BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

Q3 Report
July-September 2022

Stockholm, October 20, 2022

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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 and combination of both proprietary projects with substantial marketing and out-licensing potential and partnered projects generating income

Well-financed with more than MSEK 850 (MUSD ~77[1]) in cash and **valuable collaboration agreements**

1) FX as per September 30, 2022

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Attractive and well-balanced project portfolio

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	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					
	AD1801 (ApoE)						
	AD1503 (Trunc Abeta)						
	AD-BT2802						
	AD-BT2803 (Trunc Abeta)						
	AD2603						
PARKINSON'S DISEASE	BAN0805 (alpha-synuclein)						
	PD1601 (alpha-synuclein)						
	PD1602 (alpha-synuclein)						
OTHER CNS DISORDERS	Lecanemab (BAN2401)		Down's syndrome[4] Traumatic brain injury[4]				
	ND3014 (TDP-43)		ALS				
	ND-BT3814 (TDP-43 with BT)		ALS				
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform						

as of September 30, 2022

1) Partnered with Eisai for lecanemab (BAN2401) for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding lecanemab (BAN2401) 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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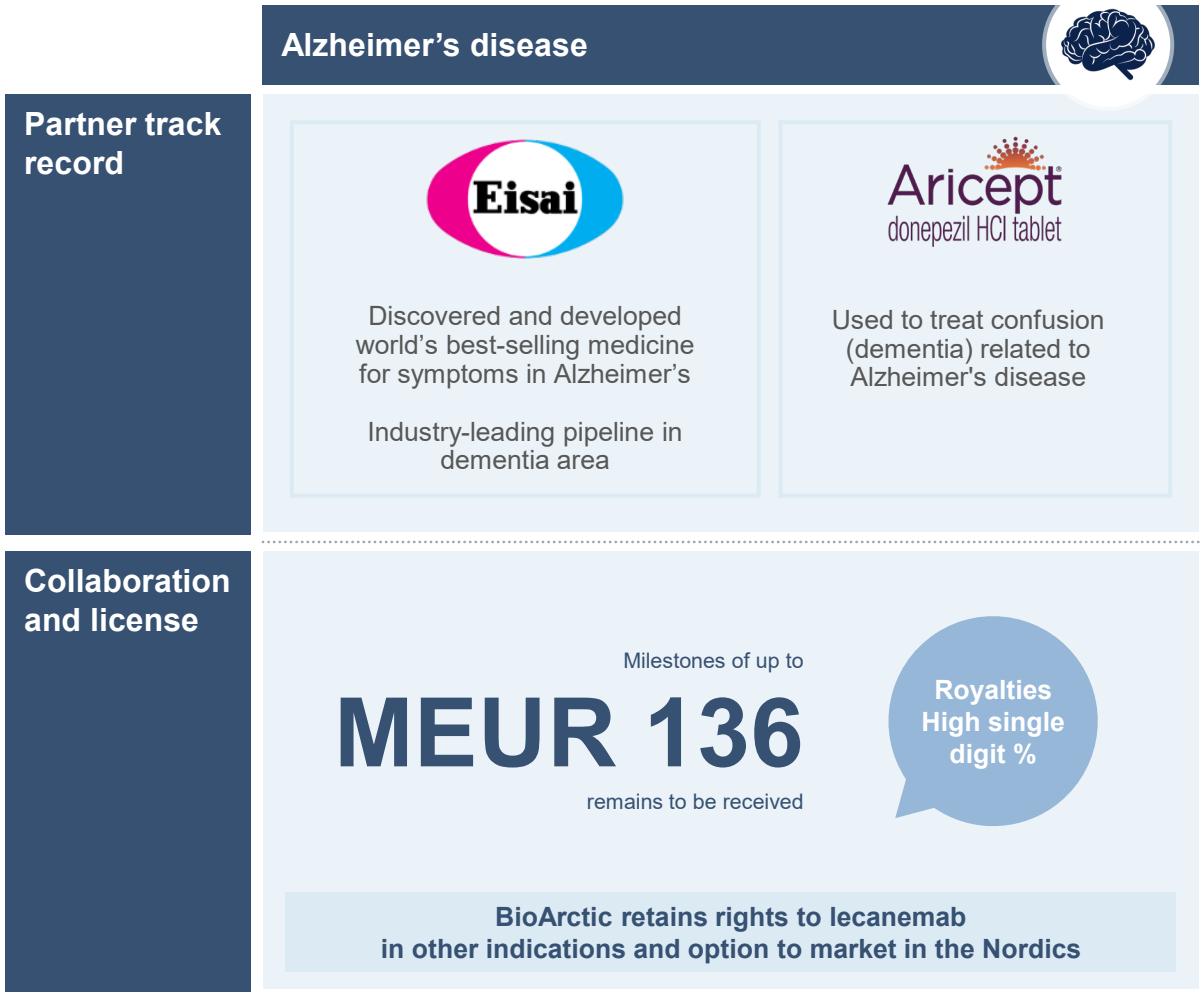
Partnership model to de-risk clinical development and optimize commercialization opportunity



