BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

Q4 Report October-December 2022

Stockholm, February 3, 2023

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BioArctic – a unique Swedish biopharma company
Improving life for patients with central nervous system disorders

High unmet need for disease-modifying treatments for Alzheimer's and Parkinson's diseases creates **large commercial opportunity**

World-class research and development driven organization with basis in founder's breakthrough discoveries and fruitful collaborations with leading **academic researchers** and **pharma companies** generating and developing **innovative projects**

Attractive and well-balanced project portfolio with projects from discovery through Phase 3, regulatory and on the market. A combination of both proprietary projects with substantial marketing and out-licensing potential and partnered projects generating income

Well-financed with more than MSEK 805 (MUSD ~77) in cash and **valuable collaboration agreements**

1) FX as per December 31, 2022

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Attractive and well-balanced project portfolio

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory & Market
ALZHEIMER'S DSEASE	Lecanemab (BAN2401) *(Clarity AD)*	Eisai[1]	Early Alzheimer's disease[2]					
	Lecanemab (BAN2401) *(AHEAD 3-45)*	Eisai[1]	Preclinical (asymptomatic) Alzheimer's disease[3]					
	BAN2401 back-up	Eisai						
	BAN1503 (Trunc Abeta)							
	AD-BT2802							
	AD-BT2803 (Trunc Abeta with BT)							
	AD2603							
PARKINSON'S DISEASE	BAN0805 (alpha-synuclein)							
	PD1601 (alpha-synuclein)							
	PD1602 (alpha-synuclein)							
	PD-BT2238 (alpha-synuclein with BT)							
OTHER CNS DISORDERS	Lecanemab (BAN2401)				Down's syndrome[4], Traumatic brain injury[4]			
	ND3014 (TDP-43)			ALS				
	ND-BT3814 (TDP-43 with BT)			ALS				
	GD-BT6822 (GCase with BT)			Gaucher's disease				
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform							

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

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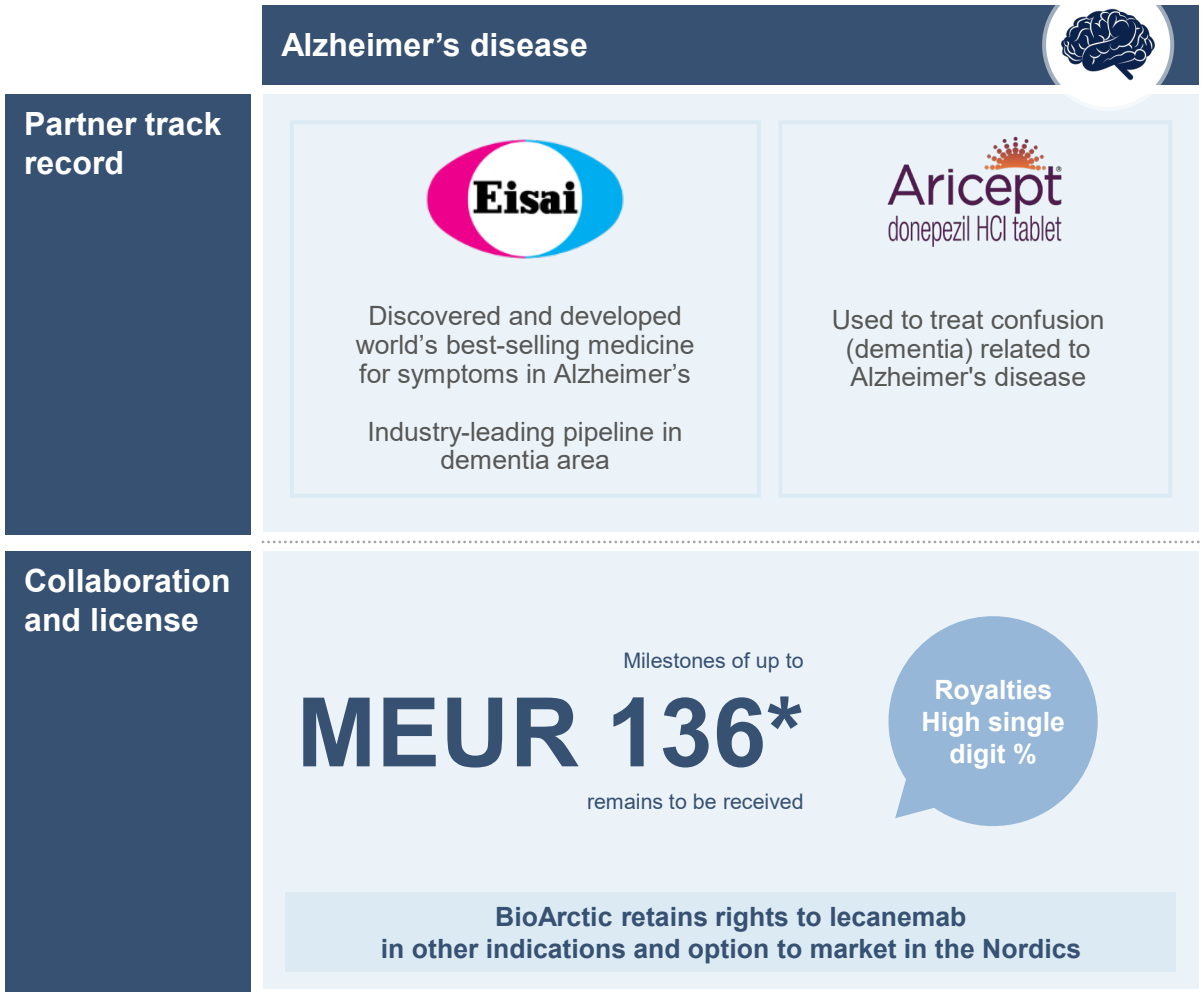
Partnership model to de-risk clinical development and optimize commercialization opportunity



