BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

Q1 Report January-March 2023

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BioArctic will, through world-leading innovative research, create drugs that improve the lives of patients with neurodegenerative diseases.

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 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

Alzheimer's disease

Partner track record

Eisai

Discovered and developed world's best-selling medicine for symptoms in Alzheimer's disease

Industry-leading pipeline in dementia area

Aricept donepezil HCl tablet

Used to treat confusion (dementia) related to Alzheimer's disease

Collaboration and license

Milestones of up to

MEUR 101

remains to be received

Royalties High single digit %

BioArctic retains rights to lecanemab in other indications and option to market in the Nordics

The approval in the US and submissions in the EU and Japan entitled BioArctic to milestones of MEUR 35 during the first quarter

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Leqembi™ (lecanemab) has the potential to become the first anti-Aβ antibody to receive full approval globally

USA

Granted accelerated approval Jan 6, 2023

Submission for full approval Jan 6, 2023. Priority review granted with PDUFA July 6, 2023

Veterans' Health Administration provided coverage for Leqembi March 13, 2023

Eisai plans to submit s.c. formulation and maintenance dosing applications by Q1 2024

Japan

Marketing authorization application submitted on January 16, 2023.

Granted priority review on January 30, 2023

Expected PMDA decision H2 2023

EU

Marketing authorization application submitted on January 9, 2023

Accepted for a standard review on January 26, 2023

Expected EMA decision Q1 2024

China

Initiated Biologics License Application in December 2022.

Granted priority review on February 28, 2023

Expected NMPA decision Q1 2024

PDUFA – Prescription Drug User Fee Act
PMDA – Pharmaceuticals and Medical Devices Agency
EMA – European Medicines Agency
NMPA – National Medical Products Administration
s.c. – subcutaneous

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AD/PD held in Gothenburg March 28 – April 1

A new era for Alzheimer's disease - Positive atmosphere focused on new treatment opportunities and the progress of blood biomarkers

New lecanemab-data presented at the AD/PD congress focused on health-related quality of life outcomes, safety and the unique binding profile of the antibody

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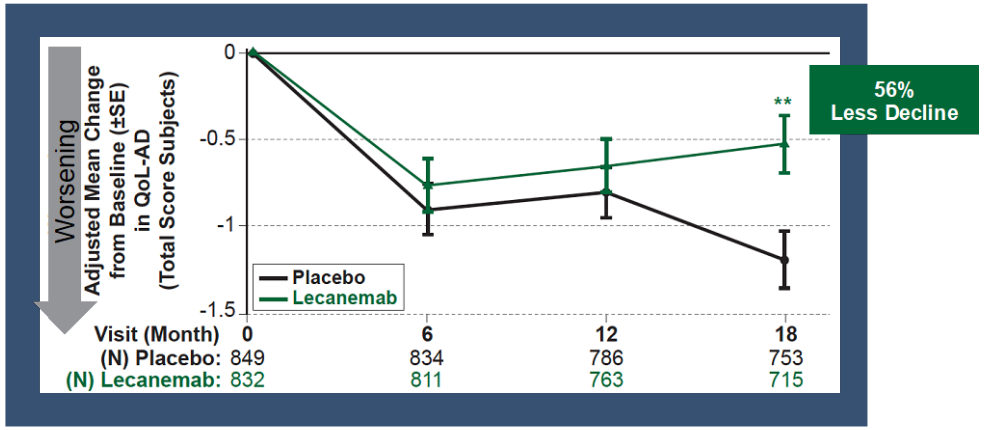
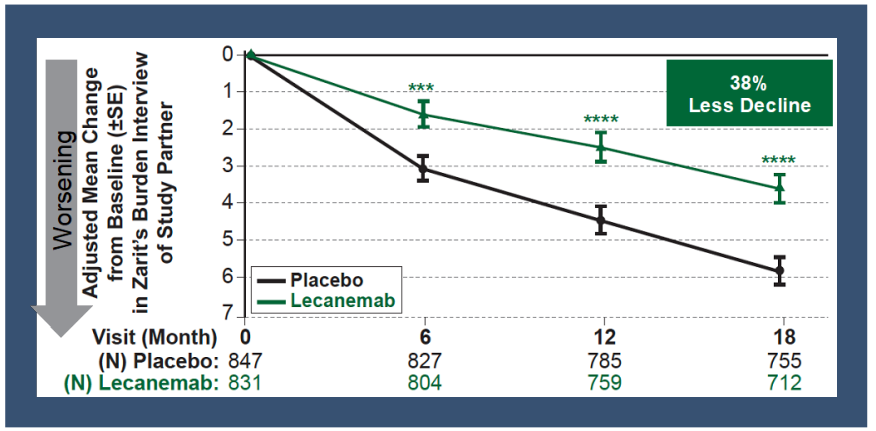
AD/PD highlights – Quality of Life (QoL) results presented

