Q1 Report
January – March 2024

Stockholm, May 17, 2024

BIOARCTIC

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Next Report:
Q2 Report
April - June 2024
on August 29, 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

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Important events in and after Q1 2024

- Leqembi approved China – launch planned for July 2024
- The EMA announced that its deliberations on lecanemab regarding the Marketing Authorisation Application has been rescheduled due to procedural reasons
- Eisai submitted an sBLA for less frequent IV maintenance dosing with lecanemab to the FDA
- BioArctic and Eisai entered into a research evaluation agreement regarding BAN2802
- Eisai initiated a rolling BLA to the FDA for Leqembi for subcutaneous maintenance dosing under Fast Track designation
- BioArctic was included in Nasdaq Stockholm's new ESG Responsibility Index

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

USA ✓

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

Eisai has submitted an IV maintenance therapy application (sBLA) and an s.c. maintenance therapy (BLA) application

Japan ✓

PMDA approval September 25, 2023

Launched December 20, 2023, following reimbursement decision

EU

Marketing authorization application submitted January 9, 2023

Accepted for a standard review January 26, 2023

Expected EMA decision Q3 2024

China ✓

NMPA approval January 5, 2024

Expected launch July 2024

Rest of World

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

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

Pen type auto-injector
Co-development by Eisai and Terumo Corporation

FDA – Food & Drug Administration
CMS – Centers for Medicare & Medicaid Services
PMDA – Pharmaceuticals and Medical Devices Agency
EMA – European Medicines Agency
NMPA – National Medical Products Administration
SC – subcutaneous

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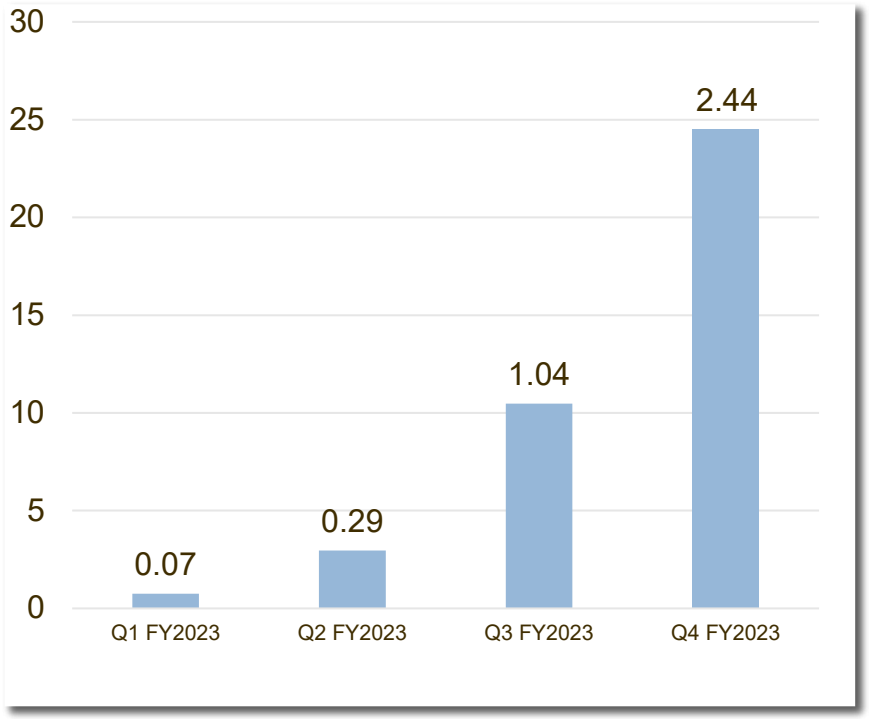
US – Leqembi launch transitioning toward a new phase

