Q2 Report
April – June 2024

Stockholm, August 29, 2024

BIOARCTIC

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Next Report:
Q3 Report
July - September 2024
on November 14, 2024

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Important events in and after Q2 2024

Lecanemab

- The FDA accepted Eisai's sBLA for less frequent monthly IV maintenance dosing of Leqembi
- Eisai received Fast Track designation and initiated a rolling BLA to the FDA for subcutaneous maintenance dosing of Leqembi
- Leqembi was approved in South Korea, Hong Kong, Israel, United Arab Emirates and Great Britain and launched in China
- CHMP adopted a negative opinion on the MAA for lecanemab. Eisai has requested a re-examination of the opinion
- Three-year data from the lecanemab extension study showed continued increasing patient benefit with maintained safety profile

Exidavnemab

- Study results from phase 1 studies with exidavnemab published in The Journal of Clinical Pharmacology

Other

- BioArctic and Eisai entered into a research evaluation agreement regarding the drug candidate BAN2802

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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)

Eisai has initiated a rolling submission (BLA) for SC auto-injector maintenance therapy

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 CHMP opinion following re-examination Q4 2024

China ✓

NMPA approval January 5, 2024

Launched June 27, 2024

Rest of World

Approvals:
South Korea, Israel, Hong Kong, UAE and Great Britain

Applications submitted in Australia, Brazil, Canada, India, Russia, Saudi Arabia, Singapore, Switzerland and Taiwan

FDA – Food & Drug Administration
CMS – Centers for Medicare & Medicaid Services
PMDA – Pharmaceuticals and Medical Devices Agency
NMPA – National Medical Products Administration
CHMP – Committee for Medicinal Products for Human Use at the European Medicines Agency
sBLA – supplemental Biologics License Application
BLA – Biologics License Application
SC – subcutaneous

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Regulatory update for the EU

LEQEMBI® (lecanemab) INJECTION FOR INTRAVENOUS USE 100 mg/mL

EU (CHMP*1) Update

Eisai

CHMP's standpoint

- On July 26, the CHMP has adopted a negative opinion on the Marketing Authorization Approval (MAA) of lecanemab after considering the balance of its benefits and risks

Eisai's Standpoint

- The protocol and statistical analytical method for Clarity AD was determined in advance in consultation with global health authorities, including the EMA*2 in which CHMP belongs
- Benefits: In this study, lecanemab achieved its primary endpoint and all key secondary endpoints, demonstrating statistically significant results. In addition, these efficacies have been sustained up to 36 months, as shown in the results of the OLE*3 study presented at AAIC2024*4.
- Risks: Data presented at AAIC2024 confirmed that ARIA*5 was very low six months after treatment and most cases were asymptomatic. The incidence of ARIA in actual clinical setting is consistent with clinical trials and is well managed in accordance with the guidelines set by each regulatory agencies.

In order to provide this treatment for AD, a progressive and fatal disease, as soon as possible to patients in EU, Eisai is confident in the Clarity AD study results and will seek re-examination of this opinion and work closely with the CHMP to receive early approval

*1: Committee for Medicinal Products for Human Use *2: European Medicines Agency *3: Open label extension *4: Alzheimer's Association International Conference (July 28 - August 1, 2024 in Philadelphia, USA)
*5: Amyloid related imaging abnormalities

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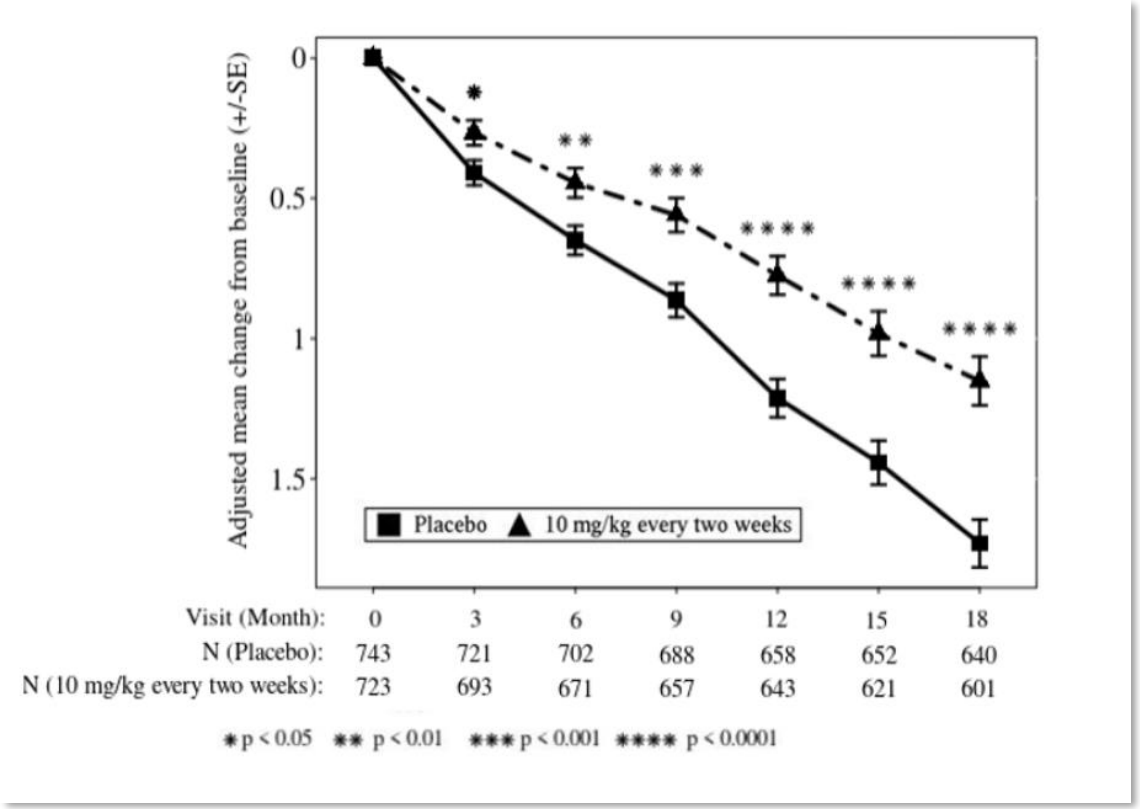
Leqembi authorised in Great Britain on August 22, 2024