- **Lecanemab** was associated with a relative **preservation of health-related quality of life and caregiver burden**, as reported by patients and their care partners, with consistent benefits seen across different scales
- At month 18, adjusted mean change from baseline in in two different **quality of life-scales by subject** (EQ-5D-5L and QOL-AD) showed **49% and 56%** less decline, respectively
- **Study partner burden** measured by Zarit Burden Interview showed **38%** less decline at 18 months
- Assessment results were consistent across randomization sub-groups incl ApoE genotype

QOL-AD (Total Score Subject)



Study Partner Burden (total score)



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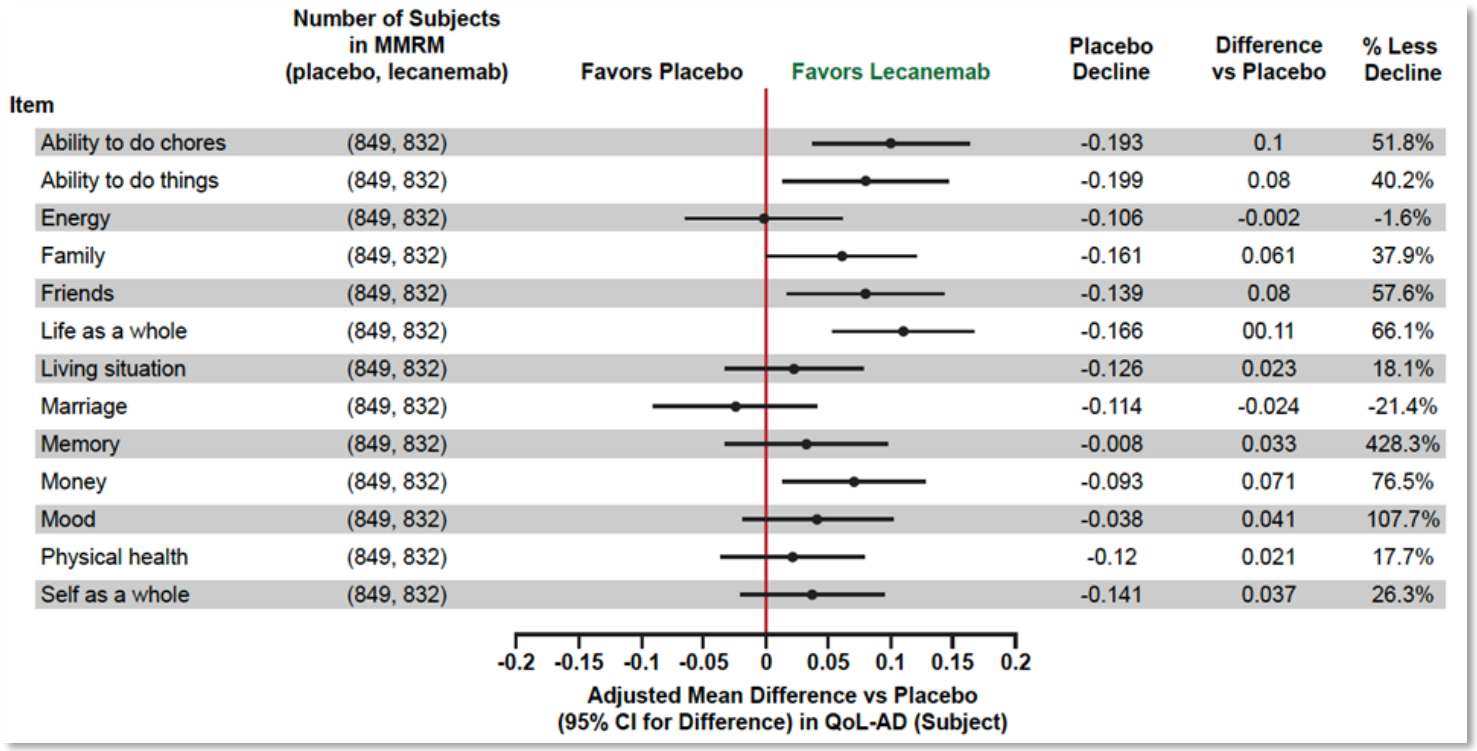
AD/PD highlights – Tangible differences in daily life activities for subjects with Alzheimer disease achieved with lecanemab treatment



