



Q3 Report July-September 2023

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BioArctic – a unique Swedish biopharma company

Improving life for patients with central nervous system disorders



- **Focus on neurodegenerative disorders**

- Disorders with significant unmet needs and large patient populations, creating big commercial opportunity



- **World-class research and development organization, collaborations with leading academic researchers and pharma companies**

- BioArctic behind Leqembi[®], the world's first fully approved* disease modifying therapy for Alzheimer's disease
- Build-up of company financed through pharma partnerships



- **Broad project portfolio**

- Several additional projects behind lead product in e.g. Parkinson's disease and ALS, as well as platform for delivering biologics to the brain



- **Well-financed from milestones and royalties from lead product**

- SEK ~1 billion in cash balance as of Sept 30, 2023

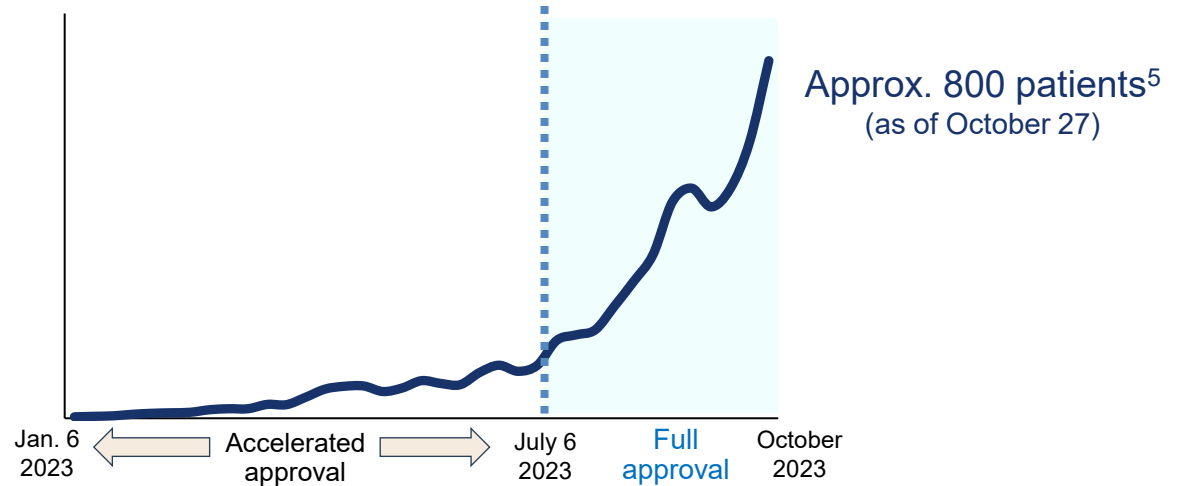
Highlights in and after the quarter

- Leqembi approved and launched in the US
- Leqembi approved in Japan, milestone of EUR 17 M
- Agreed on lecanemab commercialization and co-promotion for the Nordics with Eisai
- New data from Clarity AD OLE presented at CTAD supporting subcutaneous, early treatment and maintenance dosing
- BrainTransporter™ increased probability of success based on external validation of TfR*
- Decision to start Ph2a with exidavnemab (BAN0805) in Parkinson's disease

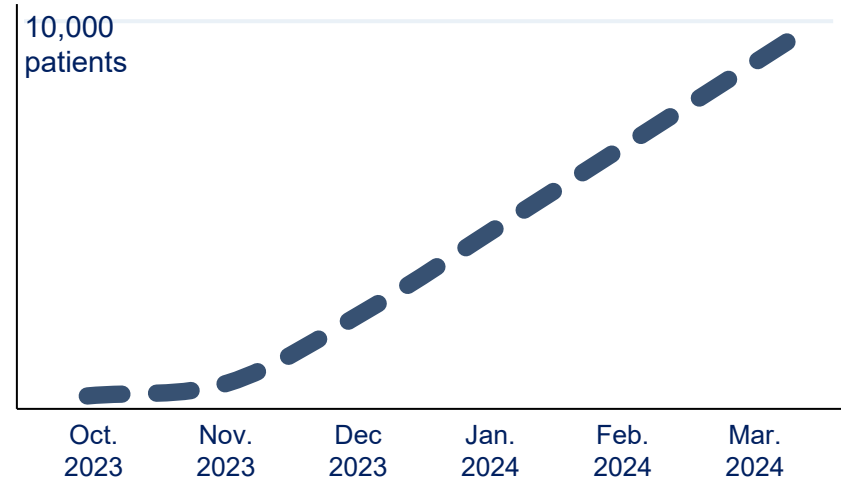


Leqembi U.S. launch progressing as planned – Eisai reiterates expectation of 10,000 patients on treatment by end of March 2024