- Leqembi authorised in Great Britain, for the treatment of early AD in adult patients that are ApoE4 heterozygotes or non-carriers
- In the indicated population, Leqembi reduced clinical decline at 18 months compared to placebo by:
  - 33% on CDR-SB[1]
  - 39% on ADCS-MCI-ADL[2]
- In the indicated population the most common adverse reactions were:
  - infusion-related reactions 26%
  - ARIA-H 13% (0.8% symptomatic)
  - fall 11%
  - headache 11%
  - and ARIA-E 9% (2% symptomatic)

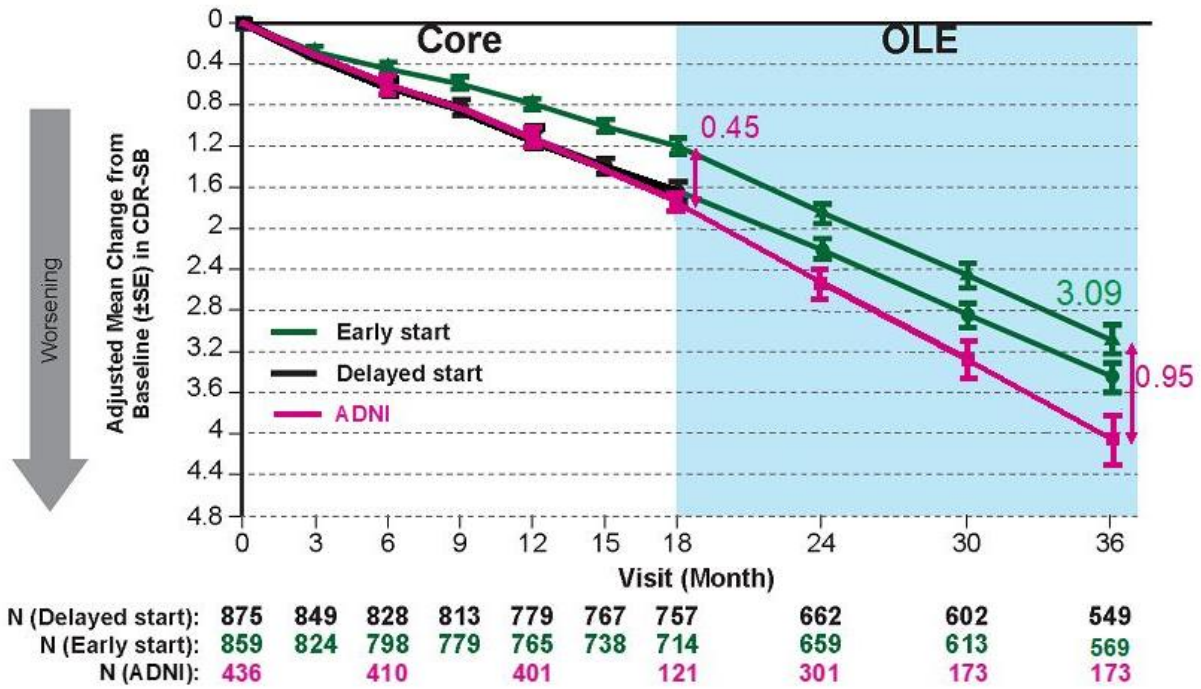
Clinical decline as measured by CDR-SB for the indicated population