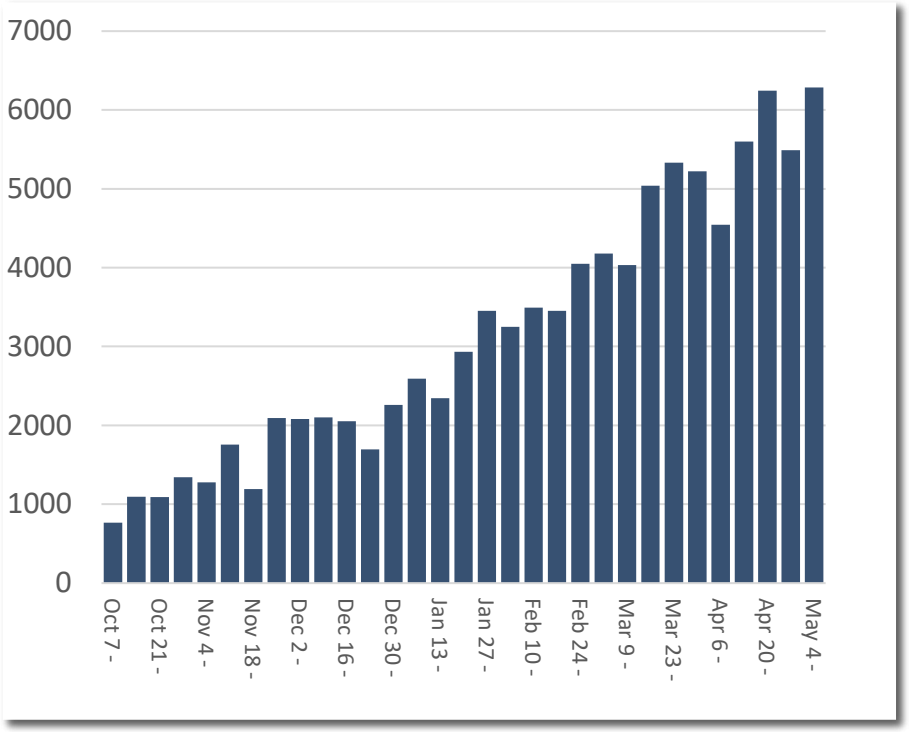
- Diagnosis and treatment pathway established to a large extent
- Transitioning to prescription expansion phase
- Strengthening Go-to-Market structure

(Billions of yen)



Leqembi US FY2023 revenue booked by Eisai

(unit: Number of vials)



Number of vials solid per week to medical institutions

Japan – Leqembi launch progressing faster than expected
China – preparing for launch in July

