Q3 Report
July – September 2024

Stockholm, November 14, 2024

BIOARCTIC

Presenting team

GUNILLA OSSWALD, CEO

ANDERS MARTIN-LÖF, CFO

IR contact:
Oskar Bosson,
VP Communications & IR
+46 704 10 71 80
ir@bioarctic.se

Next Report:
2024 Q4 & FY Report
February 14, 2024

To subscribe to financial reports/press releases and for more information, please visit www.bioarctic.com

BIOARCTIC

Disclaimer

- This presentation has been prepared and produced by BioArctic AB (publ) (“BioArctic”) solely for the benefit of investment analysis of BioArctic and may not be used for any other purpose. Unless otherwise stated, BioArctic is the source for all data contained in this presentation. Such data is provided as at the date of this presentation and is subject to change without notice.
- This presentation includes forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause BioArctic’s actual results, performance, achievements or industry results to be materially different from those expressed or implied by these forward-looking statements. Forward-looking statements speak only as of the date of this presentation and BioArctic expressly disclaims any obligation or undertaking to release any update of, or revisions to, any forward-looking statement in this presentation, as a result of any change in BioArctic’s expectations or any change in events, conditions or circumstances on which these forward-looking statements are based.
- This presentation does not constitute or form part of, and should not be construed as, an offer or invitation for the sale of or the subscription of, or a solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it or the fact of its distribution form, or be relied on in connection with, any offer, contract, commitment or investment decision relating thereto, nor does it constitute a recommendation regarding the securities of BioArctic.
- The information in this presentation has not been independently verified.
- No regulatory body in Sweden or elsewhere has examined, approved or registered this presentation.

BIOARCTIC

BioArctic – a global leader in neurodegenerative diseases

Focus on neurodegenerative disorders

- Disorders with very large unmet needs and large patient populations

World-class R&D organization leveraging strong collaborations

- BioArctic behind Leqembi®, the world's first fully approved* disease modifying therapy for Alzheimer's disease

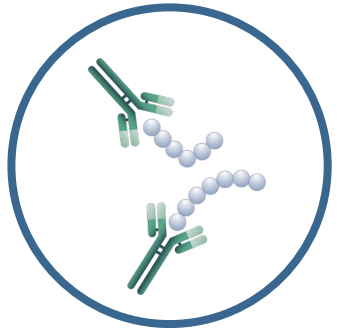
Broad project portfolio building on two technology platforms

- Several projects in Alzheimer's disease, Parkinson's disease, ALS end enzyme replacements

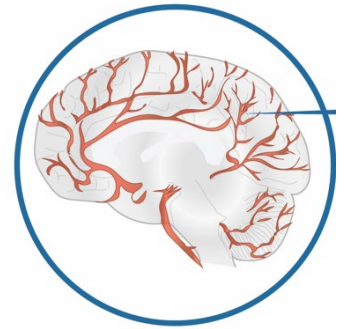
Well-financed from milestones and royalties from lead product

- 9% royalty on global Leqembi® sales plus milestones from partner Eisai
- 2023 operating profit of SEK 253 M, Cash position ~SEK 0.8 B

Highly selective antibodies targeting aggregated forms of toxic proteins



BrainTransporter™ technology delivers biotherapeutics to the brain



BIOARCTIC

- Leqembi is fully approved in the US, Japan, China, South Korea, Great Britain and several other markets and pending approval in other markets

Pipeline progressing well, with strong new data validating the BrainTransporter™ platform presented

BioArctic BrainTransporter

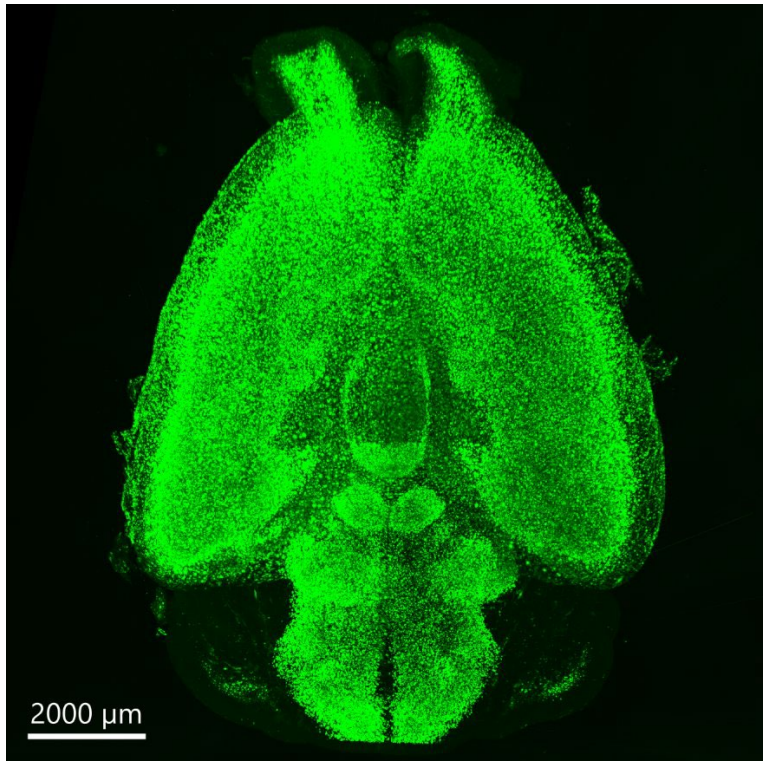
- Presented validation in NHP at PEGS conference, demonstrating rapid, broad and deep brain distribution of BT-anti amyloid Ab

