

Eisai initiates Biologics License Application of lecanemab in the US earlier than expected

EVENTS DURING THE THIRD QUARTER 2021

- Eisai has initiated a rolling submission for the US FDA Biologics License Application of lecanemab, under the accelerated approval pathway. The objective is for lecanemab to be approved for the treatment of patients with early Alzheimer’s disease.
- Data from the Phase 2b open-label extension study of lecanemab presented at the Alzheimer’s Association International Conference provided further support for the clinical effects of the drug candidate. The baseline characteristics for the Clarity AD and AHEAD 3-45 Phase 3 studies were also presented, as well as the possibility of using specific blood biomarkers to monitor the effects of the drug in individual patients.

FINANCIAL SUMMARY JULY – SEPTEMBER 2021

- Net revenues for the period amounted to MSEK 4.0 (10.5)
- Operating profit amounted to MSEK -37.4 (-20.7)
- Profit for the period amounted to MSEK -37.6 (-20.7) and earnings per share before and after dilution were SEK -0.43 (-0.23)
- Cash flow from operating activities amounted to MSEK -34.8 (-9.4)
- Cash and cash equivalents at the end of the period amounted to MSEK 892 (1,036)

FINANCIAL SUMMARY JANUARY – SEPTEMBER 2021

- Net revenues for the period amounted to MSEK 18.4 (54.0)
- Operating profit amounted to MSEK -100.4 (-54.9)
- Profit for the period amounted to MSEK -100.8 (-55.3) and earnings per share before and after dilution were SEK -1.15 (-0.63)
- Cash flow from operating activities amounted to MSEK -101.2 (-65.6)
- Cash and cash equivalents at the end of the period amounted to MSEK 892 (1,036)

KEY FINANCIAL PERFORMANCE INDICATORS

MSEK	Q3		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net revenues	4.0	10.5	18.4	54.0	62.3
Other operating income	0.7	0.9	3.0	2.2	3.6
Operating profit/loss	-37.4	-20.7	-100.4	-54.9	-85.0
Operating margin, %	neg	neg	neg	neg	neg
Profit/loss for the period	-37.6	-20.7	-100.8	-55.3	-68.5
Earnings per share before dilution, SEK	-0.43	-0.23	-1.15	-0.63	-0.78
Earnings per share after dilution, SEK	-0.43	-0.23	-1.15	-0.63	-0.78
Equity per share, SEK	9.17	10.45	9.17	10.45	10.30
Cash flow from operating activities	-34.8	-9.4	-101.2	-65.6	-92.3
Cash flow from operating activities per share, SEK	-0.39	-0.11	-1.15	-0.74	-1.05
Equity/assets ratio, %	86.3	85.5	86.3	85.5	86.4
Return on equity, %	-4.55	-2.22	-11.76	-5.84	-7.28
Share price at the end of the period, SEK	162.60	88.95	162.60	88.95	95.40

Unless otherwise stated, this Interim report refers to the Group. Figures in parentheses refer to the corresponding period last year. The amounts stated are rounded, which sometimes leads to some totals not being exact.

Comments from the CEO



On September 28, we received very positive news from our partner Eisai. After dialogue with the US Food and Drug Administration, Eisai has now initiated an application for market approval of lecanemab – significantly earlier than expected. This follows the FDA granting lecanemab a breakthrough therapy designation this past summer. On this basis, Eisai and the FDA have now reached an agreement on a time-efficient regulatory process of lecanemab. The solution was a combination of the two regulatory tracks: the Accelerated Approval Program and Rolling Review.

The accelerated approval means that the FDA will decide on a potential approval based on the clinical, biomarker, and safety data that is already available, primarily based on the comprehensive Phase 2b study in 856 patients that was concluded in the summer of 2018. Data from the ongoing open-label Phase 2b extension study and blinded safety data from the ongoing Clarity AD Phase 3 study will also be included in the application documentation. In other words, the FDA does not need the clinical efficacy results from Clarity AD for accelerated approval, but the results can serve as the confirmatory study to verify the clinical benefit of lecanemab. The rolling review in turn means that Eisai will submit completed sections of the application on a step-by-step basis, which can be reviewed on a rolling basis by the FDA. Once all documentation has been submitted, the final review of the application for accelerated market approval in the US will commence. The results of the Clarity AD Phase 3 study are expected in September 2022, after which Eisai can initiate the application for full approval. If Clarity AD confirms the results from the Phase 2b study, our drug candidate will have the possibility of becoming the first disease-modifying treatment of early Alzheimer’s disease that receives full approval in the US. It is exciting that this Swedish discovery, after decades of research, in the not-too-distant future, could reach patients and be one of the first disease-modifying treatment of Alzheimer’s disease.

Under the agreement with Eisai, BioArctic has certain rights to market and sell lecanemab in the Nordic region. Naturally this requires European market approval, which is a process that

will come a bit after the one in the US. BioArctic has already begun the build-up of a Nordic market organization in order to prepare for a potential launch. The introduction of new drugs requires careful preparation in order to provide the right patients access to treatment, and we are pleased that Anna-Kajja Grönblad, who previously was General Manager of Sanofi in Sweden, has now taken the position of Chief Commercial Officer to lead these efforts. Our confidence in lecanemab is the driving force in this initiative, but we also see that our other drug projects could benefit in future from the establishment of a market organization in the Nordic region. It is very satisfying that we now, based on our positive development, are taking the next step and switching into a higher gear from our position as a research and development company to also becoming a company that is ready to help patients and healthcare through the introduction of new drug treatments.

During the quarter, we also saw promising data for ABBV-0805, our antibody against Parkinson’s disease that has been outlicensed to AbbVie. In September, both BioArctic and AbbVie presented results, which support continued development of ABBV-0805, at the MDS conference. BioArctic’s abstract, which among other things shows that ABBV-0805 is a very selective antibody that impacts the progression of the disease in preclinical models in a positive way, was selected as a Top Abstract presentation at the conference. AbbVie presented the results from a Phase 1 study of ABBV-0805 that showed a favorable pharmacokinetics and a good safety profile for the antibody. With the continued positive results presented for ABBV-0805, we look forward to the development of this potential disease-modifying treatment of Parkinson’s disease.

In other words, BioArctic’s research continues to be of great interest. The FDA review of lecanemab for a potential approval is an important milestone in the history of BioArctic – and it is only the beginning.

Gunilla Osswald
CEO, BioArctic AB

BioArctic in short

BioArctic AB (publ) is a Swedish biopharma company developing new drugs based on groundbreaking research for patients with central nervous system disorders. For a global market, the aim is to generate transformative medicines that can stop or slow down the progression of Alzheimer's disease, Parkinson's disease and other neurological diseases. BioArctic was founded in 2003 based on innovative research from Uppsala University, Sweden. BioArctic's B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B).

