary differences and loss carry-forwards are recognized only when it is likely that the amounts can be used against future taxable profit. Deferred tax is calculated according to the statutory tax rates decided or announced at the balance sheet day and expected to be in effect when the deferred tax asset is realized or the deferred tax liability is settled.

### 3.10 RESEARCH AND DEVELOPMENT/INTANGIBLE ASSETS

An intangible asset is recognized in the balance sheet when it is likely that the future economic benefits associated with the transaction will accrue to the Group and the value of the asset can be calculated reliably. Development costs are capitalized and recognized in the balance sheet as intangible assets if the criteria for recognition in the balance sheet according to IAS 38 Intangible assets are met. The Group has no expenditures that meet these criteria.

# 3.11 TANGIBLE FIXED ASSETS

Tangible fixed assets are reported at acquisition value less accumulated depreciation and write-down. The acquisition value includes expenditures directly attributable to the acquisition of the asset. Subsequent expenditure is added to the reported value of the asset or reported as a separate asset only when it is likely that the economic benefits associated with the transaction will accrue to the Group and the acquisition value of the asset can be calculated reliably. The useful life has been assessed to be five years for equipment and machinery. Improvement expenditures for leaseholds are written-off based on estimated usage time.

note 3 cont.

### **3.12 FINANCIAL INSTRUMENTS**

A financial instrument is each form of agreement which gives rise to a financial asset or financial liability. Financial assets in the balance sheet relate to accounts receivable, other receivables, contractual accrued income and cash and cash equivalents. Financial liabilities relate to accounts payable as well as contractual accrued expenses. The group has no derivative instruments.

Financial instruments are reported in the balance sheet when the Group becomes a party to the contractual conditions of the financial instruments. Financial assets are removed from the balance sheet when the contractual rights associated with the financial asset cease, or when the financial asset and all significant risks and advantages are transferred. A financial liability is removed from the balance sheet when it is extinguished, i.e. when it is performed, cancelled or ceases.

Financial assets and liabilities are initially valued at fair value. Financial assets and liabilities are classified in the following categories; measured at amortized cost, fair value through profit or loss or fair value through other comprehensive income. During the periods included in the financial statement, all financial assets or liabilities are characterized as amortized cost. After the first reporting, financial assets which are classified in the category measured at amortized cost are valued at amortized cost using the effective interest method. Discounting is not conducted if the effect of discounting is insignificant.

Financial assets and liabilities are set off and reported net in the balance sheet only when there is a legal right to set off the reported amounts and there is an intention to settle them with a net amount or to simultaneously realize the asset and settle the liability.

## **3.13 ACCOUNTS RECEIVABLE**

Accounts receivable are reported net after provision for anticipated debts. The expected life of the accounts receivable is short, therefore the value is reported at nominal amount without discounting according to the method of amortized cost. The Group uses a simplified method when reporting accounts receivable and other receivables as well as contractual assets and it reports anticipated credit losses for the outstanding term to maturity. In conjunction with the calculation, the Group uses its historical experience, external indicators and forward-looking information in order to calculate the anticipated credit losses. The reserved amount is recognized in the income statement.

## **3.14 CASH AND CASH EQUIVALENTS**

Cash and cash equivalents include cash, bank deposits and, where appropriate, other short-term investments with maturity date within three months. Cash and cash equivalents are reported at their nominal amounts.

#### 3.15 ACCOUNTS PAYABLE

Accounts payable are obligations to pay for goods or services that have been acquired in the operating activities from suppliers. Accounts payable are categorized as other financial liabilities. As accounts payable are expected to have a short life the value is reported at nominal amount.

#### **3.16 SHARE CAPITAL**

Transaction costs directly attributable to the issue of new shares or options are reported, net after tax, in equity as a deduction from the issue proceeds.

Share premium reserve is recognized as other contributed capital and reserve fund is reported as reserves.

### **3.17 CASH FLOW STATEMENT**

Cash flow statements are prepared according to the indirect method. This means that the result is adjusted with transactions that do not involve receipts or payments, and for income and expenses relating to investing and/or financing activities.

### **3.18 ALTERNATIVE KEY RATIOS**

The group applies ESMA's guidelines on alternative key ratios. The Group's alternative key ratios are defined in Note 31 in accordance with those guidelines. The Group applies alternative key ratios since the company considers that they provide valuable complementary information for management and investors insofar as they are of key importance for understanding and assessing the Group's business.

# 3.19 THE PARENT COMPANY'S ACCOUNTING PRINCIPLES

The parent company follows the Swedish Accounting Act and The Swedish Financial Reporting Board's recommendation RFR 2 Reporting for Legal Entities. The application of RFR 2 means that the parent company in the annual report for the legal entity applies all International Financial Reporting Standards and statements approved by the EU, as far as this is possible with regard to the Swedish Accounting Act, the Pension Obligations Vesting Act and with consideration to the relationship between reporting and taxation. The recommendation specifies which exceptions and additions to IFRS that shall be made.

The parent company thus applies the principles presented in Note 3 in the consolidated financial statements, with the exceptions specified below. The principles have been applied consistently for all years presented, unless otherwise stated. Assets, provisions and liabilities have been valued at their acquisition value unless otherwise specified below.

### **3.19.1 Formats**

The income statement and balance sheet have the format defined in the Swedish Accounting Act. This means some differences compared to the consolidated financial statements, the subitems in equity are for example different.

As explained in Note 2 the Group has decided to change from a functional income statement to an income statement classified according to type of cost. This is applied also for the parent company.

## 3.19.2 Shares and participations in Group companies

Shares and participations in Group companies are reported at acquisition value after deduction of any impairment losses.

### 3.19.3 Deferred income tax

Amounts allocated to untaxed reserves constitute taxable temporary differences. However, due to the connection between accounting and taxation in a legal entity the deferred tax liability in untaxed reserves is reported as a part of the untaxed reserves. Also the appropriations in the income statement are reported including deferred tax.

