BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

Q1 Report January-March 2022

Stockholm, April 28, 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 close to MSEK 800 (MUSD ~86[1]) in cash and **valuable collaboration agreements**

1) FX as per March 31, 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	ABBV-0805[2] (alpha-synuclein)	AbbVie					
	PD1601 (alpha-synuclein)	AbbVie					
	PD1602 (alpha-synuclein)	AbbVie					
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 March 31, 2021

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 develops 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
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 to treat confusion (dementia) related to 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 license	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 global rights to alpha-synuclein portfolio for all indications**

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 evaluate the best way forward.

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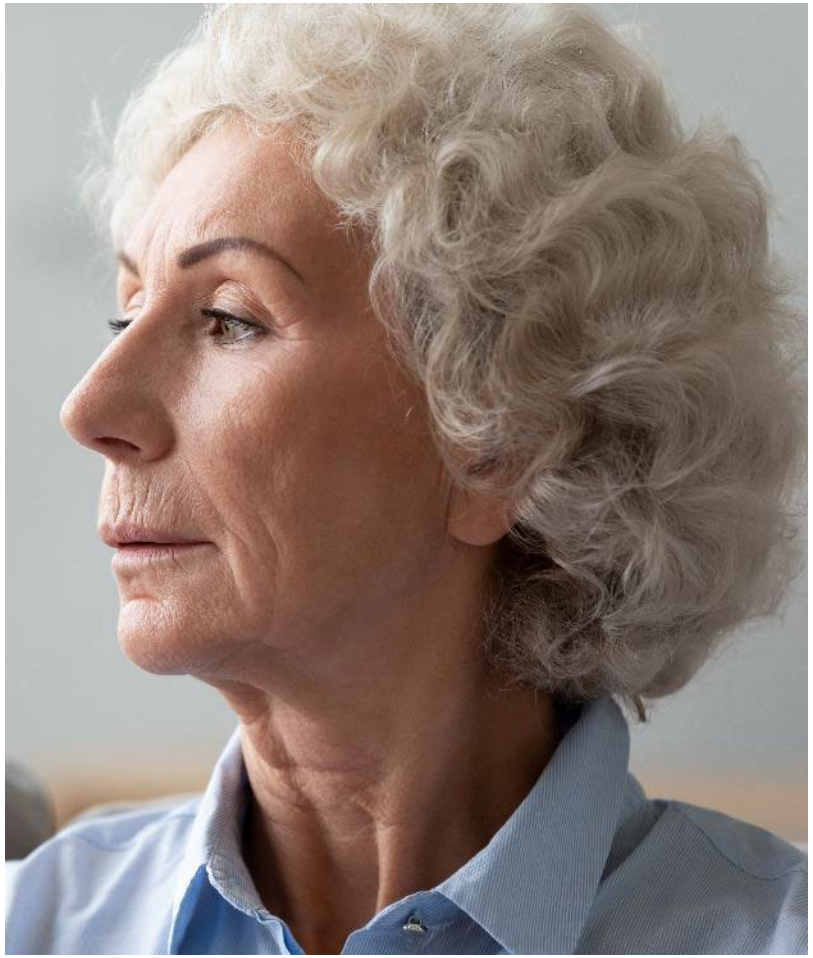
Q1 highlights

Alzheimer's disease – Lecanemab

- Eisai initiates submission of application data of lecanemab under the prior assessment consultation system in Japan, with the aim of an earlier regulatory approval
- Data presented at AD/PD congress in March continue to further strengthen and differentiate lecanemab towards competitors
- First patient enrolled in DIAN-TU NexGen study in dominantly inherited Alzheimer's disease were lecanemab is included as backbone anti-amyloid therapy in combination with tau therapies
- Project portfolio updated with one new project being added (ND-BT3814) and one being stopped (AD1502)

Other

- Continuing to build Nordic commercial organization
    - four new recruits with vast industry experience have now started



