

BioArctic: Strong continued progress year to date

Summary of key events for the third quarter 2019

- BioArctic and Eisai presented new data regarding BAN2401 at the Alzheimer's Association International Conference® (AAIC®) in July that confirmed BAN2401's unique characteristics and was consistent with previously presented results

Key events after the period

- There are no key events to report after the period

Financial summary for the period January – September 2019

- Net revenues for the period increased by MSEK 56.7 to MSEK 255.4 (198.6), primarily attributable to the received milestone payment from Eisai in May
- Operating profit amounted to MSEK 133.6 (58.5) and the operating margin was 52.3 percent (29.4) for the period
- Profit for the period amounted to MSEK 105.6 (46.4) and earnings per share were SEK 1.20 (0.53)
- Cash flow from operating activities amounted to MSEK 381.4 (-110.8)

Financial summary

MSEK	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Net revenues	20.6	94.0	255.4	198.6	714.0
Other operating income	8.6	0.6	14.8	15.6	16.3
Operating profit/loss	-10.5	33.1	133.6	58.5	488.8
Operating margin, %	-50.9	35.2	52.3	29.4	68.5
Profit/loss for the period	-8.3	25.9	105.6	46.4	381.6
Earnings per share before dilution, SEK	-0.09	0.29	1.20	0.53	4.33
Equity per share, SEK	11.26	7.75	11.26	7.75	11.56
Cash flow from operating activities	-49.4	-31.5	381.4	-110.8	-200.1
Cash flow from operating activities per share, SEK	-0.56	-0.36	4.33	-1.26	-2.27
Equity/assets ratio, %	80.0	66.1	80.0	66.1	73.1
Return on equity, %	-0.8	3.9	10.5	7.0	46.1
Share price at the end of the period	61.75	118.90	61.75	118.90	82.00

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This information is information that BioArctic AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of the named contact persons, at 08.00 a.m. CET on October 24, 2019.

Invitation to presentation of Interim Report for the period January – September 2019

BioArctic invites to an audiocast with teleconference (in English) for investors, analysts and media today, October 24, at 09:30 – 10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson will present BioArctic, comment on the Interim Report and answer questions.

Webcast: <https://tv.streamfabriken.com/bioarctic-q3-2019>

To participate in the conference call, please call: +46 8 505 583 56 (Sweden), +45 781 501 09 (Denmark), +49 692 222 203 77 (Germany) +31 207 219 495 (Netherlands), +47 235 002 43 (Norway), +41 225 675 632 (Switzerland), +44 333 300 9267 (UK) or +1 833 823 0589 (USA)

The Group is referred to unless otherwise stated in this Interim Report. Figures in parentheses refer to the corresponding period last year.

CEO comments

BioArctic focuses where high unmet medical needs exist for patients with central nervous system disorders. Our work is based on groundbreaking scientific discoveries. Our team works in close collaboration with leading competences in academia and large pharma partners.

This quarter, we received further validation for our innovative and world-leading science that is the foundation for our work to develop a safe and effective treatment for Alzheimer's disease. During the Alzheimer's Association International Conference (AAIC) in July, BioArctic's co-founder, Professor Lars Lannfelt, received a Lifetime Achievement Award, one of the world's most prestigious awards in Alzheimer's disease research, for his discoveries and research that led to the drug candidate BAN2401. We are delighted and proud that Lars Lannfelt is recognized for his important scientific contribution to the field and to BioArctic's research.

The antibody BAN2401 is specifically designed and generated to selectively bind to and eliminate the harmful forms of amyloid beta, called protofibrils, which are believed to lead to the development of Alzheimer's disease. This unique binding profile was further confirmed with new data presented in July at the AAIC. The results are consistent with what has been seen in previous studies with BAN2401, but also confirmed that BAN2401 is different from other amyloid beta antibodies. As previously presented, the large Phase 2b study with BAN2401 successfully demonstrated consistent effects on clinical function and biomarkers of disease, as well as a good safety profile. Our partner Eisai presented additional supportive data from this study at the AAIC in July. Taken together, these results strengthen BioArctic's belief that BAN2401's unique binding profile is important and differentiates it from other antibodies'.

Our partner Eisai has continued to develop BAN2401 in a stepwise fashion, taking each next step based on strong data from the previous phase. Based on the results from the Phase 2b study, the global, confirmatory Phase 3 study (Clarity AD) with BAN2401 is well underway and Eisai expects to receive study results in 2022. Eisai is also strongly committed to the overall development of BAN2401. In addition to the ongoing Phase 3-study, a Phase 2b open-label extension study with BAN2401 is ongoing and a further clinical trial aimed at prevention of Alzheimer's disease with BAN2401 is planned to start in 2020.

BioArctic's balanced portfolio, with projects from discovery to late clinical phase, has developed well.

During the year, three projects advanced to the next clinical phase in their respective development program.

In the Parkinson's program, our partner AbbVie continues the Phase 1 study with the drug candidate ABBV-0805. BioArctic continues to pursue two further research phase projects within the framework of the ongoing collaboration with AbbVie.

With SC0806, intended for complete spinal cord injury, the trial has advanced as planned and we expect to receive the results of the interim analysis of the first panel of the study in Q4 2019/Q1 2020. This will be the first time we analyze the effect of SC0806, in addition to safety.

The technology platform to facilitate passage of antibodies over the blood-brain barrier is developing well. We are grateful for the grant that we and Uppsala University received together from Vinnova (Sweden's innovation agency) earlier this year. We are also pleased to have successfully recruited world-leading scientists in this area. The research is at an early stage but has already shown very promising results and the technology has great potential in the treatment of various brain diseases.

BioArctic's finances remain strong. Our strategic partners fund and progress the costly clinical studies in Alzheimer's and Parkinson's diseases. Grants primarily fund the clinical development for our complete spinal cord injury project. Furthermore, our partnered projects' progress brings revenues to BioArctic, including the most recent MEUR 15 milestone from Eisai for the start of the Phase 3 clinical study for BAN2401 in May 2019.

Our ambition is to develop the medicines of the future that change life for people with central nervous system disorders. The company's strong cash position creates the opportunity for the continued exciting development of BioArctic.



Gunilla Osswald
CEO, BioArctic AB

Project portfolio

BioArctic builds a competitive portfolio of unique product candidates, diagnostics and technology in the company's indication areas. We run projects in three areas where effective treatments are lacking today: Alzheimer's disease, Parkinson's disease and complete spinal cord injury. The company's projects are in various phases: from discovery to late clinical phase.