*) including MEUR 35 to be paid to BioArctic in Q1 2023, based on regulatory approval and submissions

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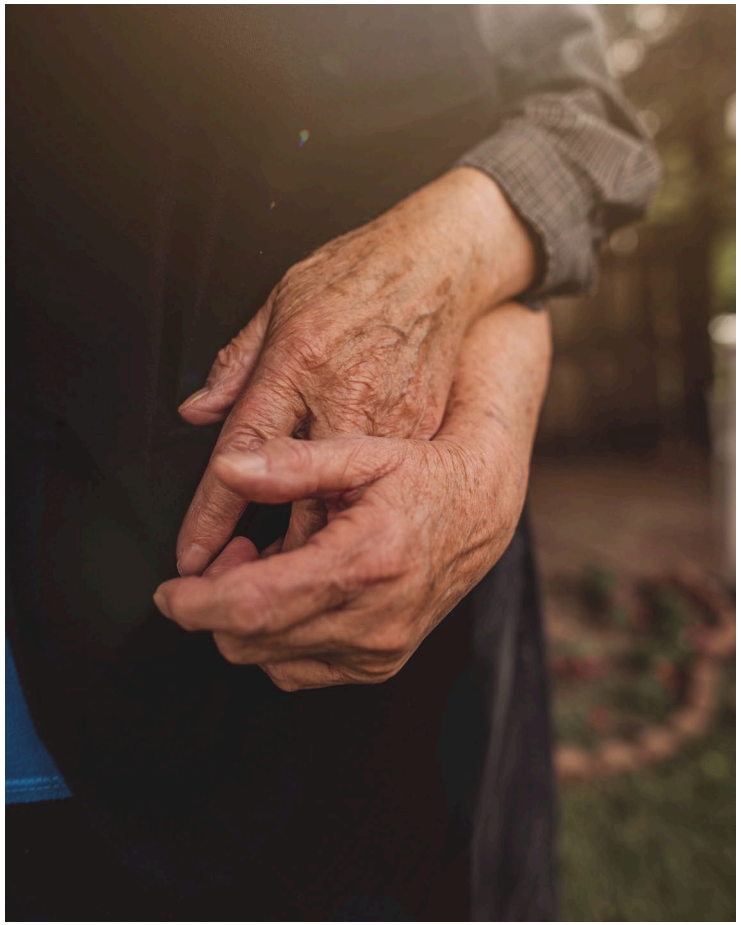
Q4 highlights

