BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

Q2 Report April-June 2022

Stockholm, July 12, 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 around MSEK 750 (MUSD ~74[1]) in cash and **valuable collaboration agreements**

1) FX as per June 30, 2021

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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[3]				
	Lecanemab (BAN2401) *(AHEAD 3-45)*	Eisai[1]	Preclinical (asymptomatic) Alzheimer's disease[4]				
	BAN2401 back-up	Eisai					
	AD1801 (ApoE)						
	AD1503 (Trunc Abeta)						
	AD-BT2802						
	AD-BT2803						
	AD2603						
PARKINSON'S DISEASE	BAN0805[2] (alpha-synuclein)						
	PD1601 (alpha-synuclein)						
	PD1602 (alpha-synuclein)						
OTHER CNS DISORDERS	Lecanemab (BAN2401)		Down's syndrome[5] Traumatic brain injury[5]				
	ND3014 (TDP-43)		ALS				
	ND-BT3814 (TDP-43 with BT)		ALS				
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform						

as of June 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) AbbVie in-licensed BAN0805 in late 2018 and has developed the antibody with the designation ABBV-0805. On April 20, 2022, AbbVie informed BioArctic that it had taken a strategic business decision to terminate the collaboration regarding BioArctic's alpha-synuclein portfolio. We are currently working with AbbVie to transfer the projects back with the aim of finding a new partner
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

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

	Alzheimer's disease	Parkinson's disease
Partner track record	Eisai: Discovered and developed world's best-selling medicine for symptoms in Alzheimer's Industry-leading pipeline in dementia area Aricept donepezil HCl tablet: Used for symptomatic treatment of Alzheimer's disease	abbvie: World's all-time best-selling medicine (BUSD 20) Duopa carbidopa/levodopa: Approved product for symptoms associated with Parkinson's disease HUMIRA adalimumab: 10 different indications in immunology
Collaboration and licenses	Milestones of up to **MEUR 151** remains to be received Royalties High single digit % **BioArctic retains rights to lecanemab in other indications and option to market in the Nordics**	Milestones of **MUSD 130** received, out of MUSD 755 Project transfer ongoing AbbVie has taken a strategic business decision to end its collaboration with BioArctic regarding its alpha-synuclein portfolio. BioArctic is currently working with AbbVie to transfer the projects back with the aim of finding a new partner.

The acceptance of the BLA by the FDA recently entitles BioArctic to a milestone payment of MEUR 15 from Eisai.

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Q2 and recent events

Alzheimer's disease – Lecanemab

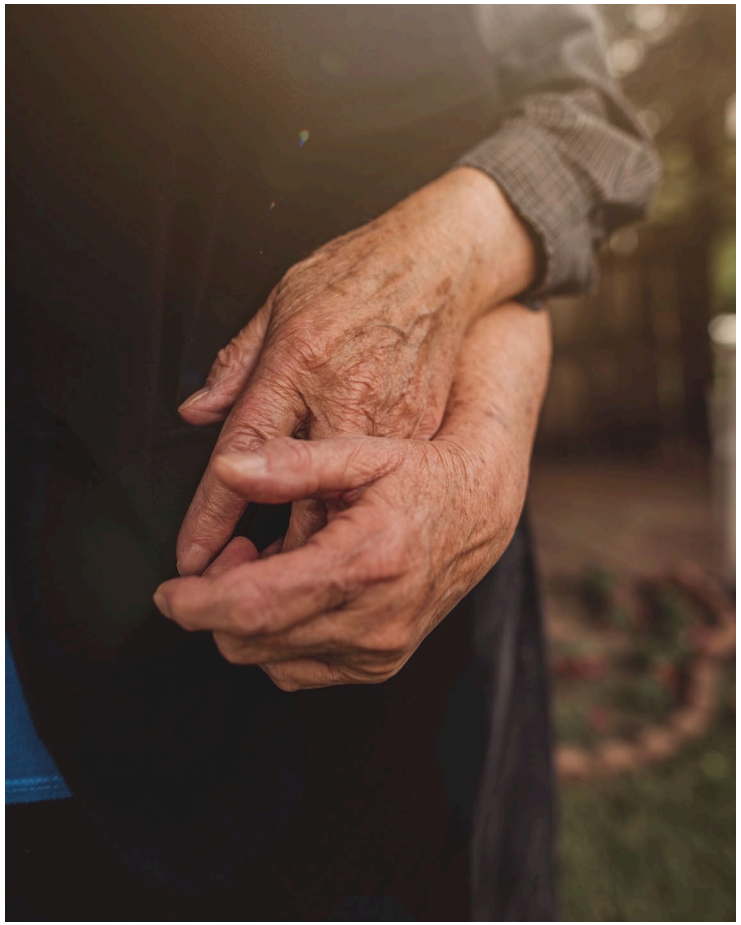
- The FDA recently notified Eisai that the Biologics License Application (BLA) for lecanemab for early Alzheimer's disease under the accelerated approval pathway has been accepted for review, with priority review granted. The PDUFA action date for the application is January 06, 2023
- Modeling published in Neurology and Therapy suggests that lecanemab could delay progression to Alzheimer's dementia by several years