Strategy for sustainable growth

BioArctic's vision is to generate innovative medicines that improve life for patients with disorders in the central nervous system. Our work is based on groundbreaking scientific discoveries, and the company's researchers collaborate with strategic partners such as research groups at universities and major pharmaceutical companies.

The company has scientific excellence and vast experience in developing drugs from idea to market. Under BioArctic's business model, the company at an early stage itself pursues project development and then, at an appropriate juncture, licenses commercial rights and late phase development to global pharmaceutical companies. In recent years, BioArctic has successfully developed high quality drug projects that have resulted in strategic license and partnership agreements in two major disease areas with high unmet medical need.

Three important cornerstones of BioArctic's strategy are:

- **CONTINUE** supporting the partnered projects with great market potential
- **DEVELOP** our own projects further, up to an appropriate time for partnership or exit
- **EXPAND** the portfolio with new projects and indications with high unmet medical need

Operations

BioArctic conducts its research in five focus areas:

- **Alzheimer's disease**
- **Parkinson's disease**
- **Other CNS disorders**
- **Blood-brain barrier technology**
- **Diagnostics**

Neurodegenerative disorders are conditions in which cells in the brain degenerate and die. Normally the neurodegenerative processes begin long before any symptoms appear. Neurodegenerative disorders affect the lives of millions of people and constitute a growing global health care problem.

A key cause of Alzheimer's disease and Parkinson's disease is believed to be misfolding and aggregation of proteins. The spreading of aggregated soluble forms of proteins leads to neuronal dysfunction, cell death, brain damage and symptoms of disease. Each neurodegenerative disorder is characterized by different aggregated proteins. The protein amyloid beta (A β) is involved in Alzheimer's disease, while the protein alpha-synuclein (α -synuclein) is involved in Parkinson's disease. BioArctic's aim with the antibodies currently in clinical phase, is to achieve a disease-modifying effect through the selective binding of antibodies, and elimination of the harmful soluble aggregated forms of the amyloid beta protein (oligomers/protofibrils) and the alpha-synuclein protein in the brain.

Project portfolio

BioArctic has a balanced, competitive portfolio consisting of unique product candidates, technology platforms and methods for diagnostics. All projects are focused on disorders of the central nervous system. The projects are a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market- and out-licensing potential. The projects are in various phases: from discovery to late clinical phase.

As of September 30, 2021, the project portfolio consisted of:

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) <i>Clarity AD</i>	Eisai ¹	Early Alzheimer's disease ³				
	Lecanemab (BAN2401) <i>AHEAD 3-45</i>	Eisai ¹	Preclinical (asymptomatic) Alzheimer's disease ⁴				
	BAN2401 back-up	Eisai					
	AD1801						
	AD1502						
	AD1503						
	AD-BT2802						
	AD-BT2803						
	AD2603						
PARKINSON'S DISEASE	ABBV-0805 ²	AbbVie					
	PD1601	AbbVie					
	PD1602	AbbVie					
OTHER CNS DISORDERS	Lecanemab (BAN2401)		Down's syndrome ⁵ Traumatic brain injury ⁵				
	ND3014						
BLOOD-BRAIN BARRIER	Brain Transporter (BT) technology platform						
DIAGNOSTICS	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

1) Partnered with Eisai for lecanemab for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding BAN2401 (lecanemab) in 2014

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

3) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease

4) Normal cognitive function with intermediate or elevated levels of amyloid in the brain

5) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury

ALZHEIMER'S DISEASE

BioArctic has developed several unique and selective antibodies with the potential to slow the progress of Alzheimer's disease. The most advanced drug candidate, lecanemab (BAN2401) is currently being evaluated in two Phase 3 studies: Clarity AD for early Alzheimer's disease and AHEAD 3-45 for preclinical (asymptomatic) Alzheimer's disease. Lecanemab previously showed convincing results in a large Phase 2b study in patients with early Alzheimer's disease. The development of lecanemab against Alzheimer's disease is being financed and pursued by BioArctic's partner Eisai, which also co-owns the rights to the lecanemab back-up in Alzheimer's disease. BioArctic has six additional antibodies projects against Alzheimer's disease in its project portfolio.

Drug candidate lecanemab (collaboration with Eisai)

In Alzheimer's disease, the amyloid beta protein clumps together into increasingly larger aggregates in the brain – from the harmless form with a normal function (monomers) to larger forms such as oligomers, protofibrils, fibrils and finally amyloid plaques containing fibrils. Oligomers and protofibrils are considered the most harmful forms of amyloid beta that initiate the process of Alzheimer's disease. Lecanemab is a drug candidate which functions by eliminating these forms of amyloid from the brain and thereby has the potential to slow down the progression of disease. BioArctic's partner Eisai is responsible for the clinical development of lecanemab in Alzheimer's disease and the project is based on research from Uppsala University, Sweden.

Eisai is conducting two global Phase 3 studies with lecanemab, one in patients with early Alzheimer's disease (Clarity AD) and one in cognitively unimpaired individuals with intermediate or elevated amyloid levels in the brain who have not yet developed symptoms of Alzheimer's disease (AHEAD 3-45).

Clarity AD is the pivotal and confirmatory Phase 3 study. It is based on the Phase 2b study with lecanemab in 856 patients with early Alzheimer's disease which demonstrated dose dependent, clinically meaningful, and statistically significant effects of lecanemab on several clinical endpoints and on biomarkers and showed good tolerability.

Clarity AD is a global placebo-controlled, double-blind, parallel-group, randomized study in 1,795 patients with early Alzheimer's disease i.e. mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease. Patients are allocated in a 1:1 ratio to receive intravenous infusion twice a month, either with placebo or with lecanemab 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) are key secondary endpoints together with brain amyloid levels as measured by amyloid-PET. According to Eisai, the aim is to obtain the primary endpoint data from the study by the end of September 2022 and thereafter apply for a full market approval.