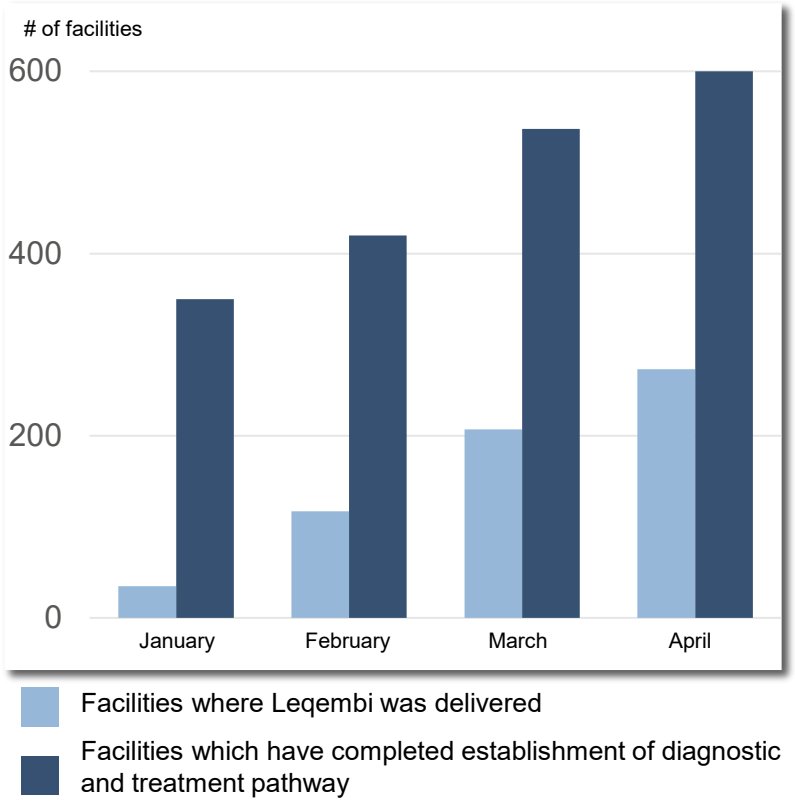
Japan

- Establishment of the pathway has been fast, and the launch is exceeding initial target
- Diagnosis and treatment for eligible patients are progressing rapidly

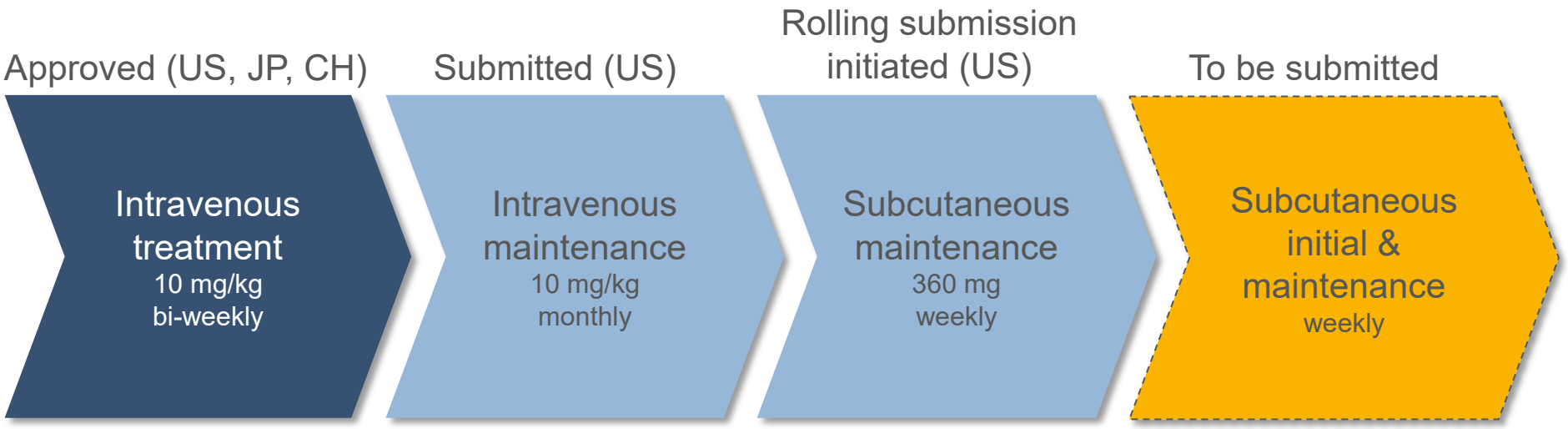
China

- Launch planned for July 2024
- Leveraging already established online health platform
- Blood based biomarkers will be key driver for diagnose and growth

Diagnosis and treatment pathway in Japan



Continued development of Leqembi increases patient convenience



Leqembi long term penetration will also be supported by simplified diagnosis with blood-based biomarkers

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Leqembi brings value to patients, caregivers and society

Broad patient population in early Alzheimer's disease (No tau PET inclusion criteria)

Early and continuous treatment for long-term patient benefit

ARIA real world clinical practice in line with clinical trials as in US Package Insert

Low levels of anti-drug antibodies for maintained treatment effect

Subcutaneous administration with autoinjector for patient and caregiver convenience

Potential expansion to pre-symptomatic Alzheimer's disease (AHEAD 3-45)

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Pipeline highlight
Next generation CNS treatments with BrainTransporter™

Active transport of treatments to the brain highlighted as next big step in CNS at AD/PD

Continued development of BioArctic's proprietary BrainTransporter (BT) technology