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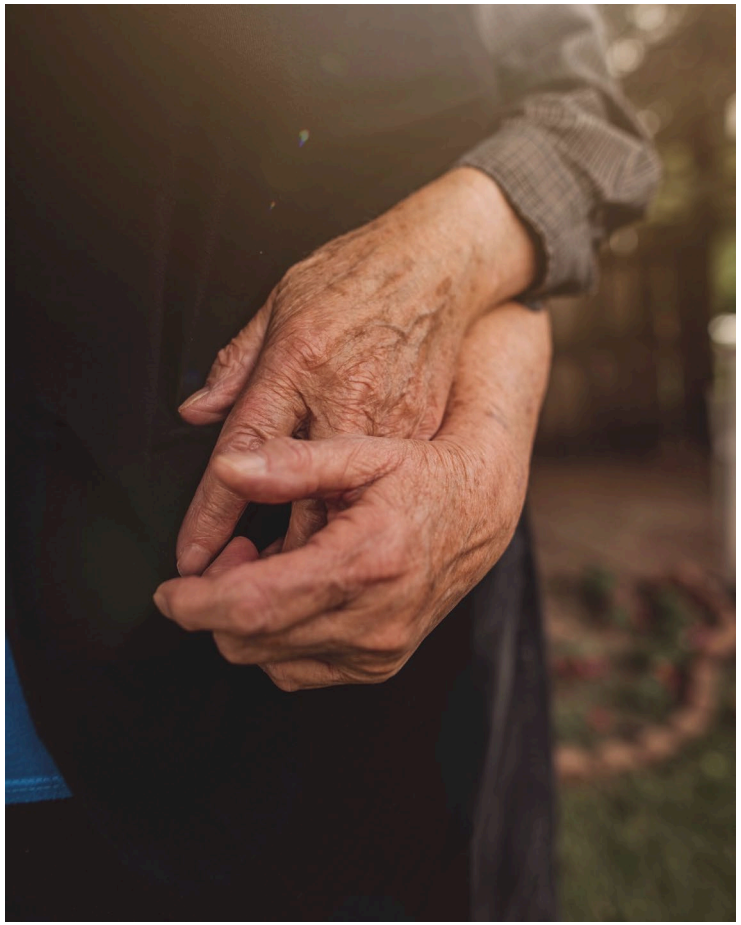
Q3 highlights

Alzheimer’s disease – Lecanemab

- Lecanemab showed positive results in the pivotal Phase 3 study, Clarity AD, in early Alzheimer's disease, and both primary and all key secondary endpoints were met with high statistical significance
- New lecanemab data were presented by Eisai at the Alzheimer's Association International Conference (AAIC), including data on a subcutaneous formulation of lecanemab
- The FDA accepted the Biologics License Application (BLA) and granted priority review for lecanemab for treatment of early Alzheimer’s disease under the accelerated approval pathway, which resulted in a milestone of MEUR 15 from Eisai in the quarter

Parkinson’s disease – BAN0805

- BioArctic has agreed with AbbVie to take back the project and transfer of data is ongoing. BioArctic is currently reviewing different options to progress the project.