An open-label extension study, without placebo control, with continued treatment with lecanemab with the highest study dose

for all participants in the Phase 2b study is in progress. During 2020 Eisai presented data from the study showing that the patients who had previously received placebo in the Phase 2b study had rapidly and continually decreasing amyloid levels in the brain after three, six and twelve months of treatment with lecanemab. Additionally, with treatment with lecanemab less than 10 percent of patients experienced ARIA-E side effects, consistent with previously reported data. This picture was further strengthened in March 2021 when Eisai presented results showing that the effects of lecanemab on reducing amyloid in the brain on average persist for at least two years following discontinuation of treatment. At the same time, it was verified that when lecanemab is administered in a dose of 10 mg/kg every other week, amyloid levels in the brains of more than 80 percent of patients decreased to levels under those that define Alzheimer's disease. These results were achieved in both the primary study and in the open-label extension study. In July 2021, Eisai presented data for the first time from a small cohort of participants in the open-label Phase 2b extension study. The results showed responses to treatment on clinical scales such as ADCOMS, CDR-SB and ADAS-Cog among patients with early Alzheimer's disease who had been recently treated with lecanemab or previously treated with placebo. The data provided additional support for the efficacy results seen in the large placebo-controlled Phase 2b study.

Lecanemab has a unique binding profile that distinguishes it from other amyloid beta antibodies and its unique binding profile has been confirmed in laboratory analyses, which are ongoing in parallel with the clinical development program. BioArctic has an ongoing research collaboration with Eisai in order to further deepen the knowledge about the drug candidate lecanemab's unique binding profile.

Lecanemab was selected by the Alzheimer's Clinical Trials Consortium (ACTC) and Eisai to be evaluated in a second clinical Phase 3 program which aims to evaluate the effects of lecanemab on preclinical asymptomatic Alzheimer's disease (AHEAD 3-45). The program, that was started 2020, include individuals that are at a very early stages of Alzheimer's disease with a high risk of developing the disease. The program consists of two clinical sub-studies: A3 and A45. After a joint screening process, the participants are included in one of the randomized, double-blind and placebo-controlled sub-studies based on amyloid levels in the brains of the specific individuals. AHEAD 3-45 is a global program that is expected to include approximately 1,400 individuals.

In June 2021 lecanemab was granted Breakthrough Therapy designation, an FDA program intended to facilitate and accelerate the development and review of drugs for serious or life-threatening conditions. This status includes more intensive guidance from the FDA on an efficient development program and eligibility for rolling review and potentially priority review.

In September 2021, Eisai announced that the company had initiated a rolling application to the FDA for approval of lecanemab in early Alzheimer's disease. The application for market approval, which was submitted for review under the Accelerated Approval Program, is based primarily on clinical, biomarker and safety data from the Phase 2b study of lecanemab in persons with early Alzheimer's disease and

confirmed A β pathology. Data from the open-label Phase 2b extension study and blinded safety data from Clarity AD will also be included to support the application for market approval.

Back-up candidate to lecanemab (collaboration with Eisai)

The antibody is a refined version of lecanemab for the treatment of Alzheimer's disease. The antibody was developed in collaboration with Eisai, which resulted in a new license agreement in 2015. The project is driven and financed by Eisai and is in the preclinical phase.

Projects AD1801, AD1502, AD1503 and AD2603 (owned by BioArctic)

BioArctic has four additional antibody projects against Alzheimer's disease in its project portfolio, all of which are in the research phase. These antibodies have different targets, and each has the potential to become a disease-modifying treatment for Alzheimer's disease. All of them are being developed to treat early Alzheimer's disease. AD1801 is an antibody project where the mechanism of action is linked to ApoE, which is the most common genetic risk factor for Alzheimer's disease. AD1503 is an antibody project against a shorter (truncated) form of amyloid beta, which has a pronounced ability to aggregate and create toxic forms that could cause Alzheimer's disease.

Drug projects AD-BT2802 and AD-BT2803 (blood-brain barrier technology owned by BioArctic)

BioArctic has two antibody projects against Alzheimer's disease that are being combined with the blood-brain barrier technology — Brain Transporter, or BT — to facilitate uptake of antibodies in the brain.

PARKINSON'S DISEASE

In the Parkinson's disease treatment area, BioArctic has been collaborating with AbbVie since 2016. In 2018, AbbVie acquired a license to develop and commercialize BioArctic's portfolio of antibodies against alpha-synuclein for Parkinson's disease and other potential indications.

Drug candidate ABBV-0805 (collaboration with AbbVie)

ABBV-0805 is a monoclonal antibody that selectively binds to and eliminates oligomers and protofibrils of alpha-synuclein. The goal is to develop a disease modifying treatment that stops or slows down disease progression. The project is based on research from Uppsala University.

In February 2019 FDA approved the application to conduct a clinical study with ABBV-0805 and the Phase 1 study started in March 2019. At the International Congress of Parkinson's Disease and Movement Disorders® (MDS) in September 2021, BioArctic presented preclinical results and AbbVie presented results from the Phase 1 study that support continued development of the antibody. AbbVie drives and finances the continued clinical development of ABBV-0805.

The scope of ABBV-0805 may be expanded to include, for example, Lewy body dementia and multiple system atrophy.

Projects PD1601 and PD1602 (collaboration with AbbVie)

The antibody projects PD1601 and PD1602 target 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 included in the collaboration with AbbVie.

OTHER CNS DISORDERS

BioArctic aims to improve the treatment of a number of central nervous system disorders. The company is evaluating the possibility of developing its existing as well as new antibodies against other diseases in the central nervous system.

Drug candidate lecanemab (indications other than Alzheimer's disease, owned by BioArctic)

Lecanemab can potentially also be used for other indications which in that case would be owned by BioArctic. The antibody is in the preclinical phase as a potential treatment of cognitive disorders in conjunction with Down's syndrome and traumatic brain injury. BioArctic and Eisai presented at the AD/PD conference 2021 findings suggesting that lecanemab also could be developed into a disease modifying treatment benefiting individuals with Down's syndrome with dementia.

Project ND3014 (owned by BioArctic)

ND3014 is intended to be a disease modifying treatment with potential to address various neurodegenerative disorders. The project is in an early research phase.

BLOOD-BRAIN BARRIER TECHNOLOGY (BRAIN TRANSPORTER) (owned by BioArctic)

The blood-brain barrier controls the passage of substances between the blood and the brain. It protects the brain from harmful substances, but at the same time it can make the delivery of therapeutic agents to the brain more difficult. BioArctic and researchers at Uppsala University are collaborating on developing technology that facilitates the passage of antibodies across the blood-brain barrier. Together with Uppsala University, BioArctic received grants from Sweden's Innovation Agency, Vinnova, for continued research in the blood-brain barrier project. The technology, which is at an early stage, has shown highly encouraging results and has significant potential for many different treatments for various diseases of the brain.