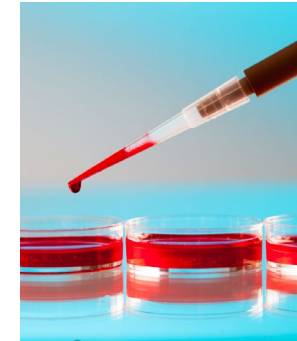
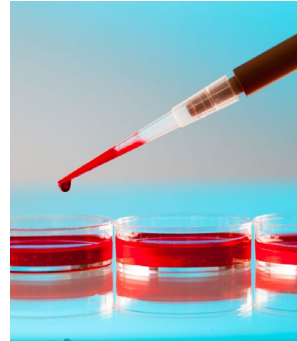
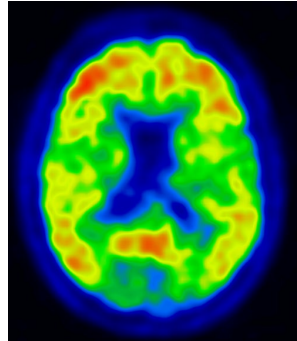
- ~2,500¹ neurologists or AD specialists have established diagnostic and infusion pathway
- Aim for further growth after Amyloid PET coverage expansion after CMS decision² on October 13
- P&T³ committee LEQEMBI approvals obtained at ~60% of top 100 IDNs⁴ in the U.S.



Simulation of growth in cumulative number of patients treated



Introduction of Leqembi facilitated by imaging and blood diagnostics



2023

2024

2025

2026

CMS reimbursement of amyloid PET expanded Oct 13

~2024 Blood biomarkers for triaging (potential)

~2026 Blood biomarkers for confirmatory in clinical praxis (potential)

Biomarkers used to identify relevant patients, diagnostics, follow disease progression and monitor treatment effect

Lecanemab has the potential to become the first anti-A β antibody to receive full approval globally

USA ✓

FDA granted Leqembi traditional approval and CMS provided broader coverage July 6, 2023

Eisai plans to submit s.c. formulation (BLA) and IV maintenance therapy (sBLA) applications by Q1 2024

Japan ✓

PMDA approval September 25, 2023

Pricing and reimbursement expected before year end 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

Rest of World

Applications submitted in Canada, Great Britain, Australia, Switzerland, South Korea, Israel, Singapore, Taiwan, Brazil and Hong Kong

Israel: priority review

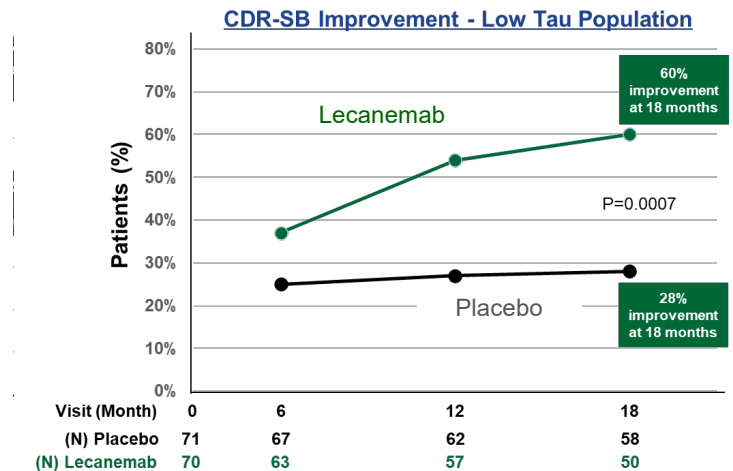
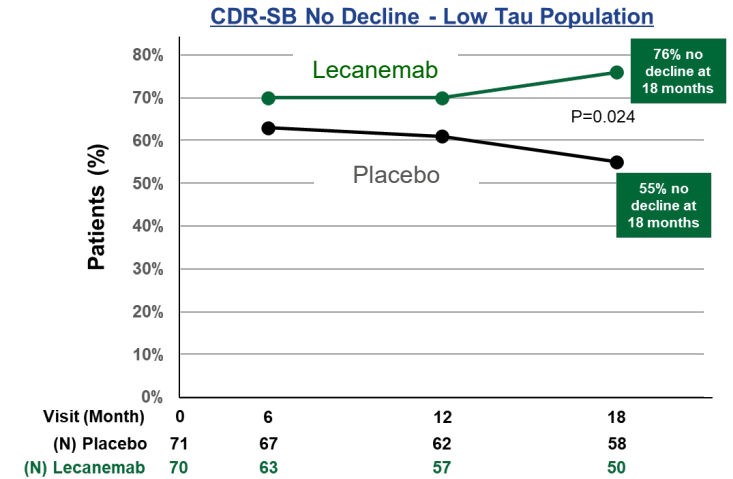
Great Britain: Innovative Licensing and Access Pathway (ILAP)