Summary as of September 30, 2019:

- During the year, three projects (BAN2401, ABBV-0805, SC0806) advanced to the next clinical phase in their respective development program.
- Three drug candidates in clinical phase: BAN2401 for early Alzheimer's disease (Phase 3), ABBV-0805 for Parkinson's disease (Phase 1) and SC0806 for complete spinal cord injury (Phase 2)
- Two drug projects in preclinical phase: BAN2401 for other indications such as Down's syndrome with dementia and BAN2401 back-up for Alzheimer's disease
- Five projects in research phase: three projects for Alzheimer's disease (AD1801, AD1502, AD 1503) and two projects for Parkinson's disease (PD1601, PD1602)
- Biomarker and diagnostics projects for Alzheimer's disease and Parkinson's disease, as well as a blood-brain barrier technology platform

	Product candidate	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Neurodegenerative diseases	BAN2401: anti- $\text{A}\beta$ antibody	Alzheimer's Disease	Eisai, Biogen ¹	→	→	→	→	→
	BAN2401: anti- $\text{A}\beta$ antibody	Down's syndrome ² Traumatic Brain Injury	BioArctic	→	→			
	BAN2401 BACK-UP: anti- $\text{A}\beta$ antibody	Alzheimer's Disease	Eisai	→	→			
	AD1801: Undisclosed information	Alzheimer's Disease	BioArctic	→	→			
	AD1502: Undisclosed information	Alzheimer's Disease	BioArctic	→	→			
	AD1503: Undisclosed information	Alzheimer's Disease	BioArctic	→	→			
	ABBV-0805³: anti- α -synuclein antibody	Parkinson's Disease	AbbVie	→	→	→		
	PD1601: anti- α -synuclein antibody	Parkinson's Disease	AbbVie	→	→			
	PD1602: anti- α -synuclein antibody	Parkinson's Disease	AbbVie	→	→			
Diagnostics & Technology	IMAGING & BIOCHEMICAL BIOMARKERS: $\text{A}\beta$	Alzheimer's Disease	BioArctic	→	→			
	IMAGING & BIOCHEMICAL BIOMARKERS: α -synuclein	Parkinson's Disease	AbbVie	→	→			
	BBB-TECHNOLOGY: blood-brain barrier	Multiple application areas	BioArctic	→	→			
Spine	SC0806: FGF1/medical device	Complete Spinal Cord Injury	BioArctic	→	→	→		

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

²) Dementia and cognitive impairment associated with Down's syndrome and Traumatic Brain Injury

³) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805

Neurodegenerative diseases

A key cause of Alzheimer's disease and Parkinson's disease is believed to be abnormal protein folding and aggregation. The spreading of aggregated soluble forms of proteins leads to neuronal dysfunction, cell death, brain damage and symptoms of disease. Each neurodegenerative disease is characterized by a different aggregated protein. In Alzheimer's disease the

protein is amyloid beta ($\text{A}\beta$), while in Parkinson's disease it is alpha-synuclein (α -synuclein).

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.

Drug candidate BAN2401

Alzheimer's disease (collaboration with Eisai):

In Alzheimer's disease, soluble, toxic amyloid beta aggregates are believed to contribute to the neurodegenerative process. The antibody BAN2401 selectively binds to these forms of amyloid beta and eliminates them. BAN2401's unique binding profile is highly selective for A β oligomers/protofibrils and binds more than 1,000 times more strongly to these than to A β monomers and approximately 10 times more strongly than to A β fibrils.

During 2018, positive and robust results were presented from the Phase 2b study with BAN2401 in 856 patients with early Alzheimer's disease. The results demonstrated consistent, dose dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints and on biomarkers including amyloid-PET and was well tolerated.

A reduced degree of decline compared with placebo exceeding 25% was predefined as clinically relevant. At the analysis after 18 months of treatment a dose-dependent slowing of cognitive decline in the clinical cognition scale ADCOMS of 30% was demonstrated with the highest BAN2401 dose of 10 mg/kg twice a month. A statistically significant slowing of decline on ADCOMS was observed as early as at 6 months as well as at 12 months. With the cognition scale ADAS-Cog a significantly reduced degree of decline of 47% was seen with the highest dose. With the cognition scale CDR-SB a reduced decline of 26% compared with placebo was seen at 18 months.

Statistically significant and dose-dependent reduction of amyloid beta in the brain was seen with amyloid-PET at 18 months. The reduction was statistically significant for all doses. After 18 months treatment a drastic reduction in the brain could be demonstrated with amyloid-PET. 81% of the patients with the highest dose went from amyloid-positive to amyloid-negative. I.e., they could no longer be classified as having Alzheimer's disease.

A major reduction of amyloid beta in the brain was demonstrated in the whole study population of early Alzheimer patients and in all subgroups: ApoE4-carriers and non-ApoE4-carriers, mild cognitive impairment with Alzheimer pathology (MCI) and mild Alzheimer's disease, with or without concomitant symptomatic medication. The dose-dependent amyloid reduction in the brain correlated with the clinical effects of BAN2401 and the clinical effects of the treatment were shown to increase with longer treatment time. Significant effects were seen with the two highest doses after 18 months on a number of biomarkers in cerebrospinal fluid, such as total-tau, phospho-tau, neurogranin and neurofilament light chain. These effects of BAN2401 on biomarkers in cerebrospinal fluid are very important as they indicate that BAN2401 interferes in the neurodegenerative process downstream of the amyloid beta pathology.

BAN2401 was well tolerated during the 18 months treatment. The most common adverse events were

reactions at the injection site and ARIA-E (Amyloid Related Imaging Abnormalities-Edema). The reactions at the injection site were mostly mild to moderate in severity. The incidence of ARIA-E was not more than 10% in any of the treatment arms. The vast majority with this adverse event, 90%, were without any symptoms and could only be seen after MRI scans.

The Phase 2b study demonstrated potential disease modifying effects on both clinical function and clearance of amyloid beta in the brain. Further, the Phase 2b study also demonstrated effects on neurodegenerative biomarkers. BAN2401 showed a good tolerability. The data support the positive effect of BAN2401 in all subgroups of early Alzheimer's disease.

For the participants in the Phase 2b study, an open-label extension study is ongoing with continued BAN2401 treatment with the highest study dose and without placebo control.