The quality-of-life scale by subject (QOL-AD) showed 56% less decline across 13 sub-domains

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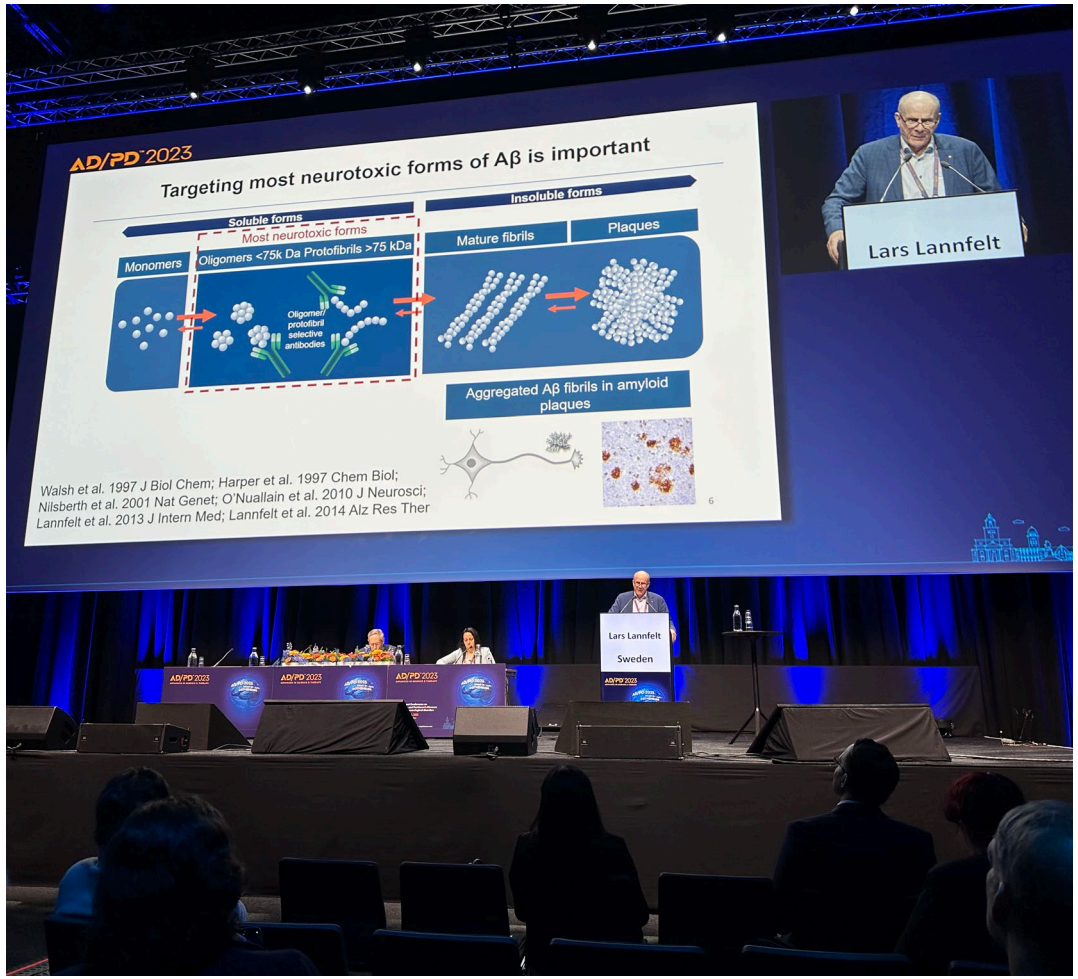
AD/PD highlights – three presentations on the unique binding properties and safety of lecanemab