FDA – Food & Drug Administration
CMS – Prescription Drug User Fee Act
VHA – Veterans' Health Administration
PMDA – Pharmaceuticals and Medical Devices Agency
EMA – European Medicines Agency
NMPA – National Medical Products Administration
s.c. – subcutaneous



Highlights from CTAD – data on subcutaneous, early and maintenance dosing further support LEQEMBI

- Strong data presented for LEQEMBI
 - Subcutaneous treatment with Leqembi leads to 14% more reduction of A β compared to intravenous with similar ARIA
 - Treatment with Leqembi that begins early in the disease potentially results in a better effect
 - Treatment with Leqembi continues to have an effect after 18 months
- External validation of TfR*
 - Increasing probability of success for BrainTransporter™
- Blood biomarkers continue to develop well for diagnostics, disease progression and treatment monitoring in Alzheimer’s disease
 - Already being included in clinical practice by leading KOLs



Alzheimer's disease & Neuronal synucleinopathies (NSD)

Lecanemab and exidavnemab

Lecanemab:

- A β -selective antibody for toxic aggregated forms
- First and only fully approved disease modifying treatment in the US and Japan
- Early Alzheimer's disease
- Other potential indications:
 - Preclinical asymptomatic Alzheimer's' disease
 - Down's syndrome with dementia
 - Traumatic Brain Injury etc.

Exidavnemab (BAN0805):

- α -syn-selective antibody for toxic aggregated forms
- Only symptomatic treatments available, exidavnemab is intended as a disease modifying treatment
- Synucleinopathies:
 - Parkinson's disease
 - Lewy body dementia
 - Parkinson's disease dementia
 - Multiple systemic atrophy

Exidavnemab (BAN0805)

potential disease modifying antibody in Parkinson's disease towards Phase 2

High unmet medical need

No existing disease-modifying treatment



Younger patient group, still at working age

TODAY

>6 million¹ people with Parkinson's disease

Unique profile

Unique and targeted binding profile

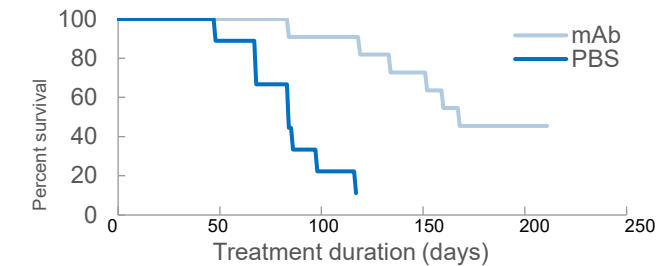
- Highly selective (>100,000) for pathological forms of misfolded alpha-synuclein (oligomers/protofibrils) vs physiological forms (monomers)

Built on genetic and pathology rationale

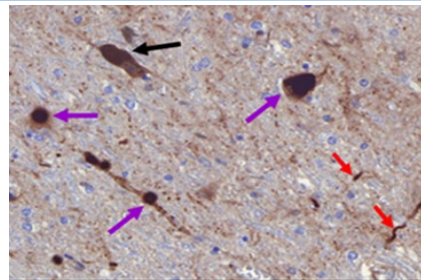
- Alpha-synuclein mutations lead to PD
- Alpha-synuclein oligomers/ protofibrils are elevated in PD

Pre-clinical proof of concept

- Reduction of neurotoxic alpha-synuclein oligomers/protofibrils
- Delays disease progression and increases lifespan