Based on the results of the Phase 2b clinical study and after discussion with regulatory agencies, our partner Eisai has started and is now driving the global, single confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease patients to support a regulatory filing for BAN2401. The start of the study triggered a MEUR 15 milestone payment to BioArctic in May.

The Phase 3 study (Clarity AD) is a global placebo-controlled, double-blind, parallel-group, randomized study in 1,566 patients with early Alzheimer's disease i.e. mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease with confirmed amyloid pathology in the brain. Patients are allocated in a 1:1 ratio to receive either placebo or treatment. Patients are dosed twice a month with placebo or BAN2401 10 mg/kg. The primary endpoint is the change from baseline in the cognition and function scale Clinical Dementia Rating-Sum of Boxes (CDR-SB) at 18 months of treatment. Changes in the clinical scales AD composite score (ADCOMS) and AD Assessment Scale-Cognitive Subscale (ADAS-Cog) will be key secondary endpoints together with brain amyloid levels as measured by amyloid PET. According to Eisai, the result from the study is targeted for 2022.

BAN2401 has earlier this year been selected by the Alzheimer's Clinical Trials Consortium (ACTC) and Eisai to be evaluated in an upcoming clinical study targeting secondary prevention of Alzheimer's disease (the A45 study). The A45 study will target the preclinical (pre-symptomatic) stage of Alzheimer's disease. The study will enroll clinically normal participants (no/minor cognitive impairment) who have elevated levels of amyloid in the brain and are at high risk for progression to mild cognitive impairment and Alzheimer's disease dementia. This study will be conducted with funding from various sources including the United States National Institute on Aging (NIA), part of the National Institutes of Health (NIH), and Eisai. According to ACTC and Eisai, the trial will be starting in early 2020.

In July, BioArctic and Eisai presented new BAN2401 data at the Alzheimer's Association International Conference® (AAIC®) in Los Angeles. The presentations included details of the binding profile of BAN2401 and additional analyses from the Phase 2b study. The results were consistent with previously presented outcomes. Additional details will be presented in December at the Clinical Trials on Alzheimer's Disease (CTAD) conference in San Diego.

Eisai is responsible for the clinical development in Alzheimer's disease. The project is based on research from Uppsala University, Sweden.

Other potential indications for BAN2401 (owned by BioArctic):

BAN2401, which is now being clinically evaluated for the treatment of Alzheimer's disease, can potentially also be used for other indications. One such potential indication is Down's syndrome with dementia, as these patients typically start developing dementia at around 40 years of age. Another potential indication is traumatic brain injury, TBI. In traumatic brain injury, some patients develop dementia after the injury. These indications are in preclinical phase.

Drug candidate BAN2401 back-up

Alzheimer's disease (collaboration with Eisai):

The antibody is a further developed version of BAN2401 for the treatment of Alzheimer's disease. The antibody was developed by BioArctic in collaboration with Eisai, which led to a new license agreement in 2015. The project is driven by Eisai and is in preclinical phase.

Drug candidates AD1801, AD1502 and AD1503

Alzheimer's disease (owned by BioArctic):

At BioArctic, research is in progress to develop new antibodies for the treatment of Alzheimer's disease aimed at slowing down or stopping disease progression by addressing novel targets.

Drug candidate ABBV-0805

Parkinson's disease (collaboration with AbbVie):

The drug candidate ABBV-0805 is a monoclonal antibody that selectively binds and eliminates oligomers and protofibrils of alpha-synuclein. The goal is to develop a disease modifying treatment that stops or slows down disease progression. A collaboration with AbbVie was started in 2016 concerning the continued development of BioArctic's Parkinson's program focusing on BAN0805, now under the designation ABBV-0805, as well as additional antibodies and diagnostics.

At the end of 2018, AbbVie exercised its option to license BioArctic's alpha-synuclein antibody portfolio for Parkinson's disease and other potential indications. The license was acquired after clearance by the U.S. competition authority and triggered a milestone payment of USD 50 million. In February 2019, the U.S. Food and Drug Administration, FDA, approved the application to conduct a clinical study with ABBV-0805 and the Phase 1 study started already in March. AbbVie finances and progresses the development of ABBV-0805.

The project is based on research from Uppsala University.

Drug candidates PD1601 and PD1602

Parkinson's disease (collaboration with AbbVie):

The antibodies PD1601 and PD1602 are targeting alpha-synuclein for treatment of Parkinson's disease. The goal is to develop a disease modifying treatment that stops or slows down disease progression. The projects are conducted by BioArctic within the framework of the collaboration with AbbVie.

Diagnostics and technology

Alzheimer's disease diagnostics (owned by BioArctic) and Parkinson's disease diagnostics (collaboration with AbbVie):

In collaboration with scientists at Uppsala University, BioArctic is developing a new type of PET tracer for imaging of the brain in Alzheimer's disease by using BioArctic's antibodies. Within the Parkinson's field, the development of diagnostic methods based on BioArctic's antibodies is part of the collaboration with AbbVie. The goal is to create tools to better diagnose the disease, follow the disease progression and objectively measure the effect of drug treatment.

BioArctic also develops improved biochemical methods for the identification and precise measurement of responses to treatment and for the measurement of disease progression of Alzheimer's disease and Parkinson's disease. This is done in collaboration with Brain Biomarker Solutions in Gothenburg AB and the University of Gothenburg, Sweden.

Blood-brain barrier technology platform (owned by BioArctic):

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 may also limit the delivery of therapeutic agents to the brain.

In collaboration with Uppsala University, BioArctic is developing novel technologies to increase the passage of antibodies into the brain across the blood-brain barrier. This technology platform has great commercial potential and could be a general technology for improved and more effective treatment of brain diseases.

Complete Spinal Cord Injury

Product candidate SC0806

Traumatic complete spinal cord injury (owned by BioArctic):

The product candidate SC0806 is a combination of a biodegradable medical device and a drug substance (FGF1). The first patient was treated in 2016 with subsequent rehabilitation for 18 months. Since August 2017, the patients receiving SC0806 treatment in the ongoing Phase 1/2 clinical trial have been given the option of 12 months additional participation in an extension study. The inclusion of patients with complete spinal cord injury to the first of three panels of BioArctic's ongoing clinical Phase 1/2 study was

completed in April 2018. The study is approved for inclusion of patients by the regulatory authorities and ethics committees in Sweden, Estonia, Norway and Finland.