Clarity AD – pivotal Phase 3 study confirmed positive Phase 2b results with primary and all key secondary endpoints met with high statistical significance

Important parameters

- Right target
- Right patient population
- Right dose & exposure
- Right study design
- Right safety
- Right collaborations

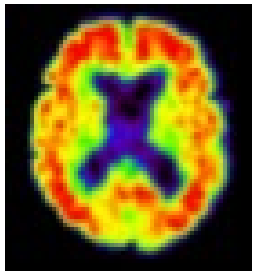
Phase 3 Study Design

Patient inclusion

Global recruitment:
- US, EU and Asia

Inclusion criteria:
- Early AD = MCI due to AD or mild AD
- Positive amyloid PET/CSF

1,795
Early Alzheimer patients



Treatment 18 months

Randomized, double-blind, placebo controlled, parallel-group study

Lecanemab
10 mg/kg twice a month

Placebo twice a month

Primary analysis:
- Change from baseline in CDR-SB
- Safety and tolerability

Key secondary analyses:
- Change from baseline in brain amyloid PET centiloid
- Change from baseline in ADAS-cog14, ADCOMS, ADCS MCI-ADL

Other key analyses:
- Population PK and Biomarkers: amyloid PET SUVr and positive to negative conversion, tau PET, blood and CSF biomarkers incl. Aβ42/40, p-tau, t-tau, neurogranin, Neurofilament light

Open-label extension (OLE)

Lecanemab
10 mg/kg twice a month

Once a week subcutaneous dosing being explored

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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 as shown in Phase 2b[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. 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.

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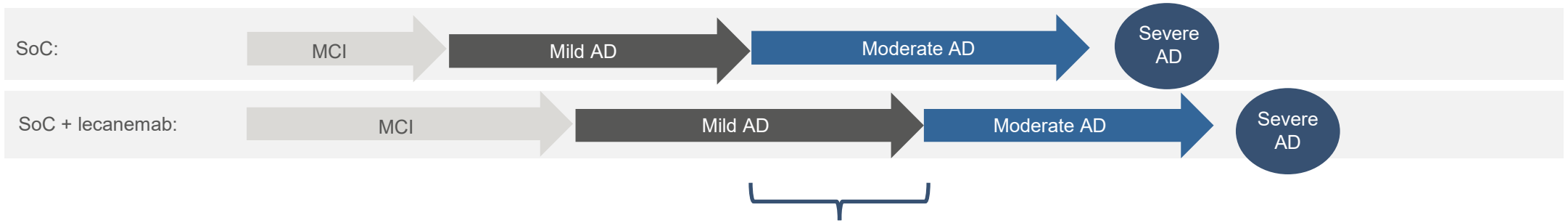
Disease modeling suggests that lecanemab could delay progression to moderate Alzheimer´s Dementia by several years