DIAGNOSTICS

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

BioArctic is engaged in the development of new diagnostic methods that improve the ability to diagnose and monitor the treatment of Alzheimer's and Parkinson's disease. The company conducts a number of projects in collaboration with commercial and academic partners. Among other things, BioArctic is developing biochemical methods based on the company's antibodies to be applied to cerebral spinal fluid (CSF) testing. Beyond this, the company is exploring the possibilities to measure biomarkers with a simple blood test. BioArctic is also active in projects to improve the diagnostic imaging (PET) of the brain of patients. The goal is to create tools to better diagnose the disease, follow the disease progression and objectively measure the effect of drug treatment.

Comments to the financial development

REVENUES AND RESULT

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

Net revenues in the third quarter amounted to MSEK 4.0 (10.5). Net revenues for the period January – September amounted to 18.4 MSEK (54.0). The decrease for the period compared to last year relates to lower revenue from the Parkinson's program, which was according to plan. Further a lump sum of MSEK 22.8 was recorded attributable to a remeasurement of the total costs of the Parkinson's program during the first quarter last year.

Other operating income relates to research grants and operating exchange rate gains. Other operating income amounted to MSEK 0.7 (0.9) in the third quarter and for the period January – September to MSEK 3.0 (2.2). The increase is mainly attributable to exchange rate gains.

Total operating expenses for the third quarter amounted to MSEK -42.1 (-32.2) and for the period January – September to MSEK -121.8 (-111.1). Project expenses for projects fully owned by BioArctic increased due to a higher activity within those projects. The expenses for personnel in the third quarter and for the period increased as a result of an increase in the number of employees and cost of bonuses. Other external costs was unchanged both in the quarter as well as for the period. Other operating expenses mainly consist of realized operating exchange rate losses.

Since BioArctic's own projects are in an early research phase they did not meet all the conditions for R&D costs to be capitalized and thus, all such costs have been charged to the income statement. The external projects are owned by our partners and BioArctic has no costs for the clinical programs.

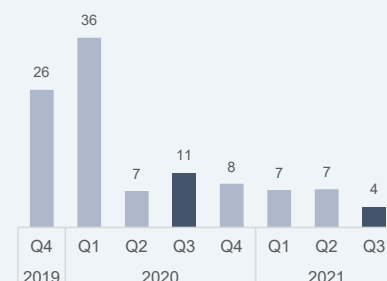
Operating profit before financial items (EBIT) amounted to MSEK -37.4 (-20.7) for the third quarter and to MSEK -100.4 (-54.9) for the period January – September. The decrease in operating profit was primarily attributable to lower revenue from the Parkinson's program, which was according to plan and increased costs for personnel.

Net financial items totaled MSEK -0.2 (0.0) for the third quarter and to MSEK -0.5 (-0.6) 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 liabilities.

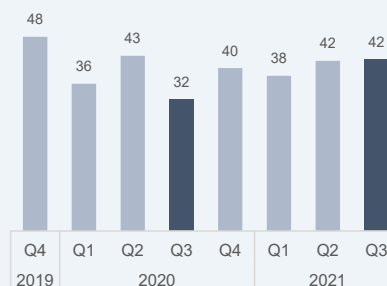
Profit (loss) amounted to MSEK -37.6 (-20.7) for the third quarter and to MSEK -100.8 (-55.3) for the nine-month period.

Earnings per share before and after dilution amounted to SEK -0.43 (-0.23) for the third quarter and to SEK -1.15 (-0.63) for the period January – September.

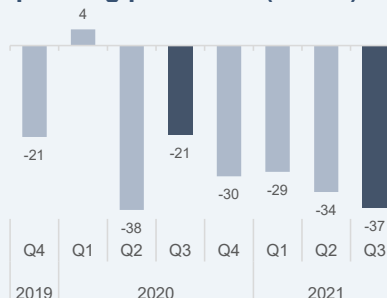
Net revenues (MSEK)



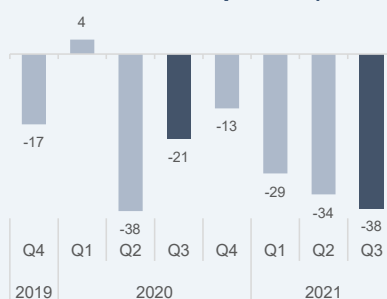
Operating expenses (MSEK)



Operating profit/loss (MSEK)



Profit/loss for the period (MSEK)



LIQUIDITY AND FINANCIAL POSITION

Equity amounted to MSEK 807.2 as of September 30, 2021 compared with MSEK 907.3 as of December 31, 2020. This corresponds to equity per outstanding share of SEK 9.17 (10.45). The equity/asset ratio was 86.3 percent as of September 30, 2021 compared with 86.4 percent as of December 31, 2020. Compared with the third quarter last year, the equity/asset ratio increased from 85.5 percent to 86.3 percent.

The Group's cash and cash equivalents consist of bank balances that at the end of the period amounted to MSEK 891.5 compared with MSEK 999.9 as of December 31, 2020. There were no loans as of September 30, 2021 and no loans have been taken since this date. The Group has no other credit facility or loan commitments.

In order to neutralize foreign exchange rate exposure some liquid funds are held in foreign currency. This has 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.

CASH FLOW AND INVESTMENTS

Cash flow from operating activities for the third quarter amounted to MSEK -34.8 (-9.4) and to MSEK -101.2 (-65.6) for the nine-month period.

For the third quarter cash flow from investing activities amounted to MSEK -1.5 (-3.3) and to MSEK -2.5 MSEK (-5.1) for the nine-month period. The investments were mainly related to laboratory equipment. Cash flow from financing activities amounted to MSEK -1.9 (-0.9) for the third quarter and to MSEK -5.5 (-5.3) for January - September and relates to the amortization of leasing liabilities.