A safety evaluation of all the patients in the first panel has been performed and provided support to start the next panel. The first patient in the second panel has received treatment with SC0806 and hereby the Phase 2 has started. An interim analysis of both safety and efficacy from the first panel is expected in Q4 2019/Q1 2020.

SC0806 obtained orphan drug designation in 2010 in the EU and in 2011 in the U.S., which may give the company

10 and 7 years of market exclusivity in Europe and the U.S., respectively.

The project is in-licensed from Swenora Biotech AB and is based on research from Karolinska Institutet and Karolinska University Hospital, in Sweden.

Patents

Patents are crucial to the company's future commercial opportunities. BioArctic has therefore an active patent strategy covering all major pharmaceutical markets, including the US, EU, Japan and China. BioArctic's patent portfolio consisted at the end of the period of 14 patent families with more than 200 granted patents.

Comments to the financial report

The Group is referred to unless otherwise stated in this Interim Report. Figures in parentheses refer to the corresponding period last year. All amounts stated are rounded up or down, which may lead to some totals not matching exactly.

Revenues and results

Revenues consist of milestone payments, payments from research agreements and research grants. Because of the nature of the business operations, there may be large fluctuations between revenues for different periods, as revenues from milestone payments are recognized at a point in time when performance obligations are fulfilled.

Net revenues in the third quarter decreased to MSEK 20.6 (94.0) as a result from lower revenues from the Parkinson program compared with same period previous year. Net revenues for the period January – September increased by MSEK 56.7 compared with the same period the previous year and amounted to MSEK 255.4 (198.6). The increase during the period January – September is attributable to the milestone payment from Eisai of MSEK 162.0 (MEUR 15.0) offset by to lower revenues from the Parkinson program.

Other operating income relates to research grants, operating exchange rate gains and expenses incurred but onward invoiced. Other operating income amounted to MSEK 8.6 (0.6) for the third quarter and MSEK 14.8 (15.6) for the period January – September. The increase during the third quarter relates to operating exchange rate gains and the decrease during the period January – September mainly relates to lower revenue recognition from research grants.

Total operating expenses for the third quarter decreased by MSEK 21.7 to MSEK 39.7 (61.5) compared to the same period previous year and the total operating expenses for the period January – September decreased by MSEK 19.2 to MSEK 136.5 (155.7). Project expenses for the third quarter and for the period January – September decreased due to lower activity in the Parkinson program as planned offset by increased expenses for own projects. The increase in personnel expenses for the period January – September is related primarily to variable remuneration to employees and an increased number of employees. The increase in depreciation of tangible assets during both the third quarter and the period January – September is an effect from the application of IFRS 16 Leases, (see note 2). Other operating expenses consist of realized operating exchange rate losses.

Since BioArctic's own projects are in an early research phase they did not meet all the conditions for R&D costs to be capitalized and thus, all such costs have been charged to the P&L.

Operating profit before financial items (EBIT) amounted to MSEK -10.5 (33.1) for the third quarter and to MSEK 133.6 (58.5) for the period January – September. The increase in operating profit during the period January – September is mainly attributable to the received milestone payment from Eisai of MSEK 162.0 (MEUR 15.0).

Net financial items totaled MSEK 0.0 (0.1) for the third quarter and amounted to MSEK 0.9 (1.2) for the period January – September. Financial income consists of financial exchange rate gains and financial expenses consists of negative interest on cash and cash equivalents and interest on leasing debt according to IFRS 16 Leases.

Profit/loss for the period amounted to MSEK -8.3 (25.9) for the third quarter and MSEK 105.6 (46.4) for the period January – September. The application of IFRS 16 Leases has affected the profit/loss in the third quarter by MSEK -0.1 and in the period January – September by MSEK -0.5.

Earnings per share before dilution amounted to SEK -0.09 (0.29) for the third quarter and to SEK 1.20 (0.53) for the period January – September.

Financial position

Equity amounted to MSEK 991.3 (682.5) as of September 30, 2019. This corresponds to equity per outstanding share of SEK 11.26 (7.75).

The equity/asset ratio has increased from 73.1 percent as of December 31, 2018 to 80.0 percent as of September 30, 2019.

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to MSEK 1,170.2 (1,008.5). The leasing liabilities as of September 30, 2019 of MSEK 28.5 relate to financial leasing and is an effect from the application of IFRS 16 Leases. There were no loans as of September 30, 2019 and no loans have been taken since this date. The Group has no other credit facility or loan commitments.

In order to reduce foreign exchange rate exposure some liquid funds are invested in foreign currency. This has reporting effects in connection with the recalculation of currency to the current rate. These effects are recognized in the operating profit and in financial income and expenses.

Investments and cash flow

Investments in the third quarter amounted to MSEK 1.6 (0.5) and to MSEK 2.9 (1.4) for the period January – September. The investments are mainly related to laboratory equipment.

Cash flow from financing activities amounted to MSEK -1.5 (0.0) for the third quarter and to MSEK -137.0 (0.0) for the period January – September. MSEK 132.1 (0.0) of the cash flow from financing activities relates to the dividend paid and the remaining amount relates to the amortization of lease debt, which is an effect of the application of IFRS 16 Leases.

Cash flow from operating activities for the third quarter amounted to MSEK -49.4 (-31.5), a decrease of MSEK 18.0. The cash flow from operating activities for the period January – September increased by MSEK 492.2 and amounted to MSEK 381.4 (-110.8). The increase in the cash flow for the period January – September relates to the received milestone payments from AbbVie of MSEK 460.0 and from Eisai of MSEK 162.0.

Employees

At the end of the period, the number of employees was 41 (30) of which 15 (12) are men and 26 (18) women. Approximately 85 percent are active in R&D and approximately 70 percent are PhDs; of these, one is an Associate Professor and two are Professors.

Consultants

A cost efficient organization at BioArctic is achieved by hiring consultants for specific assignments and for tasks in competence areas that the company lacks or only has a need for periodically. As of September 30, 2019, these corresponded to 12 (13) full-time positions.