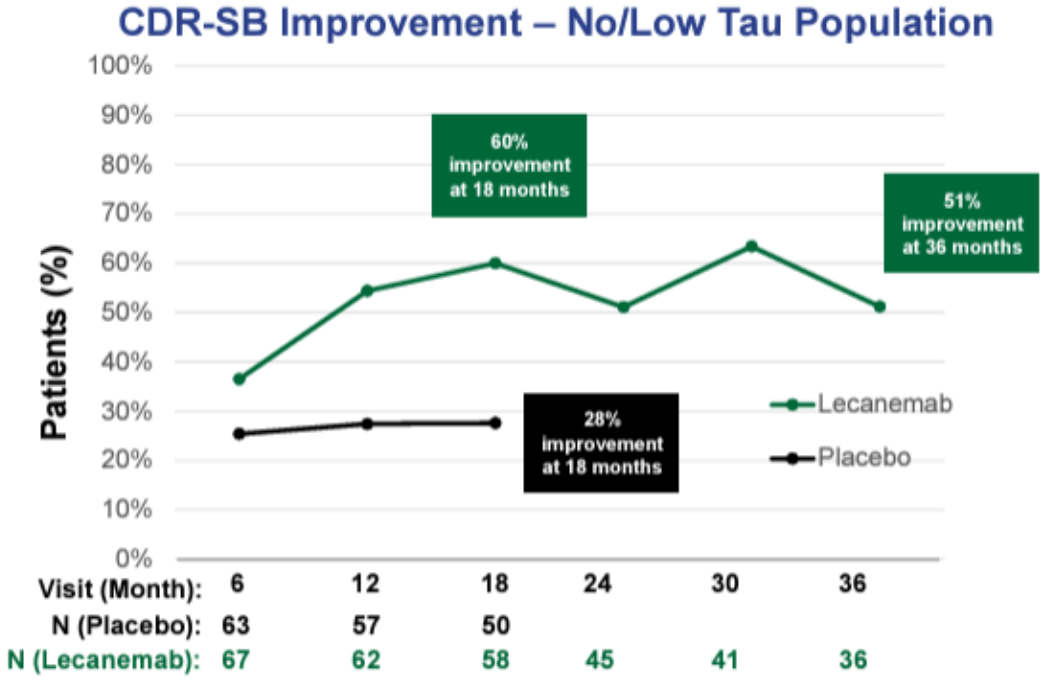
1. CDR-SB is a global cognitive and functional scale that measures six domains of functioning, including memory, orientation, judgement and problem solving, community affairs, home and hobbies, and personal care.
2. The ADCS-MCI-ADL assesses the ability of patients to function independently, including being able to dress, feed themselves and participate in community activities.

AAIC highlights – Long-term lecanemab data show increased patient benefit with maintained safety profile

36-month data showed increasing clear and meaningful long-term treatment effect



>50% of patients in the earliest stage of AD continued to show improvement after 36 months



No new safety findings were reported and very low frequency of ARIA after the first 6 months of treatment

Source: Eisai AAIC 2024 presentations with data from Clarity AD and Clarity AD OLE

Clinical Dementia Rating (CDR) – 0.5 points matter

Lecanemab prolongs time in the earlier stages of disease where individuals are still independent

	Impairment				
	None 0	Questionable 0.5	Mild 1	Moderate 2	Severe 3
Memory	No memory loss or slight inconsistent forgetfulness	Consistent slight forgetfulness; partial recollection of events; "benign" forgetfulness	Moderate memory loss; more marked for recent events; defect interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
Orientation	Fully oriented	Fully oriented except for slight difficulty with time relationships	Moderate difficulty with time relationships; oriented for place at examination; may have geographic disorientation elsewhere	Severe difficulty with time relationships; usually disoriented to time, often to place	Oriented to person only
Judgment & Problem Solving	Solves everyday problems & handles business & financial affairs well; judgment good in relation to past performance	Slight impairment in solving problems, similarities, and differences	Moderate difficulty in handling problems, similarities, and differences; social judgment usually maintained	Severely impaired in handling problems, similarities, and differences; social judgment usually impaired	Unable to make judgments or solve problems
Community Affairs	Independent function at usual level in job, shopping, volunteer and social groups	Slight impairment in these activities	Unable to function independently at these activities although may still be engaged in some; appears normal to casual inspection	No pretense of independent function outside home Appears well enough to be taken to functions outside a family home	Appears too ill to be taken to functions outside a family home
Home and Hobbies	Life at home, hobbies, and intellectual interests well maintained	Life at home, hobbies, and intellectual interests slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly maintained	No significant function in home
Personal Care	Fully capable of self-care		Needs prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; frequent incontinence

CDR-SB score

0.5 – 4.0 MCI

4.5 – 9.0 Mild AD

9.5 – 15.5 Moderate AD

16 – 18 Severe AD

Clarity AD baseline: 3.2

Source: https://knightadrc.wustl.edu/professionals-clinicians/cdr-dementia-staging-instrument/cdr-scoring-table/