Lecanemab's unique binding properties
Lecanemab has shown relatively low binding to a specific form of Aβ (CAA fibrils) which potentially explains low frequency of ARIA

ARIA With the Use of Antiplatelets or Anticoagulants in Early Alzheimer's Disease
In Clarity AD, ARIA occurred at similar frequency in lecanemab-treated participants irrespective of antiplatelet or anticoagulant drug use.

Isolated ARIA-H in Patients Treated with Lecanemab in the Clarity AD Study in Early Alzheimer's Disease
In Clarity AD, the frequency, temporal pattern and association with ApoE genotype of isolated ARIA-H in lecanemab group was similar to that in the placebo group.



CAA – Cerebral Amyloid Angiopathy
ARIA-E – Amyloid Related Imaging Abnormalities Edema
ARIA-H – Amyloid Related Imaging Abnormalities Hemorrhage

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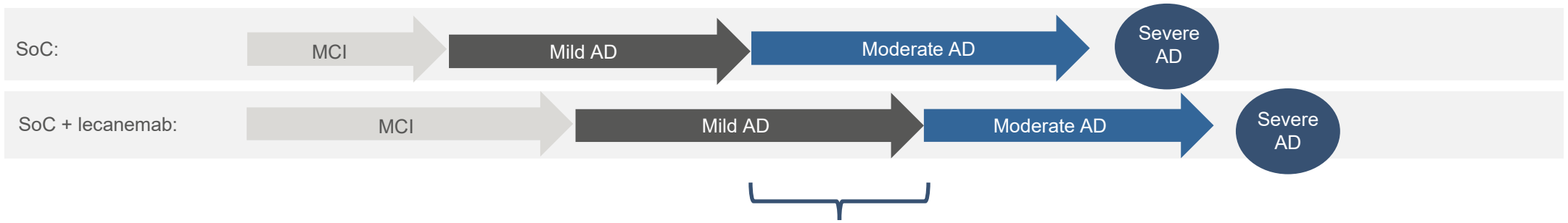
After the period – modelling study shows that lecanemab could delay progression to later stages of disease with 2-3 years

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: + 2-3 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. Tahami Monfared, A.A., Ye, W., Sardesai, A. *et al.* A Path to Improved Alzheimer's Care: Simulating Long-Term Health Outcomes of Lecanemab in Early Alzheimer's Disease from the CLARITY AD Trial. *Neurol Ther* (2023). https://doi.org/10.1007/s40120-023-00473-w