Key events during the period January – September

- BioArctic announced in February that the company's partner Eisai will initiate the single confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease and published information concerning the design of the study and timelines
- The U.S. Food and Drug Administration approved in February the application to start a clinical study in the Parkinson program with ABBV-0805, previously named BAN0805
- BioArctic's product candidate SC0806 for complete spinal cord injury advanced into Phase 2 in the ongoing Phase 1/2 study in February
- Eisai initiated in March the confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease
- BioArctic announced the start of the clinical Phase 1 study with ABBV-0805 in the Parkinson program in March
- BioArctic received in May MEUR 15 milestone payment from Eisai for start of BAN2401 confirmatory Phase 3 study in early Alzheimer's disease
- Alzheimer's Clinical Trials Consortium and Eisai announced in May that BAN2401 will be evaluated in a clinical study for prevention of Alzheimer's disease
- The Annual General Meeting approved the introduction of an employee warrant program 2019/2028 for the company's management, researchers and other staff and a dividend to shareholders in the amount of SEK 1.50 per share, a total of MSEK 132.1. Ewa Björling was elected new member of the board
- BioArctic and Eisai presented new data regarding BAN2401 at the Alzheimer's Association International Conference® (AAIC®) in July that confirmed BAN2401's unique characteristics and was consistent with previously presented results

The share and shareholdings

The share capital in BioArctic amounts to SEK 1,761,200 divided by 88,059,985 shares which is split between 14,399,996 A-shares and 73,659,989 B-shares. The quotient value for both A- and B-shares is SEK 0.02. The A-share has 10 votes per share and the B-share has 1 vote per share.

The largest shareholders at September 30, 2019¹

Shareholder	Number of A-shares	Number of B-shares	Share of capital, %	Share of votes, %
Demban AB (Lars Lannfelt)	8,639,998	22,723,707	35.6	50.1
Ackelsta AB (Pär Gellerfors)	5,759,998	15,150,036	23.7	33.4
Third Swedish National Pension Fund	-	4,073,032	4.6	1.9
Fourth Swedish National Pension Fund	-	3,796,684	4.3	1.7
Norron Funds	-	3,054,022	3.5	1.4
AMF Insurance & Funds	-	2,335,046	2.7	1.1
Investment AB Öresund	-	2,050,000	2.3	0.9
Handelsbanken Funds	-	1,965,000	2.2	0.9
Unionen	-	1,763,000	2.0	0.8
Second Swedish National Pension Fund	-	1,441,666	1.6	0.7
Total 10 largest shareholders	14,399,996	58,352,193	82.5	92.9
Other	-	15,307,796	17.5	7.1
Total	14,399,996	73,659,989	100.0	100.0

¹ Source: Monitor by Modular Finance AB. Compiled and processed data from various sources, including Euroclear, Morningstar and the Swedish Financial Supervisory Authority (Finansinspektionen).

Risks and uncertainty factors

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

The risks can be divided into financial risks as well as operational and external risks. BioArctic's operational and external risks mainly consist of risks related to research and development, clinical trials and dependence on key employees.

A detailed description of exposure and risk management is presented in the Annual Report 2018, pages 44-46. The board has determined that the risks are unchanged.

Parent Company

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

Expected development of operating expenses

Operating expenses are expected to be in the range of MSEK 190 - 210 for the fiscal year January – December 2019.

Employee warrant program

The Annual General Meeting approved the Board of Directors' proposal for resolution concerning an employee warrant program for the company's management, researchers and other staff, a directed issue of warrants and the transfer of warrants or shares in the company to the participants in the employee warrant program.

The employee warrant program 2019/2028 shall include not more than 1,000,000 warrants. To enable the company's delivery of shares under the employee warrant program 2019/2028, the Annual General Meeting approved a directed issue of a maximum of 1,000,000 warrants.

The dilutive effect of the employee warrant program 2019/2028 is estimated to be a maximum of 1.1 percent of the share capital and 0.5 percent of the votes in the company (calculated on the number of existing shares in the company), assuming full exercise of all employee warrants. 460,000 employee warrants were allocated during the third quarter, which resulted in a personnel expense of MSEK 0.1. There is no dilutive effect as of September 30, 2019, according to IAS 33.47, as the average market price for the period is lower than the exercise price.

More information is available at www.bioarctic.com.

Future reports

The Full Year Report 2019 will be published on February 6, 2020.

This Interim Report has been reviewed by BioArctic's auditors.

Stockholm, Sweden, October 23, 2019

Gunilla Osswald
CEO, BioArctic AB

Report on Review of Interim Financial Information

Introduction

We have reviewed the accompanying balance sheet of BioArctic AB (publ) as of September 30, 2019 and the related statements of income, changes in equity and cash flows for the nine-month period then ended, and a summary of significant accounting policies and other explanatory notes. Management is responsible for the preparation and fair presentation of this interim financial information in accordance with IFRS. Our responsibility is to express a conclusion on this interim financial information based on our review.

Scope of Review

We conducted our review in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity." A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the accompanying interim financial information does not give a true and fair view of the financial position of the entity as at September 30, 2019, and of its financial performance and its cash flows for the nine-month period then ended in accordance with IFRS.

Stockholm, October 23, 2019

Grant Thornton Sweden AB

Mia Rutenius
Authorized public accountant
Auditor in charge

Therese Utengen
Authorized public accountant

Financial statements, Group

Consolidated income statement

kSEK	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Net revenues (note 4)	20,631	94,045	255,351	198,650	713,970
Other operating income	8,602	556	14,791	15,552	16,259
Operating revenues	29,234	94,602	270,142	214,202	730,229
Operating expenses					
Project related expenses	-13,488	-42,738	-51,451	-97,327	-145,357
Other external expenses	-7,013	-6,675	-23,365	-21,907	-31,949
Personnel expenses	-11,316	-11,039	-44,447	-33,410	-57,039
Depreciations of tangible assets	-2,414	-624	-7,175	-1,392	-2,059
Other operating expenses	-5,512	-402	-10,092	-1,692	-5,031
Operating profit/loss	-10,510	33,125	133,612	58,474	488,794
Financial income	270	453	1,793	2,283	2,171
Financial expenses	-301	-342	-891	-1,067	-1,371
Profit/loss before tax	-10,541	33,236	134,514	59,689	489,593
Tax	2,210	-7,379	-28,950	-13,292	-107,991
Profit/loss for the period	-8,331	25,856	105,564	46,397	381,602
Earnings per share					
Earnings per share before dilution, SEK	-0.09	0.29	1.20	0.53	4.33
Earnings per share after dilution, SEK ¹	-0.09	0.29	1.20	0.53	4.33

¹ There is no dilutive effect according to IAS 33.47 as the average market price for the period is lower than the exercise price as of September 30, 2019.