Alzheimer

- BAN2802 (undisclosed target with BT) – research evaluation agreement signed with Eisai
- BAN2803 (PyroGlu Aβ antibody with BT) – proprietary development program progressing towards IND[1]

Parkinson

- PD-BT2238 (alpha-synuclein antibody with BT) – proprietary development program progressing towards CD[2] nomination

1 Investigational New Drug Application
2 Candidate Drug

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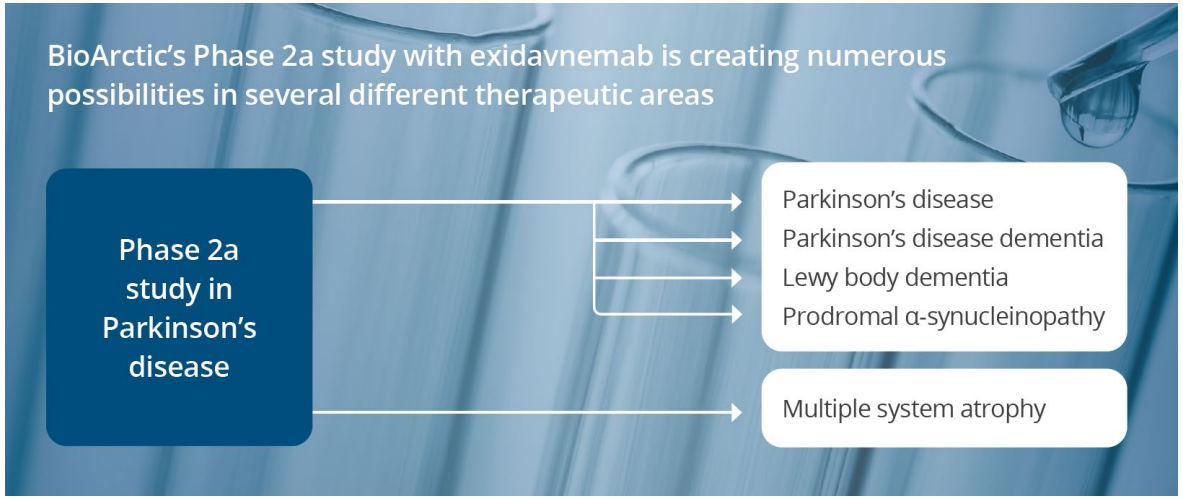
Pipeline highlight
Exidavnemab – possibilities in several different indications

Development of treatments and biomarkers for neuronal synucleinopathies highlighted at AD/PD

Preparing for Phase 2a in Parkinson's disease (EXIST)

- Study focused on safety, tolerability and pharmacokinetics
- Will include exploratory biomarkers, such as a new seeding amplification assay and digital biomarkers
- Study protocol currently being finalized with regulatory authorities
- Drug product available
- Study will take place in the EU, with first patient expected to be dosed in Q4 2024



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) *(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 (PyroGlu Aβ)							
	BAN2802	Eisai						
	BAN2803 (PyroGlu Aβ 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 (GCase 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