MCI – Mild cognitive Impairment

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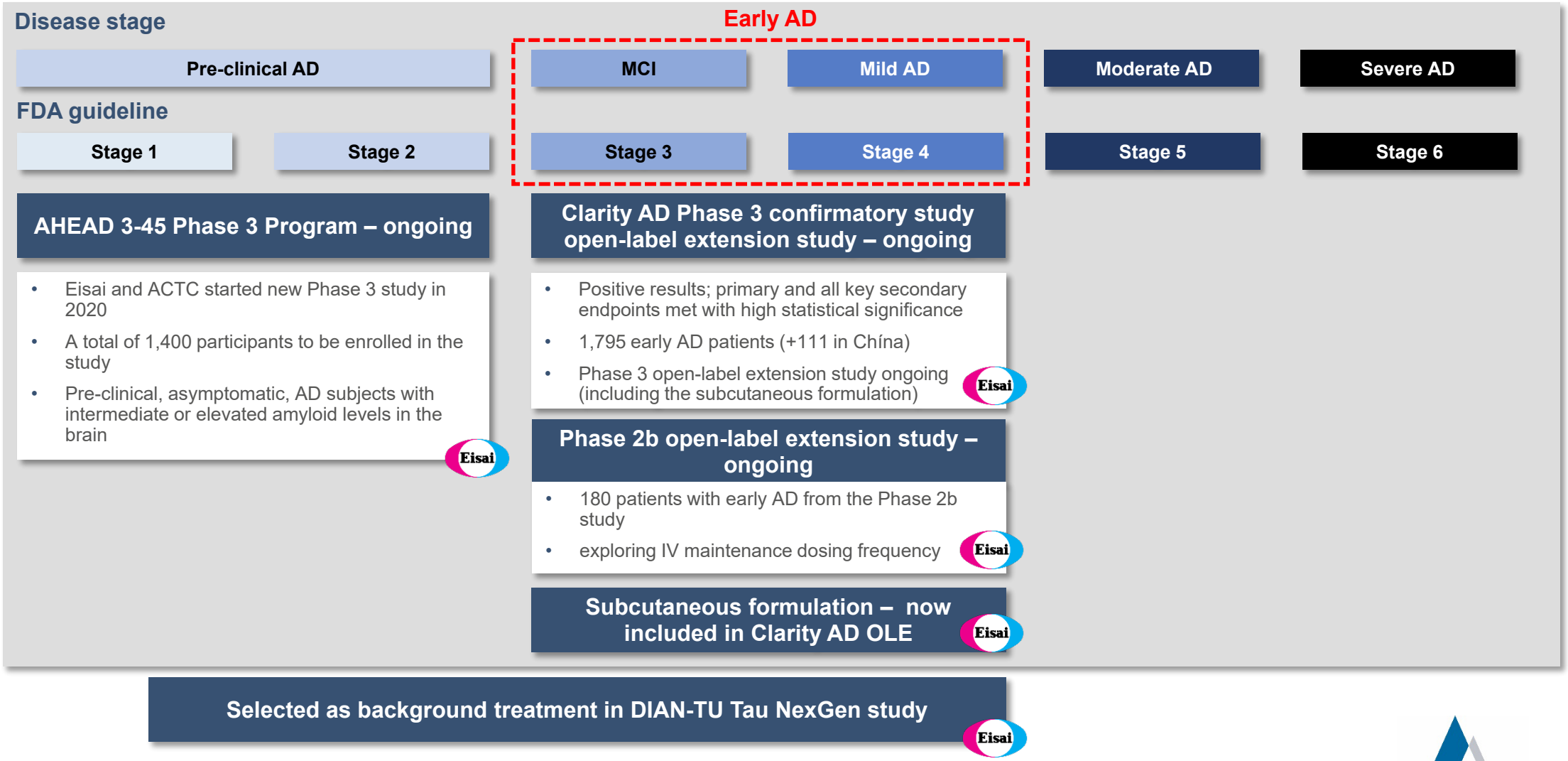
Lecanemab – broad late-stage clinical program



MCI – Mild Cognitive Impairment
OLE – Open Label Extension
ACTC – Alzheimer's Clinical Trials Consortium
IV – Intravenous Infusion