Exidavnemab

- Phase 2a study initiated in Parkinson's disease, exploring to also include MSA patients

Other

- Lars Lannfelt received Lifetime Achievement Award at CTAD conference



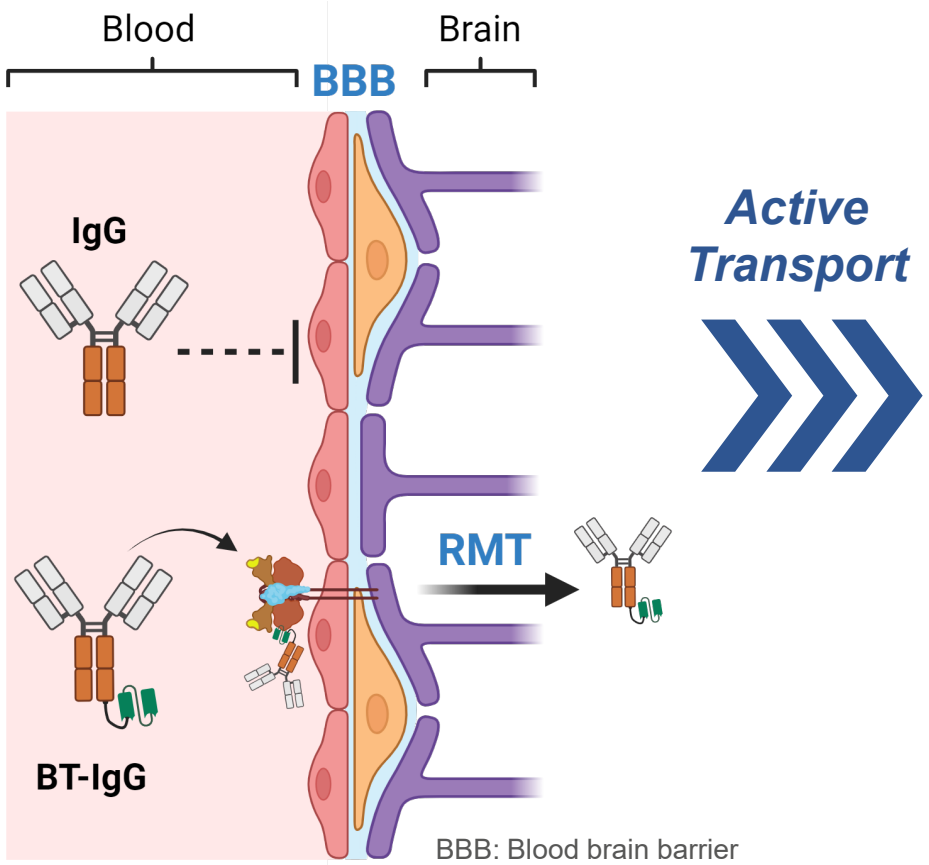
BIOARCTIC

The BrainTransporter platform

Active transport of biotherapeutics across the blood brain barrier

Overcome the BBB obstacle

RMT across the BBB



BBB: Blood brain barrier
RMT: Receptor-mediated transport

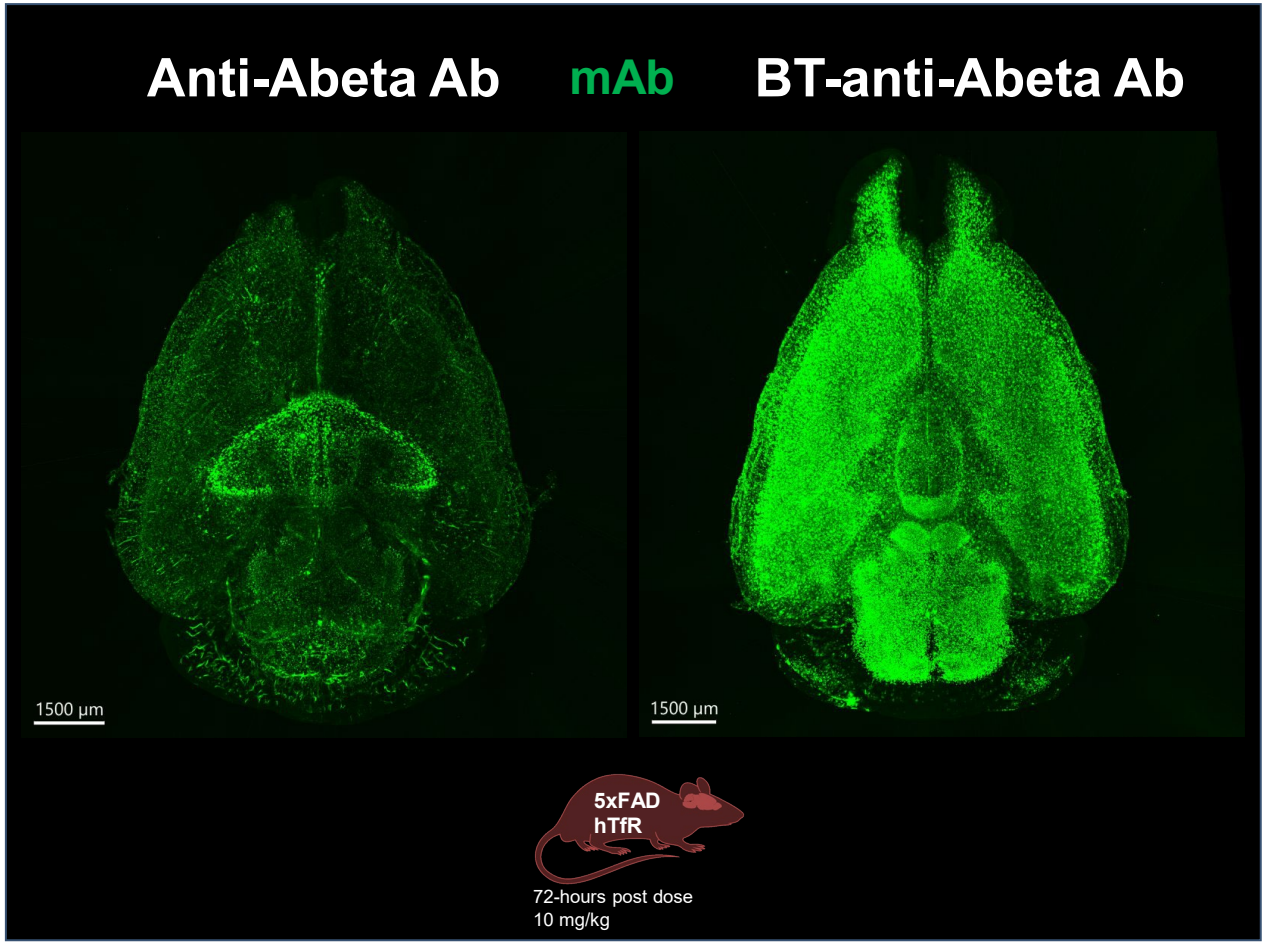
Several opportunities to further enhance antibodies and other modalities in clinic

Opportunities	Note
Increased brain exposure	Promotes **active transport** across the BBB
Broader brain distribution	Access **deeper brain structures** using the brain capillary network