Alzheimer's disease – Lecanemab

- Detailed and positive lecanemab data from the Phase 3 study, Clarity AD, were presented by Eisai at the CTAD Alzheimer Congress. The results were simultaneously published in the New England Journal of Medicine
- Eisai initiated submission of data for Biologics License Application (BLA) to the National Medical Products Administration (NMPA) of China for lecanemab

Early portfolio

- Project AD1803 – data-driven decision to stop the project
- Project AD1503 CD nominated, now called BAN1503 and combined with BT technology in project AD-BT2803
- BioArctic started two new projects, both combined with the company's Brain Transporter technology;
    - PD-BT2238, a selective antibody against soluble alpha-synuclein aggregates (oligomers/protofibrils), and
    - GD-BT6822, an enzyme replacement therapy for Gaucher's disease



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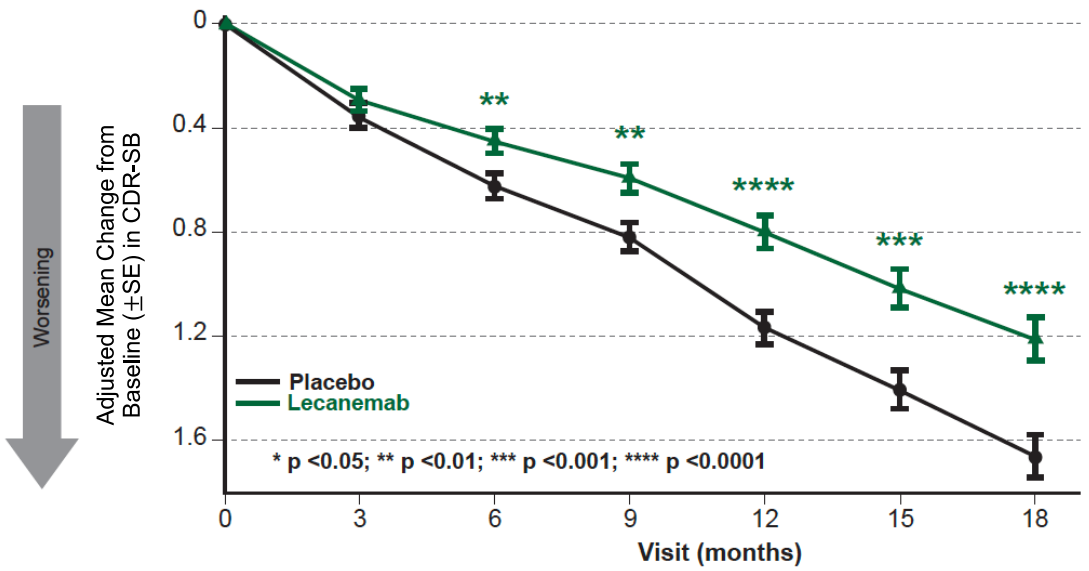
Events after the end of the quarter

- In the U.S., lecanemab (brand name: LEQEMBI™) was granted accelerated approval as a treatment for Alzheimer's disease by the FDA on January 6, 2023. Eisai submitted a Supplemental Biologics License Application (sBLA) to the FDA for a full approval under the traditional pathway on the same day
- In Europe, Eisai submitted marketing authorization application (MAA) to the European Medicines Agency (EMA) on January 9, 2023. The application was accepted for a standard review on January 26
- In Japan, Eisai submitted a marketing authorization application to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023. The application was granted priority review on January 30