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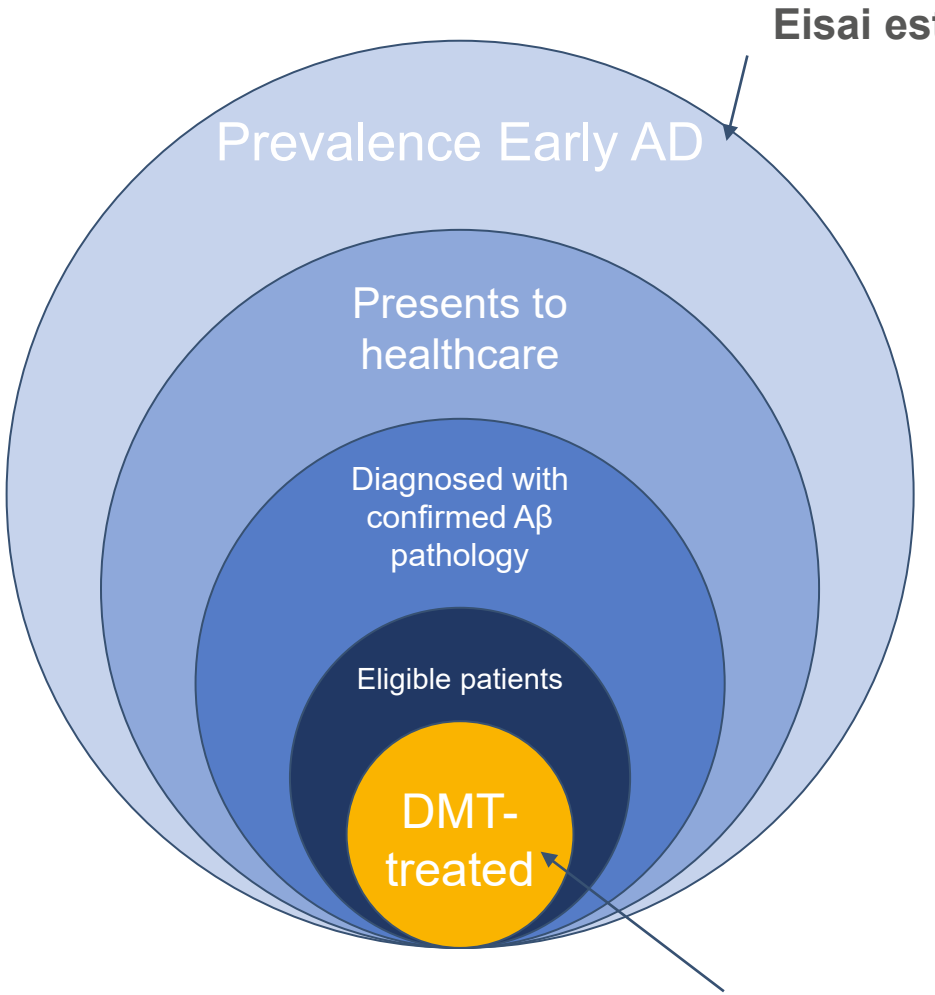
Global estimates for future early AD patients treated with disease modifying treatments (DMTs) offer substantial room for growth



Opportunities that could increase patient access:

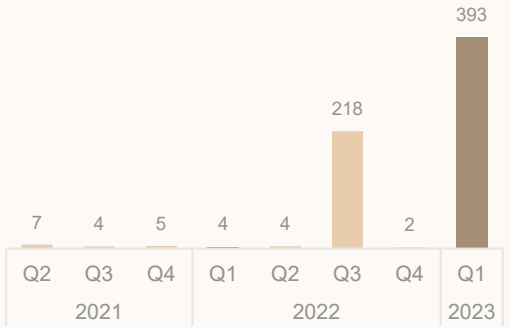
- Patient awareness and less stigma
- Education at primary care
- Access to specialist care
- Improved diagnostics
- Subcutaneous formulation

