



Q4 Report
October-December 2023

Stockholm, February 14, 2024

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BioArctic – a unique Swedish biopharma company

Improving life for patients with central nervous system disorders



Focus on neurodegenerative disorders with large unmet medical need



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



Broad project portfolio – building on the success of Leqembi®



Well-financed from milestones and royalties from lead product



Award-winning science and leadership

Highlights in and after the quarter

- New data at CTAD congress in October supporting subcutaneous formulation
- Leqembi launched in Japan in December
- Leqembi approved in China in January
- EMA to convene a scientific advisory group to discuss lecanemab
- BioArctic and Eisai have agreed on commercialization and co-promotion for the Nordic countries



Lecanemab is the first AD disease-modifying treatment to receive full approval globally, establishing new standard of care

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

2,000 patients treated as of January 2024 (~4x waiting)

Japan ✓

PMDA approval September 25, 2023

Launched on December 20, 2023, following reimbursement decision

100 patients on treatment as of January 2024 (~300 scheduled for treatment)

EU

Marketing authorization application submitted on January 9, 2023

Accepted for a standard review on January 26, 2023

Expected CHMP opinion Q1 2024

China ✓

Granted approval January 5, 2024

Expected launch in Q3 2024

Rest of World

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

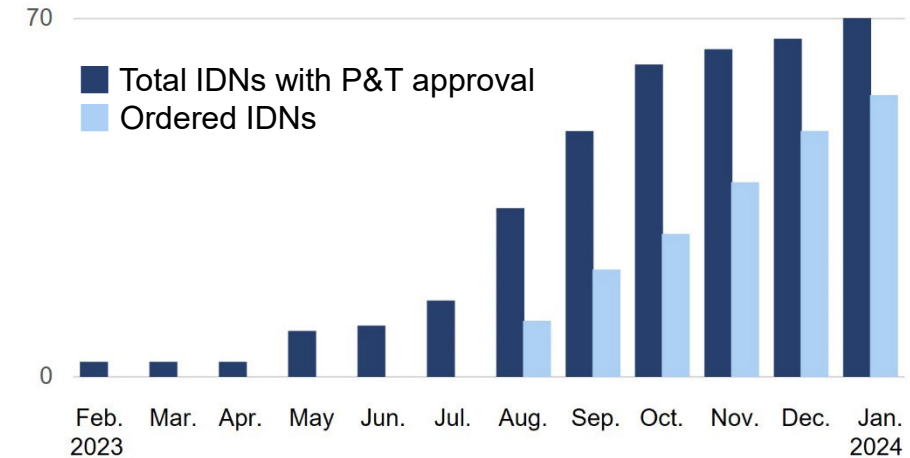
Israel: priority review
Great Britain: Innovative Licensing and Access Pathway (ILAP)