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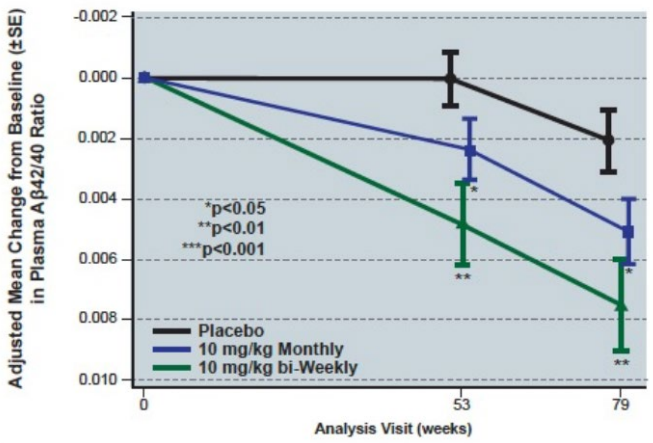
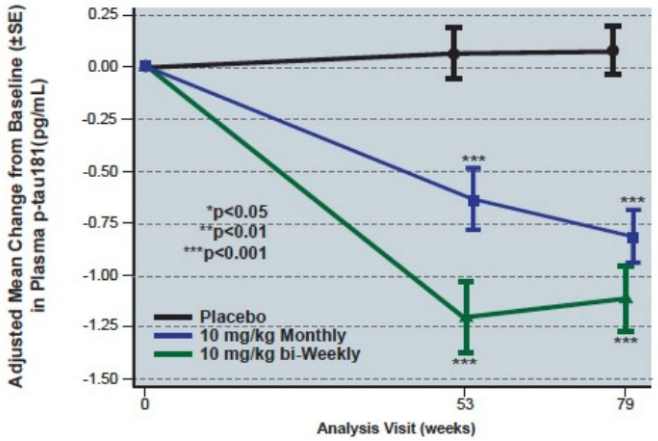
New data presented at AD/PD 2022 continues to strengthen lecanemab Robust effect on blood biomarkers in Phase 2b (Aβ 42/40 and p-tau 181)

"the AD/PD conference 2022 showcases the great achievements being done within the field and there is excitement towards the key results coming later this year"





Blood biomarker Aβ42/40 ratio

Robust effect on plasma Aβ42/40 ratio by lecanemab

Plasma Aβ42/40 ratio correlates with brain amyloid PET clearance

Blood biomarker p-tau 181

Robust effect on plasma p-tau181 by lecanemab

Targeting amyloid influence the downstream tau-related processes

Y-axis was inverted for plasma Aβ42/40 Ratio. Increase in plasma Aβ42/40 Ratio reflects decrease in brain amyloid levels for this inverted figure.