Parkinson's disease – BAN0805

- BioArctic received a new drug substance patent in the US for BAN0805 against Parkinson's disease
- AbbVie terminated the collaboration with BioArctic on the company's alpha-synuclein projects due to a strategic business decision. BioArctic is actively working together with AbbVie to transfer the projects back with the aim of finding a new partner

ALS – ND3014

- The TDP-43 project is progressing very well utilizing BioArctic's technology platform and vast experience in development of antibodies targeting aggregating proteins. Humanization of antibodies has been initiated



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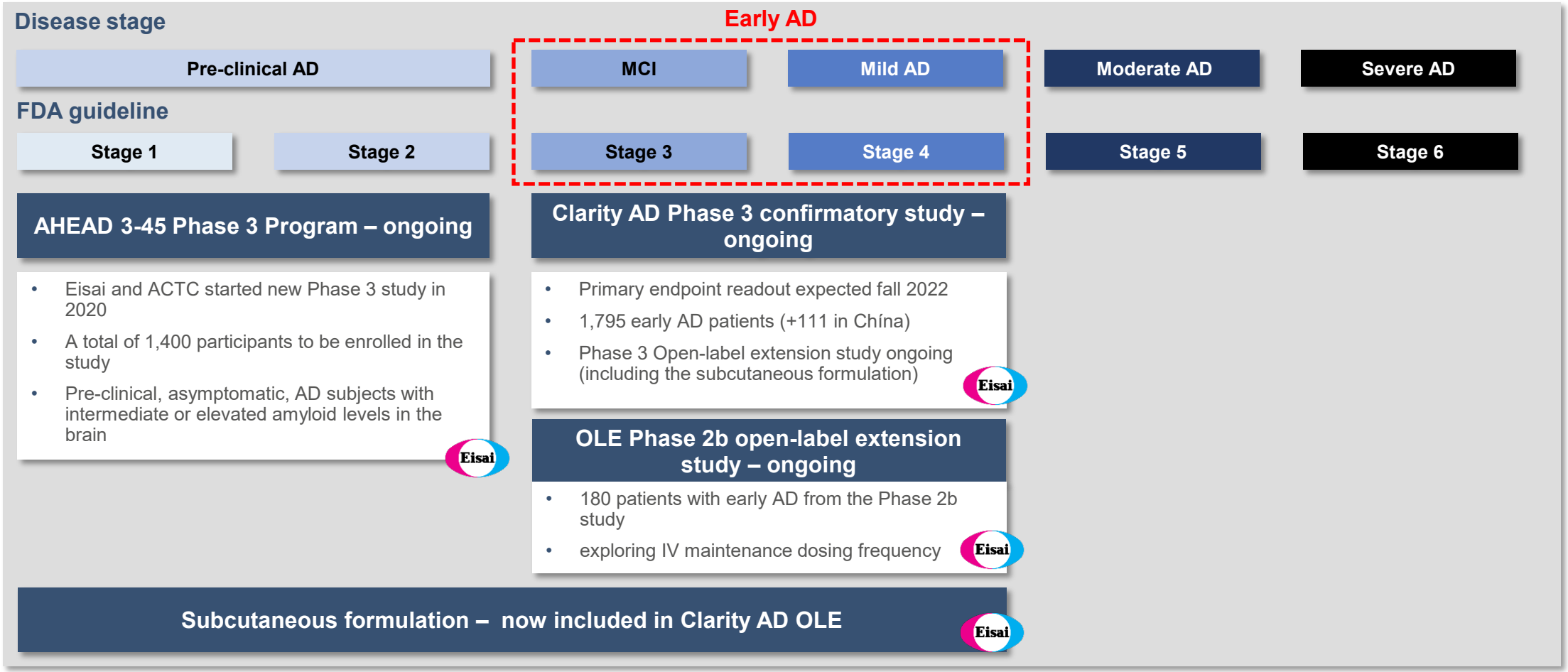
Lecanemab – broad late-stage clinical program