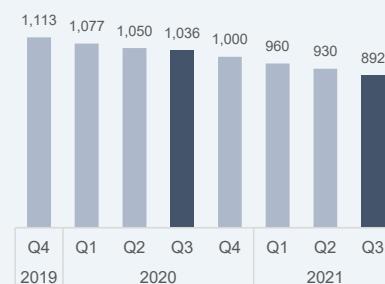
PARENT COMPANY

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

EVENTS DURING THE PERIOD JANUARY – SEPTEMBER 2021

- Eisai has initiated a rolling submission of the BLA to the US FDA for market approval for lecanemab, through an accelerated approval process.
- Data from the Phase 2b open-label extension study of lecanemab presented at the Alzheimer's Association International Conference provided further support for the clinical effects of the drug candidate. The baseline characteristics for the Clarity AD and AHEAD 3-45 Phase 3 studies were also presented, as well as the possibility of using specific blood biomarkers to monitor the effects of the drug in individual patients.
- At the International Congress of Parkinson's Disease and Movement Disorders® (MDS), BioArctic presented the preclinical results and AbbVie presented results from the Phase 1 study that support continued development of the antibody.
- The US FDA granted Breakthrough Therapy designation for lecanemab in Alzheimer's disease.
- BioArctic supports research into physical activity and brain health in an eight-year research project being conducted by the Swedish School of Sport and Health Sciences.
- BioArctic received a Japanese patent for new antibodies against Alzheimer's disease.
- Lecanemab Phase 2b study results in early Alzheimer's disease published in peer-reviewed journal, Alzheimer's Research and Therapy, and lecanemab confirmatory Phase 3 Clarity AD clinical trial completed enrollment with 1,795 patients.
- BioArctic presented findings at the AD/PD conference suggesting that lecanemab also could be developed into a disease modifying treatment benefiting individuals with Down's syndrome with dementia.
- New preliminary results that Eisai presented at the AD/PD conference from the ongoing open-label extension of the Phase 2b study in early Alzheimer's disease continued to support the effect of lecanemab on brain amyloid levels.
- Eisai increased the number of participants in Clarity AD with 200 patients to ensure a robust dataset. Eisai expects readout by end of September 2021.
- BioArctic received patent approval from the European Patent Office for antibodies against truncated amyloid beta, which are linked to the AD1503 project.

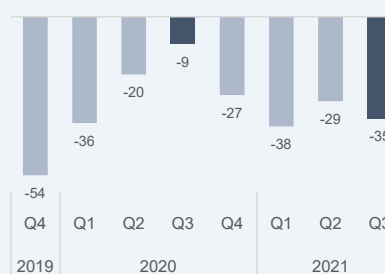
Cash and cash equivalents (MSEK)



Financial position (MSEK)

	30 Sep 2021	31 dec 2020
Non-current lease liabilities	9.8	13.6
Current lease liabilities	8.0	7.1
Cash and cash equivalents	891.5	999.9
Net cash position	873.7	979.2

Cash flow from operating activities (MSEK)



Cash position
(MSEK)
892

Other information

PATENTS

Patents are crucial to the company's future commercial opportunities. BioArctic has therefore an active patent strategy covering all major pharmaceutical markets including the US, EU, Japan and China. At the end of the quarter, BioArctic's patent portfolio consisted of 14 patent families with more than 230 granted patents and more than 40 ongoing patent applications.

PARTNERSHIPS, COLLABORATIONS AND MAJOR AGREEMENTS

Collaborations and license agreements with leading pharma and biopharma companies are an important part of BioArctic's strategy. In addition to financial compensation, BioArctic benefits from the expertise the company's partners contribute in drug development, manufacturing and commercialization. BioArctic has entered into a number of such agreements with the Japanese global pharma company Eisai and 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 BioArctic's product candidates in preclinical and clinical phase, manufacturing and marketing competence, geographic coverage and other resources.

BioArctic has been collaborating with Eisai in the field of Alzheimer's disease since 2005. The company has signed research and licensing agreements concerning the lecanemab and BAN2401 back-up antibodies. The total value of these agreements may amount to MEUR 222 in addition to royalties. To date, approximately MEUR 66 has been received and recognized.

BioArctic has been collaborating with AbbVie in the field of Parkinson's disease since 2016, when a research agreement was signed that included products such as the antibody BAN0805, now designated ABBV-0805. 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. BioArctic has had primary responsibility for the preclinical development work and AbbVie is responsible for the clinical development. The total value of the agreement could amount to MUS\$ 755 in addition to royalty payments. To date, MUS\$ 130 has been received. For more information regarding BioArctic's two large collaboration partners, please see the Annual Report 2020 on pages 22, 29, 43 and 44.

Collaborating with universities is also of great importance to BioArctic. The company has ongoing collaborations with academic research groups at a number of universities.

RISKS AND UNCERTAINTY FACTORS

The management makes assumptions, judgments and estimates that affect the content of the financial statements. Actual results may differ from these assumptions and estimates, as is also stated in the accounting principles. The

objective of the Group's risk management is to identify, mitigate, measure, control and limit the risks of the business. Significant risks are the same for the Parent Company and the Group.

BioArctic's operational and external risks mainly consist of risks related to research and development, clinical trials and dependence on key employees.

A detailed description of exposure and risk management is presented in the Annual Report 2020 on pages 50 - 53. In all material respects, the risks identified in conjunction with the 2020 Annual Report remain unchanged.

FLUCTUATIONS IN REVENUE GENERATION

Currently, BioArctic does not have any drugs on the market. The company develops a number of drug candidates and diagnostics for Alzheimer's and Parkinson's diseases in collaboration with global pharmaceutical companies. The company also conducts research for wholly owned projects including new potential antibody treatments, diagnostics, as well as a blood-brain barrier technology platform. The company signs research and licensing agreements with partners and then receives remuneration for research as well as milestone payments and royalties, which the company uses to finance current and new projects. Milestone payments are normally received when the project reaches predetermined development targets – the start of clinical trials, for example – or when clinical trials move from one phase to a later phase. Thus, these payments arise unevenly over time.

FUTURE PROSPECTS

The company enjoys a strong financial position and has a business model in which its revenue and earnings are currently primarily based on non-recurring revenue from research and licensing agreements the company signed. The company's liquidity facilitates continued development of the projects covered by strategic partnership agreements as well as financing of the company's own projects in early phase and therefore are less costly. BioArctic's focus areas comprise unique drug candidates, innovative blood-brain barrier technology and diagnostics, areas with high unmet medical need. All projects are focused on disorders of the central nervous system and have great market potential. BioArctic's ambition is to generate the medicines of the future for patients with central nervous system disorders.

EXPECTED DEVELOPMENT OF OPERATING EXPENSES

Operating expenses are expected to be in the range of MSEK 160 – 190 for the fiscal year January – December 2021 (previously expectation MSEK 170 – 200). During 2020 operating expenses were MSEK 151 and during the last three years the average annual level of the operating expenses has been approximately MSEK 190.

EMPLOYEES

At the end of the period, the number of employees was 49 (45) of which 19 (17) are men and 30 (28) women. Just over 80 percent work in R&D and just over 70 percent are PhDs.

A cost-efficient organization at BioArctic is achieved by hiring consultants for specific assignments and tasks in competence areas that the company lacks or only has need for periodically. As of September 30, 2021, these corresponded to 10 (10) full-time positions.

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.