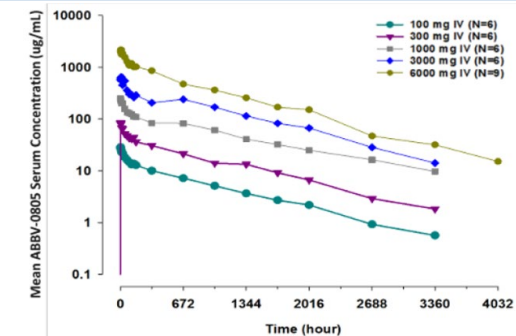


Human target binding of BAN0805 in PD brain



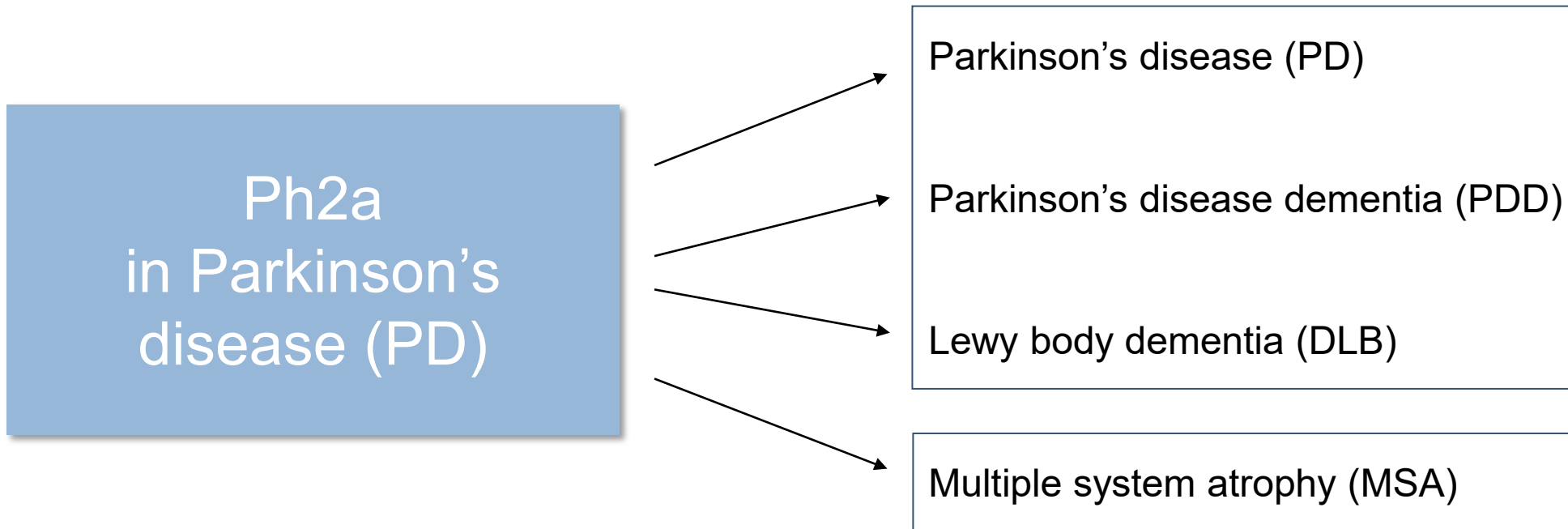
Black: neuromelanin, Purple: Lewy bodies, Red: Lewy neurites

Phase 1 results support Phase 2 development with dosing once a month



Patent up until 2046 including extensions (Granted: US, Japan, Pending: Europe, China and other countries)

Decision to start Phase 2a for Exidavnemab (BAN0805) 2024 Offers opportunities in several neuronal synucleinopathies (NSD)



Biomarkers available to identify patients with pathological α -syn

A balanced project portfolio, with a focus on neurodegenerative diseases

September 30, 2023	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Regulatory & Market
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) (<i>Clarity AD</i>)	Eisai ¹	Early Alzheimer's disease²					
	Lecanemab (BAN2401) (<i>AHEAD 3-45</i>)	Eisai ¹	Preclinical (asymptomatic) Alzheimer's disease³					
	BAN2401 back-up	Eisai						
	BAN1503 (PyroGlu A β)							
	AD-BT2802							
	AD-BT2803 (PyroGlu A β 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 syndrome⁴, Traumatic brain injury⁴
	ND3014 (TDP-43)							ALS
	ND-BT3814 (TDP-43 with BT)							ALS
	GD-BT6822 (GCCase with BT)							Gaucher disease
BLOOD BRAIN BARRIER	BrainTransporter™ (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