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

Eisai

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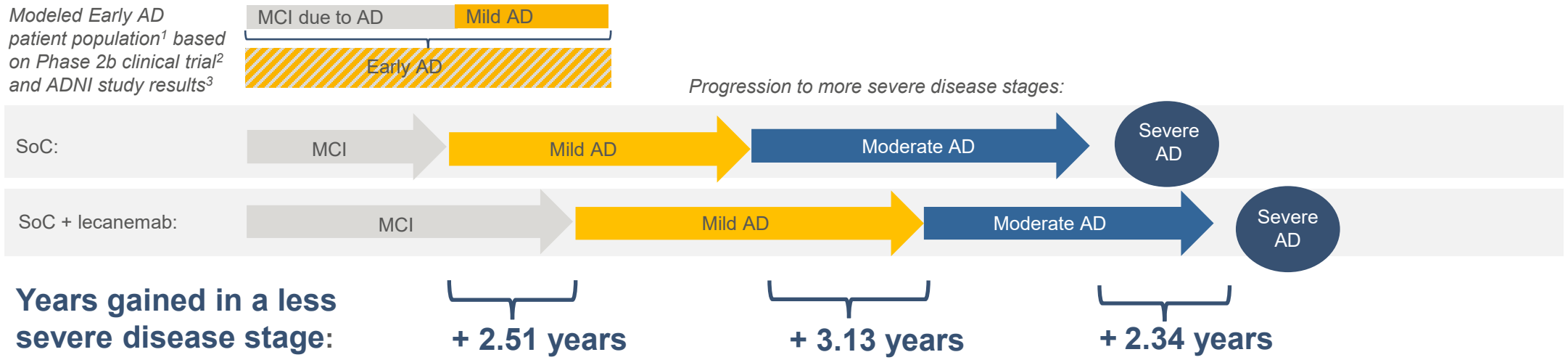
Disease modeling suggests that lecanemab could delay progression to Alzheimer´s dementia by several years

Simulated mean time advancing to mild, moderate, and severe Alzheimer's disease (AD) dementia was longer for patients in the lecanemab-treated group than for patients in the standard of care group



The results from the modeling show the potential clinical value of lecanemab for patients with early AD and how it can slow the rate of disease progression, delay progression to AD dementia with several years and 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 – 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" designed to confirm the positive Phase 2b results

✓

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, pending topline Phase 3 data expected fall 2022

✓

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 low ARIA-E 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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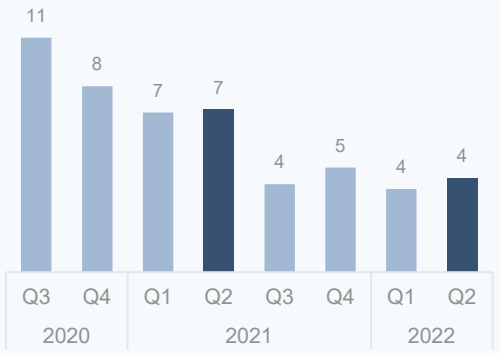
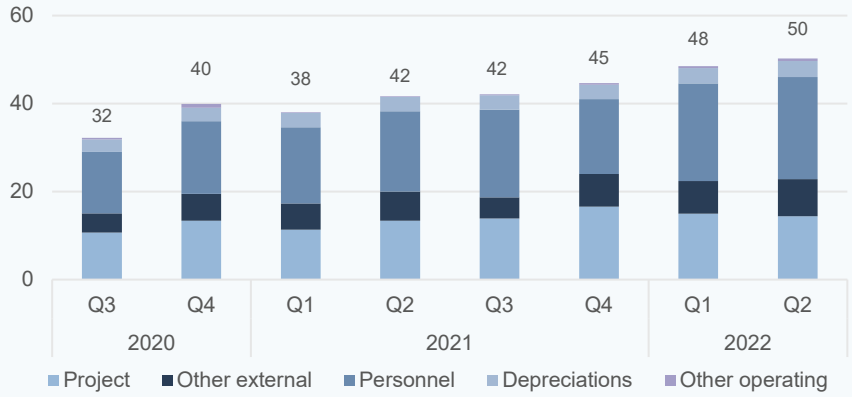
Financial Summary