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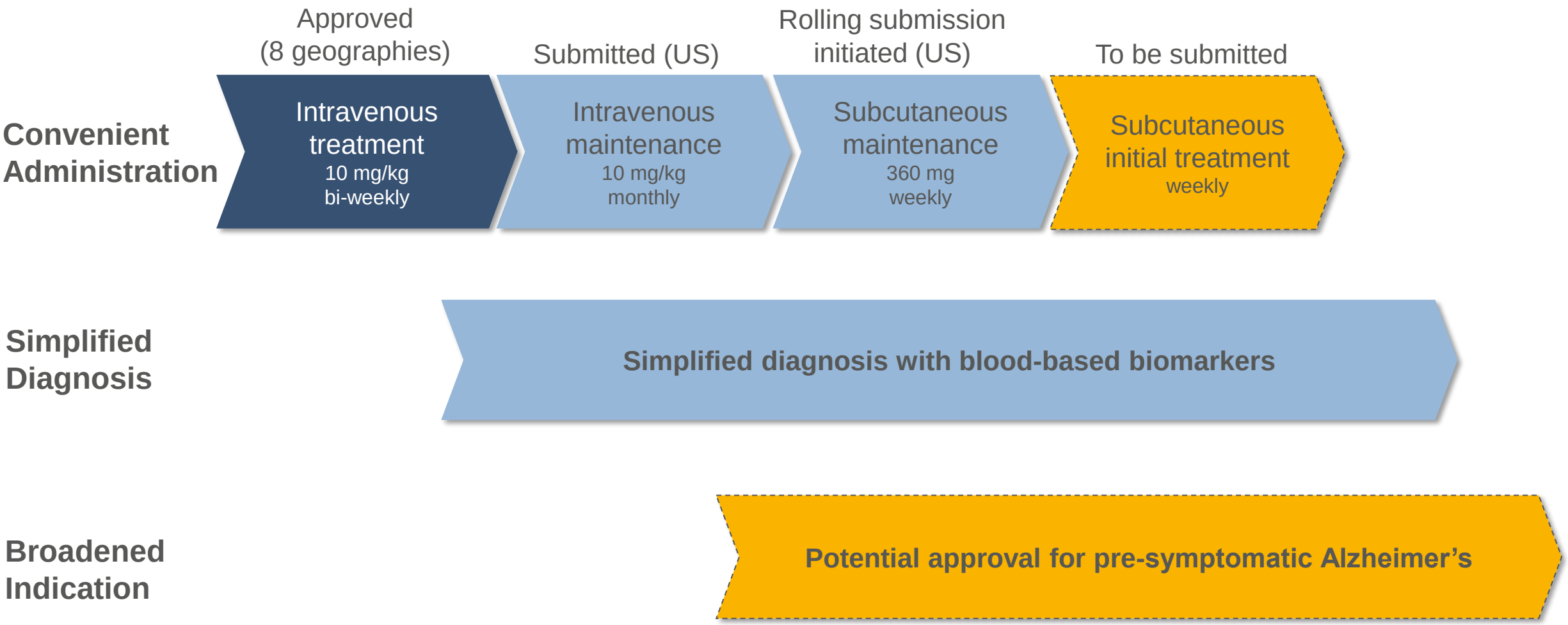
Simplified diagnosis and continued development of Leqembi could increase patient population and convenience



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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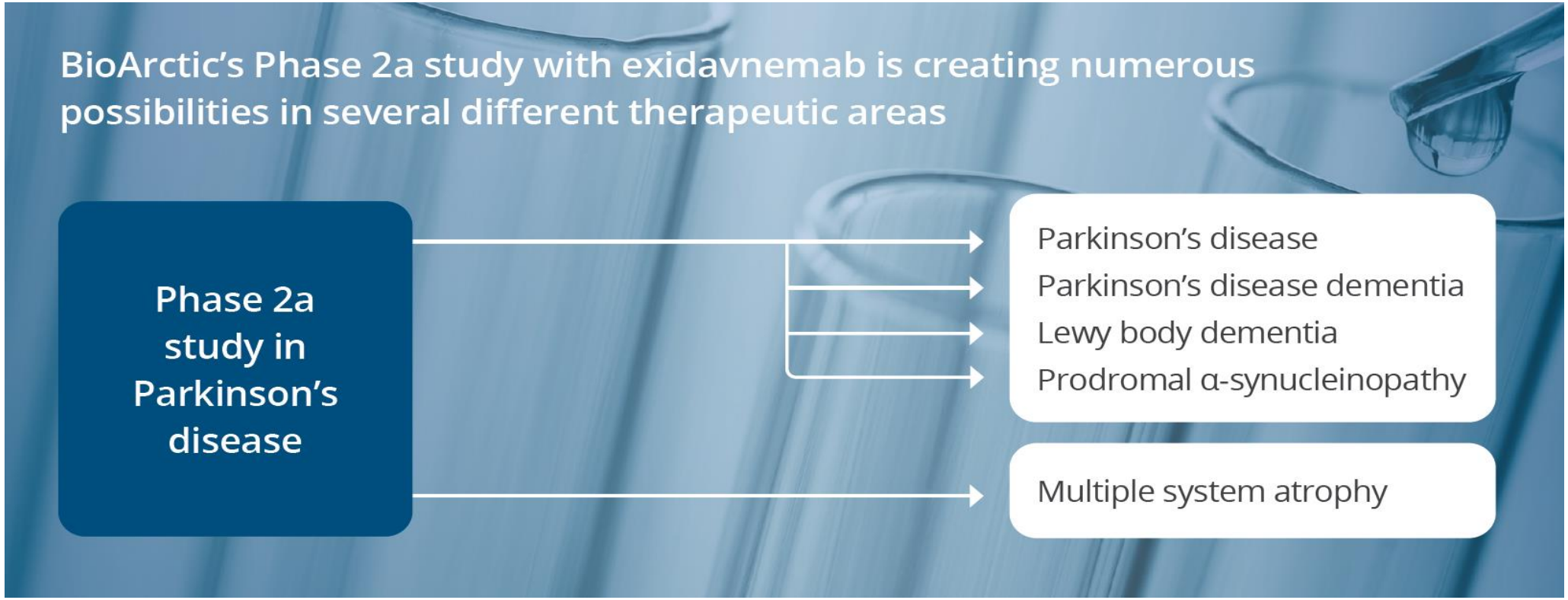
Preparation for Phase 2a for exidavnemab 2024
Offers opportunities in several neuronal synucleinopathies (NSD)



Biomarkers available to identify patients with pathological α-syn

Exidavnemab Phase 2a study “EXIST” in Parkinson's disease

EXIST PHASE 2A STUDY DESIGN

Patient inclusion

Patients with Mild to Moderate Parkinson's Disease (PD)