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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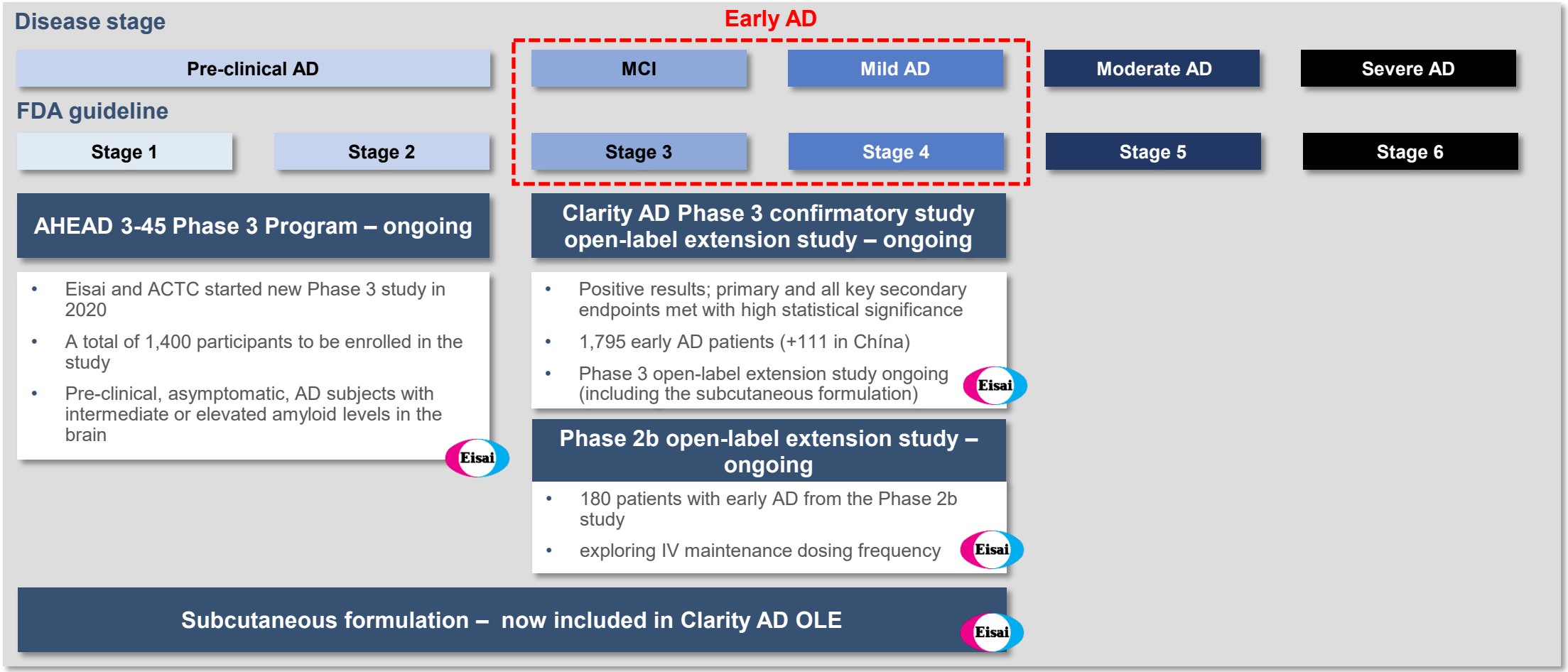
Lecanemab – broad late-stage clinical program



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

Eisai

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Lecanemab – potential to lead the paradigm shift in the treatment of Alzheimer's disease

Increased likelihood for lecanemab success

- → Positive and consistent Phase 2b results
- → Phase 2b OLE further strengthens the Phase 2b results
- → Phase 3 study "Clarity AD" was positive and confirmed the positive Phase 2b results
- → Phase 3 met the primary and all key secondary endpoints with high statistical significance

✓

Opportunity to be first with full approval in US, Japan and EU

- → BLA submission under the accelerated approval pathway accepted by the FDA in July 2022 with Priority Review (PDUFA, Jan 6, 2023)
- → Submission for full approval in the US, EU and Japan planned by Q1 2023

✓

Opportunity to differentiate

- → Unique binding profile
- → Rapid and profound brain amyloid clearance
- → Early onset of clinical effect in slowing cognitive decline
- → Good tolerability profile with relatively low ARIA incidence
- → Full dose from day one

✓

Further development programs

- → Subcutaneous injection
- → Blood biomarkers utilized for screening and to explore reduced dosing frequency for maintenance treatment
- → Expanded Alzheimer's disease populations:
  - → Selected for AHEAD in pre-symptomatic individuals
  - → Selected as background treatment for DIAN-TU NexGen study – dominantly inherited Alzheimer disease

✓

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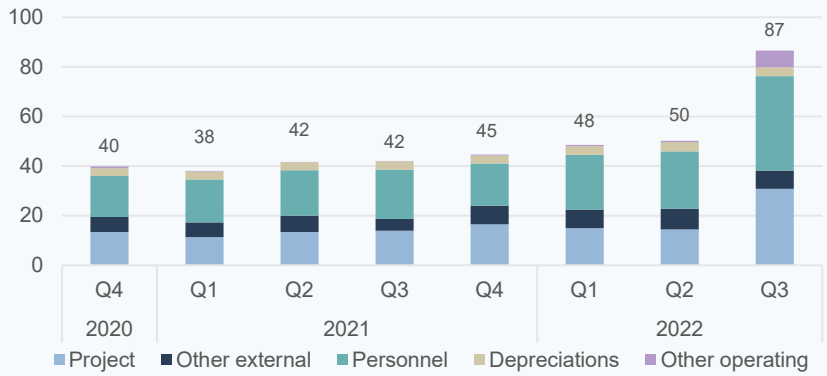
Financial Summary