Faster efficacy	Promotes **rapid brain exposure** due fast BBB transport
Stronger efficacy	**Complete access to the target population** by increased exposure and broader brain distribution
Convenience – lower dose	**Reduced volume** and **number of injections** required for clinical effect
Safety – lower dose/different distribution	**Reduce the total drug load** required for clinical effect

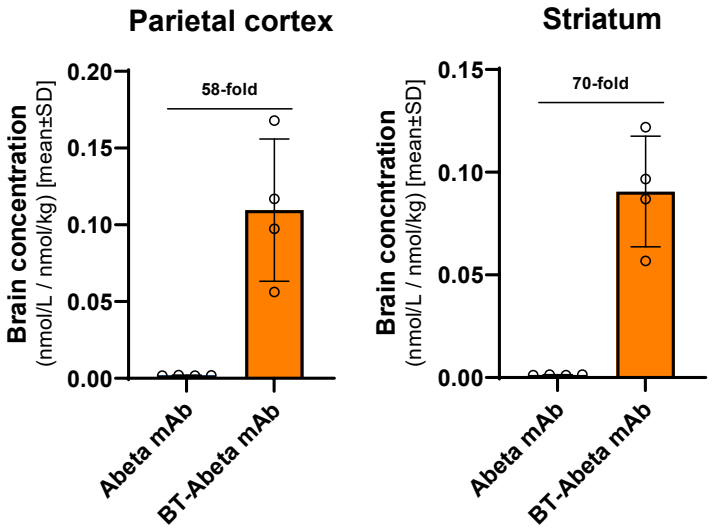
BIOARCTIC

Stronger, deeper and broader brain distribution with the BT approach

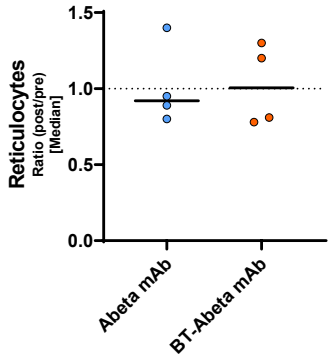
Validated in non-human primates with substantially increased brain exposure without affecting hematology including reticulocytes