Note: Size of circles are not indicative of actual proportions

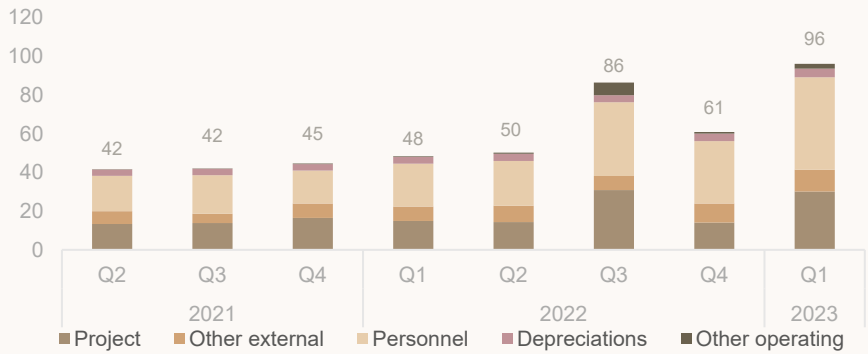
Financial Summary

Operating expenses 2023 within guidance

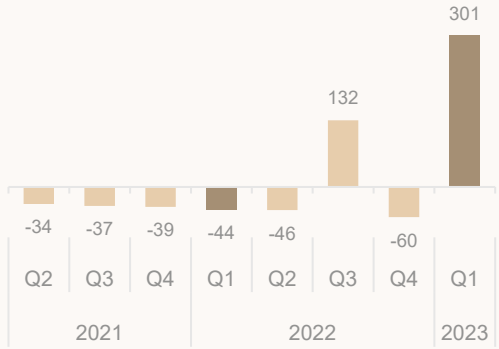
Net Revenues (MSEK)



OPEX by item (MSEK)



Operating Profit/Loss (MSEK)



- Net revenues were MSEK 393 (4) for the first quarter, mainly explained by three milestone payments of MSEK 391 (MEUR 35)

- 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 linked to BioArctic's achieved milestones
- Costs will increase going forward as we continue to build a commercial organization and continue to progress our project portfolio

- Operating profit was MSEK 301 (-44) for the first quarter

Operating expenses are expected to be in the range of MSEK 330 - 380 for the financial year January - December 2023, compared to MSEK 246 in 2022

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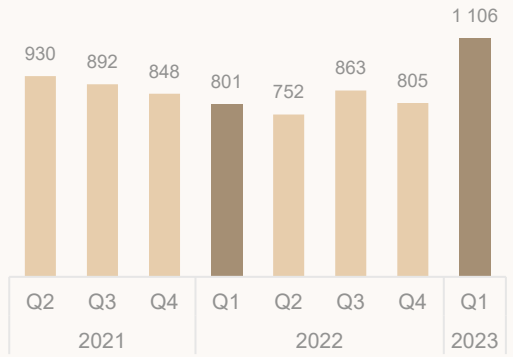
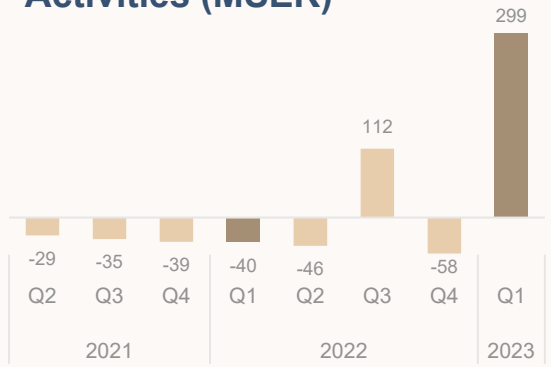
BioArctic strengthens its financial position

Cash Balance (MSEK)



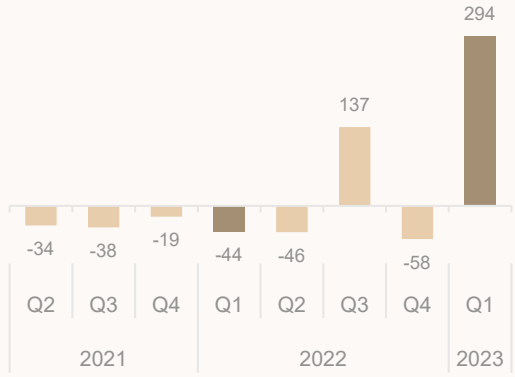
- Cash balance amounted to MSEK 1 106 at the end of the first quarter

Cash Flow From Operating Activities (MSEK)



- Operating cash flow amounted to MSEK 299 (-40) during Q1

Net Result (MSEK)