NOTE 4

**FINANCIAL RISK MANAGEMENT** 

### **4.1 FINANCIAL RISK FACTORS**

Through its operations the Group is exposed to various types of financial risk. The overall objective of the financial risk management is to minimize the risks for negative impact on the Group's result.

# 4.1.1 Currency risk

Currency risk is the risk for impact on the Group's result and financial position as a result of changes in exchange rates. The Group has no loans in foreign currency and is therefore

not exposed to any currency risk associated with borrowing. Purchases and revenue in foreign currency give rise to transaction exposure. Purchases in foreign currency are primarily made in EUR, USD, GBP and CHF. In 2018 purchases amounted to kEUR 430 (576), kUSD 956 (2,399), kGBP 7,486 (561) and kCHF 901 (684). The table below shows the essential balance sheet items in foreign currency that the Group has at December 31, 2018, and how a currency change of 10 percent of the GBP, USD, EUR and CHF against the Swedish krona would impact the result.

## Amount in kSEK at December 31, 2018

Currency	Accrued income	Cash and and cash equivalents	Accounts payables	Net per currency	10%	Before tax	After tax
CHF	-	3,436	-557	2,879	+/-	288	225
EUR	9,860	9,561	-551	18,870	+/-	1,887	1,472
GBP	-	57,028	-7,152	49,876	+/-	4,988	3,890
USD	448,550	8,314	-339	456,524	+/-	45,652	35,609
Total	458,410	78,339	-8,599	528,149	+/-	52,815	41,196

note 4 cont.

### 4.1.2 Interest rate risk

The Group has significant bank balances which are affected by interest rates. Thus, the Group is exposed to an interest rate risk. On December 31, 2018, the Group has cash and cash equivalents amounting to kSEK 917,307 (1,110,367)). An interest rate change of 0.5 percentage points would mean an annual impact on the result to the amount of kSEK 4,587 before tax and kSEK 3,577 after tax. On December 31, 2018 the Group has no external loan financing and is thus not exposed to any interest risk for such commitments.

# 4.1.3 Financing risk

Access to capital is influenced by several factors, the development of current research and development projects and collaboration and license agreements, among others. The timing and size of additional funding is dependent on this, but also on whether the Group manages to enter into new collaboration agreements and on the market's acceptance of products. The overall availability of credit and BioArctic's credit rating also affect the financial risk.

## 4.1.4 Liquidity risk

The liquidity risk, i.e. ensuring that the Group has sufficient cash to meet the demands of the operating activities, is assessed as low as the Group has a good supply of cash and cash equivalents. Group management actively follows the liquidity situation for timely attention to liquidity risks. The Group has no placements in addition to bank balances and the Group wants to minimize the risk exposure on cash and cash equivalents and financial assets.

### 4.1.5 Credit risk

Credit risk arises through cash and cash equivalents and deposits with banks and credit institutions, and through credit exposure to customers, including outstanding receivables and agreed transactions. The Group has large amounts of cash at the Group's banks. The Group considers the banks to be reliable. The Group is dependent on a few major partners and it is of the utmost importance that they fulfil their commitments under the agreements.

### 4.2 OPERATIONAL AND EXTERNAL RISKS

See the section Risks and uncertainties in the Board of directors' report for a description of the major operational and external risks. These risks relate to the market, projects and products, decisions by authorities, competition and commercial success, research and development, product liability and insurance, production, intellectual property rights, collaboration agreements, clinical trials, safety and efficacy criteria and dependence on key personnel and partners.

### 4.3 SENSITIVITY ANALYSIS

No further analysis has been established in addition to the sensitivity analyses mentioned above.

## **4.4 MANAGEMENT OF CAPITAL**

The Group's goal concerning the capital structure is to secure the Group's continued operations and business, so that it can continue to generate a return for the shareholders and benefits for other stakeholders. An optimal capital structure keeps the costs for capital down. In order to maintain and adjust the capital structure the Group can issue new shares. In the Group this capital has been defined as equity.

# NOTE 5

# SIGNIFICANT ACCOUNTING ESTIMATES AND JUDGEMENTS

In order to prepare financial statements in accordance with IFRS the company management and board must make estimates and assumptions. These impact the reported assets, liabilities, income and costs and other information given. The judgements are based on experience and assumptions that the management and the board find to be reasonable during the present circumstances. The actual results can then differ from these judgements if other circumstances arise. In the following the most significant judgements made in the preparation of the Group's and parent company's financial statements are described.

### Revenue from research collaborations

The reporting of revenue from research collaboration projects is based on the fulfillment of performance obligations. The performance obligations may change as some operations may be terminated while other may need to be added or redone. This can lead to that the assessed course towards complete fulfilment of the performance obligations is changed, which may entail an adjustment of revenue.

The Group makes a review of all projects on a quarterly basis to ensure that the revenue is based on a course towards complete fulfilment of performance obligations. See Note 6 for further information.

## NOTE 6

**NET REVENUES** 

## **GEOGRAPHIC BREAKDOWN OF NET REVENUES**

	Gro	oup	Parent company		
Amounts in kSEK	2018	2017	2018	2017	
Europe	712,489	135,494	712,489	135,494	
Other	1,481	5,212	1,481	5,212	
Total net revenues	713,970	140,706	713,970	140,706	

## **NET REVENUES PER MAJOR REVENUE TYPE**

	Gro	oup	Parent comp	
Amounts in kSEK	2018	2017	2018	2017
Milestone payments	448,550	-	448,550	-
Income from research collaborations	265,420	140,275	265,420	140,275
Other items	-	431	-	431
Total net revenues	713,970	140,706	713,970	140,706

In both the financial years 2018 and 2017 one single customer accounted for more than 10% of the turnover.

Revenues for 2018 include MSEK 263.9 (135.5) which is included in deferred income at the beginning of the financial year.