LARGEST SHAREHOLDERS AS OF SEPTEMBER 30, 2021¹

	Number		Share of (%)	
	A-shares	B-shares	capital	votes
Demban AB (Lars Lannfelt)	8,639,998	22,628,052	35.5	50.1
Ackelsta AB (Pär Gellerfors)	5,759,998	15,086,301	23.7	33.4
Fourth AP-Fund	-	4,300,000	4.9	2.0
Third AP-Fund	-	2,946,784	3.3	1.4
Unionen	-	2,391,835	2.7	1.1
Gladiator	-	2,103,860	2.4	1.0
Swedbank Robur Funds	-	1,895,515	2.2	0.9
Investment AB Öresund	-	1,330,000	1.5	0.6
Wellington Management	-	1,266,319	1.4	0.6
Handelsbanken Funds	-	1,236,703	1.4	0.6
Tot. 10 largest shareholde	14,399,996	55,185,369	79.0	91.7
Other	-	18,474,620	21.0	8.3
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 Swedish Financial Supervisory Authority (Finansinspektionen).

LONG-TERM INCENTIVE PROGRAMS

The Annual General Meeting 2019 approved the Board of Directors' proposal for resolution concerning an employee warrant program for the company's management, researchers and other staff, a directed issue of warrants and the transfer of warrants or shares in the company to the participants in the employee warrant program.

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

The dilutive effect of the employee warrant program 2019/2028 is estimated to be a maximum of 1.1 percent of the share capital and 0.5 percent of the votes in the company (calculated on the number of existing shares in the company), assuming full exercise of all employee warrants. The employee warrants can be exercised three years after allocation at the earliest. As of the end of the period, 580,000 employee warrants were allocated. 30,000 warrants were allocated in the third quarter 2021. The allocation of employee warrants had a dilutive effect corresponding to 550,000 shares, or 0.62 percent, at the end of the period. More information is available on www.bioarctic.com

The information was submitted for publication, though the agency of the named contact persons, at 08:00 a.m. CET on October 21, 2021.

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

Stockholm, Sweden, October 21, 2021

Gunilla Osswald
CEO, BioArctic AB (publ)

INVITATION TO PRESENTATION OF INTERIM REPORT FOR THE PERIOD JANUARY – SEPTEMBER 2021

BioArctic invites investors, analysts, and media to an audiocast with teleconference (in English) today, October 21, at 9:30–10:30 a.m. CET. CEO Gunilla Osswald and CFO Jan Mattsson will present BioArctic, comment on the interim report and answer questions.



Webcast: <https://tv.streamfabriken.com/bioarctic-q3-2021>

To participate in the conference, please call: +46 8 505 583 69 (Sweden),
+45 781 501 08 (Denmark), +31 207 219 496 (Netherlands),
+47 239 639 38 (Norway), +41 225 675 632 (Switzerland),
+44 333 300 92 66 (UK), +49 692 222 391 66 (Germany)
or +1 646 722 4957 (USA)

CALENDAR 2021

Full Year Report Jan-Dec 2021	Feb 3, 2022, at 08:00 a.m. CET
Interim report Jan-Mar 2022	Apr 28, 2022, at 08:00 a.m. CET
Annual General Meeting 2022	May 5, 2022, at 04:30 p.m. CET
Interim report Jan-Mar 2022	July 12, 2022, at 08:00 a.m. CET
Interim report Jan-Sep 2022	October 20, 2022, at 08:00 a.m. CET
Full Year Report Jan-Dec 2022	February 3, 2023, at 08:00 a.m. CET



FOR FURTHER INFORMATION, PLEASE CONTACT

Gunilla Osswald, CEO, gunilla.osswald@bioarctic.se, phone +46 8 695 69 30
Jan Mattsson, CFO, jan.mattsson@bioarctic.se, phone +46 70 352 27 72
Oskar Bosson, VP Communications & Investor Relations, oskar.bosson@bioarctic.se,
phone +46 70 410 71 80



BioArctic AB (publ)

Swedish Corporate Identity Number 556601-2679
Warfvinges väg 35, SE-112 51, Stockholm, Sweden
Telephone +46 (0)8 695 69 30
www.bioarctic.com

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

Report on Review of Interim Financial Information

INTRODUCTION

We have reviewed the accompanying balance sheet of BioArctic AB (publ) as of September 30, 2021 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, 2021, and of its financial performance and its cash flows for the nine-month period then ended in accordance with IFRS.

Stockholm October 21, 2021

Grant Thornton Sweden AB

Mia Rutenius
Authorized public accountant
Auditor in charge

Therese Utengen
Authorized public accountant

Financial statements, Group

CONSOLIDATED INCOME STATEMENT

kSEK	Q3		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net revenues (note 4)	3,952	10,549	18,440	53,986	62,347
Other operating income	737	904	2,973	2,238	3,597
Operating revenues	4,689	11,452	21,413	56,224	65,943
Operating expenses					
Project related expenses	-13,884	-10,664	-38,539	-36,866	-50,242
Other external expenses	-4,784	-4,382	-17,433	-17,285	-23,370
Personnel expenses	-19,896	-13,957	-55,421	-46,453	-62,977
Depreciations of tangible assets	-3,318	-2,849	-9,854	-7,938	-11,013
Other operating expenses	-216	-308	-531	-2,536	-3,353
Operating expenses	-42,098	-32,160	-121,778	-111,078	-150,955
Operating profit/loss	-37,409	-20,708	-100,365	-54,853	-85,012
Financial income	37	234	154	234	7
Financial expenses	-214	-222	-679	-820	-1,686
Profit/loss before tax	-37,586	-20,696	-100,890	-55,440	-86,691
Tax	15	45	56	122	18,174
Profit/loss for the period	-37,571	-20,650	-100,834	-55,319	-68,517
Earnings per share					
Earnings per share before dilution, SEK	-0.43	-0.23	-1.15	-0.63	-0.78
Earnings per share after dilution, SEK	-0.43	-0.23	-1.15	-0.63	-0.78

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

kSEK	Q3		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Profit/loss for the period	-37,571	-20,650	-100,834	-55,319	-68,517
Other comprehensive income	-	-	-	-	-
Comprehensive income for the period	-37,571	-20,650	-100,834	-55,319	-68,517

CONSOLIDATED BALANCE SHEET

kSEK	30 Sep 2021	30 Sep 2020	31 dec 2020
ASSETS			
Tangible fixed assets	16,373	11,011	18,120
Right-to-use assets	18,678	23,125	21,820
Deferred tax assets	607	419	452
Other financial assets	1,588	1,534	1,562
Current assets excluding cash and cash equivalents	6,451	3,716	8,420
Cash and cash equivalents	891,525	1,036,295	999,940
TOTAL ASSETS	935,222	1,076,101	1,050,313
EQUITY AND LIABILITIES			
Equity	807,185	920,163	907,299
Deferred tax liabilities	20,666	38,685	20,666
Non-current lease liabilities	9,783	15,155	13,627
Current lease liabilities	8,030	6,870	7,141
Other current liabilities	11,537	8,994	17,887
Accrued expenses and deferred income	78,021	86,233	83,692
EQUITY AND LIABILITIES	935,222	1,076,101	1,050,313