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

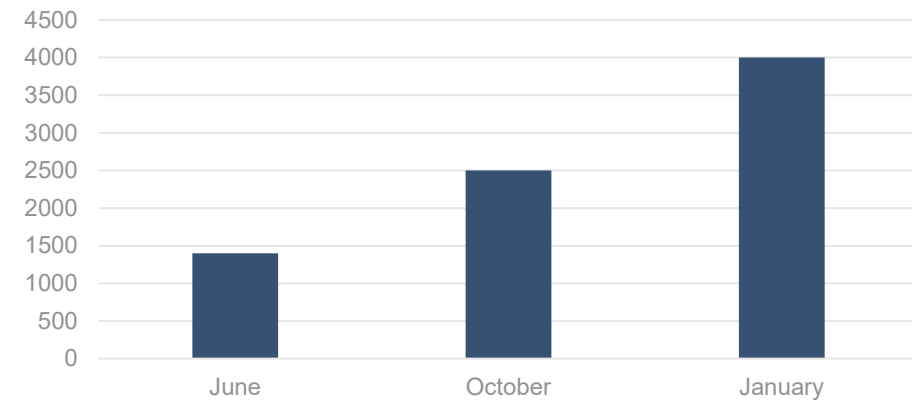


Steady progress of the Leqembi U.S. launch

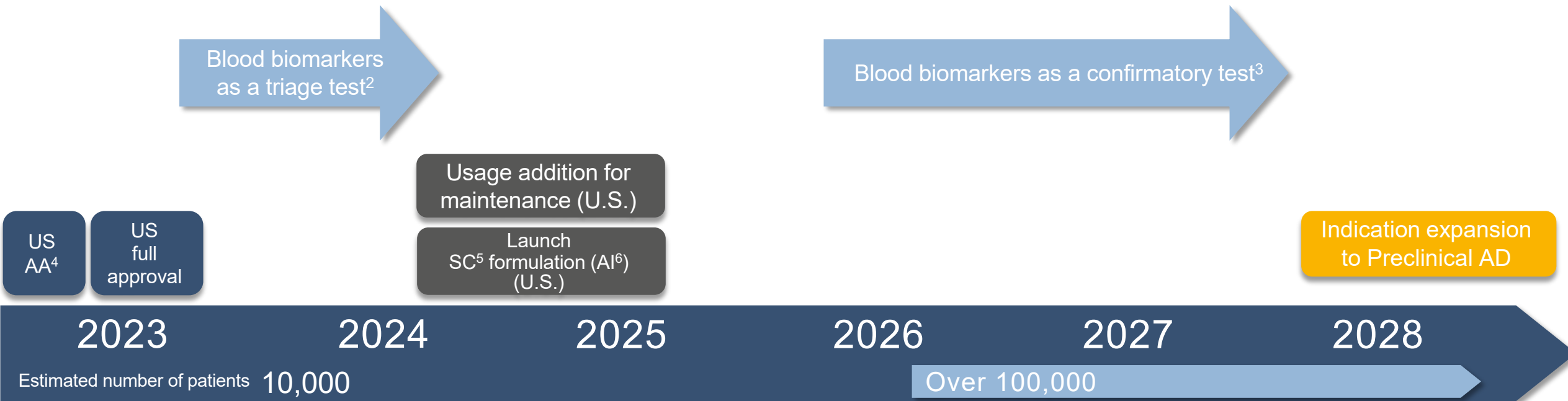
- P&T¹ committee Leqembi approvals obtained at ~70% of top 100 IDNs² in the U.S., and ~55% have now started ordering Leqembi
- ~4,000³ neurologists or AD specialists have established diagnostic and infusion pathway
- Steeper growth after Amyloid PET coverage expansion after CMS decision⁴ on October 13
- Access has been secured for around 90% of people who are potentially eligible to receive treatment for AD in the U.S.
- Biogen to realign resources for Alzheimer's disease franchise



of specialist physicians ready to prescribe Leqembi



Leqembi long term penetration will be supported by simplified diagnosis and more convenient treatment as well as label expansion



1. A preliminary test conducted to minimize the need for highly invasive CSF tests and expensive PET tests. If the test result is negative, the criteria for A β aggregation are likely to be negative, and a final definitive diagnosis of AD cannot be made. If the test is positive, CSF or PET tests are performed to confirm the diagnosis of AD
 2. Confirmatory test to identify the disease
 3. Accelerated approval
 4. Subcutaneous formulation *6: Auto injector