BT substantially increases brain exposure



BT-Abeta mAb does not induce reticulocyte loss



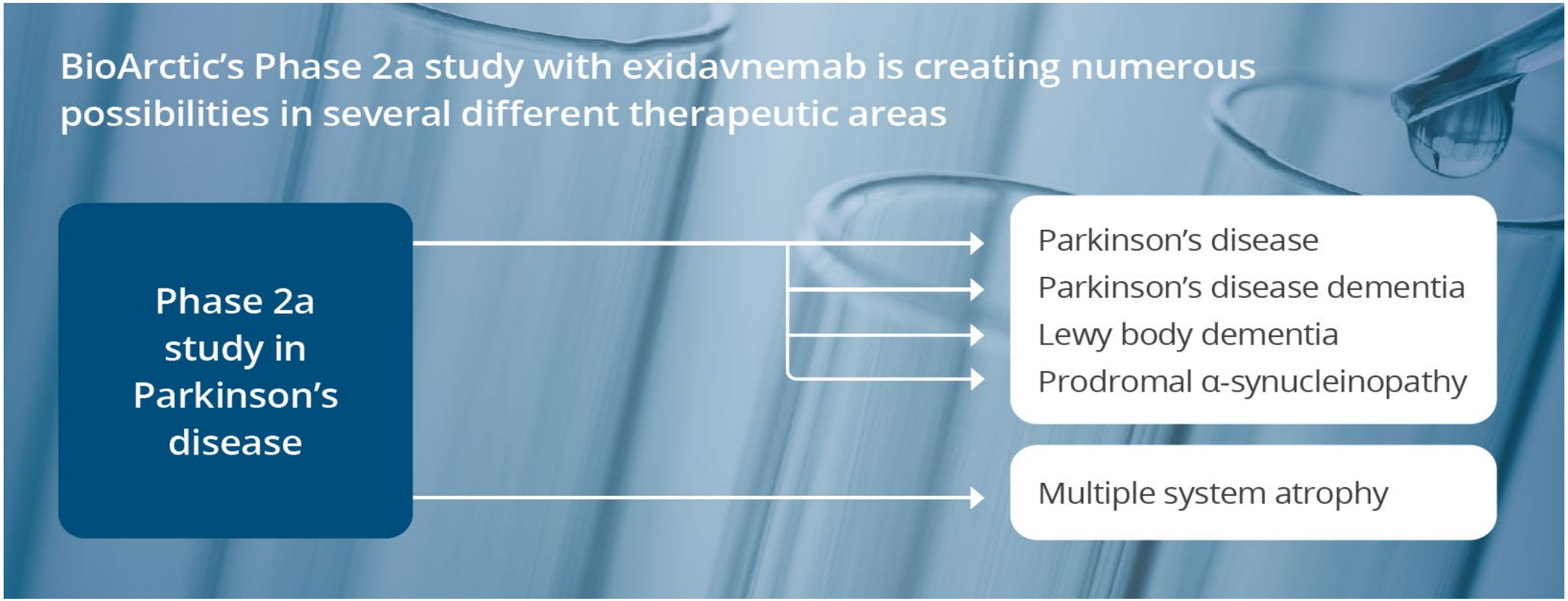
p = 0.95 (unpaired t test)

Applied in all parts of BioArctic's project portfolio
Opportunities also in other therapeutic areas

BIOARCTIC

Screening for exidavnemab Phase 2a study ongoing

Offers opportunities in several neuronal synucleinopathies (NSD)



Biomarkers available to identify patients with pathological α-syn

BIOARCTIC

Exidavnemab Phase 2a study “EXIST” in Parkinson's disease Exploring to add a MSA cohort

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:

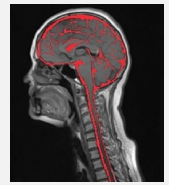
Safety & tolerability

Key secondary endpoints:

PK & Immunogenicity

Exploratory:

Biomarkers



Plasma & CSF

Digital -motor -cognition

* SAA = Seeding amplification assay

BIOARCTIC

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)							
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							

as of September 30, 2024

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

BIOARCTIC

Number of patients treated with Leqembi continues to expand with clinical experience safety data on par or better than phase 3

Leqembi

Commercial

- Royalties grew >60% quarter-on-quarter; 70 MSEK
- Continued growth in the US market, Japan and China above expectations
- Eisai lowered fiscal year (Apr 2024 – Mar 2025) outlook from JPY 56.5 billion to JPY 42.5 billion

Regulatory

- Approved and launched also in Hong Kong, Israel, UAE and Great Britain
- Regulatory reviews ongoing in 17 markets and regions, incl. EU
- Subcutaneous maintenance dosing rolling submission finalized in the US

Development

- Preclinical AD Phase 3 study AHEAD 3-45 recruitment completed Oct 15
- New data from Clarity AD OLE presented at CTAD and AAIC supporting early treatment and maintenance dosing

BIOARCTIC

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

USA ✓

Approved
July 2023

IV maintenance therapy submitted Q1 2024, PDUFA 25th of Jan 2025

Rolling submission for subcutaneous autoinjector maintenance dosing completed October 2024