The Group evaluates the projects regularly and, during the third quarter of 2018, the remaining costs for fulfilment of the performance obligations in the research collaboration project with AbbVie were assessed as being lower than previously estimated. The new assessment entails a positive one-time effect on revenues of MSEK 20.1 and that the margin for revenues reported over time will be higher in the future. As of December 31, 2018, MSEK 492.5 has been reported as revenue over time in respect of the research collaboration agreement with AbbVie and MSEK 209.1 remains to be reported as revenue over time until the end of the project.

Fixed amount payment has been received in advance with respect to current research agreements. With respect to milestone payments, fixed amounts agreed in advance can be received based on agreed milestones.

Presented below are total amounts for transaction prices regarding performance obligations from existing agreements which are wholly or partially unfulfilled as of December 31, 2018.

			2021 and	
Amounts in kSEK	2019	2020	forward	Total
Expected net revenues from remaining performance obligations	157,548	26,016	25,550	209,114

# NOTE 7 OTHER OPERATING INCOME

	Gro	oup	Parent company	
Amounts in kSEK	2018	2017	2018	2017
Rental income	-	678	-	678
Operating foreign exchange gains	7,999	324	7,999	324
EU grants	8,254	14,534	8,254	14,534
Public grants	-	1,585	-	1,585
Gain from disposal of tangible assets	-	635	-	635
Other items	7	1,288	7	1,288
Total other operating income	16,259	19,044	16,259	19,044

# NOTE 8 EMPLOYEES

# **AVERAGE NUMBER OF EMPLOYEES**

	Gre	oup	Parent company		
Number	2018	2017	2018	2017	
Women	18	15	18	15	
Men	11	11	11	11	
Total	29	26	29	26	

# **BOARD OF DIRECTORS AND SENIOR EXECUTIVES**

	20	18	20	17
Number	Balance sheet date	Whereof	Balance sheet date	Whereof women
BioArctic AB				
Board of directors	7	1	6	1
CEO and other senior executives	8	4	8	3

# SALARIES, REMUNERATION AND SOCIAL COSTS

	Gro	oup	Parent compa	
Amounts in kSEK	2018	2017	2018	2017
Salaries and remuneration				
Board of directors, CEO and other senior executives	20,797	12,504	20,797	12,504
(whereof variable)	(6,594)	(547)	(6,594)	(547)
Other employees	19,527	10,483	19,527	10,483
Total salaries and remuneration	40,324	22,987	40,324	22,987
Social costs	11,058	5,834	11,058	5,834
Pension cost	4,429	3,678	4,429	3,678
(whereof board of directors, CEO and other senior executives)	(2,881)	(2,510)	(2,881)	(2,510)
Total salaries, remuneration and social costs	55,811	32,499	55,811	32,499

The company has no outstanding pension obligations.

### **REMUNERATION AND OTHER BENEFITS DURING 2018**

	Base salary/	Variable remunera-		
Amounts in kSEK	fee	tion	Pension	Total
Board of directors				
Wenche Rolfsen (chairman) 3)	543	-	-	543
Lars Lannfelt 1)	1,984	-	151	2,135
Pär Gellerfors 2)	1,169	-	208	1,377
Eugen Steiner	300	-	-	300
Ivar Verner <sup>3)</sup>	319	-	-	319
Hans Ekelund 3)	320	-	-	320
Mikael Smedeby 4)	117	-	-	117
Senior executives				
CEO Gunilla Osswald	2,505	1,815	872	5,193
Other senior executives (7 persons) 1,5)	11,912	4,779	1,650	18,341
Total remuneration and other benefits	19,170	6,594	2,881	28,646

# $^{1)}$ Lars Lannfelt is active in the company and employed at a 100% duty rate. He is co-opted to the management team since September 1, 2018, but he is reported in the table above only in the board in order not to be counted twice.

CEO Gunilla Osswald received remuneration amounting to kSEK 2,505 as fixed annual salary and in addition 35 percent in pension provision. The CEO is covered by the incentive program covering all employees, see below. In 2018 the CEO had variable compensation up to 35 percent of the annual salary. Between the company and the CEO there is a termination period of 12 months by the company and 6 months by the CEO. Upon termination by the company there is no work obligation during the notice period, but the CEO shall be available to the company as needed.

Company management consists of 8 persons and one co-opted person. Senior executives except for the CEO receive normal market remuneration and individually negotiated premiums for occupational pension, or premiums under the terms of the company's pension policy. All other employees receive market salaries and premiums are allocated to the occupational pension in accordance with the terms of the company's pension policy. All employees have a contractual mutual termination period of

### **REMUNERATION AND OTHER BENEFITS DURING 2017**

Amounts in kSEK	Base salary/ fee	Variable remunera-	Pension	Total
Board of directors	100		rension	Totat
Wenche Rolfsen				
(chariman)	279	-	-	279
Lars Lannfelt	1,552	-	214	1,765
Pär Gellerfors	1,620	-	356	1,976
Eugen Steiner	150	-	-	150
Ivar Verner	173	-	-	173
Hans Ekelund	175	-	-	175
Mikael Smedeby	131	-	-	131
Senior executives				
CEO Gunilla Osswald	2,223	417	841	3,482
Other senior executives (7 persons)	9,253	130	1,099	10,481
Total remuneration and other benefits	15,555	547	2,510	18,613

three months, or according to the employment protection act. Severance pay is not applied. To the board members who are not employees of the company fees have been paid pursuant to the Annual General Meeting's decision.

BioArctic has two incentive programs, covering all permanent employees. One condition for receiving variable remuneration is that the employee has been employed for at least six months at the time when the goal is achieved that is the basis for payment of variable remuneration. The goals are linked to achieved milestone goals in the clinical research programs for the drug candidates BAN2401 for Alzheimer's disease and BAN0805 for Parkinson's disease. The potential variable remuneration for the employee amounts to one monthly salary per milestone goal. The variable remuneration is not pensionable. For 2018, in addition to variable remuneration to the CEO, the other senior executives have the possibility of variable remuneration amounting to 20 to 25 percent of the annual salary.