CONSOLIDATED STATEMENT OF CHANGE IN EQUITY (CONDENSED)¹

kSEK	30 Sep 2021	30 Sep 2020	31 dec 2020
Opening balance at 1 January	907,299	974,497	974,497
Correction of opening balance	-402	-	-
Comprehensive income for the period	-100,834	-55,319	-68,517
Share-based payments	1,121	984	1,319
Paid dividend	-	-	-
Closing balance	807,185	920,163	907,299

CONSOLIDATED STATEMENT OF CASH FLOW (CONDENSED)²

kSEK	Q3		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Operating profit	-37,409	-20,708	-100,365	-54,853	-85,012
Adjustment for non-cash items	1,713	1,584	3,670	-21,758	-19,991
Interest received/paid	-178	-222	-526	-820	-1,679
Income tax paid	-425	-367	116	-11,850	-12,217
Cash flow from operating activities before changes in working capital	-36,299	-19,713	-97,105	-89,282	-118,899
Change in working capital	1,527	10,284	-4,098	23,712	26,558
Cash flow from operating activities after changes in working capital	-34,772	-9,429	-101,203	-65,570	-92,341
Cash flow from investing activities	-1,530	-3,332	-2,524	-5,077	-12,524
Cash flow from financing activities	-1,917	-942	-5,453	-5,341	-6,598
Cash flow for the period	-38,219	-13,702	-109,180	-75,988	-111,463
Cash and cash equivalents at beginning of period	929,570	1,049,934	999,940	1,112,770	1,112,770
Exchange rate differences in cash and cash equivalents	174	63	765	-486	-1,367
Cash and cash equivalents at end of period	891,525	1,036,295	891,525	1,036,295	999,940

1) A minor error was discovered during the transition to a new system for translation in accordance with IFRS 16, which affects the opening balance for equity by MSEK 0.4, corresponding to 0.05%.

2) For the comparison period Jan-Dec 2020, an adjustment of kSEK 1,460 has been made between the lines Change in working capital and Cash flow from investing activities compared with the Full Year Report 2020.

CONSOLIDATED QUARTERLY DATA

MSEK	2021 Q3	2021 Q2	2021 Q1	2020 Q4	2020 Q3	2020 Q2	2020 Q1	2019 Q4
Income statement								
Net revenues	4	7	7	8	11	7	36	26
Other operating income	1	1	2	1	1	-2	3	0
Operating expenses	-42	-42	-38	-40	-32	-43	-36	-48
Operating profit/loss	-37	-34	-29	-30	-21	-38	4	-21
Operating margin, %	neg	neg	neg	neg	neg	neg	10.4	neg
Profit/loss for the period	-38	-34	-29	-13	-21	-38	4	-17
Balance sheet								
Fixed assets	37	39	40	42	36	35	37	39
Current assets	6	5	5	8	4	14	29	32
Cash and cash equivalents	892	930	960	1,000	1,036	1,050	1,077	1,113
Equity	807	844	879	907	920	940	978	974
Deferred tax liabilities	21	21	21	21	39	39	39	39
Lease liabilities	18	19	19	21	22	23	25	27
Current liabilities	90	89	87	102	95	98	101	143
Cash flow								
From operating activities	-35	-29	-38	-27	-9	-20	-36	-54
From investing activities	-2	-0	-1	-7	-3	-1	-0	-0
From financing activities	-2	-2	-2	-1	-1	-2	-3	-2
Cash flow for the period	-38	-31	-40	-35	-14	-23	-39	-56
Key ratios								
Equity/asset ratio, %	86.3	86.7	87.3	86.4	85.5	85.5	85.6	82.4
Return on equity, %	-4.5	-4.0	-3.3	-1.4	-2.2	-4.0	0.4	-1.7
Data per share								
Earnings per share before dilution, SEK	-0.43	-0.39	-0.33	-0.15	-0.23	-0.43	0.04	-0.19
Earnings per share after dilution, SEK	-0.43	-0.39	-0.33	-0.15	-0.23	-0.43	0.04	-0.19
Equity per share, SEK	9.17	9.59	9.98	10.30	10.45	10.68	11.11	11.07
Cash flow operating activities per share, SEK	-0.39	-0.33	-0.43	-0.30	-0.11	-0.22	-0.41	-0.62
Share price at the end of the period, SEK	162.60	137.80	91.00	95.40	88.95	73.35	61.50	94.90
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	88,060
Average number of shares outstanding after dilution, thousands	89,380	89,105	88,855	88,355	88,082	88,060	88,060	88,060

Financial statements, Parent company

PARENT COMPANY INCOME STATEMENT

kSEK	Q3		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Net revenues	3,952	10,549	18,440	53,986	62,347
Other operating income	737	904	2,973	2,238	3,597
Operating revenues	4,689	11,452	21,413	56,224	65,943
Operating expenses					
Project related expenses	-13,884	-10,664	-38,539	-36,866	-50,242
Other external expenses	-6,899	-6,409	-23,693	-23,066	-31,161
Personnel expenses	-19,896	-13,957	-55,421	-46,453	-62,977
Depreciations of tangible assets	-1,424	-941	-4,244	-2,588	-3,829
Other operating expenses	-216	-308	-531	-2,536	-3,353
Operating expenses	-42,319	-32,278	-122,428	-111,508	-151,561
Operating profit/loss	-37,630	-20,825	-101,015	-55,284	-85,618
Financial income	37	234	154	234	7
Financial expenses	-10	26	-25	-65	-707
Profit/loss after financial items	-37,603	-20,566	-100,886	-55,115	-86,318
Change in tax allocation reserves	-	-	-	-	81,865
Profit/loss before tax	-37,603	-20,566	-100,886	-55,115	-4,453
Tax	19	18	55	53	75
Profit/loss for the period	-37,584	-20,548	-100,830	-55,062	-4,378

There are no items recognized as other comprehensive income in the Parent Company. Accordingly, total comprehensive income matches profit for the year.