Preparing for filing of subcutaneous induction treatment

Japan ✓

Approved
September 2023

Launched
December 2023

EU

Marketing authorization application submitted
January 2023

Negative CHMP opinion
July 2024

Re-examination ongoing. Final CHMP opinion expected November 15, 2024

China ✓

Approved
January 2024

Launched
June 2024

Rest of World ✓

Approved in
South Korea, Israel, Hong Kong, United Arab Emirates, Great Britain

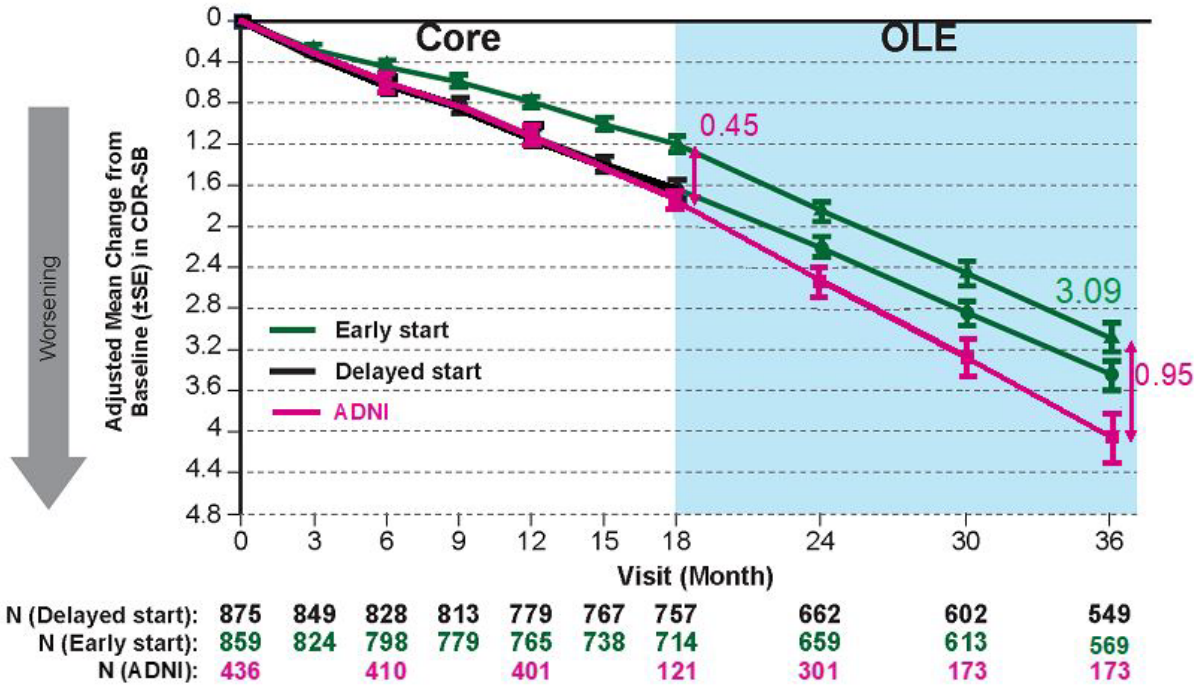
Applications submitted:
Australia (reconsideration) Canada, Switzerland, Taiwan, Singapore, Brazil, Russia, Saudi Arabia, India, South Africa, The Philippines, Thailand, Vietnam, Malaysia, Mexico, Indonesia

FDA – Food & Drug Administration
CMS – Centers for Medicare & Medicaid Services
PMDA – Pharmaceuticals and Medical Devices Agency
EMA – European Medicines Agency
S.C. – subcutaneous
A.I. – Auto-injector

BIOARCTIC

36-month data showed increasing clear and meaningful long-term treatment effect with no new safety findings reported

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



Experience from clinical practice from the US and Japan presented at CTAD:

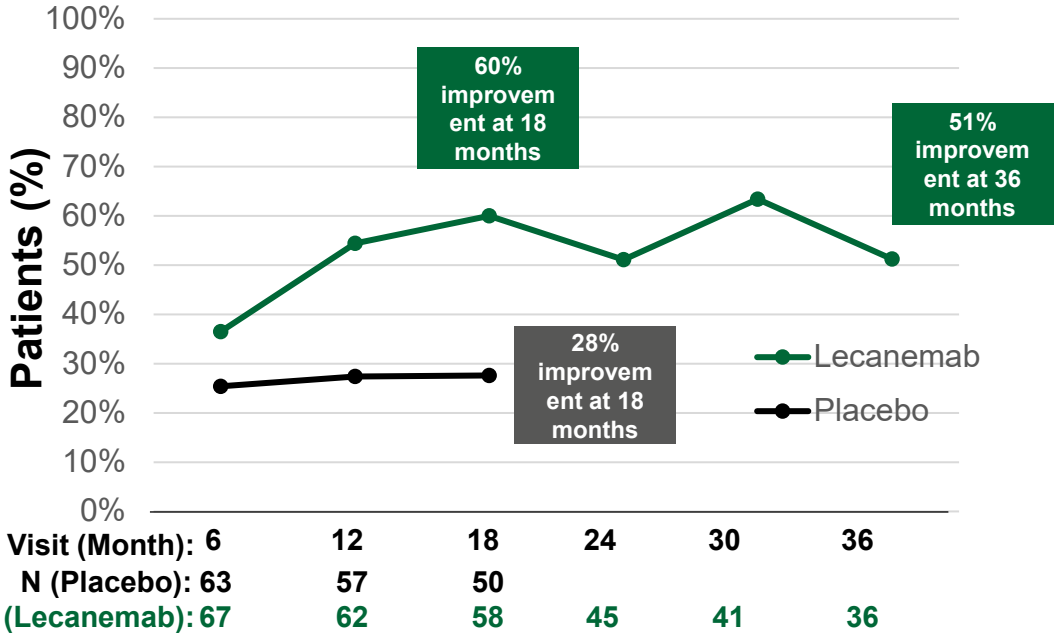
- Wide patient acceptance and compliance
- Treatment is safe and side effects are manageable
- ARIA E&H rates are similar to clinical studies
- Patient journey improving