<sup>&</sup>lt;sup>2)</sup> Pär Gellerfors was active in the company with a 100% duty rate up to September 1, 2018, when he left his position. He is now only a board member.

<sup>3)</sup> Part of the board fee including social cost is invoiced until the Annual General Meeting 2018.

<sup>4)</sup> Mikael Smedeby is member of the board since May 15, 2018.

<sup>5)</sup> This amount includes invoiced fees to the amount of kSEK 4,462.

# NOTE 9 REMUNERATION TO THE AUDITORS

	Gro	roup Parent con		ompany
Amounts in kSEK	2018	2017	2018	2017
Grant Thornton				
Audit engagement	583	521	583	521
Audit services in addition to audit engagement	9	1,232	9	1,232
Tax advisory service	145	83	145	83
Other services	491	359	491	359
Total remuneration to Grant Thornton	1,228	2,195	1,228	2,195

Audit assignments include the auditing of the annual accounts, the accounting records and the board's and the CEO's management, other tasks that are incumbent on auditors to perform, as well as advice or other assistance arising from observations made during such auditing or the performance of such other tasks. In 2017, audit related tasks in addition to the audit assignment were mainly related to the Group's listing on Nasdaq Stockholm.

Tax advice includes advice on income taxation and VAT. Other services are advice not attributable to any of the above categories of service.

# NOTE 10 COMMITMENTS

### **LEASING**

The Group leases office premises under non-cancellable operational leases where the remaining leasing period is 5 years (1).

## **COSTS FOR MINIMUM LEASE PAYMENTS**

	Group Parent		ompany	
Amounts in kSEK	2018	2017	2018	2017
Leasing fee for premises	6,522	6,456	6,522	6,456
Total	6,522	6,456	6,522	6,456

# FUTURE MINIMUM LEASE PAYMENTS CONCERNING NON-CANCELLABLE LEASES

	Gro	oup	Parent company		
Amounts in kSEK	2018	2017	2018	2017	
Within 1 year	6,999	6,425	6,999	6,425	
Between 1 and 5 years	26,982	-	26,982	-	
More than 5 years	-	-	-	-	
Total	33,981	6,425	33,981	6,425	

### Other commitments

BioArctic has committed to conduct research activities to achieve pre-defined milestones. For BioArctic's commitment advance payment amounting to approximately MSEK 702 has been received. At the closing date revenue amounting to approximately MSEK 209 remains to be recognized. The costs for meeting the commitment are estimated to an amount lower than this remaining revenue.

# NOTE 11 OTHER OPERATING EXPENSES

	Gro	oup	Parent company		
Amounts in kSEK	2018	2017	2018	2017	
Loss from disposal of tangible assets	-	6	-	6	
Operating foreign exchange losses	5,031	5,683	5,031	5,683	
Total other operating expenses	5,031	5,689	5,031	5,689	

# NOTE 12 FINANCIAL INCOME AND EXPENSES

	Gro	oup	Parent company		
Amounts in kSEK	2018	2017	2018	2017	
Interest income	40	65	40	65	
Foreign exchange gains	2,131	979	2,131	979	
Total financial income	2,171	1,043	2,171	1,043	
Interest expenses	-1,371	-647	-1,371	-647	
Total financial expenses	-1,371	-647	-1,371	-647	
Total financial income and expenses	800	396	800	396	

# NOTE 13 TAX

	Gro	oup	Parent company		
Amounts in kSEK	2018	2017	2018	2017	
Current tax	-80,919	-3,240	-80,919	-3,240	
Deferred taxes	-27,073	-1,294	-40	57	
Total tax on profit for the year	-107,991	-4,534	-80,959	-3,183	

# Reconciliation of effective tax

In the table below reported tax is reconciled to tax based on the Swedish tax rate of 22%.

# **RECONCILIATION OF TAX**

		Parent company		
2018	2017	2018	2017	
489,593	19,690	366,718	13,550	
-107,711	-4,332	-80,678	-2,981	
-257	-187	-257	-187	
-	0	0	0	
-19	-15	-19	-15	
-5	-	-5	-	
-107,991	-4,534	-80,959	-3,183	
22.1	23.0	22.1	23.5	
	-107,711 -257 -19 -5 -107,991	-107,711 -4,332 -257 -187 - 0 -19 -15 -5107,991 -4,534	489,593       19,690       366,718         -107,711       -4,332       -80,678         -257       -187       -257         -       0       0         -19       -15       -19         -5       -       -5         -107,991       -4,534       -80,959	

# note 13 cont.

# **CURRENT TAX LIABILITIES**

	Gro	oup	Parent company		
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017	
Current tax liabilities	73,339	3,310	73,339	3,310	
Total current tax liabil- ities	73,339	3,310	73,339	3,310	

# **Deferred tax**

Deferred tax is made up of tax items that will be regulated in the future. The table (to the right) specifies deferred tax assets and liabilities with respect to temporary differences between the book value and tax base of assets and liabilities.