Consolidated statement of comprehensive income

kSEK	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Profit/loss for the period	-8,331	25,856	105,564	46,397	381,602
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	-8,331	25,856	105,564	46,397	381,602

Consolidated balance sheet (condensed)

kSEK	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
ASSETS			
Tangible fixed assets	9,969	7,065	9,289
Right-to-use assets	28,335	-	-
Deferred tax assets	357	180	189
Other financial assets	1,511	2,675	1,500
Current assets excluding cash and cash equivalents	29,248	13,824	464,757
Cash and cash equivalents	1,170,178	1,008,522	917,307
TOTAL ASSETS	1,239,598	1,032,266	1,393,042
EQUITY AND LIABILITIES			
Equity	991,267	682,531	1,017,736
Deferred tax liabilities	32,520	5,487	32,520
Long-term leasing liabilities	22,187	-	-
Short-term leasing liabilities	6,277	-	-
Other current liabilities	35,169	18,538	91,996
Accrued expenses and deferred income	152,178	325,710	250,791
EQUITY AND LIABILITIES	1,239,598	1,032,266	1,393,042

Consolidated statement of change in equity (condensed)

kSEK	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
Opening balance at 1 January	1,017,736	636,134	636,134
Comprehensive income for the period	105,564	46,397	381,602
Share-based payments	57	-	-
Paid dividend	-132,090	-	-
Closing balance	991,267	682,531	1,017,736

Consolidated statement of cash flow (condensed)

kSEK	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Operating profit	-10,510	33,125	133,612	58,474	488,794
Adjustment for non-cash items	-22,177	-93,925	-84,245	-211,526	-726,886
Interest received/paid	-311	-342	-701	-1,067	-1,331
Income tax paid	-2,067	-2,067	-78,851	-8,822	-10,889
Cash flow from operating activities before changes in working capital	-35,066	-63,209	-30,186	-162,942	-250,313
Change in working capital	-14,366	31,752	411,558	52,139	50,256
Cash flow from operating activities after changes in working capital	-49,432	-31,456	381,372	-110,803	-200,057
Cash flow from investing activities	-1,586	-498	-2,865	-1,364	-3,080
Cash flow from financing activities	-1,529	-	-136,962	-	-
Cash flow for the period	-52,547	-31,954	241,544	-112,168	-203,136
Cash and cash equivalents at beginning of period	1,218,437	1,041,740	917,307	1,110,367	1,110,367
Exchange rate differences in cash and cash equivalents	4,287	-1,264	11,326	10,323	10,076
Cash and cash equivalents at end of period	1,170,178	1,008,522	1,170,178	1,008,522	917,307

Consolidated quarterly data

MSEK	2019 Q3	2019 Q2	2019 Q1	2018 Q4	2018 Q3	2018 Q2	2018 Q1	2017 Q4
Income statement								
Net revenues	20.6	171.3	63.4	515.3	94.0	52.3	52.3	51.0
Other operating income	8.6	-0.7	6.9	0.7	0.6	3.6	11.4	10.4
Operating profit/loss	-10.5	126.8	17.3	430.3	33.1	6.4	18.9	14.7
Operating margin, %	-50.9	74.0	27.3	83.5	35.2	12.3	36.1	28.9
Profit/loss for the period	-8.3	100.3	13.6	335.2	25.9	5.1	15.4	11.8
Balance sheet								
Fixed assets	40.2	41.0	42.6	11.0	9.9	10.0	9.6	10.0
Current assets	29.2	15.9	16.3	464.8	13.8	12.0	20.3	20.1
Cash and cash equivalents	1,170.2	1,218.4	1,255.6	917.3	1,008.5	1,041.7	1,078.7	1,110.4
Equity	991.3	999.5	1,031.4	1,017.7	682.5	656.7	651.6	636.1
Deferred tax liabilities	32.5	32.5	32.5	32.5	5.5	5.5	5.5	5.5
Lease liabilities	28.5	30.0	31.5	-	-	-	-	-
Current liabilities	187.3	213.2	219.0	342.8	344.2	401.6	451.6	498.9
Cash flow								
From operating activities	-49.4	97.2	333.6	-89.3	-31.5	-37.3	-42.0	-45.7
From investing activities	-1.6	-0.7	-0.6	-1.7	-0.5	-0.7	-0.2	0.5
From financing activities	-1.5	-133.6	-1.8	-	-	-	-	560.2
Cash flow for the period	-52.5	-37.1	331.2	-91.0	-32.0	-38.0	-42.2	515.0
Data per share								
Earnings per share before dilution, SEK	-0.09	1.14	0.15	3.81	0.29	0.06	0.18	0.16
Earnings per share after dilution, SEK ¹	-0.09	1.14	0.15	3.81	0.29	0.06	0.18	0.16
Equity per share, SEK	11.26	11.35	11.71	11.56	7.75	7.46	7.40	7.22
Cash flow operating activities, SEK	-0.56	1.10	3.79	-1.01	-0.36	-0.42	-0.48	-0.60
Share price at the end of the period, SEK	61.75	74.40	78.00	82.00	118.90	21.80	21.40	26.00
Number of shares outstanding at the end of the period, thousands	88,060	88,060	88,060	88,060	88,060	88,060	88,060	88,060
Average number of shares outstanding before dilution, thousands	88,060	88,060	88,060	88,060	88,060	88,060	88,060	75,560
Average number of shares outstanding after dilution, thousands ¹	88,060	88,060	88,060	88,060	88,060	88,060	88,060	75,560

¹ There is no dilutive effect according to IAS 33.47 as the average market price for the period is lower than the exercise price per September 30, 2019.