Source: Data presented at AD/PD 2022 by BioArctic and Eisai

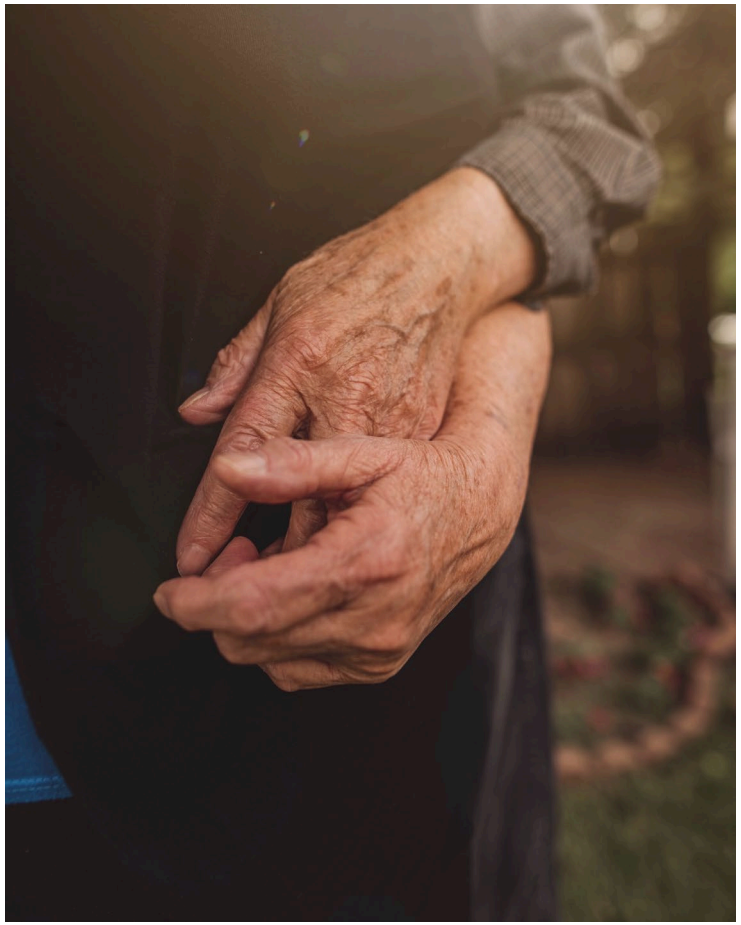
Events after the quarter

Parkinson's disease – AbbVie

- AbbVie took a strategic business decision to end its collaboration with BioArctic on the alpha-synuclein portfolio, including ABBV-0805. BioArctic will now, in accordance with the license agreement, take back the project and evaluate the best way forward.

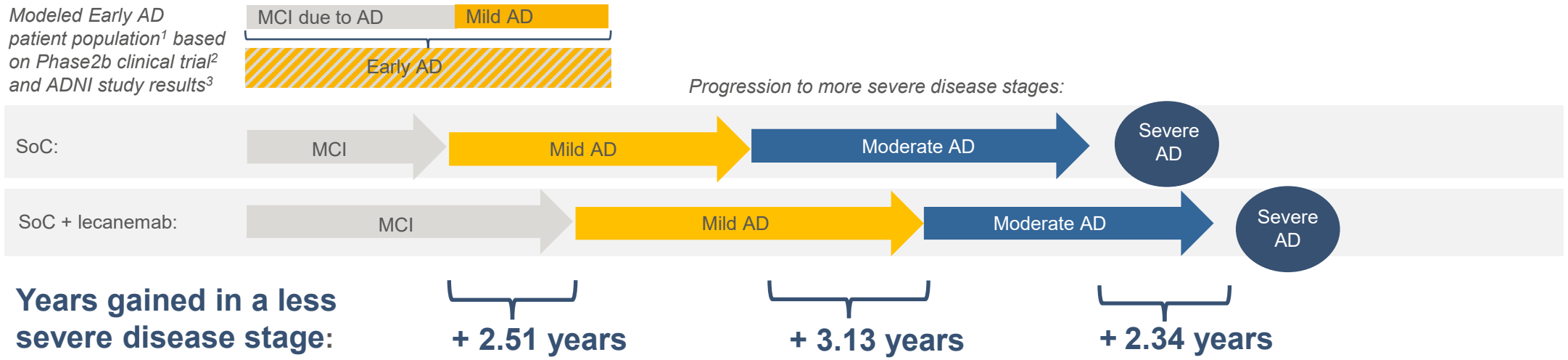
Alzheimer's disease – Lecanemab

- A recently published article in Neurology and Therapy based on disease modeling suggests that lecanemab could delay the progression to Alzheimer's dementia by several years.