# **DEFERRED TAX ON TEMPORARY DIFFERENCES**

	Gro	oup	Parent company		
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017	
Leasehold improvements	189	230	189	230	
Total deferred tax asset	189	230	189	230	
Tax allocation reserve	-32,165	-5,192	-	-	
Accelerated depreciation	-355	-295	-	-	
Total deferred tax liabilities	-32,520	-5,487	0	0	
Total net deferred tax	-32,330	-5,257	189	230	

# **CHANGE IN DEFERRED TAX**

	Group			Parent company		
Amounts in kSEK	January 1, 2018	Presented in income statement	December 31, 2018	January 1, 2018	Presented in income statement	December 31, 2018
Leasehold improvements	230	-40	189	230	-40	189
Total deferred tax asset	230	-40	189	230	-40	189
Tax allocation reserve	-5,192	-26,973	-32,165	0	-	0
Accelerated depreciation	-295	-60	-355	0	-	0
Total deferred tax liabilities	-5,487	-27,033	-32,520	0	0	0
Total net deferred tax	-5,257	-27,073	-32,330	230	-40	189

Amounts in kSEK	Group			Parent company			
	January 1, 2017	Presented in income statement	December 31, 2017	January 1, 2017	Presented in income statement	December 31, 2017	
Leasehold improvements	172	57	230	172	57	230	
Total deferred tax asset	172	57	230	172	57	230	
Tax allocation reserve	-4,136	-1,056	-5,192	0	-	0	
Accelerated depreciation	0	-295	-295	0	-	0	
Total deferred tax liabilities	-4,136	-1,351	-5,487	0	0	0	
Total net deferred tax	-3,964	-1,294	-5,257	172	57	230	

#### NOTE 14 **EARNINGS PER SHARE AND SHARE DATA**

Earnings per share are calculated by dividing the profit attributable to the parent company's shareholders by a weighted average number of outstanding ordinary shares during the period.

	Group	
	2018	2017
Comprehensive income for the year attributable to owners of the parent company, kSEK	381,602	15,157
Weighted average number of outstanding shares <sup>1, 2)</sup>	88,059,985	68,059,985
Earnings per share, SEK	4.33	0.22
Proposed dividend per share, SEK	1.50	None
Number of outstanding shares at at balance sheet date <sup>1,2)</sup>	88,059,985	88,059,985

#### NOTE 15 **TANGIBLE ASSETS**

		Group			Parent company			
Amounts in kSEK	Leasehold improvements	Equipment	Total	Leasehold improvements	Equipment	Total		
Acquisition value at January 1, 2018	2,257	17,994	20,251	2,257	17,994	20,251		
Acquisitions	-	4,255	4,255	-	4,255	4,255		
Acquisition value at December 31, 2018	2,257	22,249	24,506	2,257	22,249	24,506		
Depreciations at January 1, 2018	-1,310	-11,849	-13,158	-1,310	-11,849	-13,158		
Depreciations	46	-2,105	-2,059	46	-2,105	-2,059		
Depreciations at December 31, 2018	-1,264	-13,953	-15,217	-1,264	-13,953	-15,217		
Book value at January 1, 2018	947	6,146	7,093	947	6,146	7,093		
Book value at December 31, 2018	993	8,296	9,289	993	8,296	9,289		

 $<sup>^{1)}</sup>$  No potential shares exist, thus there is no dilution effect.  $^{2)}$  The comparative numbers have been recalculated as a result of the 15:1 split carried out on August 1, 2017.

# note 15 cont.

		Group		Parent company			
Amounts in kSEK	Leasehold improve- ments	Equipment	Total	Leasehold improve- ments	Equipment	Total	
Acquisition value at January 1, 2017	2,212	16,923	19,136	2,212	16,923	19,136	
Acquisitions	44	3,403	3,448	44	3,403	3,448	
Sales/disposals	-	-2,332	-2,332	-	-2,332	-2,332	
Acquisition value at December 31, 2017	2,257	17,994	20,251	2,257	17,994	20,251	
Depreciations at January 1, 2017	-937	-12,554	-13,491	-937	-12,554	-13,491	
Sales/disposals	-	2,326	2,326	-	2,326	2,326	
Depreciations	-372	-1,621	-1,993	-372	-1,621	-1,993	
Depreciations at December 31, 2017	-1,310	-11,849	-13,158	-1,310	-11,849	-13,158	
Book value at January 1, 2017	1,275	4,369	5,644	1,275	4,369	5,644	
Book value at December 31, 2017	947	6,146	7,093	947	6,146	7,093	

	Parent company		
Amounts in kSEK	December 31, 2018	December 31, 2017	
Opening acquisition value	100	100	
Closing acquisition value	100	100	

	Gro	oup	Parent c	ompany
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017
Deposit	1,500	2,675	1,500	2,675
Total other non-current financial assets	1,500	2,675	1,500	2,675

# SPECIFICATION OF PARENT COMPANY SHARES IN SUBSIDIARIES

Relating to the deposit for premises in the form of restricted cash, see Note 26.

Company/ Reg no/ Reg office	Owned in %1)	Equity	Profit for the year
SpineMedical AB, 559003-7080,	111 76	Equity	- the year
Stockholm	100.0	48	-1
LPB Sweden AB, 559035-9112, Stockholm	100.0	50	-

 $<sup>^{\</sup>rm IJ}$  Owned share of capital is referred to, which also corresponds to the share of the votes for the total number of shares.

# NOTE 18 OVERVIEW OF FINANCIAL INSTRUMENTS

# **CATEGORIES OF FINANCIAL ASSETS AND LIABILITIES**

The Group's financial assets and liabilities are entirely related to cash and cash equivalents, current receivables, contractual accrued income, accounts payable and contractual accrued expenses. The Group has no foreign exchange contracts or listed securities.

December 31, 2018 Amount in kSEK	Note	Measured at amortized cost	Fair value through profit or loss	Fair value through other comprehensive income
Financial assets				
Other current receivables	19	384	-	-
Contractual accrued income	20	448,550	-	-
Cash and cash equivalents	21	917,307	-	-
Total financial assets		1,366,241	0	0
Financial liabilities				
Accounts payable		-14,808	-	-
Contractual accrued expenses	25	-20,873	-	-
Total financial liabilities		-35,681	0	0
Total financial instruments (assets + / liabilities -)		1,330,560	0	0

December 31, 2017 Amount in kSEK	Note	Measurement level	Financial liabilities measured at amortized cost	Loans and receivables	Total book value	Fair value
Financial assets						
Other current receivables	19	-	-	4,728	4,728	4,728
Cash and cash equivalents	21	-	-	1,110,367	1,110,367	1,110,367
Total financial assets			0	1,115,095	1,115,095	1,115,095
Financial liabilities						
Accounts payable		-	-7,586	-	-7,586	-7,586
Other current liabilities		-	-1,263	-	-1,263	-1,263
Total financial liabilities			-8,850	0	-8,850	-8,850
Total financial instruments (assets + / liabilities -)			-8,850	1,115,095	1,106,246	1,106,246