Net revenues and operating profit/loss Q2 2022

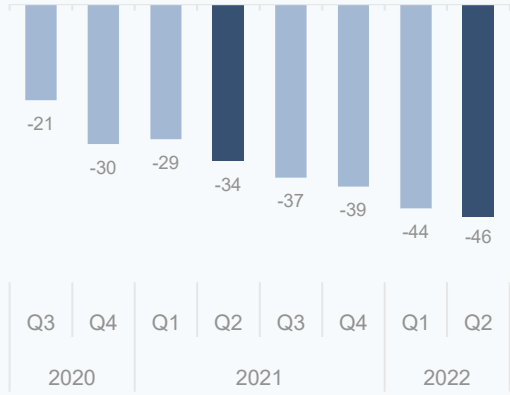
Net Revenues (MSEK)



OPEX by item (MSEK)



Operating Profit/Loss (MSEK)



- Net revenues were 4 MSEK (7) for the second quarter
- Milestone payment from Eisai of 15 MEUR will be recognized in the third quarter

- Total costs in the quarter were higher than the same period previous year
- Costs will increase going forward as we continue to build a commercial organization and continue to progress our expanded project portfolio

- Operating loss was -46 MSEK (-34) for the second quarter

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

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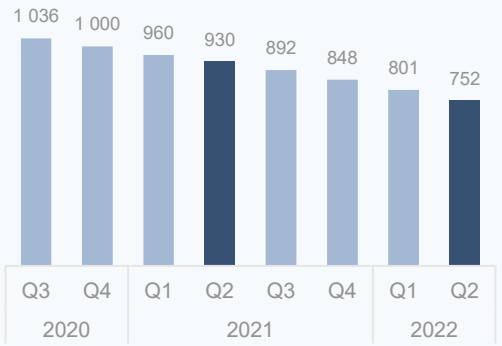
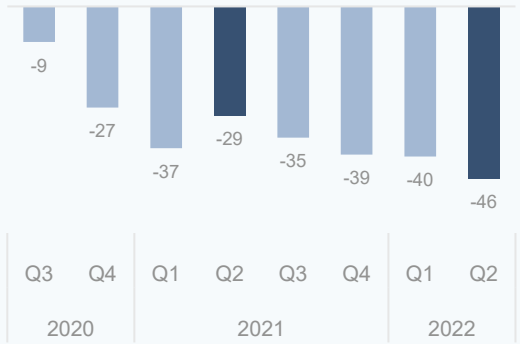
Cash and net result Q2 2022

Cash Balance (MSEK)



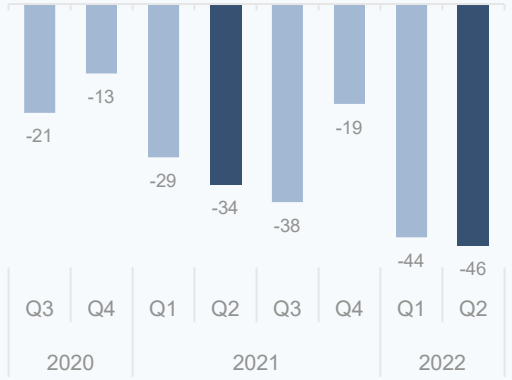
- Cash balance amounted to 752 MSEK at the end of the second quarter
- Milestone payment from Eisai of 15 MEUR will be received in the third quarter

Cash Flow From Operating Activities (MSEK)



- Operating cash flow amounted to -46 MSEK (-29) during Q2

Net Result (MSEK)



- Net result for the period was -46 MSEK (-34)