- Net result for the period was MSEK 294 (-44)
- The increase was mainly related to the three milestone payments of MSEK 391 (MEUR 35)

BioArctic received milestones from Eisai of MEUR 35 in Q1 2023 which further strengthened the company's financial position

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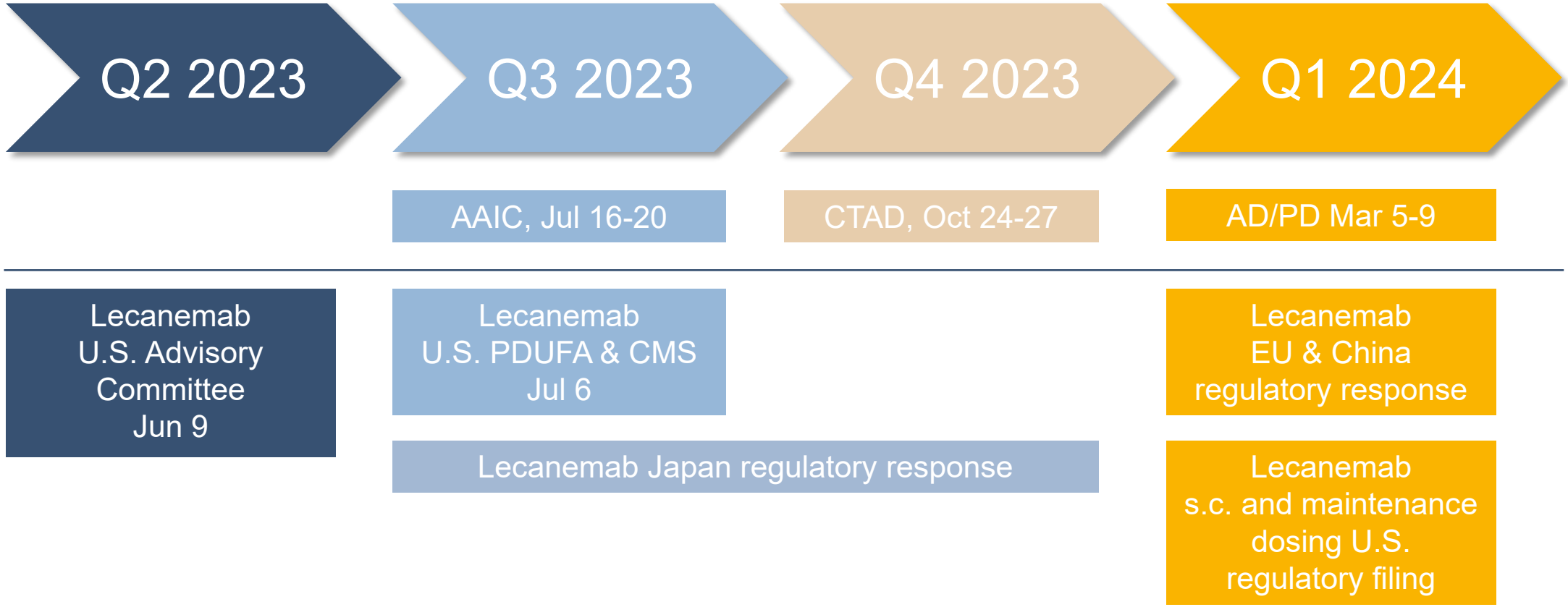
Upcoming news flow and closing remarks

Upcoming news flow



PDUFA – Prescription Drug User Fee Act
CMS – Centers for Medicare & Medicaid Services
s.c. – subcutaneous

Thank you Jan Mattsson, and welcome Anders Martin-Löf!

As of May 1, 2023

Jan Mattsson
VP Finance

Anders Martin-Löf
CFO

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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:**
  Q2 Report
  Apr-Jun 2023
  on July 12, 2023
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Why invest in BioArctic?

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 BSEK 1.1 (MUSD ~110) in cash and **valuable collaboration agreements**

1) FX as per March 31, 2023

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