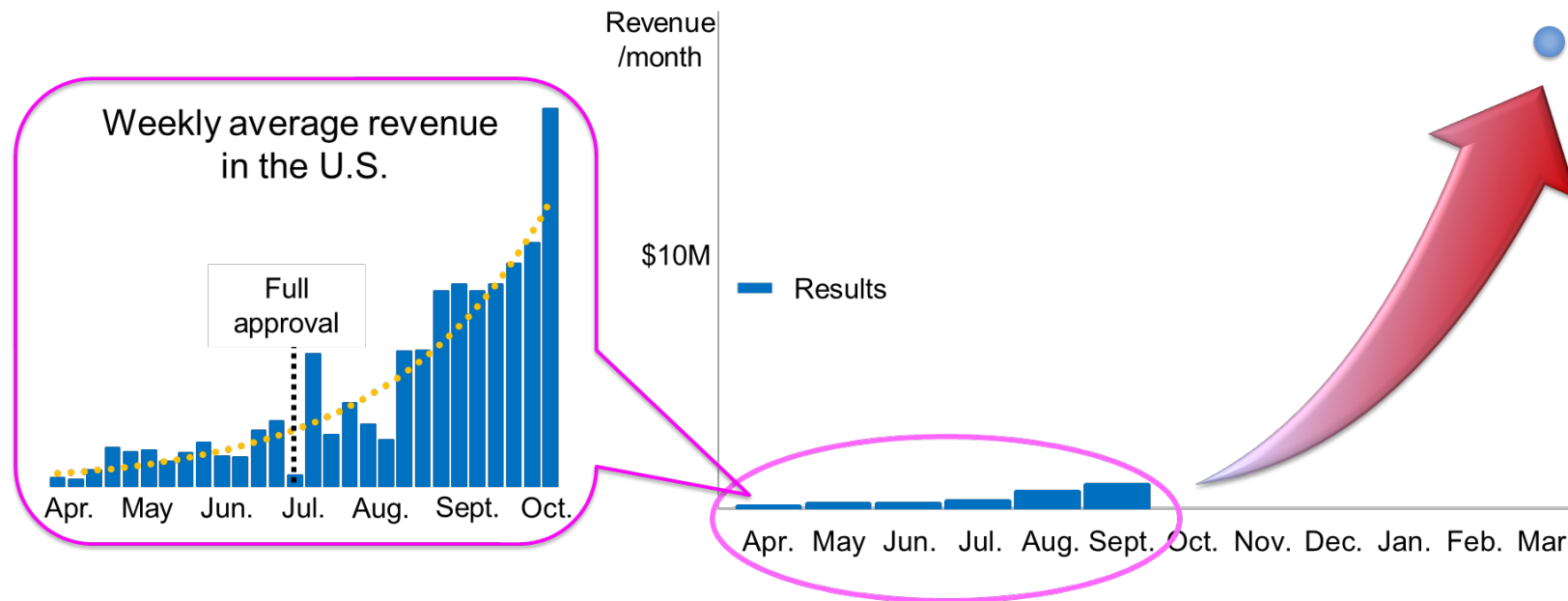
4) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury



Financial Summary

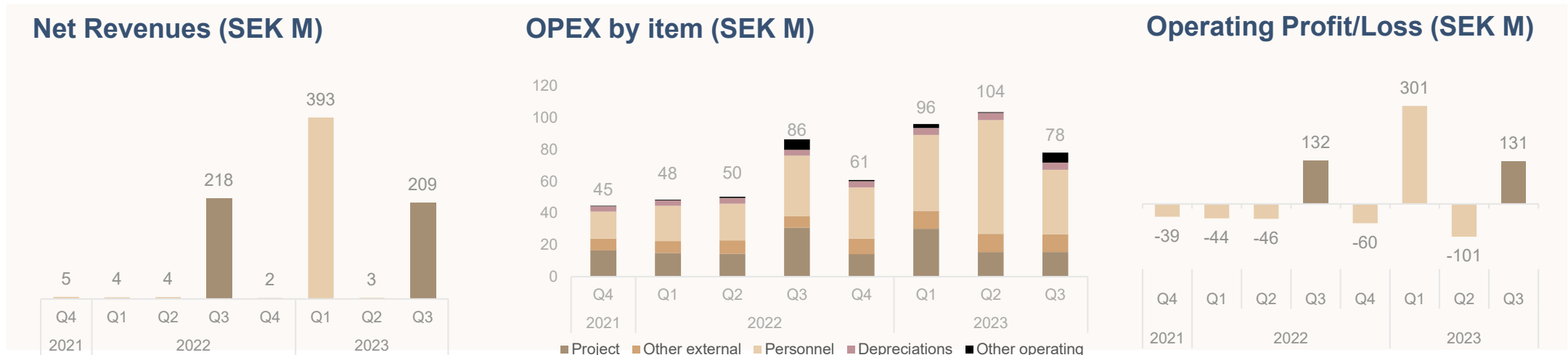
Eisai aims to achieve ¥ 10 B revenue level in fiscal year 2023 (Apr-23 to Mar-24)

Current rapid US sales growth week over week sets foundation for FY 2023 aim



- Leqembi sales in Q3 were ¥ 0.4 B
- Recorded Q3 BioArctic royalty was SEK 2.5 M
- Eisai aim to reach ¥ 10 B in Apr-23 – Mar-24 (SEK ~700 M)
- BioArctic has the right to high single digit royalty

Operating expenses 2023 within guidance



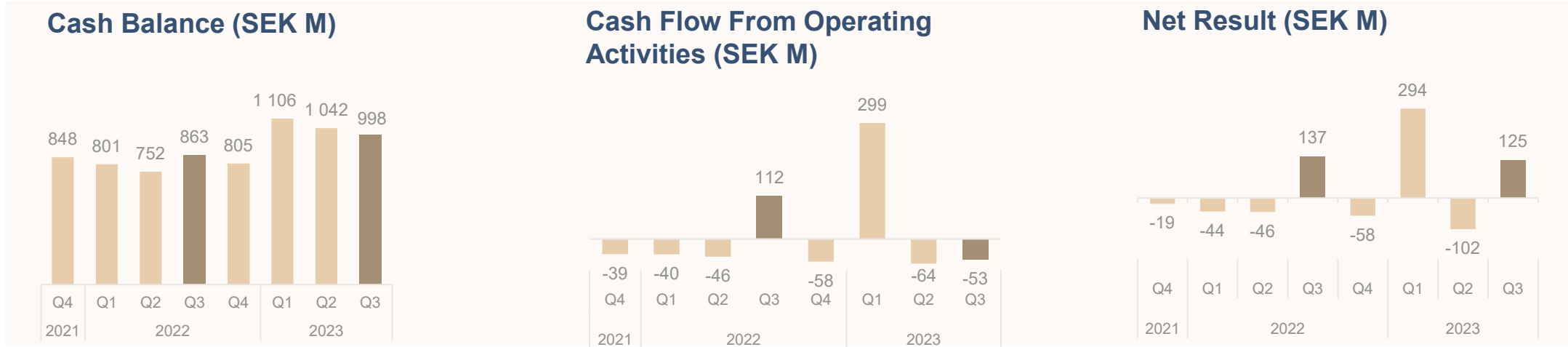
- Net revenues were SEK 209 M (218) in Q3 and SEK 605 M (226) Jan-Sep
 - Four milestone payments totaling SEK 592 M (€ 52 M) Jan-Sep out of which SEK 201 M (€ 17 M) in Q3
- Two new revenue streams will shift revenue mix over time
 - Royalty SEK 2.5 M in Q3
 - Co-promotion revenues SEK 3.6 M in Q3

- Operating expenses decreased to SEK 78 M (86) in Q3 but increased to SEK 278 M (185) Jan-Sep
 - Personnel costs decreased from SEK 72 M in Q2 to SEK 41 M (38) in Q3 mainly due to non-recurring effects in Q2
- Costs will increase longer term
 - Progression of project portfolio
 - Build-up of commercial organization

- Operating profit was SEK 131 M (132) for Q3, and for Jan-Sep operating profit was SEK 331 M (42)

Full-year operating expense guidance narrowed down within previous range: SEK 350 – 370 M for 2023, compared to SEK 246 M in 2022