Inclusion criteria:

- Idiopathic PD with confirmed dopamine transporter deficit
- Stable symptomatic PD medication
- Cognition inconsistent with dementia
- Hyposmia as shown by positive smell test

Stratification:

α-synuclein SAA* positive

No of subjects:

24

Treatment 3 mo

Randomized, double-blind, placebo-controlled trial

Exidavnemab low dose	Exidavnemab high dose
Placebo	Placebo

2H 2024 Initiation

Mid 2025 Safety review

1H 2026 Results

Read-outs

Primary endpoints:
Safety & tolerability

Key endpoints:
PK & Immunogenicity

Exploratory:
Biomarkers

Plasma & CSF

Digital -motor -cognition

* SAA = Seeding amplification assay

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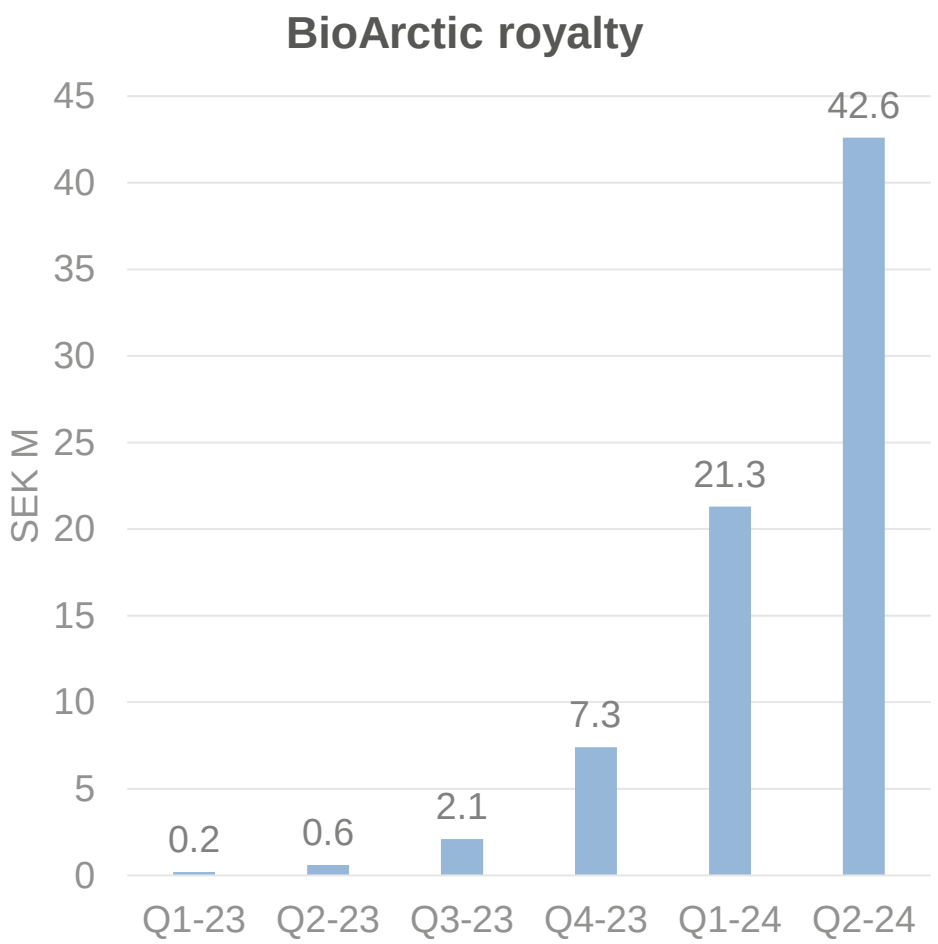
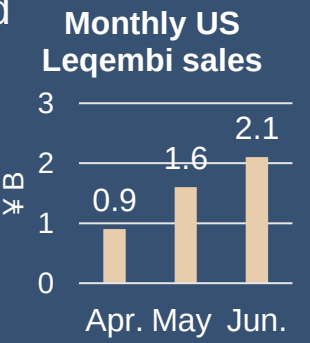
Financial Summary

Leqembi royalties are growing fast



- Global Q2-24 sales were ¥ 6,3 B ($ ~40 M), ~120% increase over Q1-24
- US expansion started picking up speed in May
  - Eisai/Biogen 30% increase in commercial structure completed, ~450 positions in place
  - Number of institutions ordering grew by ~40% over Q1
  - Monthly US sales grew from $ ~6 M in April to ~13 M in June



- Very strong start in Japan
  - ¥ 1.5 B in Q2, i.e. approximately a third of US sales
  - ~500 facilities have started prescribing out of 650 that had established pathway
  - ~800 doctors have prescribed but only 70 to more than 10 patients
- Launch in China ahead of schedule on June 27
  - Initially targeting private market using online platform
  - Already adopted at 148 hospitals in 57 cities