In summary, BioArctic continues to have a strong financial position

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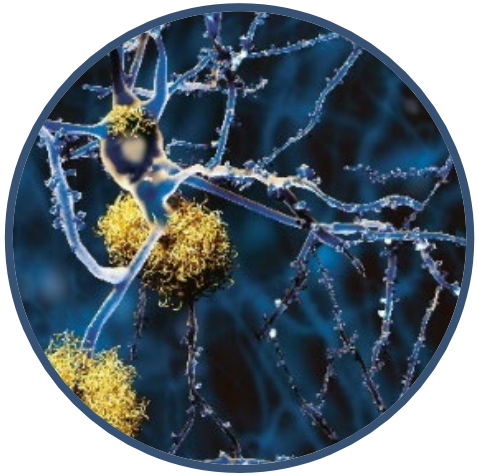
Upcoming news and closing remarks

Upcoming news flow

Alzheimer's disease



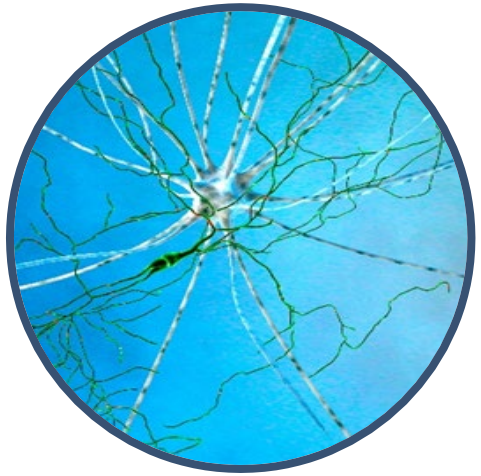
Lecanemab (Eisai)

- Clarity AD topline data fall 2022
- 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

Discovery stage programs

- Advancement of projects

Parkinson's disease

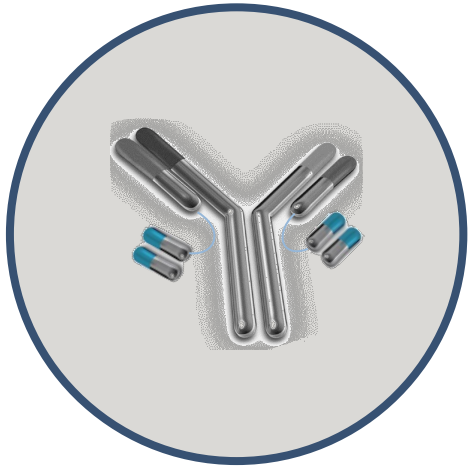


BAN0805

Data presented at international congresses

AbbVie has taken a strategic business decision to end its collaboration with BioArctic regarding its alpha-synuclein portfolio. BioArctic will now, in accordance with the license agreement, take back the project and prepare for future partnering.

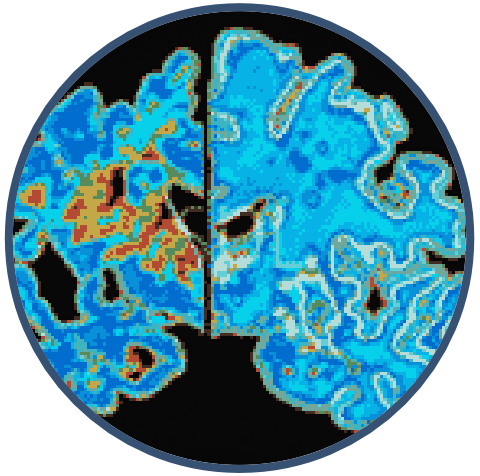
Blood-brain barrier



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:**
  Q3 Jun-Sep 2022
  on Oct 20, 2022
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Clarity AD – pivotal Phase 3 study to confirm positive Phase 2b results

Important parameters

- Right target
- Right patient population
- Right dose & exposure
- Right measurements
- Right safety

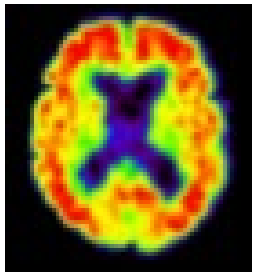
Phase 3 Study Design

Patient inclusion

Global recruitment:
- US, EU and Asia

Inclusion criteria:
- 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

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

Key analyses:
- Change from baseline in ADCOMS, ADAS-cog, ADCS MCI-ADL
- Change from baseline in brain amyloid PET SUVr
- Biomarkers: amyloid PET positive to negative conversion, tau PET, blood and CSF biomarkers incl. Aβ, 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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