Strong financial position



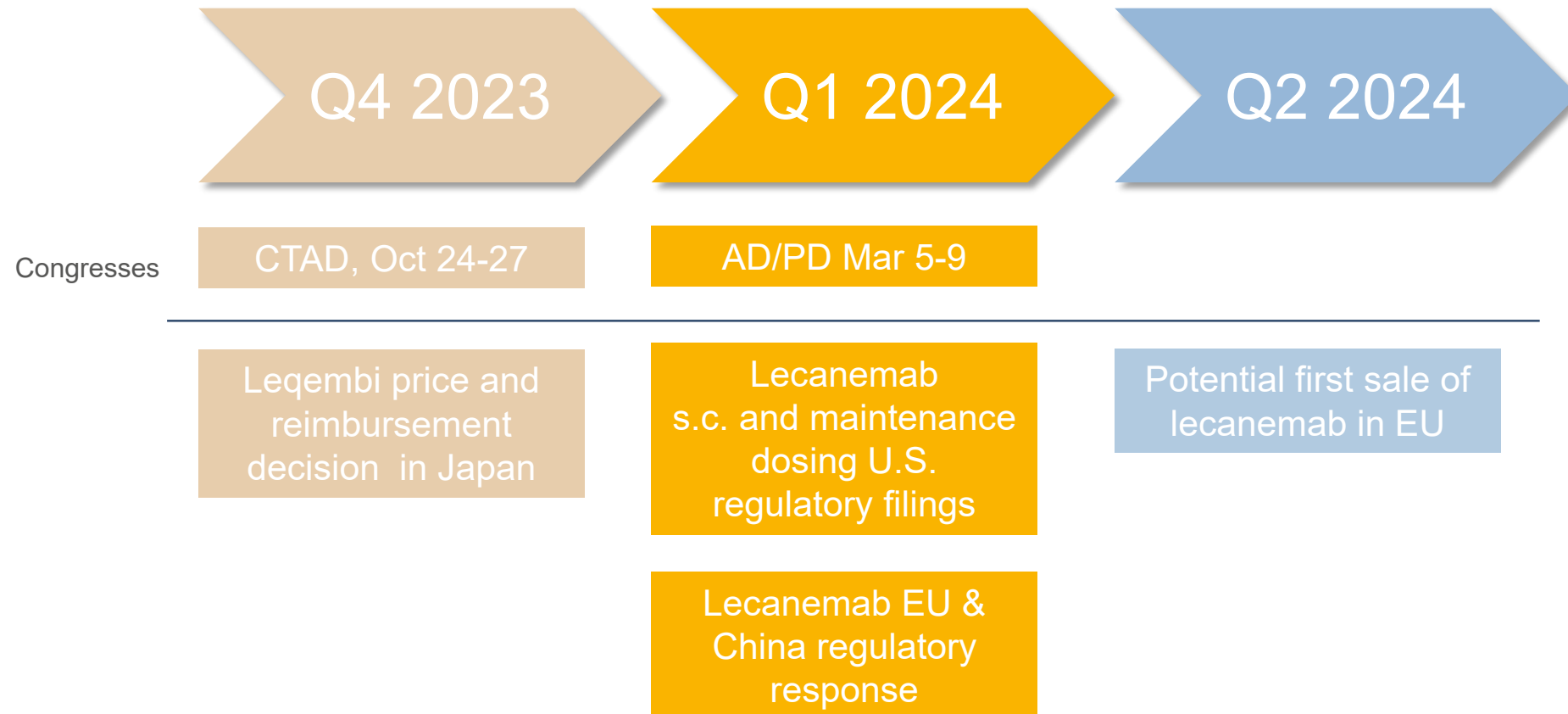
- Cash balance including short term investments amounted to SEK 998 M at the end of the third quarter
- Operating cash flow was a negative SEK 53 M (pos. 112) in Q3, positive SEK 182 M (27) for Jan-Sep
- Net profit for Q3 was SEK 125 M (137), net profit of SEK 316 M (47) for Jan-Sep

Milestone from Eisai of € 17 M (SEK 201 M) recorded in Q3 2023 not included in cash balance at end of quarter



**Upcoming news flow
and closing remarks**

Upcoming news flow



s.c. – subcutaneous



”

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

IR team

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on February 14, 2024