# THE GROUP'S MATURITY STRUCTURE FOR UNDISCOUNTED FINACIAL LIABILITIES

Amounts in kSEK	2019	2020	2021	2022	2023
Accounts payable	14,808	-	-	-	-
Contracted accrued expenses	20,873	-	-	-	-
Total	35,681	0	0	0	0

# NOTE 19 OTHER CURRENT RECEIVABLES

	Group		Parent company		
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017	
VAT receivables	3,520	3,865	3,520	3,865	
Tax account	-	861	-	861	
Other	384	2	384	2	
Total other current receivables	3,904	4,728	3,904	4,728	

# NOTE 21 CASH AND CASH EQUIVALENTS

	Gr	oup	Parent company		
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017	
Cash and bank balances	917,307	1,110,367	917,209	1,110,269	
Total cash and cash equivalents	917,307	1,110,367	917,209	1,110,269	

# NOTE 20 PREPAID EXPENSES AND ACCRUED INCOME

	Group		Parent company		
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017	
Prepaid rent	1,696	1,606	1,696	1,606	
Other prepaid expenses	747	1,206	747	1,206	
Accrued EU grants	9,860	12,578	9,860	12,578	
Contractual accrued income	448,550	-	448,550	-	
Total prepaid expenses and accrued income	460,853	15,390	460,853	15,390	

# NOTE 22 SHARE CAPITAL

Class of shares	Numbers 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	73,659,989	1,473,200	0.02	1	73,659,989
Total	88,059,985	1,761,200			217,659,949

# **DEVELOPMENT OF SHARE CAPITAL**

Year	Event	Number of new shares	A-shares	B-shares	Total number of shares	Change in share capital, SEK	Total share capital
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 A- 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 A- 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
		88,059,985				1,761,200	

Concerning changes in equity, see the Group's and the parent company's reports of changes in equity.

# NOTE 23 PROPOSED APPROPRIATION OF RETAINED EARNINGS

The board proposes that available funds, amounting to SEK 899,721,875, be disposed of as follows:

Amounts in SEK	December 31, 2018
Dividend	132,089,978
Carried forward	767,631,898
Total	899,721,875

The proposed dividend amounts to SEK 132,089,978, or SEK 1.50 per share. The Board has concluded that the company's financial resources are sufficient to finance its projects and programs as planned without additional share issue.

# NOTE 24 UNTAXED RESERVES

	Parent company			
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017		
Tax allocation reserve, 2016	18,800	18,800		
Tax allocation reserve, 2017	4,800	4,800		
Tax allocation reserve, 2018	122,603	-		
Total tax allocation reserve	146,203	23,600		
Accelerated depreciation	1,614	1,341		
Total accelerated depreciation 147,817		24,941		

# NOTE 25 ACCRUED EXPENSES AND PREPAID INCOME

	Gro	oup	Parent company		
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017	
Accrued personnel expenses	18,721	3,979	18,721	3,979	
Contractual accrued expenses	20,873	9,413	20,873	9,413	
Prepaid income	209,114	473,311	209,114	473,311	
Prepaid EU grants	2,083	-	2,083	-	
Total accrued expenses and prepaid income	250,791	486,702	250,791	486,702	

- Within the framework of received Swedish public grants
  the company has a repayment obligation if the projects are
  terminated, or the company does not carry out the projects
  according to instructions, and the accumulated project costs
  are less than what has been paid.
- The spinal cord injury project includes patients who either are treated with SC0806, i.e. undergo surgery, or participate as control patients. So far six patients have had surgery and another three patients participate in the study's control group. BioArctic has made a commitment to the control group that these patients shall get treatment with SC0806 in the case that the study produces a positive result.

All projects are running according to plan and there are no indications that repayment obligations or other obligations could arise. The same assessment was made in 2017.

NOTE 26

PLEDGED ASSETS AND CONTINGENT LIABILITIES

### **PLEDGED ASSETS**

Pledged assets according to the table below are pledged as security for office space.

	Gro	oup	Parent company		
Amounts in kSEK	Dec. 31, 2018	Dec. 31, 2017	Dec. 31, 2018	Dec. 31, 2017	
Restricted cash	1,500	2,675	1,500	2,675	
Total pledged assets	1,500	2,675	1,500	2,675	

# **CONTINGENT LIABILITIES**

The following contingent liabilities have been identified applying to the Group as well as the parent company:

 BioArctic has under existing EU research collaborations a repayment obligation towards contracting party in case of termination of the projects and if advance payments received are exceeding the costs incurred. BioArctic also has an obligation to pay for health care needs of patients included in these studies. NOTE 27 DISCLOSURES ON THE CASH FLOW STATEMENT

# **ADJUSTMENT FOR NON-CASH ITEMS**

	Gro	oup	Parent company		
Amounts in kSEK	2018	2017	2018	2017	
Depreciations of tangible assets	2,059	1,993	2,059	1,993	
Profit(-) / Loss (+) on sales of tangible assets	-	-629	-	-629	
Prepaid income	-721,000	-150,037	-721,000	-150,037	
Unrealized foreign exchange gains (-) / losses (+)	-7,945	5,219	-7,945	5,219	
Total adjustment for non-cash items	-726,886	-143,453	-726,886	-143,453	

# NOTE 28 TRANSACTIONS WITH AFFILIATED PARTIES

Mikael Smedeby, who was elected board member at the Annual General Meeting on May 15, 2018, is active as a lawyer and partner in Advokatfirman Lindahl KB, which provides day-to-day business legal advice to BioArctic against compensation on market terms. In 2018 Advokatfirman Lindahl's invoiced fees amounted to approximately MSEK 0.6. In 2017 the invoiced fees amounted to MSEK 5.2, mainly consisting of costs due to the stock exchange listing in October 2017.