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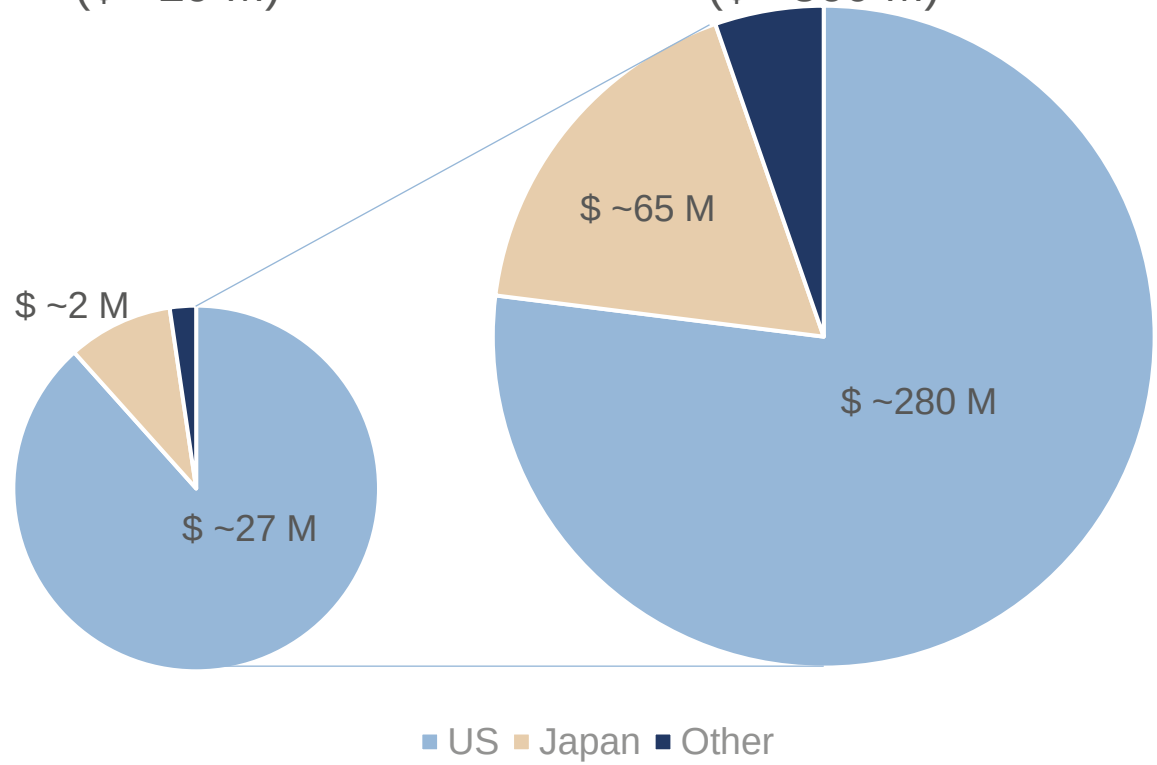
Eisai forecast reiterated with more than tenfold sales increase for Leqembi in their fiscal year 2024 (Q2-24 to Q1-25)

FY 2023
(Q2-23 to Q1-24)

¥ 4.3 B
($ ~29 M)

FY 2024
(Q2-24 to Q1-25)

¥ 56.5 B
($ ~360 M)



- This corresponds to SEK ~400 M in royalty Q2-24 to Q1-25
- Eisai's mid-term revenue simulation presented in March: ¥ 290 B ($ 1.9 B) in FY 2026

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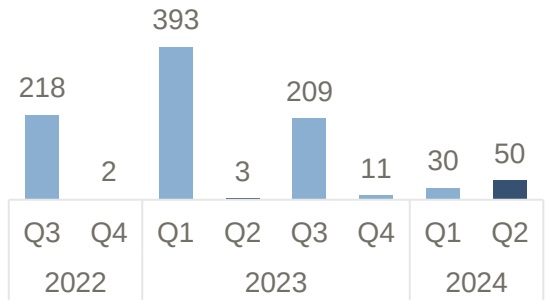
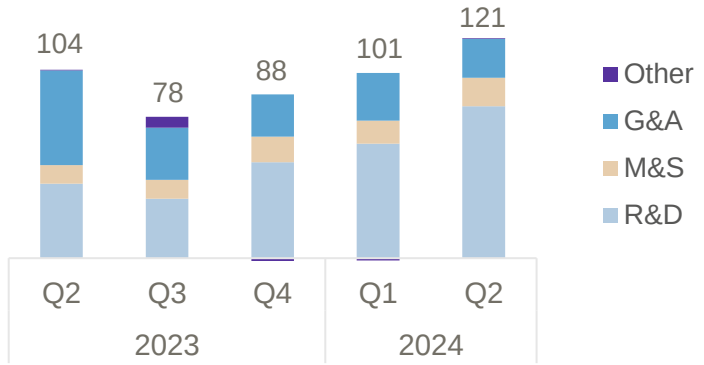
Operating loss of SEK 76 M in the second quarter

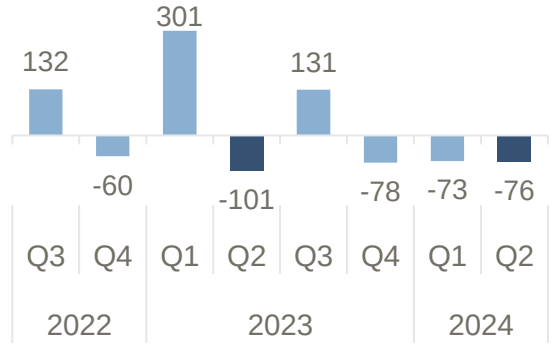
Net Revenues (SEK M)



OPEX by function (SEK M)



Operating Profit/Loss (SEK M)