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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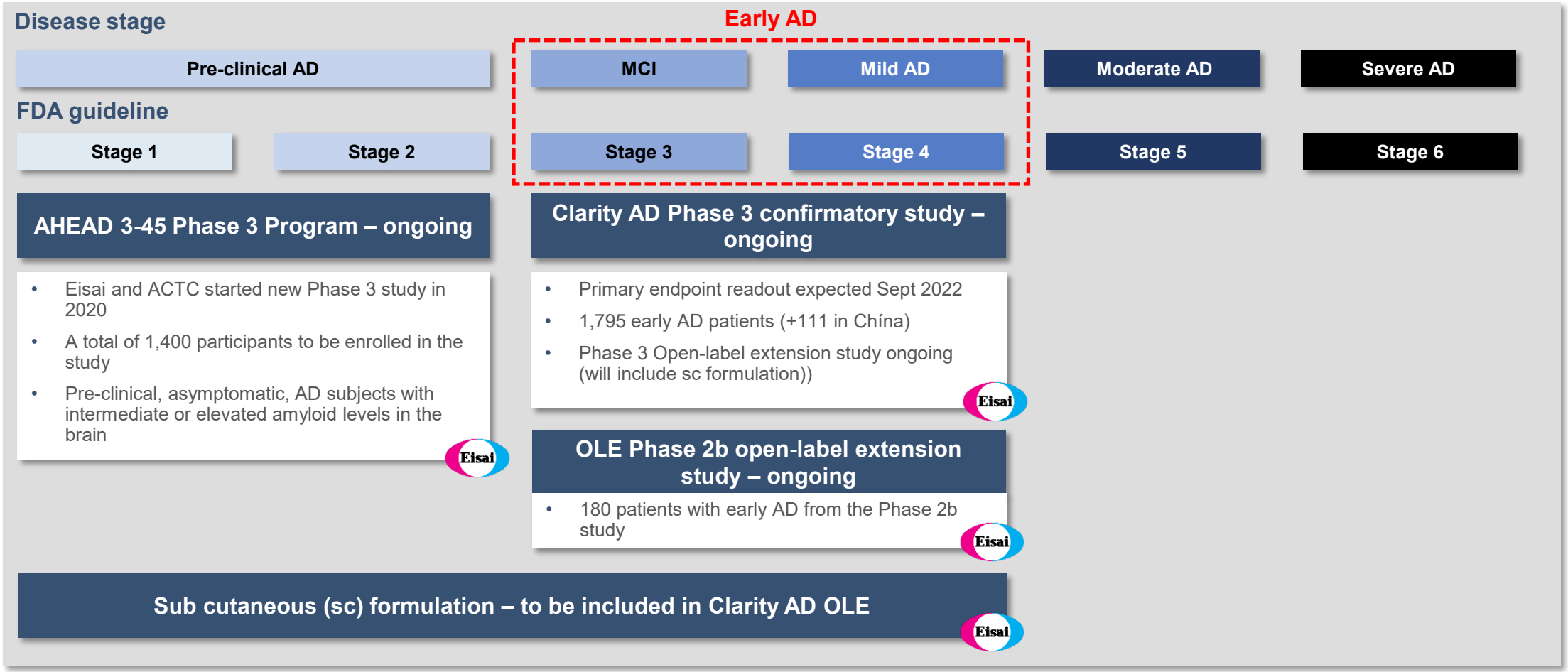
Lecanemab – broad late-stage clinical program



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" designed to confirm the positive Phase 2b results

✓

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

- → Accelerated approval pathway ongoing in the US and submission is expected to be completed Q2 2022
- → Submission for full approval in the US, EU and Japan planned by Q1 2023, pending topline Phase 3 data expected Sept 2022

✓

Opportunity to differentiate

- → Rapid and profound brain amyloid clearance
- → Early onset of clinical effect in slowing cognitive decline
- → Better tolerability profile than competition
- → Full dose from day one