Financial statements, Parent company

Parent company income statement

kSEK	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Net revenues	20,631	94,045	255,351	198,650	713,970
Other operating income	8,602	556	14,791	15,552	16,259
Operating revenues	29,234	94,602	270,142	214,202	730,229
Operating expenses					
Project related expenses	-13,488	-42,738	-51,451	-97,327	-145,357
Other external expenses	-8,858	-6,675	-28,585	-21,907	-31,949
Personnel expenses	-11,316	-11,039	-44,447	-33,410	-57,039
Depreciations of tangible assets	-747	-624	-2,175	-1,392	-2,059
Other operating expenses	-5,512	-402	-10,092	-1,692	-5,031
Operating profit/loss	-10,688	33,125	133,392	58,474	488,794
Financial income	270	453	1,793	2,283	2,171
Financial expenses	-11	-342	-86	-1,067	-1,371
Profit/loss after financial items	-10,429	33,236	135,099	59,689	489,594
Change in tax allocation reserves	-	-	-	-	-122,876
Profit/loss before tax	-10,429	33,236	135,099	59,689	366,718
Tax	2,186	-7,379	-29,075	-13,292	-80,959
Profit/loss for the period	-8,243	25,856	106,024	46,397	285,759

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 (condensed)

kSEK	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
ASSETS			
Tangible fixed assets	9,969	7,065	9,289
Deferred tax assets	232	180	189
Other financial assets	1,611	2,775	1,600
Current assets excluding cash and cash equivalents	29,248	13,824	464,757
Cash and cash equivalents	1,170,080	1,008,424	917,209
TOTAL ASSETS	1,211,139	1,032,268	1,393,044
EQUITY AND LIABILITIES			
Equity	876,432	663,078	902,441
Tax allocation reserve	147,817	24,941	147,817
Other current liabilities	34,903	18,538	91,996
Accrued expenses and deferred income	151,989	325,710	250,791
EQUITY AND LIABILITIES	1,211,139	1,032,268	1,393,044

Notes

Note 1 General information

This Interim Report for the period January – September 2019 covers the Swedish Parent Company BioArctic AB, Swedish Corporate Identity Number 556601-2679, and the two fully owned subsidiaries SpineMedical AB, Swedish Corporate Identity Number 559003-7080, and LPB Sweden AB, Swedish Corporate Identity Number 559035-9112. All the Group's business operations are conducted in the Parent Company. The Parent Company is a Swedish limited liability company registered in and with its registered office in Stockholm. The head office is located at Warfvings väg 35, SE-112 51, Stockholm, Sweden.

The BioArctic Group's Interim Report for the period January – September 2019 was approved by the Company's board on October 23, 2019.

Note 2 Accounting principles

The consolidated financial statements for BioArctic AB have been prepared in accordance with IFRS (International Financial Reporting Standards) as adopted by the EU, the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's RFR 1 Supplementary Accounting Rules for Groups. The Parent Company's financial statements are presented in accordance with the Swedish Annual Accounts Act and RFR 2 Accounting for Legal Entities.

The Interim Report for the period January – September 2019 is presented in accordance with IAS 34 Interim Financial Reporting and the Swedish Annual Accounts Act. Disclosures in accordance with IAS 34 are presented both in notes and elsewhere in the Interim Report.

The guidelines of the European Securities and Markets Authority (ESMA) on alternative performance measures have been applied. This involves disclosure requirements for financial measures that are not defined by IFRS. For performance measures not defined by IFRS, see the Calculations of key figures section.

IFRS 16 Leases has replaced IAS 17 Leases and the appropriate interpretations IFRIC 4, SIC-15 and SIC-27 as of January 1, 2019. This standard requires that assets and liabilities attributable to all leasing agreements, with a few exceptions, are recognized on 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. BioArctic has elected to apply the modified retrospective approach. The effect of the application of IFRS 16 Leases 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 effects of applying IFRS 16 Leases on January 1, 2019 can be seen below:

- The Group's assets and liabilities have increased with MSEK 33.3 million which means that the balances increased by 2.4 percent
- Equity assets ratio has decreased with 1.7 percentage points from 73.1 percent to 71.4 percent

Under IFRS 16 Leases, a marginal interest rate of 4 percent has been used. For more information of the application of IFRS 16 Leases see the Annual Report for 2018, note 3.3.

The accounting principles and calculation methods applied are in all other respects in line with those described in the Annual Report 2018.

Note 3 Segment information

An operating segment is a part of the Group that conducts operations from which it can generate income and incur costs and for which independent financial information is available. The highest executive decision-maker in the Group follows up the operations on aggregated level, which means that the operations constitute one and the same segment and thus no separate segment information is presented. The Board of Directors is identified as the highest executive decision maker in the Group.

Note 4 Net revenues

kSEK	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Jan-Dec 2018
Geographic breakdown of net revenues					
Europe	20,631	94,045	93,375	197,169	712,489
Asia	-	-	161,976	1,481	1,481
Total net revenues	20,631	94,045	255,351	198,650	713,970
Net revenues per revenue type					
Milestone payments	-	-	173,407	-	448,550
Income from research collaborations	20,631	94,045	81,944	198,650	265,420
Total net revenues	20,631	94,045	255,351	198,650	713,970

BioArctic's net revenues essentially consist of income from the research collaborations concerning Parkinson's disease with AbbVie and Alzheimer's disease with Eisai. Under the collaboration agreement with AbbVie, BioArctic received an initial payment of MSEK 701.6 (MUSD 80) during the third quarter 2016. This payment is related to compensation for the preclinical development work that BioArctic will carry out under the agreement. Of the initial payment, MSEK 70.4 was reported as a one-time payment in 2016. The rest of the payment will be accrued based on the costs incurred up until the completion of the project. The project is continuously evaluated with the regard to status and remaining costs. As of September 30, 2019, MSEK 574.5 has been recognized as revenue and the remaining amount to be recognized as a revenue up until the completion of the project is MSEK 127.2. During the period January – September, a milestone payment of MSEK 162.0 (MEUR 15.0) was received from the research collaboration with Eisai. This payment was recognized as revenue since all performance obligations were fulfilled.

Note 5 Transactions with affiliated parties

The board member Mikael Smedeby was until May 2019 active as lawyer and co-owner of Advokatfirman Lindahl KB, which provides ongoing business legal advice to BioArctic for compensation that is in line with market rates. During the period January – September, Advokatfirman Lindahl invoiced fees amounting to approximately MSEK 0.4 (0.4). The board member Pär Gellerfors has, in addition to the board fee, invoiced through Acelsta AB a consultant fee in line with market rates of MSEK 0.1 (0.0) during the period January – September.

In addition to the compensation to Advokatfirman Lindahl and Pär Gellerfors described above and salary to Lars Lannfelt, no significant transactions have taken place between the Group and related parties. All transactions have been in line with market rates.