Clarity AD: lecanemab demonstrates Clinically Meaningful Effect

Lecanemab met primary and all key secondary endpoints in Phase 3 Clarity AD study in 1795 early AD subjects with highly statistically significant results, reducing disease progression by 27% as measured by the primary endpoint CDR-SB* with relatively low frequency of the side effect ARIA



Clarity AD shows consistent highly statistically significant effects and confirms Phase 2b results

Safety profile confirmed in Phase 3 with low rates of ARIA, despite no titration and full dose from day 1

Slowing down disease progression means more time in less severe stages of Alzheimer's disease[1]

Lecanemab modifies the underlying disease pathology[2]

*CDR-SB: Clinical Dementia Rating Scale Summary of Boxes, measures key cognitive and functional symptoms in Alzheimer's Disease

Source: *1. Monfared et al. "Long-Term Health Outcomes of Lecanemab in Patients with Early Alzheimer's Disease Using Simulation Modeling". Neurol Ther. 2022.*
2. van Dyck et al. "Lecanemab in Early Alzheimer's Disease" N Engl J Med 2023; 388:9-21.

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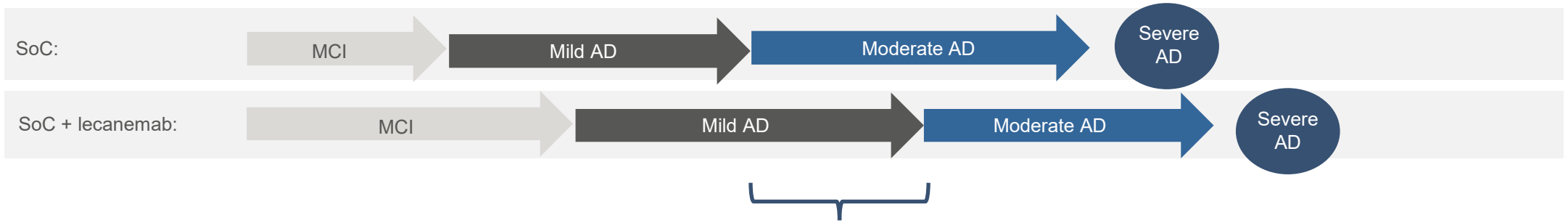
Disease modeling suggests that lecanemab could delay progression to moderate Alzheimer´s Dementia by several years

Estimated progression time to moderate Alzheimer's Disease (AD) for patients completing the full lecanemab dosing regime compared with patients subject to standard of care (SOC) only



Estimated time gained before reaching moderate AD: + 3.13 years

The results from the modeling show the potential clinical value of lecanemab for patients with early Alzheimer's disease and how it can slow the rate of disease progression, delay progression to moderate Alzheimer's dementia with several years and consequently reduce the need for institutionalized care

1. Monfared et al. "Long-Term Health Outcomes of Lecanemab in Patients with Early Alzheimer's Disease Using Simulation Modeling". Neurol Ther. 2022. 2.Swanson et al. " A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody". Alzheimer's Res Ther. 2021. 3. ADNI (Alzheimer's Disease Neuroimaging Initiative) study.