✓

Further development programs

- → Subcutaneous injection
- → Blood biomarkers utilized 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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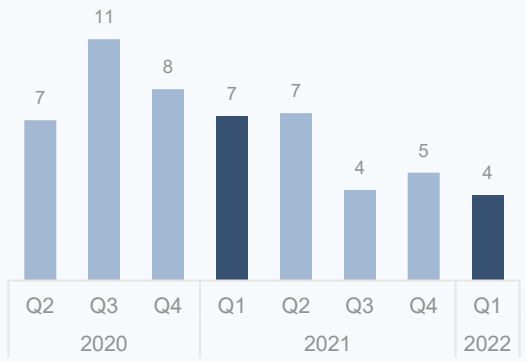
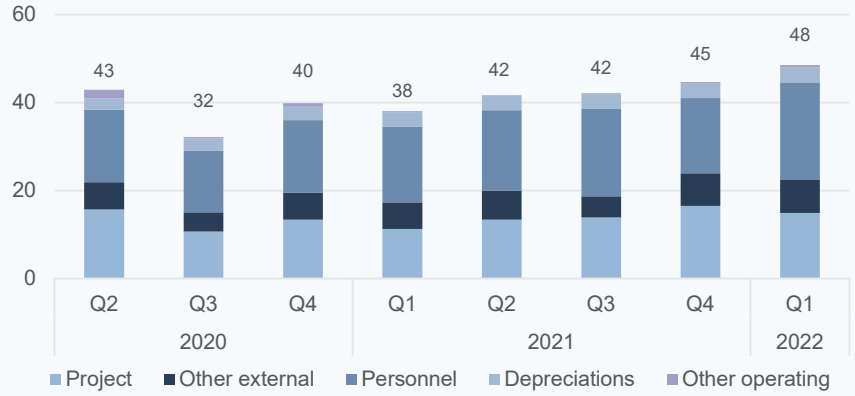
Financial Summary

Net revenues and operating profit/loss Q1 2022

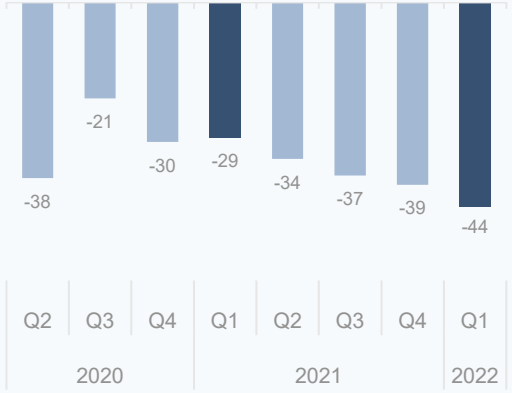
Net Revenues (MSEK)



OPEX by item (MSEK)



Operating Profit/Loss (MSEK)



- Net revenues were 4 MSEK (7) for the first 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 project portfolio

- Operating loss was -44 MSEK (-29) for the first 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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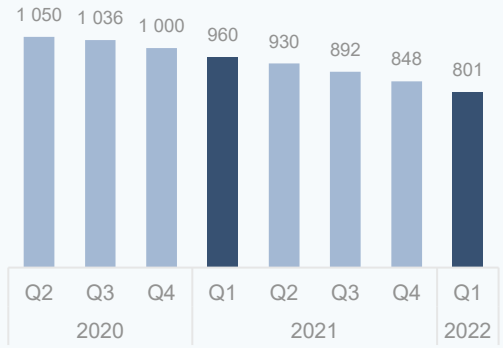
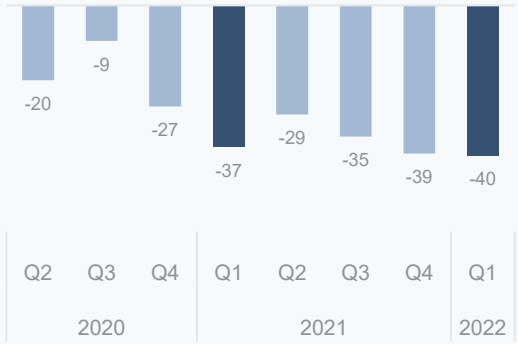
Cash and net result Q1 2022

Cash Balance (MSEK)



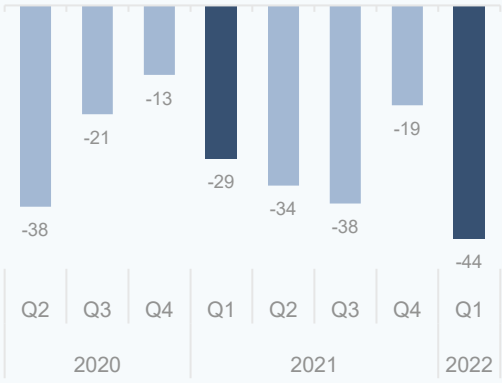
- Cash balance amounted to 801 MSEK at the end of the first quarter