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

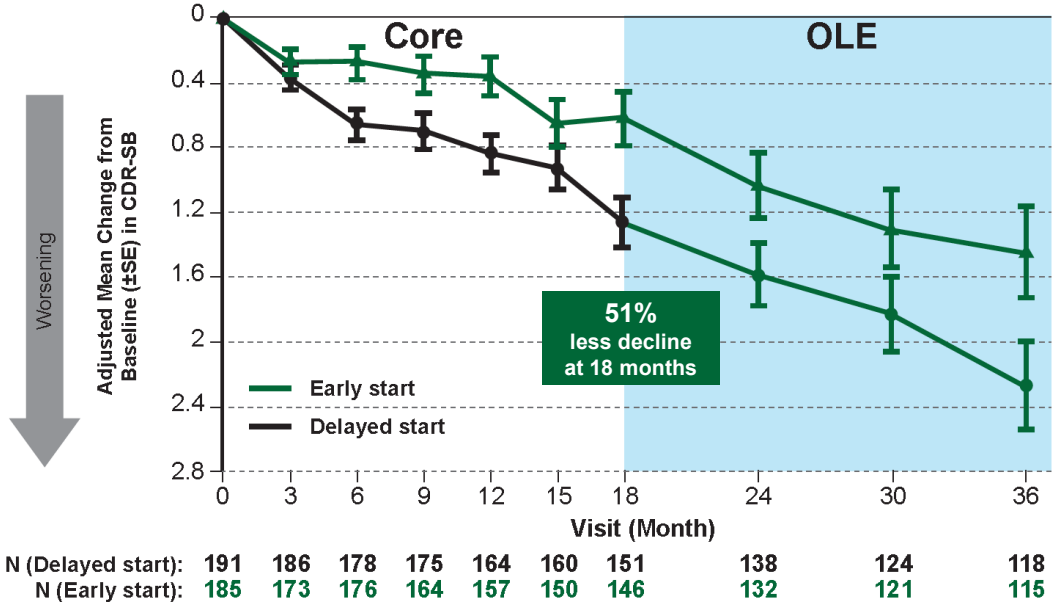
BIOARCTIC

Earlier patients benefit more from early initiation and continued dosing – majority improved or maintained out to 36 months

CDR-SB Improvement – No/Low Tau Population



CDR-SB – Aβ Baseline < 60 CL



Similar results were observed for ADAS-Cog14 and ADCS MCI-ADL

BIOARCTIC

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

Convenient Administration

Approved (8 geographies)	Submitted (US)	Rolling submission finalized (US)	To be submitted
Intravenous treatment 10 mg/kg bi-weekly	Intravenous maintenance 10 mg/kg monthly	Subcutaneous maintenance 360 mg weekly	Subcutaneous initial treatment weekly