- Q2 net revenues were SEK 50 M (3)
  - No milestone payments
- The two new revenue streams will shift revenue mix over time
  - Royalty SEK 42.6 M in Q2
  - Co-promotion SEK 2.7 M in Q2

- Operating expenses increased to SEK 121 M (104) in Q2
  - R&D 69% of total operating expenses, M&S 13%

Costs expected to increase during remainder of 2024

- Progression of project portfolio
- Increased activity in commercial organization but no expansion until final CHMP opinion

- Operating loss was SEK 76 M (101) for Q2

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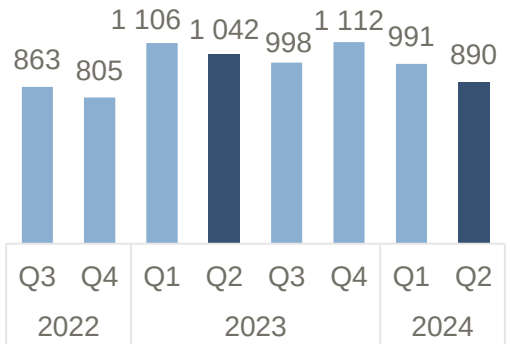
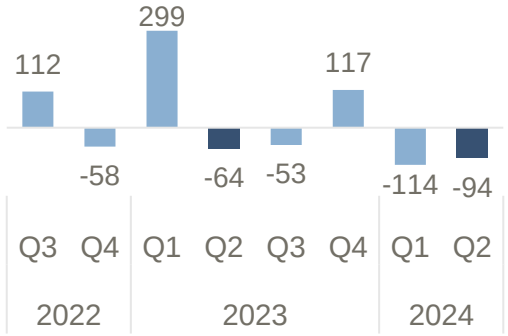
Strong financial position going forward

Cash Balance (SEK M)



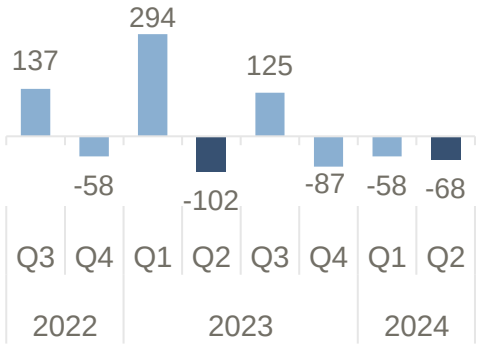
- Cash balance including short-term investments SEK 890 M at the end of the second quarter

Cash Flow From Operating Activities (SEK M)



- Operating cash flow was a negative SEK 94 M (neg. 64) in Q2

Net Result (SEK M)



- Net loss for Q2 was SEK 68 M (102)

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

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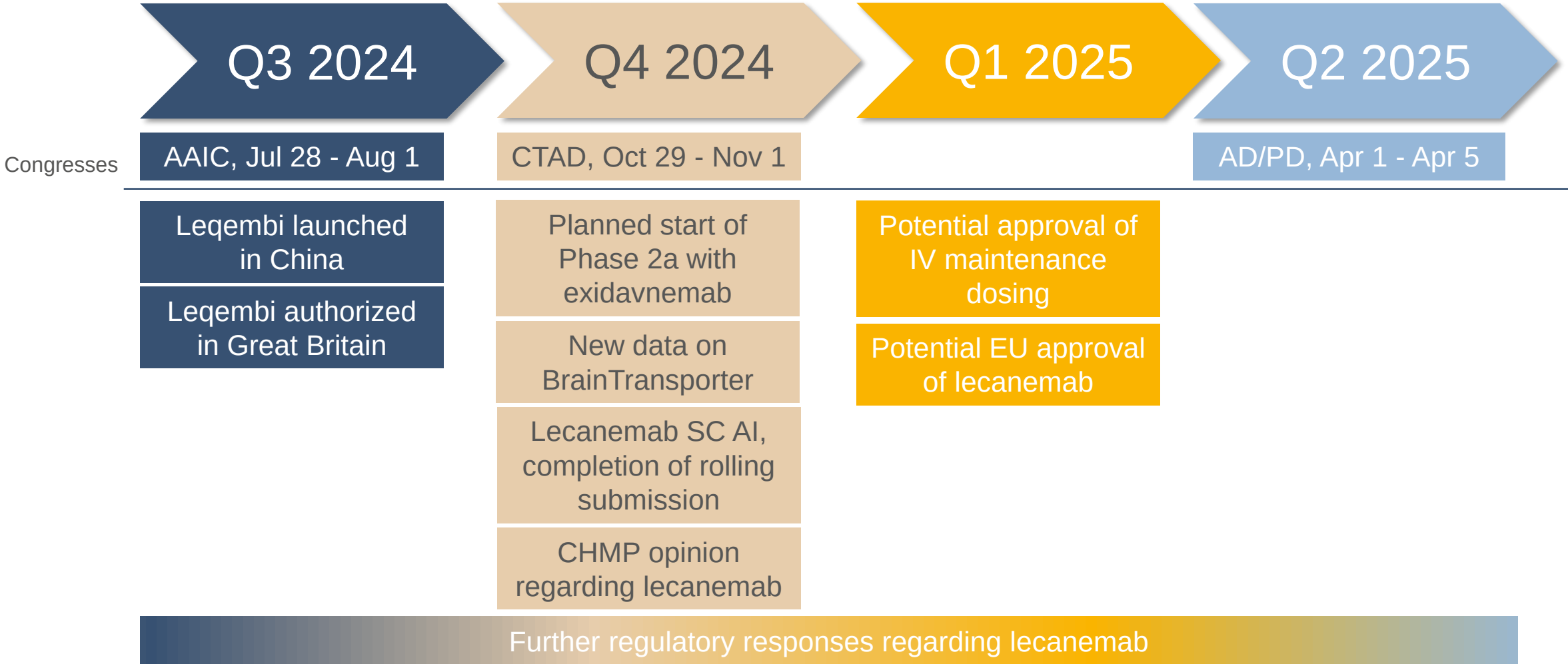
Upcoming news flow and closing remarks