Cash Flow From Operating Activities (MSEK)



- Operating cash flow amounted to -40 MSEK (-37) during Q1

Net Result (MSEK)



- Net result for the period was -44 MSEK (-29)

In summary, BioArctic continues to have a strong financial position

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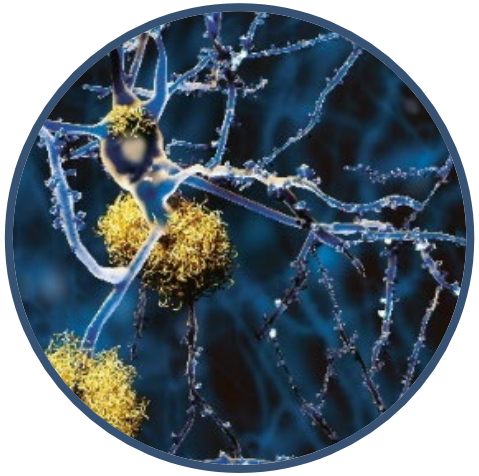
Upcoming news and closing remarks

Upcoming news flow

Alzheimer's disease



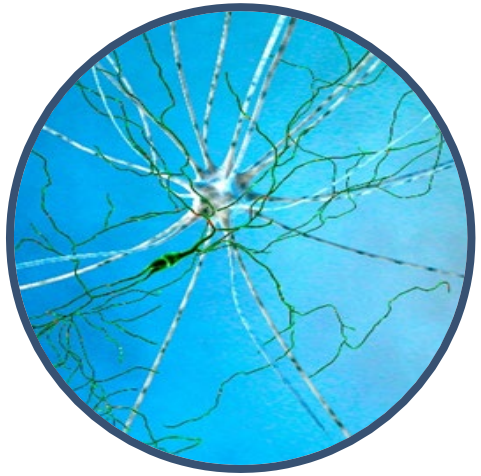
Lecanemab (Eisai)

- Rolling submission for accelerated approval in the US expected to be completed Q2 2022
- Clarity AD topline data expected in September 2022
- Data to be disclosed at international congresses

Discovery stage programs

- Advancement of projects

Parkinson's disease

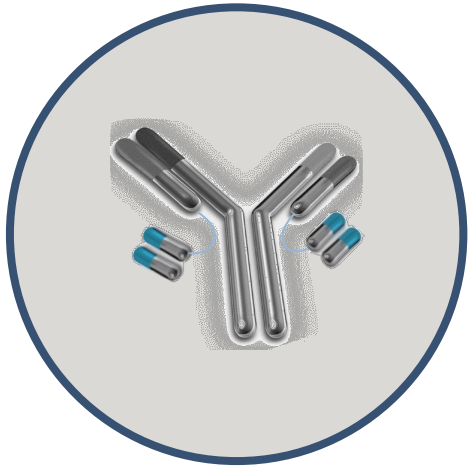


ABBV-0805 (AbbVie*)

- 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 evaluate the best way forward.

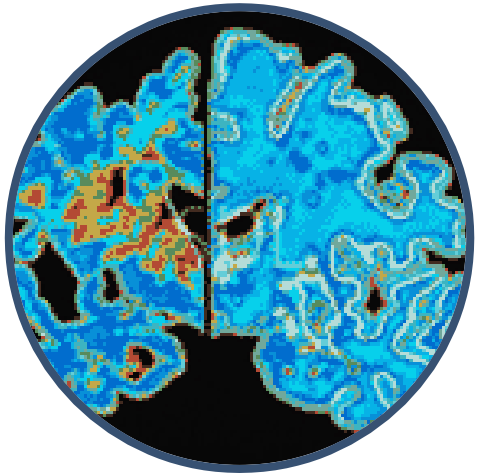
Blood-brain barrier



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

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