Net revenues and operating profit Q3 2022

Net Revenues (MSEK)

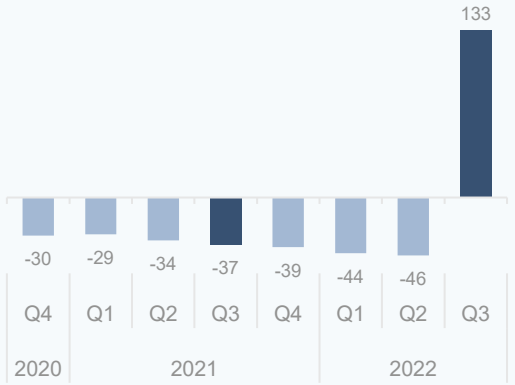
- Net revenues were 218 MSEK (4) for the third quarter. The increase in the third quarter is mainly explained by the milestone payment of 15 MEUR from Eisai and the settlement with AbbVie which contributed 48 MSEK to net revenue.

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 133 MSEK (-37) for the third quarter

Operating expenses are expected to be in the range of 220 - 260 MSEK for the financial year January - December 2022, compared to MSEK 166 in 2021

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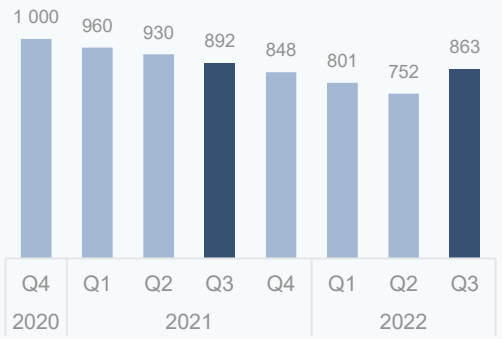
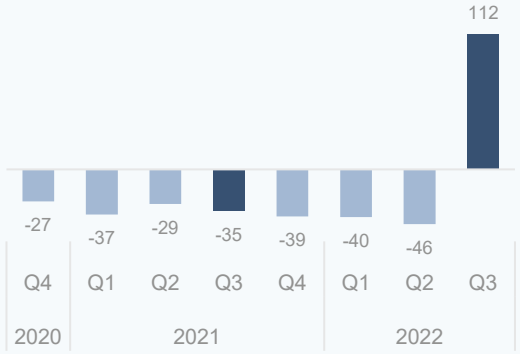
Cash and net result Q3 2022

Cash Balance (MSEK)



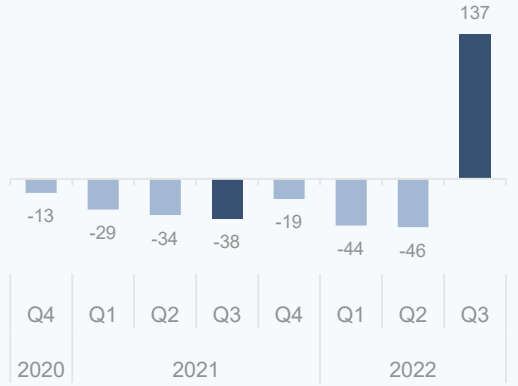
- Cash balance amounted to 863 MSEK at the end of the third quarter

Cash Flow From Operating Activities (MSEK)



- Operating cash flow amounted to 112 MSEK (-35) during Q3

Net Result (MSEK)



- Net result for the period was 137 MSEK (-38)
- The increase was mainly related to the 15 MEUR milestone payment from Eisai

In summary, BioArctic continues to have a strong financial position

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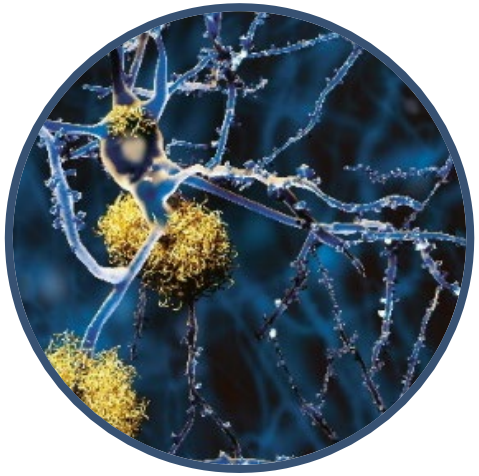
Upcoming news and closing remarks