A consultancy agreement regarding support in the area of contracts and patents was signed in December, 2018 between Ackelsta AB, owned by Pär Gellerfors, and BioArctic AB. No payments have been made under this agreement during 2018.

In addition to the compensation to Advokatfirman Lindahl KB described above and fixed salary and fees to Lars Lannfelt and Pär Gellerfors no additional significant transactions have occurred between the Group and related parties. All transactions have been made on market terms.

# NOTE 29 EVENTS AFTER THE BALANCE SHEET DATE

BioArctic announced that Eisai will start a single confirmatory Phase 3 study with BAN2401 for early Alzheimer's disease in the first quarter of 2019. The study was initiated in March.

The U.S. Food and Drug Administration, FDA, approved the Investigational New Drug Application for ABBV-0805, previously called BAN0805. The clinical Phase 1 study with ABBV-0805 started in March 2019.

BioArctic's product candidate SC0806 for patients with complete spinal cord injury has entered the Phase 2 part of the Phase 1/2 study.

NOTE 30

INFORMATION ON PURCHASES AND SALES WITHIN THE GROUP

No purchases or sales have taken place within the Group.

# NOTE 31 DEFINITION AND RECONCILIATION OF KEY RATIOS

Key ratio	Definition
Other operating income	Other income than net revenues
Operating profit/loss	Result before financial items
Operating margin, %	Result before financial items divided by net revenues
Earnings per share	Profit for the year divided by a weighted average number of outstanding shares
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	The period's cash flow from operating activities divided by a weighted average number of outstanding shares
Equity/asset ratio, %	Adjusted equity in percent of the balance sheet total
Return on equity	Profit after tax in percent of average adjusted equity

note 31 cont.

Amounts in kSEK	2018	2017	2016	2015	2014
Operating margin					
Operating profit	488,794	19,294	74,631	4,844	6,926
Net revenues	713,970	140,706	105,613	41,573	53,712
Operating margin, %	68.5	13.7	70.7	11.7	12.9
Earnings per share					
Profit for the year	381,602	15,157	57,580	3,710	6,788
Weighted average number of outstanding shares <sup>1</sup>	88,059,985	68,059,985	63,059,985	63,059,985	63,059,985
Earning per share, SEK	4.33	0.22	0.91	0.06	0.11
Equity per share					
Equity	1,017,736	636,134	60,760	108,285	104,570
Number of outstanding shares <sup>1</sup>	88,059,985	88,059,985	63,059,985	63,059,985	63,059,985
Equity per share	11.56	7.22	0.96	1.72	1.66
Cash flow from operating activities per share					
Cash flow from operating activities	-200,057	-135,327	675,131	-16,434	-24,184
Weighted average number of outstanding shares <sup>1</sup>	88,059,985	68,059,985	63,059,985	63,059,985	63,059,985
Cash flow from operating activities per share	-2.27	-1.99	10.71	-0.26	-0.38
Equity/asset ratio					
Adjusted equity	1,017,736	636,134	60,760	108,285	104,570
Balance sheet total	1,393,042	1,140,483	707,976	131,111	154,387
Equity/asset ratio, %	73.1	55.8	8.6	82.6	67.7
Return on equity					
Profit for the year	381,602	15,157	57,580	3,710	6,788
Average adjusted equity	826,935	348,447	84,522	106,428	101,176
Return on equity, %	46.1	4.3	68.1	3.5	6.7

<sup>&</sup>lt;sup>1)</sup> The comparative figures have been recalculated as a result of the 15:1 split executed on August 1, 2017.

# Assurance of the Board of directors and CEO

The undersigned hereby assure that the consolidated accounts and annual report were prepared as per 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 position and performance, and that the administration report provides a true and fair view of

the development of the Group's and parent company's operations, 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 May 9, 2019.

Stockholm, Sweden on April 8, 2019

Wenche Rolfsen Ivar Verner Hans Ekelund
Chairman Deputy Chairman Board member

Pär GellerforsLars LannfeltMikael SmedebyBoard memberBoard memberBoard member

Eugen Steiner
Board member

Gunilla Osswald Chief Executive Officer

Our audit report is issued on April 8, 2019

Grant Thornton Sweden AB

Mia Rutenius Authorized public accountant Auditor in charge Rutger Nordström 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 2018, with the exception of the Corporate Governance Report on pages 48–55. The annual accounts and consolidated accounts of the company are included on pages 40–87 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, 2018 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, 2018 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. Our statements do not include the Corporate Governance Report on the pages 48–55. 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, 2018 is kSEK 713 970, and mainly includes compensations related to research collaborations and milestone payments. 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 includes significant elements of assessments revenues have been assessed as a key audit matter. For further information on accounting policies for revenue recognition, see note 3 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 of valuation regarding assets and liabilities related to revenue,
- 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 2–39.

The Board of Directors and the Managing Director are responsible for this other information.

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.

- valuate 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.
- 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 2018 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 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.

# Auditor's report on the corporate governance statement

It is the board of directors who is responsible for the corporate governance statement found on pages 48-55 and that it

has been prepared in accordance with the Annual Accounts Act. Our review has been conducted in accordance with FAR's auditing standard RevU 16 *The auditor's review of the corporate governance statement*. This means that our review 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 review has provided us with sufficient basis for our 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.

Grant Thornton Sweden AB, Sveavägen 20 SE 111 57 Stockholm, was appointed auditor of BioArctic AB (publ) by the general meeting of the shareholders on the May 15, 2018 and has been the company's auditor since the June, 22 2016. The audit assignment has since November 22, 2000, been held by a public accountant elected in a personal capacity employed by Grant Thornton Sweden AB.