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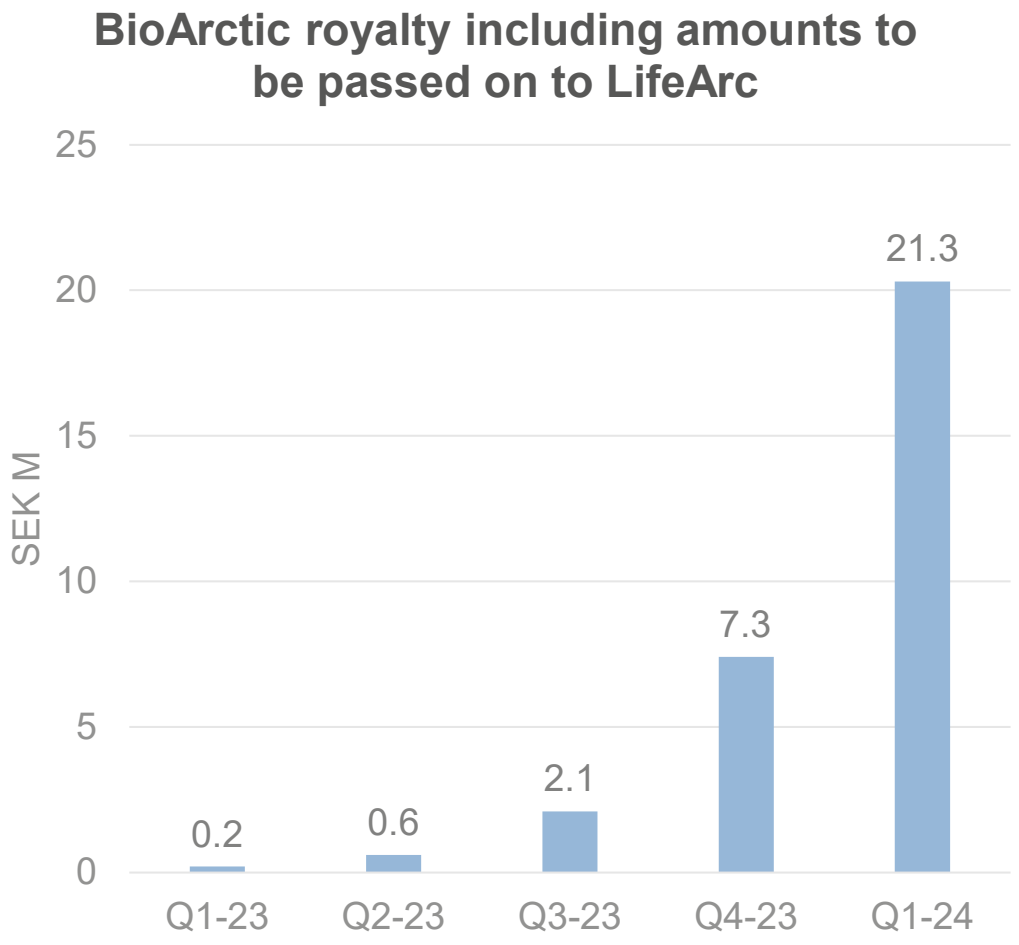
Financial Summary

Leqembi royalties are growing fast



- Global Leqembi Q1-24 sales were ¥ 2.82 B (SEK ~200 M), ~170% increase over Q4-23
- 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 launch entering expansion phase
  - Establishment phase finished, Top institutions have rolled out in main locations
  - Shift towards scaling up in satellite clinics, supported by Eisai/Biogen 30% increase in sales force
- Strong start in Japan
  - Diagnosis and treatment pathway established at 600 facilities within four months of launch
- Launch planned in China in July