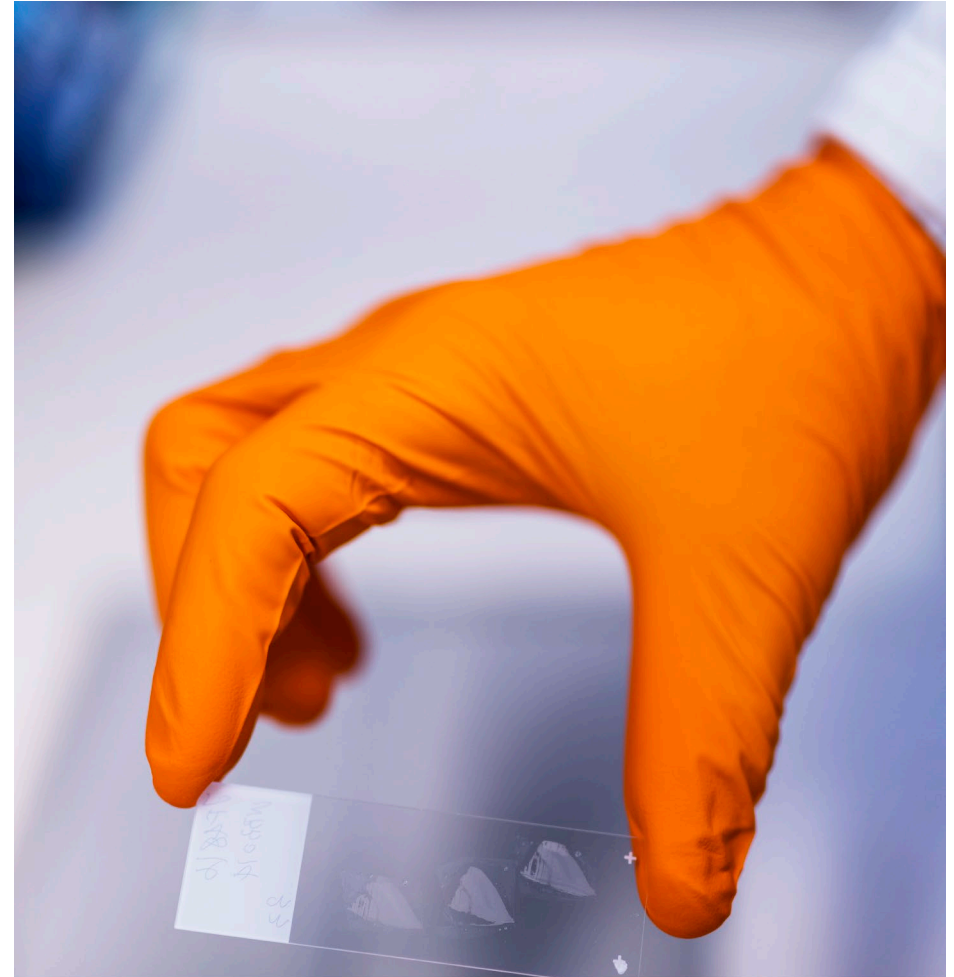
Q4 pipeline highlights

Next generation Alzheimer treatments

- Investment decision to progress BrainTransporter™ technology. Two candidate drugs (CD) nominated:
 - BAN2802 (undisclosed target with BT)
 - BAN2803 (PyroGlu A β Ab with BT)

Preparing for Phase 2a in Parkinson's disease

- EXIST – Study focused on safety, tolerability and pharmacokinetics, with exploratory biomarkers



A broad project portfolio with a focus on neurodegenerative diseases

	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)							
	BAN2802							
	BAN2803 (PyroGlu A β Ab with BT)							
	AD2603							
PARKINSON'S DISEASE	Exidavnemab (BAN0805) (alpha-synuclein)							
	PD1601 (alpha-synuclein)							
	PD1602 (alpha-synuclein)							
	PD-BT2238 (alpha-synuclein with BT)							
OTHER CNS DISORDERS	Lecanemab ⁴ (BAN2401)							
	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