Definition of key ratios

In this financial report BioArctic reports key financial ratios, some of which are not defined by IFRS. The Company's assesses that these key ratios are important additional information, since they enable investors, securities analysts, management of the company and other stakeholders to better analyze and evaluate the company's business and financial trends. These key ratios should not be analyzed separately or replace key ratios that have been calculated in accordance with IFRS. Neither should they be compared to other key ratios with similar names applied by other companies, as key ratios cannot always be defined in the same way. Other companies may calculate them in a different way than BioArctic.

The key ratios "Net revenues", "Result for the period", "Earnings per share" and "Cash flow from operating activities" are defined according to IFRS.

Key ratios	Definition
Other income	Other income than net revenues
Operating profit	Result before financial items
Operating margin, %	Operating profit divided by net revenues
Cash flow from operating activities per share, SEK	The period's cash flow from operating activities divided by the weighted number of shares
Equity/asset ratio	Adjusted equity divided by total assets
Return on equity	Net income divided by equity expressed as a percentage
Equity per share	Adjusted equity divided by the number of shares at the end of the period

About BioArctic

BioArctic AB (publ) is a research-based biopharmaceutical 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 was founded in 2003 based on innovative research from Uppsala University, Sweden.

The company has cutting-edge 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. Through long-term collaboration agreements with global pharmaceutical companies, BioArctic has demonstrated high skills and great ability to deliver innovative pharmaceutical projects.

In Alzheimer's disease, BioArctic has collaborated with Eisai since 2005. The company has entered into three research agreements and two license agreements relating to the antibodies BAN2401 and BAN2401 back-up. The total aggregated value of these agreements may amount to MEUR 218 and, in addition, payments of royalty. So far, MEUR 62 has been received. In Parkinson's disease, BioArctic has collaborated with AbbVie since 2016, when a research collaboration agreement was entered including i.a. the antibody BAN0805. The total aggregated value of the agreement may amount to

MUSD 755 and, in addition, payments of royalty. So far, MUSD 130 has been received.

The project portfolio consists of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. For information about the projects, see the section Project portfolio. BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B).

Goal and strategy for sustainable growth

BioArctic's goal is to change life for patients with diseases in the central nervous system. We would like to contribute to society by developing innovative disease-modifying treatments based on antibodies (immunotherapy) for neurodegenerative diseases, i.e. diseases where the nervous system atrophies. BioArctic develops entirely new types of treatments that hopefully may halt or delay the disease progression in patients with Alzheimer's disease and Parkinson's disease, unlike today's symptomatic treatments. The company is also developing a new treatment concept for complete spinal cord injuries as well as an innovative technology platform to facilitate passage of antibodies over the blood-brain barrier.

The strategy work has been intensified to enable BioArctic to fully utilize the project portfolio's many opportunities. The company is well positioned to advance the on-going projects in order to build further value and to create new successful collaboration. In combination this creates sustainable growth.

Strategic target areas

BioArctic focuses on building 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, partly through research collaborations with strategic partners in the form of research groups at universities, pharma companies, and the health care sector.

Our strategy is to out-license certain commercial rights to global pharma companies at an appropriate time. In line with this strategy, BioArctic's research and development work continues. Important elements of BioArctic's strategy are:

CONTINUE focusing on the partnership projects and on driving/intensifying the in-house projects with great out-licensing and market potential

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

EXPAND the portfolio with new targets, indications for orphan drug, new projects and diagnostics

INVEST in:

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

Collaborations and partnerships

Collaborating with universities is of great importance to BioArctic. The company has on-going collaborations with academic research groups at a number of universities. Collaborations and license agreements with leading pharma and biopharma companies are also an important part of BioArctic's strategy. In addition to financial compensation we get access to our partners' skills in drug development, manufacturing and commercialization. BioArctic has entered into a number of such agreements with the Japanese international pharma company Eisai and the American global biopharma company AbbVie. These strategic partnerships with leading global companies confirm that BioArctic's research is of very high quality.

In the future BioArctic may enter into additional agreements that can contribute further funding and research and development competence for product candidates in preclinical and clinical phase, manufacturing and marketing competence, geographic coverage and other resources.

For more information regarding BioArctic's two large collaboration partners, please see the Annual Report 2018 on page 10.

Glossary

ADAS-Cog

ADAS-Cog (Alzheimer's Disease Assessment Scale-cognitive subscale) is a well-established cognition scale whereof parts are included in ADCOMS

ADCOMS

Alzheimer's Disease Composite Score – A cognition scale consisting of parts from three different scales (CDR-SB, ADAS-cog and MMSE) developed by Eisai. The cognition scale enables a sensitive detection of changes in clinical functions of symptoms in early Alzheimer's disease

Alpha-synuclein (α -synuclein)

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

Amyloid beta ($A\beta$)

A 40-42 amino acids long peptide, split from the parent protein APP, amyloid precursor protein. Amyloid 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

ApoE4

Apolipoprotein E (ApoE) transports fats in the blood. Individuals expressing ApoE4 develop more Alzheimer changes in the form of plaques and amyloid beta in the brain blood vessel walls.

ARIA

Amyloid-Related Imaging Abnormalities (ARIA) are brain-changes seen in Magnetic Resonance Imaging of Alzheimer's disease patients, which are commonly observed in clinical trials of amyloid-modifying therapies

ARIA-E

There are two types of ARIA; ARIA-E and ARIA-H. ARIA-E refers to observations of edema and the other ARIA-H to observations of small hemorrhages

Binding profile

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

Biomarker

A measurable 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

CDR-SB

CDR-SB (Clinical Dementia Rating Sum of Boxes) is a cognition and function scale which is part of ADCOMS

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 complete 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

Dose dependent

Increased effect at higher dose

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

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 U.S.

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 aggregated monomers

Orphan drugs

Drugs for patients with rare and serious diseases

Peptide

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

PET

Positron emission tomography, an investigation imaging method

Phase 1 studies

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

Phase 2 studies

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

Phase 3 studies

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

Product candidate

A product under development that has not yet gained marketing approval

Protofibril

A molecular chain consisting of several aggregated monomers

Research phase

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

Secondary prevention

Preventive measures where symptoms or biomarkers may indicate disease

Statistically significant

A clinical study result is defined as statistically significant in accordance with the preset criteria for the study or in adherence to a generally recognized standard, most commonly defined as less than 5% probability of obtaining a similar or stronger result due to chance, i.e. $p < 0.05$

Tolerability

How a person reacts to a drug

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