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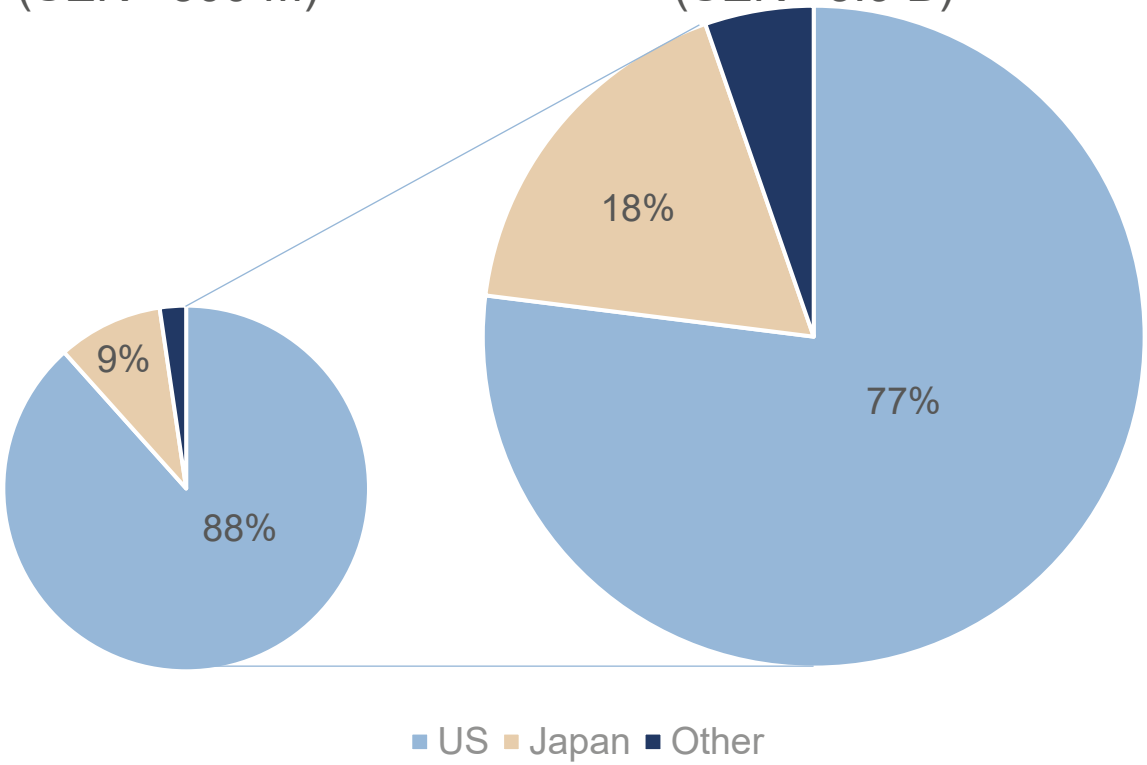
Eisai forecasts more than tenfold sales increase for Leqembi in their fiscal year 2024 (Q2-24 to Q1-25)

FY 2023
(Q2-23 to Q1-24)

¥ 4.3 B
(SEK ~300 M)

FY 2024
(Q2-24 to Q1-25)

¥ 56.5 B
(SEK ~3.9 B)



- This corresponds to SEK ~400 M in royalty Q2-24 to Q1-25
- Eisai's mid-term revenue simulation presented in March: ¥ 290 B (SEK ~20 B) in FY 2026

Approximated SEK amounts converted from JPY using exchange rate from May16 2024 of 14,51 JPY/SEK

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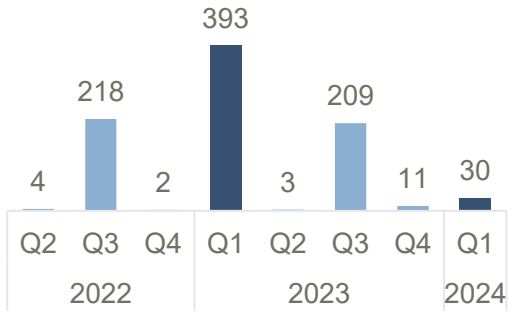
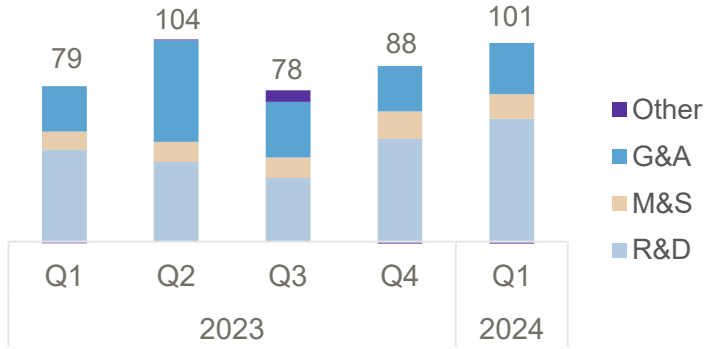
Operating loss of SEK 73 M in the first quarter