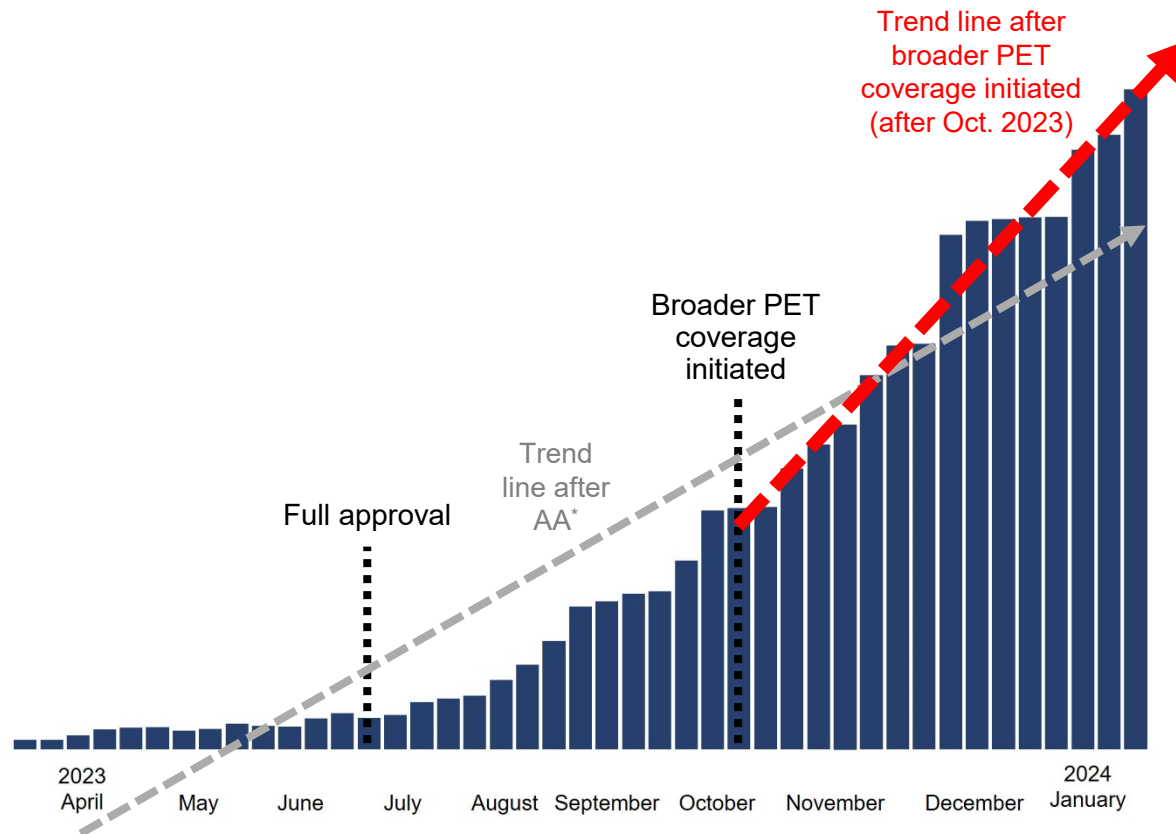
4) Dementia and cognitive impairment associated with Down's syndrome and with traumatic brain injury