PARENT COMPANY BALANCE SHEET (CONDENSED)

	30 Sep 2021	30 Sep 2020	31 dec 2020
ASSETS			
Tangible fixed assets	16,373	11,011	18,120
Deferred tax assets	380	302	325
Other financial assets	1,638	1,634	1,612
Current assets excluding cash and cash equivalents	8,417	5,175	9,882
Cash and cash equivalents	891,478	1,036,200	999,892
TOTAL ASSETS	918,286	1,054,323	1,029,831
EQUITY AND LIABILITIES			
Equity	733,919	782,609	833,628
Tax allocation reserve	94,809	176,674	94,809
Other current liabilities	11,537	8,806	17,702
Accrued expenses and deferred income	78,021	86,233	83,692
EQUITY AND LIABILITIES	918,286	1,054,323	1,029,831

Notes

NOTE 1 GENERAL INFORMATION

This Interim Report for the period January – September 2021 covers the Swedish Parent Company BioArctic AB (publ), Swedish Corporate Identity Number 556601-2679, and the fully owned subsidiary LPB Sweden AB, Swedish Corporate Identity Number 559035-9112. All the Group's business operations are conducted in the Parent Company. BioArctic is a Swedish limited liability company registered in and with its registered office in Stockholm. The head office is located at Warfväges väg 35, SE-112 51, Stockholm, Sweden.

NOTE 2 ACCOUNTING PRINCIPLES

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

The Interim Report for the period January – September 2021 is presented in accordance with IAS 34 Interim Financial Reporting and the Swedish Annual Accounts Act. Disclosures in accordance with IAS 34 are presented both in

notes and elsewhere in interim report. The accounting principles and calculation methods applied are in accordance with those described in the Annual Report 2020. New and amended IFRS standards and interpretations applied from 2021 have not had a material impact on the financial statements.

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

NOTE 3 SEGMENT INFORMATION

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

NOTE 4 NET REVENUES

kSEK	Q3		Jan-Sep		Jan-Dec
	2021	2020	2021	2020	2020
Geographic breakdown of net revenues					
Europe	1,863	1,680	6,540	31,514	33,805
Asia	2,089	8,868	11,900	22,472	28,541
Total net revenues	3,952	10,549	18,440	53,986	62,347
Net revenues per revenue type					
Milestone payments, recognized at a given point in time	-	-	-	-	-
Income from research collaborations, recognized over time	3,952	10,549	18,440	53,986	62,347
Total net revenues	3,952	10,549	18,440	53,986	62,347

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, or 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. In conjunction with a restatement of the total costs of the Parkinson's program in light of better performance than originally planned, a positive lump sum of MSEK 22.8 in revenue has been recorded during the first quarter 2020. As of September 30,

2021, MSEK 641.2 has been recognized as revenue and the remaining amount to be recognized as a revenue up until the completion of the project is MSEK 60.4. MSEK 1.9 was recognized as revenue in the period July–September 2021.

Current research collaboration agreement with Eisai refers to the period July 2021 to June 2022. The revenue for the research collaboration is recognized over time based on the fulfillment of the performance obligation. At September 30, 2021, MSEK 2.1 had been recognized as revenue.

Definition of key ratios

In this financial report BioArctic reports key financial ratios, some of which are not defined by IFRS. The Company's assesses that these key ratios are important additional information, since they enable investors, securities analysts, management of the company and other stakeholders to better analyze and evaluate the company's business and financial trends. These key ratios should not be analyzed separately or replace key ratios that have been calculated in accordance with IFRS. Neither should they be compared to other key

ratios with similar names applied by other companies, as key ratios cannot always be defined in the same way. Other companies may calculate them in a different way than BioArctic.

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

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

Glossary

Accelerated approval

An application process which gives an opportunity for an early approval of a drug candidate, where the company at a later stage is required to present additional data to verify clinical effect in order to receive full market approval.

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.

ADCS-ADL-MCI

ADCS-ADL-MCI (Alzheimer's Disease Cooperative Study - Activities of Daily Living - Mild cognitive impairment) is a clinical scale focusing on activities of daily living particularly relevant in mild cognitive impairment.

Alfa-synuclein (α -synuclein)

A naturally occurring protein in the body that, in conjunction with Parkinson's disease, misfolds and forms harmful structures in brain cells.

Amyloid beta ($A\beta$)

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

Antibody

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

ApoE (Apolipoprotein E)

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

ARIA-E

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

Binding profile

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

Biomarker

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

Blood-brain barrier

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

Breakthrough therapy designation

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

CDR-SB

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

Central nervous system (CNS)

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

Clinical studies

Drug trials performed in human subjects.

Disease modifying treatment

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

Dose dependent

Increased effect at higher dose.

Drug candidate

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

Early Alzheimer's disease

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

Interim analysis

A statistical analysis conducted during an ongoing clinical trial to evaluate preliminary findings.

Licensing

Agreement where a company that has invented a drug gives another company the right to further develop and sell the drug for certain payments.

Milestone payment

Financial remuneration received as part of a project or collaboration agreement once a specified goal has been achieved.

Monomer

An individual molecule with the ability to bind to other similar molecules to form larger structures such as oligomers and protofibrils.

Neurodegenerative disease

A disease that entails a gradual breakdown and degeneration in brain and nervous system function.

Oligomer

Molecules consisting of a number of monomers.

Open-label extension study

Clinical study conducted after a completed randomized and placebo-controlled study in which all patients receive active substance.

Pathology

The study of diseases and how they are diagnosed, through analysis of molecules, cells, tissues and organs.

PET

Positron emission tomography, an imaging method used to perform medical examinations.

Phase 1 studies

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

Phase 2 studies

Studies the safety and efficacy of a drug. Performed in a limited number of patients. Later stages of phase 2 studies can be called phase 2b and evaluate the optimal dose of the studied drug.

Phase 3 studies

Confirms the efficacy and safety of a drug. Performed in a large number of patients.

Placebo-controlled

A study design in research which means that some of the patients receive inactive compound to obtain a relevant control group.

Preclinical (asymptomatic) Alzheimer's disease

Normal cognitive function but with intermediate or elevated levels of amyloid in the brain.

Preclinical phase

Stage of development where preclinical studies of drug candidates are conducted to prepare for clinical studies.

Preclinical studies

Studies conducted in model systems in laboratories prior to conducting clinical trials in humans.

Product candidate

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

Protofibril

A harmful aggregation of amyloid beta formed in the brain, which gives rise to Alzheimer's disease, or a harmful aggregation of alpha-synuclein formed in the brain and gives rise to Parkinson's disease.

Research phase

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

Selective binding

The affinity of a molecule for binding to a specific receptor.

Tolerability

The degree of side effects from a drug that can be tolerated by a patient.

Truncated amyloid beta

Shortened (truncated) forms of the amyloid beta protein.