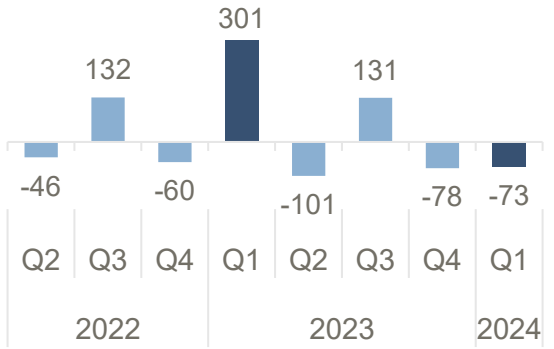
Net Revenues (SEK M)



OPEX by function (SEK M)



Operating Profit/Loss (SEK M)



- Q1 net revenues were SEK 30 M (393)
  - Decrease mainly due to milestone payments in 2023
- The two new revenue streams will shift revenue mix over time
  - Royalty SEK 21.3 M in Q1
  - Co-promotion SEK 2.9 M in Q1

- Operating expenses increased to SEK 101 M (79) in Q1
  - Transition to function-based P/L in 2024
  - R&D 63% of total operating expenses

Costs will increase during 2024

- Progression of project portfolio
- Build-up of commercial organization

- Operating loss was SEK 73 M (profit 301) for Q1

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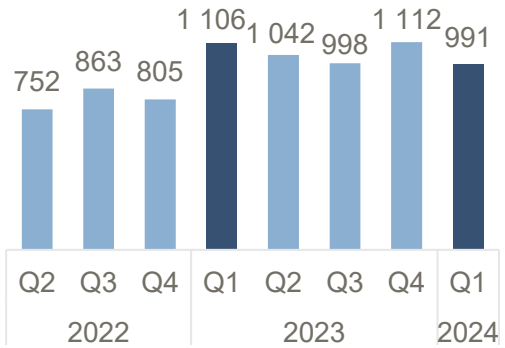
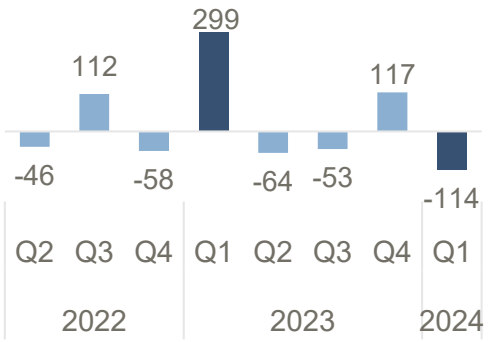
Strong financial position going forward

Cash Balance (SEK M)



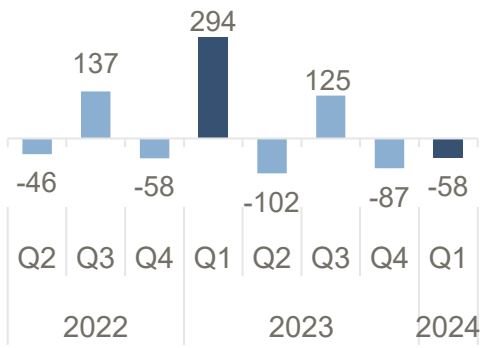
- Cash balance including short-term investments amounted to SEK 991M at the end of the first quarter

Cash Flow From Operating Activities (SEK M)



- Operating cash flow was a negative SEK 114 M (pos. 299) in Q1

Net Result (SEK M)



- Net loss for Q1 was SEK 58 M (profit 294)

Revenues will continue to increase going forward, expecting to be profitable from 2025 and onwards

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Upcoming news flow and closing remarks

Upcoming news flow

Congresses

	AAIC, Jul 28 - Aug 1	CTAD, Oct 29 - Nov 1

Potential approval of lecanemab in Great Britain	Launch of Leqembi in China	Planned start of Phase 2a with exidavnemab
US submission of lecanemab SC-AI maintenance dosing	Potential EU approval of lecanemab	New data on BrainTransporter expected

Further regulatory responses regarding lecanemab

AI – autoinjector
SC – subcutaneous

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In summary

Leqembi sales in the US and Japan showing strong momentum. China launching in July

Early pipeline progressing well and first BrainTransporter agreement signed

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.

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