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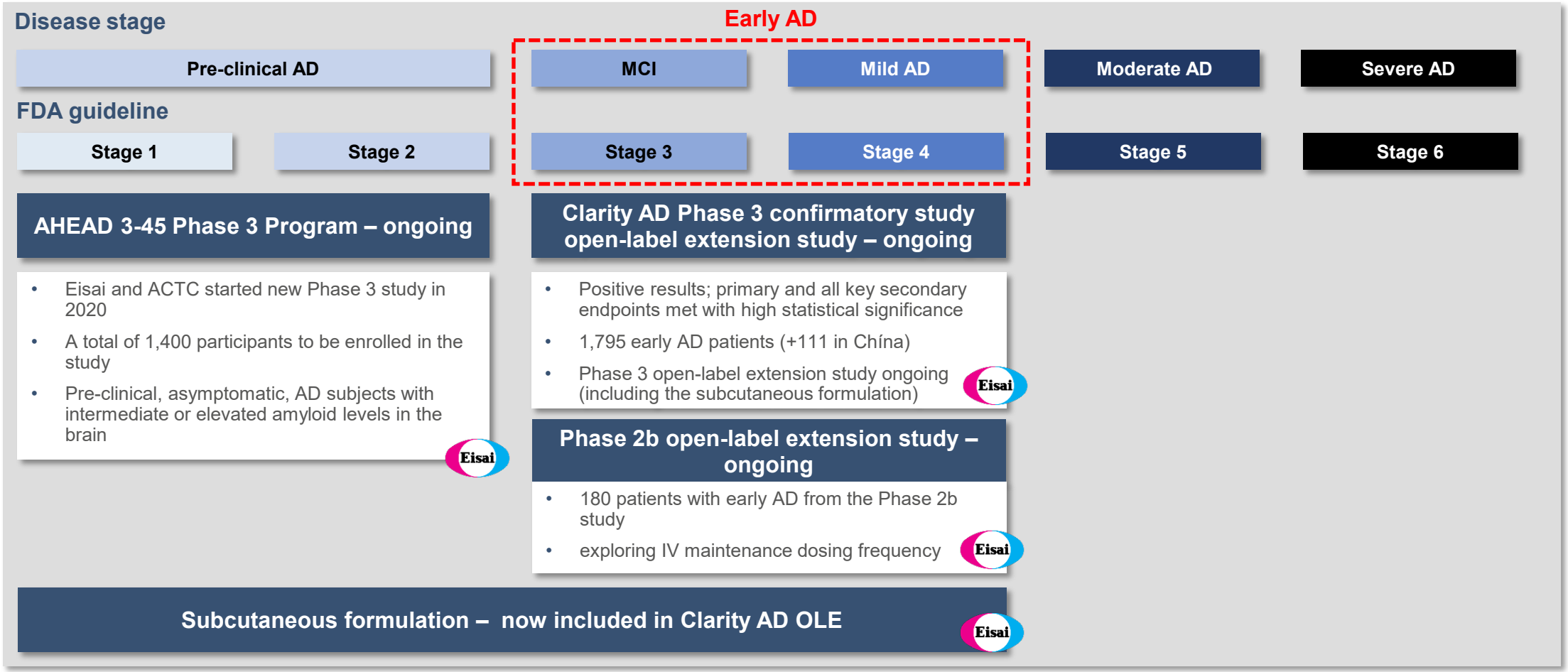
Lecanemab – broad late-stage clinical program



Selected as background treatment in DIAN-TU Tau NexGen study – first patient enrolled in January 2022

Eisai

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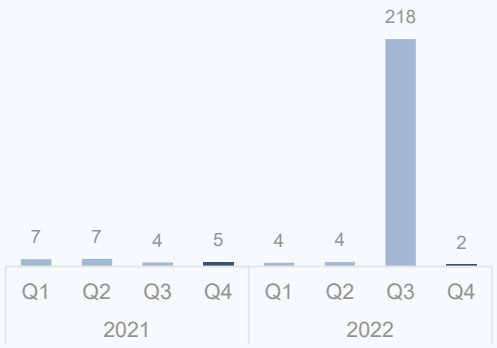
Financial Summary

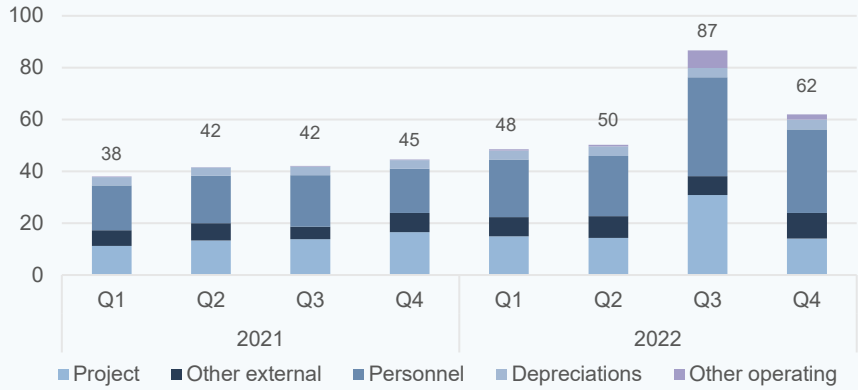
Operating expenses 2022 within guidance

Net Revenues (MSEK)