Stockholm April 8, 2019 Grant Thornton Sweden AB

Mia Rutenius Authorized public accountant Auditor in charge Rutger Nordström Authorized public accountant

# Notice of Annual General Meeting

The Annual General Meeting of BioArctic AB (publ) will be held on Thursday, May 9, 2019, at 5 p.m., at Grant Thornton Sweden AB, Sveavägen 20, Stockholm, Sweden.

The complete notice to attend the general meeting and the proposals and documentation that will be presented at the Annual General Meeting are available at www.bioarctic.com under the Corporate Governance section.

## PARTICIPATION AT THE ANNUAL GENERAL MEETING

Shareholders who wish to participate in the Annual General Meeting must be registered in the share register kept by Euroclear Sweden AB on Friday, May 3, 2019, and give notice to the company of its intention to participate at the general meeting no later than on Monday, May 6, 2019. Such notice can be made by email to ir@bioarctic.se, by phone + 46 (0)8 695 69 30 weekdays between 9 a.m. to 5 p.m. or by mail to BioArctic AB, Warfvinges väg 35, SE-112 51 Stockholm, Sweden.

The notice shall include the shareholder's name, personal identification number or corporate identity number, address and daytime telephone number, number of shares, details on advisors (no more than two), and the details of any

representatives or proxies. If the shareholder participates through a representative, a power of attorney in original form (along with any authorization documents such as a registration certificate) must be presented to the company before the Annual General Meeting.

### NOMINEE-REGISTERED SHARES

To be entitled to participate in the Annual General Meeting, shareholders whose shares are registered in the name of a nominee must temporarily re-register their shares in their own names in the share register maintained by Euroclear Sweden AB in order to be entitled to attend the Annual General Meeting. Such registration must be duly effected in the share register on May 3, 2019, and the shareholders must therefore advise their nominees well in advance of such date.

## **DIVIDEND**

The Board of directors proposes the Annual General Meeting a dividend of SEK 1.50, a total of approximately MSEK 132. Record day for entitlement to dividends is proposed to be Monday May 13, 2019.

# Glossary



## Alpha-synuclein (a-synuclein)

A protein in the nervous system, present in Lewy bodies in some structures of the brain in Parkinson's disease

# Amyloid beta (Aß)

A 40-42 amino acids long peptide, split from the parent protein APP, amyloid precursor protein. A $\beta$  is the main constituent of the plaques found in the brain of Alzheimer patients

# **Antibody**

Protein used by the body's immune system to detect and destroy foreign substances

## **Arctic mutation**

A mutation in the amyloid precursor protein (APP) leading to an increase of oligomers/protofibrils of Aβ. Individuals with the Arctic mutation develop Alzheimer's disease at an early age. The Arctic mutation was discovered by Professor Lars Lannfelt and his research group and has given name to the company

### **Axon**

Nerve fibers that are outgrowths from nerve cells (neurons)



# **Biomarker**

A measurable indicator of a medical condition

### **Blood-brain barrier**

A physiological mechanism in which merged capillary walls in the brain's blood vessels regulate the transport of molecules between the blood and the brain tissue, with the function to protect the brain against viruses and other harmful agents



## Central nervous system

The central nervous system consists of the brain and the spinal cord

### **Clinical studies**

Drug trials performed in human subjects

## **Complete Spinal Cord Injury**

A complete injury means that the spinal cord is completely severed. In an incomplete injury there are still a few nerve contacts left



# Disease modifying treatment

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

# **Drug candidate**

A drug under development that has not yet gained marketing approval



# **Humanized antibody**

An antibody in which the sequence has been changed to resemble a human antibody



## Immune therapy

Treatment that strengthens the body's immune system and ability to attack a pathogen, or defend against/prevent auto-immune reactions

## Interim analysis

In clinical trials and other scientific studies, an interim analysis is an analysis of data that is conducted before data collection has been completed

# Investigational New Drug (IND) application

Application to the U.S. Food and Drug Administration (FDA) for the approval to conduct a clinical study in the US



### **Lewy bodies**

Lewy bodies are small round protein accumulations in the nerve cells

# Ligand

Molecule that binds to the desired target in the body



# Medical device for implantation

A medical device that is intended to be totally or partially introduced, surgically or medically, into the human body, or through a medical procedure in a body opening, and intended to remain there after the operation

# Milestone payment

Financial compensation obtained within the framework of a project or collaboration agreement when a certain specified objective has been achieved

## Monoclonal antibody

An antibody that can be produced so that all copies are exactly alike

## **Monomer**

A monomer is the starting molecule in polymerization. The monomers are joined into long molecular chains through the polymerization, resulting in a polymer with the monomer as the repeating unit



# Neurodegenerative disease

Disease in which the nervous system atrophies



# Oligomer

A molecular chain consisting of several monomers aggregated

# **Orphan drugs**

Drugs for patients with rare and serious diseases



### **Pathogens**

Substances or organisms that cause disease or are toxic

## **Peptide**

A molecule made up of amino acids connected into a short chain

### PET

Positron emission tomography, an investigation imaging method

### Phase 1 study

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

## Phase 2 study

Studies of the safety and efficacy of a drug and dose finding. Performed on a limited number of patients

### Phase 3 study

Confirmatory studies of the safety and efficacy of a drug in a clinical setting. Performed on a large number of patients

# **Preclinical phase**

Preclinical studies of drug candidates to prepare for clinical studies

## **Preclinical studies**

Studies performed in model systems, i.e. not in humans

### **Prodromal**

Early phase, before the disease has developed

## **Product candidate**

A product under development that has not yet gained marketing approval

## **Protofibrils**

A molecular chain consisting of several monomers aggregated



# Research phase

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



## **Swedish mutation**

A mutation in the amyloid precursor protein leading to increased production of  $A\beta$  and early development of Alzheimer's disease. Discovered in a Swedish family in 1992 by Professor Lars Lannfelt and his research group



## **Tolerability**

How a person reacts to a drug