Financial Summary

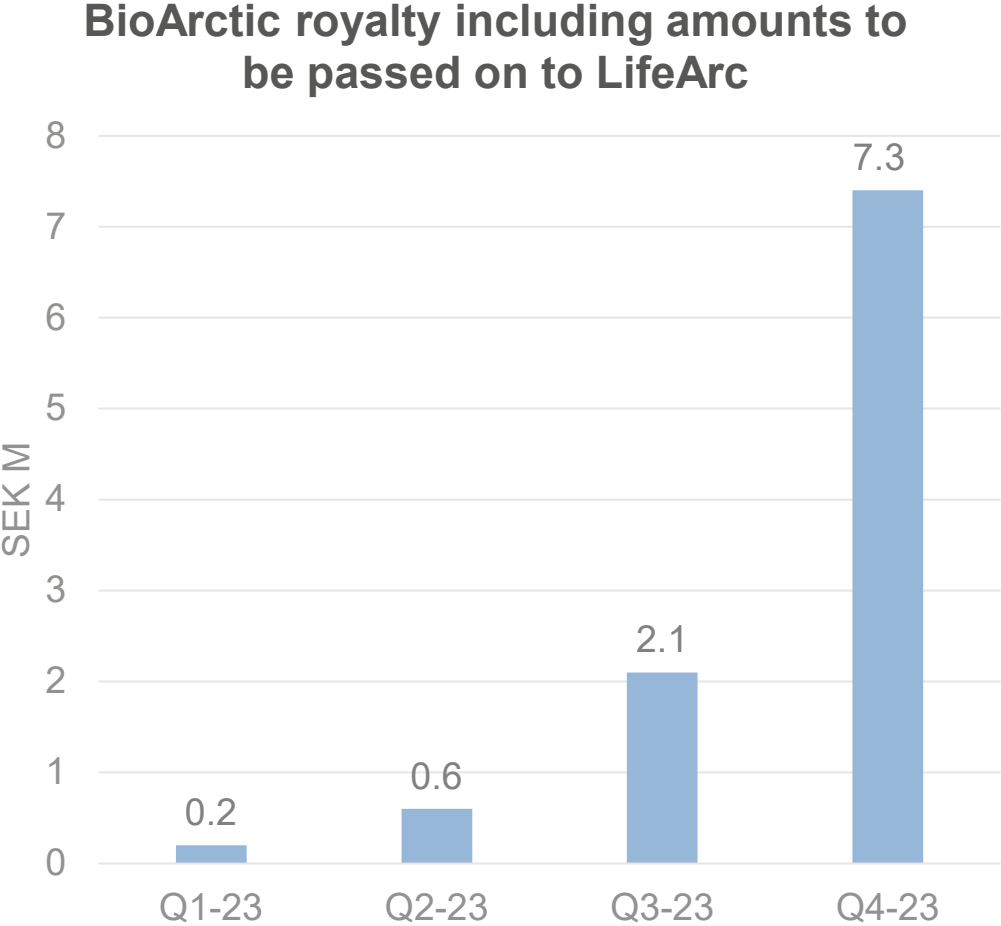
2,000 patients on Leqembi treatment in January with around four times as many waiting to begin treatment

Number of patients on Leqembi treatment



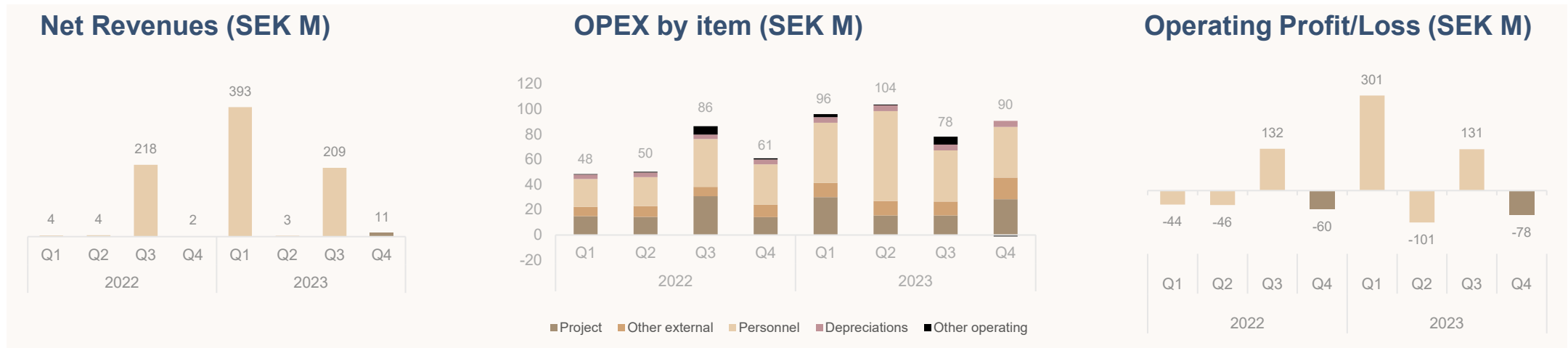
- Eisai stated that 2,000 patients on treatment last week of January
 - "Challenging" to reach 10,000 patients in Q1
- Around four times as many waiting to begin treatment
 - "Generally treated within 1-3 months"
- Sales and waiting list are growing fast
 - More and more hospitals are ordering
 - Biogen sales force is now starting to support Eisai
- Long term potential of +100,000 patients in late 2026 and beyond