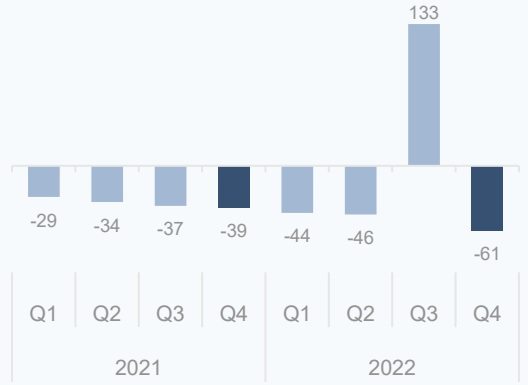
- Net revenues were 2 MSEK (5) for the fourth quarter.

OPEX by item (MSEK)



- Total costs in the quarter were higher than the same period previous year
- The major part of the cost increase were related to one-time effects
- Costs will increase going forward as we continue to build a commercial organization and continue to progress our project portfolio

Operating Profit/Loss (MSEK)



- Operating profit was -61 MSEK (-39) for the fourth quarter

Operating expenses are expected to be in the range of 330 - 380 MSEK for the financial year January - December 2023, compared to MSEK 247 in 2022

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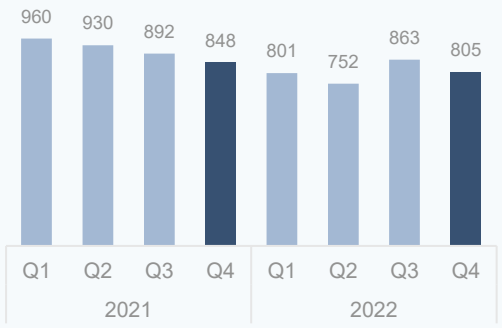
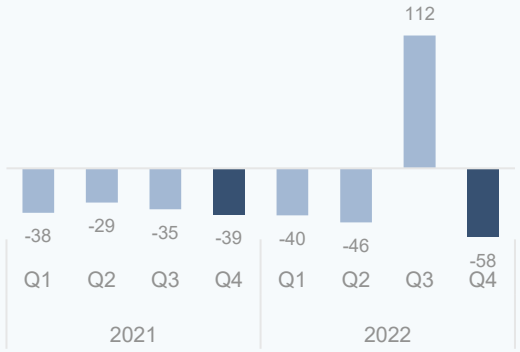
BioArctic continues to have a strong financial position

Cash Balance (MSEK)



- Cash balance amounted to 805 MSEK at the end of the fourth quarter

Cash Flow From Operating Activities (MSEK)



- Operating cash flow amounted to -58 MSEK (-39) during Q4

Net Result (MSEK)

- Net result for the period was -58 MSEK (-19)
- The decrease was mainly related to a positive tax effect in 2021

BioArctic will receive milestones from Eisai of MEUR 35 in Q1 2023 which will further strengthen the financial position

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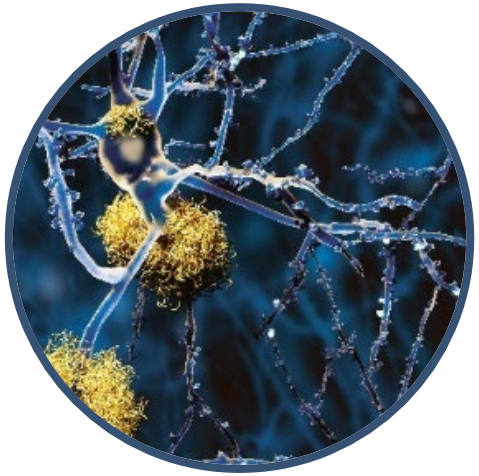
Upcoming news and closing remarks