Simplified Diagnosis

Simplified diagnosis with blood-based biomarkers
Screening & confirmational

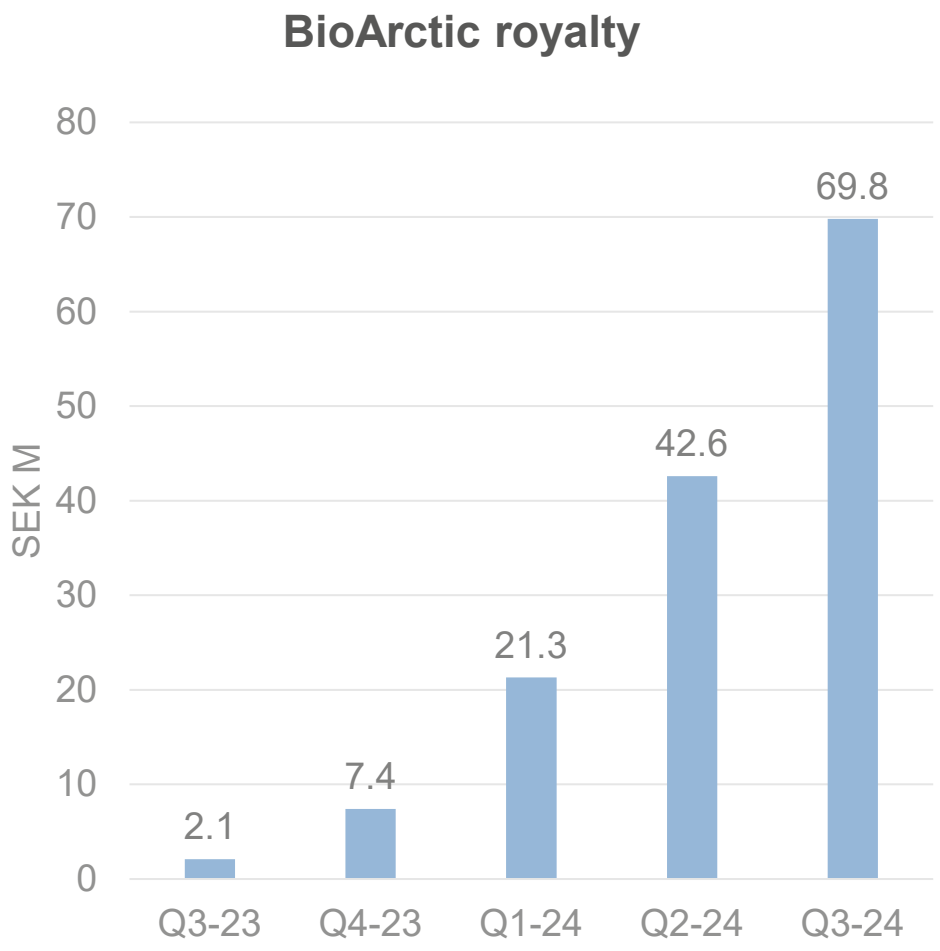
Broadened Indication

Potential approval for pre-symptomatic Alzheimer's

BIOARCTIC

Financial Summary

Leqembi US sales lower than expected, offset by strong development in Japan and China – Eisai revises forecast

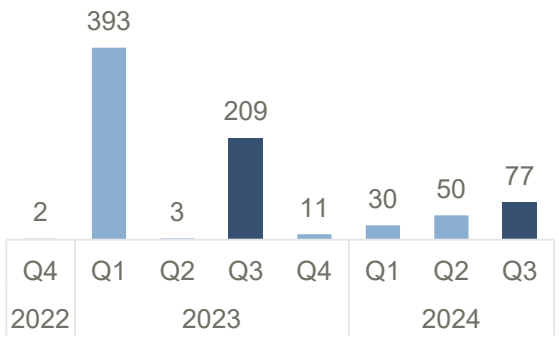


- Global sales Q3-24 were ¥ 10 B (~67 MUSD), ~66% increase from Q2-24
  - Royalties increased by 64% to SEK 69.8 M
- US expansion slower than expected
  - ~ ¥ 5.9 B in Q3 (~39 MUSD), ~30% growth from Q2
  - Strong demand but bottleneck in infusion capacity, ~6,000 patients waiting for treatment
  - Infusion capacity will increase during q4 and q1 by 80-90%
- Continued strong development in Japan
  - ~ ¥ 2.7 B in Q3 (~18 MUSD), ~80% growth from Q2
  - ~800 facilities treating ~5.000 patients
  - TV DTC campaign starting Nov. 15 to raise awareness about MCI and promote early diagnosis
- Strong start in China after launch in end of June
  - ~ ¥ 1.2 B in Q3 (~8 MUSD)
  - ~240 hospitals treating ~3.000 patients
  - Self-pay market using blood-based biomarkers and digital platform
- Eisai adjusted FY 2024 (q2-24 - q1-25) forecast of ¥ 56.5 B (~370 MUSD) to ¥ 42.5 B (~280 MUSD)
  - Mid- and long-term forecasts unchanged

BIOARCTIC

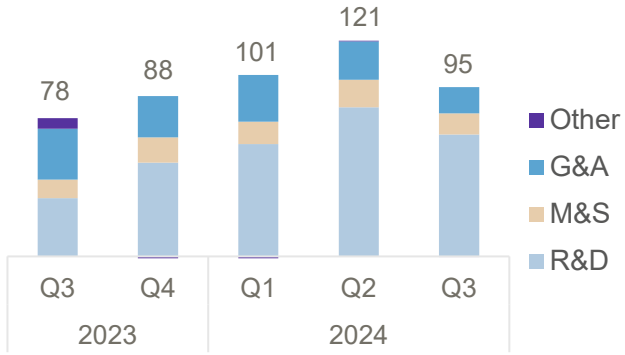
Operating loss of SEK 26 M in the third quarter

Net Revenues (SEK M)



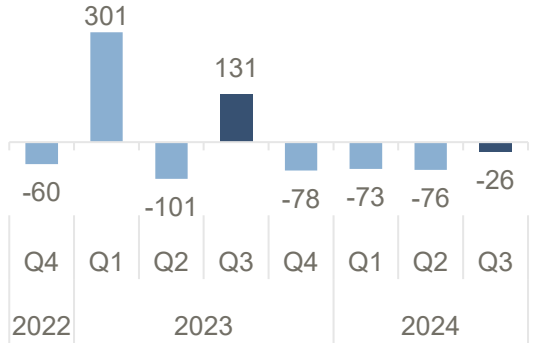
- Q3 net revenues were SEK 77 M (209)
  - No milestone payments Q3 2024
- The two new revenue streams will continue to shift revenue mix over time
  - Royalty SEK 69.8 M in Q3
  - Co-promotion SEK 3.0 M in Q3

OPEX by function (SEK M)



- Operating expenses increased to SEK 95 M (78) in Q3
  - R&D 72% of total operating expenses, M&S 12%
- Costs expected to increase during remainder of 2024
  - Progression of project portfolio
  - No expansion in commercial organization until final CHMP opinion

Operating Profit/Loss (SEK M)