Upcoming news flow

Alzheimer's disease



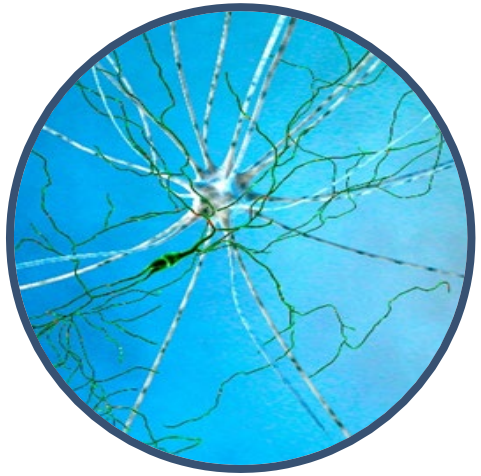
Lecanemab (Eisai)

- BLA submission under the accelerated approval pathway accepted by the FDA in July 2022 with Priority Review (PDUFA, Jan 6, 2023)
- Data to be disclosed at international congresses
- Regulatory submissions

Discovery stage programs

- Advancement of projects

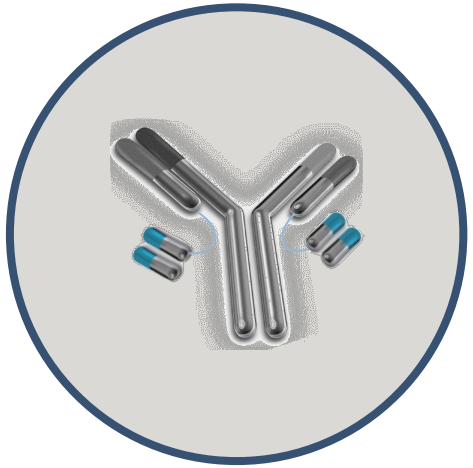
Parkinson's disease



BAN0805

Data presented at international congresses

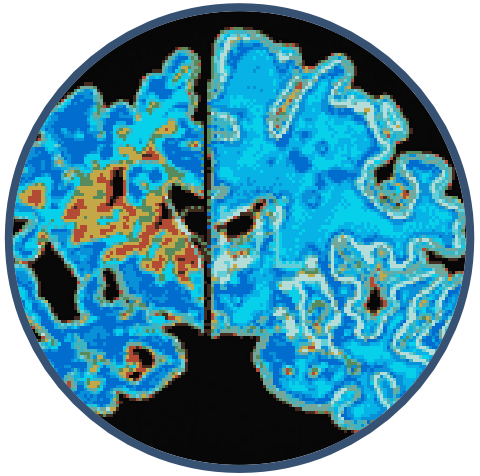
Blood-brain barrier



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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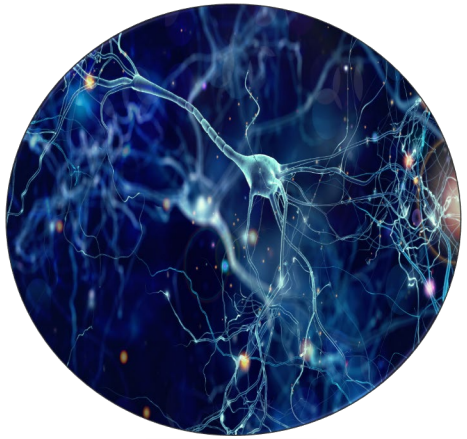
BioArctic: With Patients in Mind

Great science



Great projects

Great partners

Great people

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GUNILLA OSSWALD, CEO

JAN MATTSSON, CFO

OSKAR BOSSON, VP COMMUNICATIONS & IR

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- **Next Report:**
  Full Year Report
  Jan-Dec 2022
  on Feb 3, 2023
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