Upcoming news flow



AI – autoinjector
SC – subcutaneous

In summary

Leqembi sales growing fast. Now launched in the US, Japan and China

Early pipeline progressing well

Finances remain solid

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

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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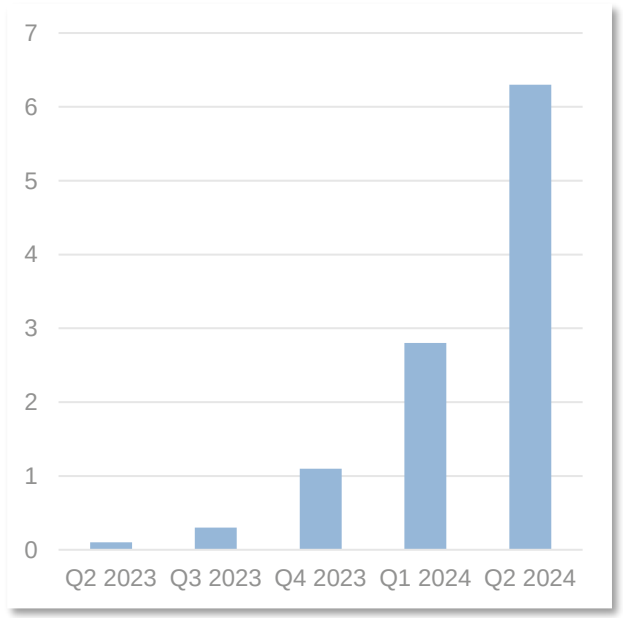
Leqembi launch is taking off

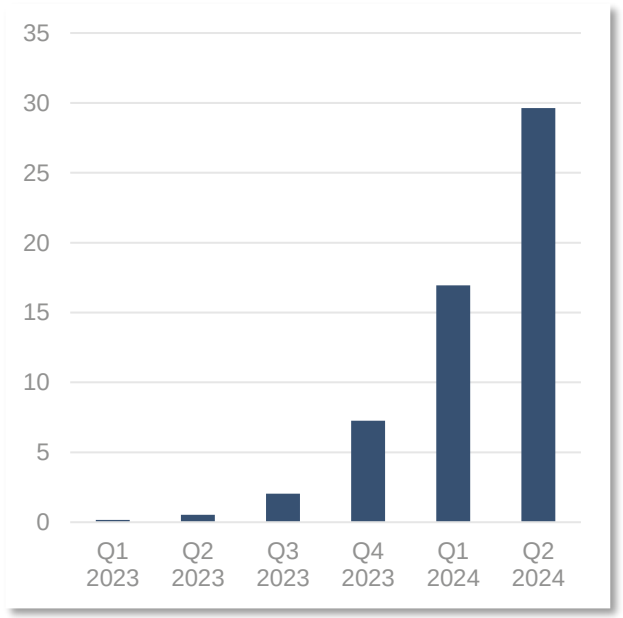
- **US:** Sustained rate of new patient growth and strong growth in number of prescribing physicians
- **Japan:** Rapidly increasing number of treated patients, with revenue increasing by approx. 5 times compared to the previous quarter
- **China:** Launched on June 27 – already adopted by around 150 hospitals across the country

Billion JPY



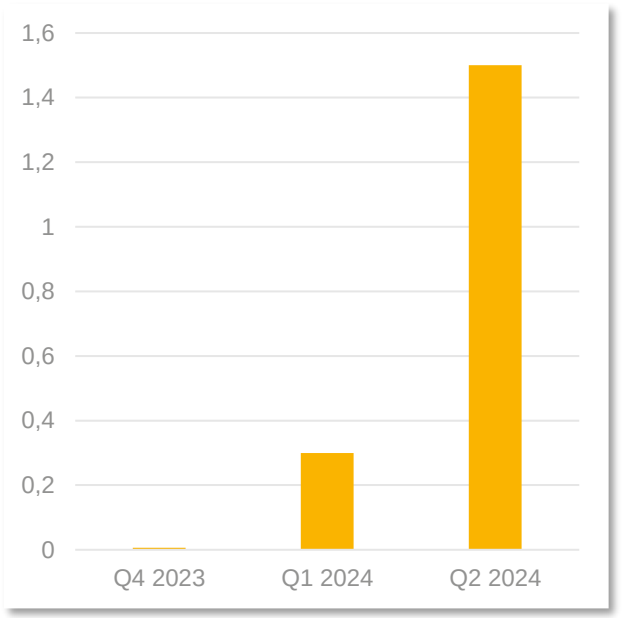
Leqembi Global revenue

Million USD



Leqembi US revenue

Billion JPY



Leqembi Japan revenue