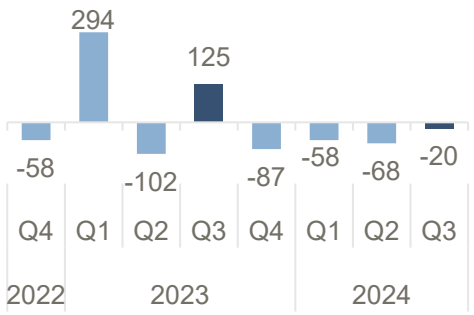


- Operating loss was SEK 26 M (profit 131) for Q3
  - Milestone payment received in Q3 2023

BIOARCTIC

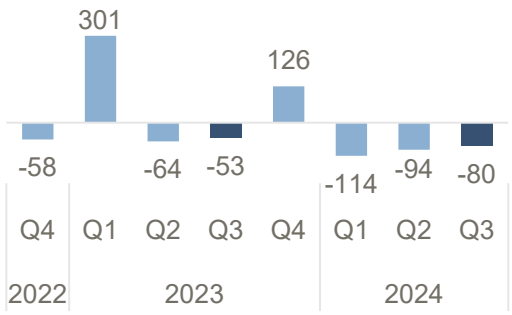
Growing royalties further strengthen the financial base

Net Result (SEK M)



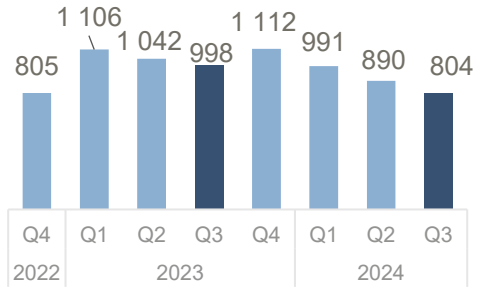
- Net loss for Q3 was SEK 20 M (125)

Cash Flow From Operating Activities (SEK M)



- Operating cash flow was a negative SEK 80 M (neg. 53) in Q3

Cash Balance (SEK M)



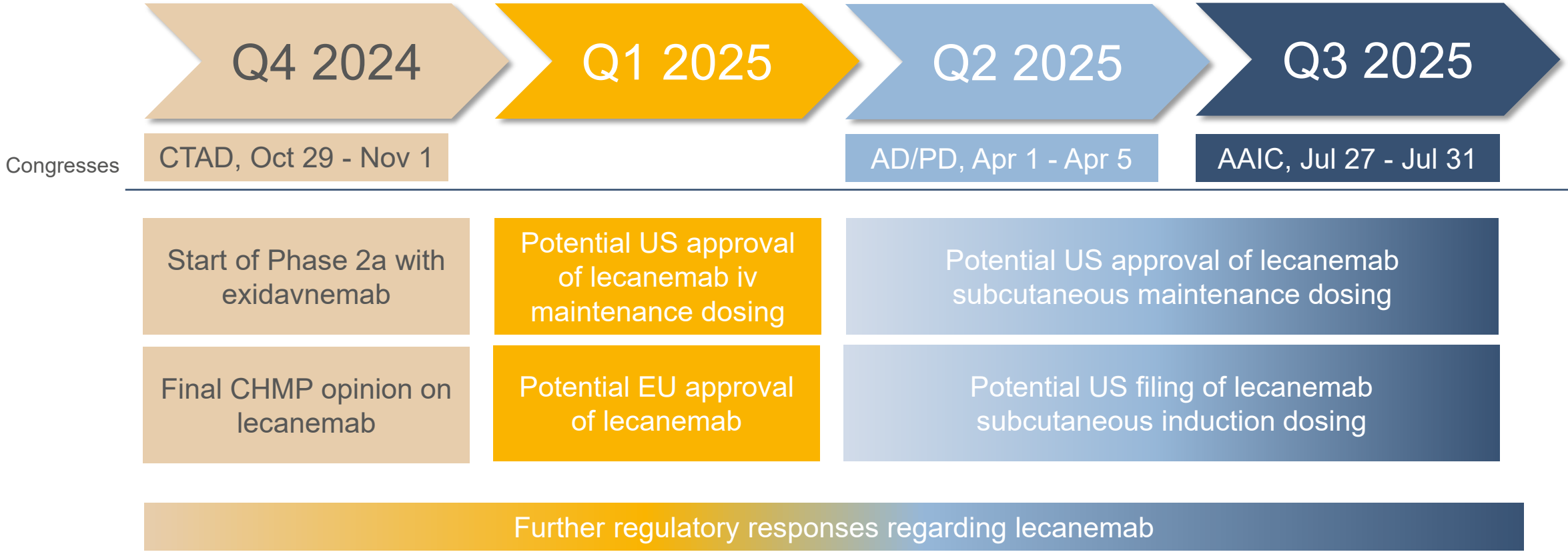
- Cash balance including short-term investments was SEK 804 M at the end of the third quarter

Revenues will continue to increase going forward, expected to lead to profitability

BIOARCTIC

Upcoming news flow and closing remarks

Upcoming news flow



AI – autoinjector
SC – subcutaneous

In summary

Early pipeline progressing well

Leqembi royalty revenue continues to grow

Finances remain solid

BIOARCTIC

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