Upcoming news flow

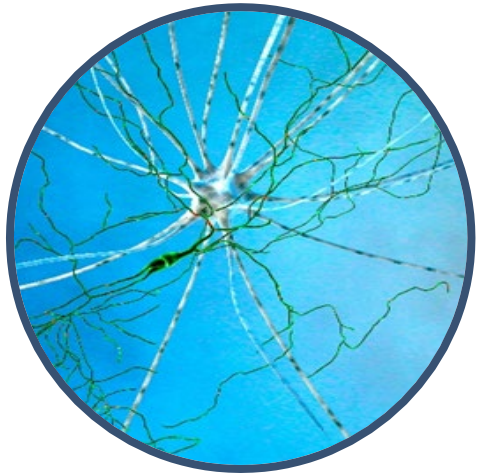
Alzheimer's disease



Lecanemab (Eisai)
- Data to be disclosed at international congresses, including AD/PD in Gothenburg in March/April
- Regulatory progress

Discovery stage programs
- Advancement of projects

Parkinson's disease



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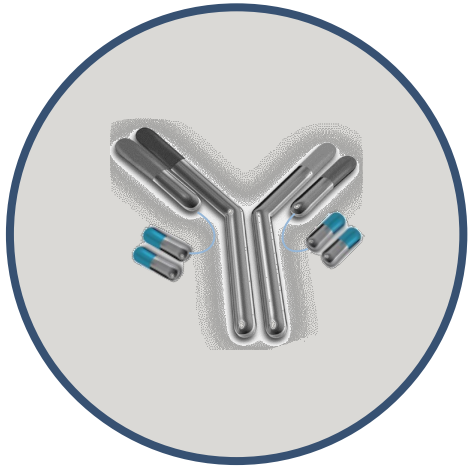
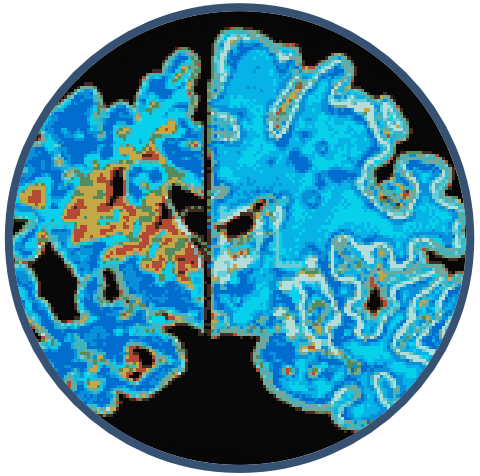
Data presented at international congresses

Blood-brain barrier



Brain Transporter (BT) technology platform
- Further development of the technology platform
- Data to be disclosed at international congresses
- BT supporting the expansion of the project portfolio

Other CNS disorders



Neurodegeneration
- Data to be disclosed at international congresses

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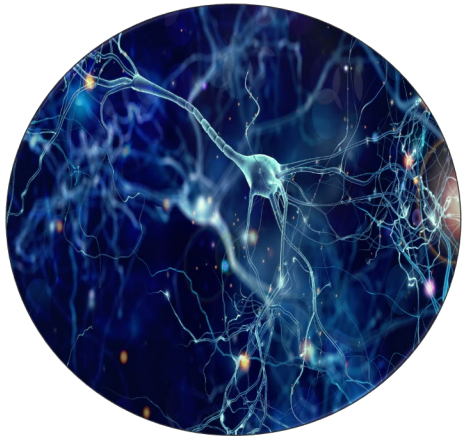
BioArctic: With Patients in Mind

Great science



Great projects

Great partners

Great people

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GUNILLA OSSWALD, CEO

JAN MATTSSON, CFO

OSKAR BOSSON, VP COMMUNICATIONS & IR

NEXT REPORT & IR CONTACT

- **Next Report:**
  Q1 Report
  Jan-Mar 2023
  on Apr 27, 2023
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