Leqembi royalties are growing fast



- Royalty rate of 9% on global net sales
 - Recorded royalty includes additional 1% on US sales and 1.5% on ex-US sales that passes through to LifeArc
- US Q4 sales were \$ 7.2 M but weekly sales \$ 1.5 M last week of January
 - ~150% higher than q4 average
- Progressing towards 10,000 patients
 - 10,000 patients on average on treatment one quarter equates to SEK ~50 M in royalties
- Positive impact from Japan & China towards end of 2024 if Eisai expectations are met
 - ~7,000 patients in Japan end of March 2025, list price \$ ~20,000
 - ~1,500 patients in China in 2024

Operating expenses for 2023 within guidance, operating profit SEK 253 M

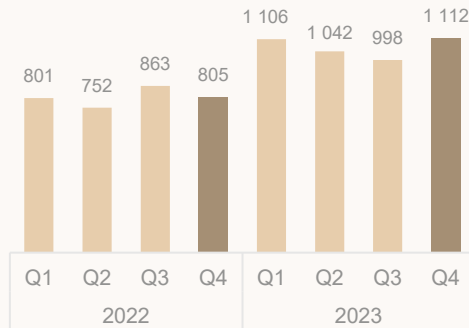


- Net revenues were SEK 11 M (2) in Q4 and SEK 616 M (228) Jan-Dec
 - Four milestone payments totaling SEK 592 M (€ 52 M) Jan-Dec
 - The two new revenue streams will shift revenue mix over time
 - Royalty SEK 7.3 M in Q4, 10.2 M Jan-Dec
 - Co-promotion SEK 1.9 M in Q4, 5.5 M Jan-Dec
 - Operating expenses increased to SEK 90 M (61) in Q4 and to SEK 367 M (246) Jan-Dec
 - Personnel costs were SEK 40 M in Q4 compared to SEK 32 M in the same period previous year
 - Operating loss was SEK 78 M (60) for Q4, and for Jan-Dec the operating profit was SEK 253 M (neg. 17)
- Costs will increase in 2024
- Progression of project portfolio
 - Build-up of commercial organization

No forecast presented for 2024 as visibility is limited

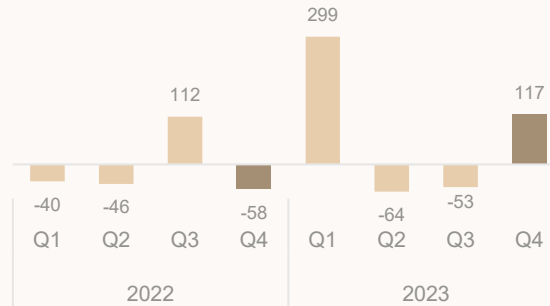
Strong financial position going forward

Cash Balance (SEK M)



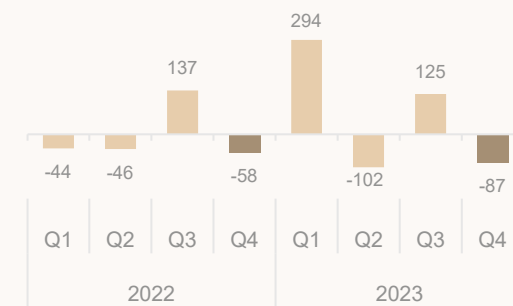
- Cash balance including short-term investments amounted to SEK 1 112 M at the end of the fourth quarter

Cash Flow From Operating Activities (SEK M)



- Operating cash flow was a positive SEK 117 M (neg. 58) in Q4, and SEK 299 M (neg. 32) for Jan-Dec

Net Result (SEK M)



- Net result for Q4 was SEK neg. 87 M (neg. 58), and for Jan-Dec the net profit was SEK 229 M (neg. 11)
- Effective tax rate 17%, no more tax losses carried forward

Profitability in 2024 will depend on Leqembi roll-out, profitability improving from 2025 and onwards



**Upcoming news flow
and closing remarks**

Upcoming news flow



s.c. – subcutaneous

In summary

Leqembi now
approved in the US,
Japan and China with
sales starting to pick
up

Our early pipeline
continues to progress

Finances remain
solid



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

IR team

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