

**BIOARCTIC AB (PUBL)  
NASDAQ STOCKHOLM: BIOA B**

# Full Year Report January-December 2021

Stockholm, February 3, 2022

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# BioArctic – a unique Swedish biopharma company

## Improving life for patients with central nervous system disorders

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**High unmet need** for disease-modifying treatments for Alzheimer's and Parkinson's diseases creates **large commercial opportunity**



**World-class research and development driven organization** with basis in founder's breakthrough discoveries and fruitful collaborations with leading **academic researchers** and **pharma companies** generating and developing **innovative projects**



**Attractive and well-balanced project portfolio** with projects from discovery through Phase 3 and combination of both proprietary projects with substantial marketing and out-licensing potential and partnered projects generating income



**Well-financed** with close to MSEK 850 (MUSD ~94<sup>1</sup>) in cash and **valuable collaboration agreements** totaling BSEK 9.1<sup>2</sup> (BUSD ~1) plus royalties

# Attractive and well-balanced project portfolio combines fully-financed partner projects and cutting-edge proprietary projects

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) ( <i>Clarity AD</i> )	Eisai <sup>1</sup>	Early Alzheimer's disease <sup>3</sup>				
	Lecanemab (BAN2401) ( <i>AHEAD 3-45</i> )	Eisai <sup>1</sup>	Preclinical (asymptomatic) Alzheimer's disease <sup>4</sup>				
	BAN2401 back-up	Eisai					
	AD1801						
	AD1502						
	AD1503						
	AD-BT2802						
	AD-BT2803						
	AD2603						
PARKINSON'S DISEASE	ABBV-0805 <sup>2</sup>	AbbVie					
	PD1601	AbbVie					
	PD1602	AbbVie					
OTHER CNS DISORDERS	Lecanemab (BAN2401)		Down's syndrome <sup>5</sup> Traumatic brain injury <sup>5</sup>				
	ND3014						
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform						
DIAGNOSTICS	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

as of December 31, 2021

1) Partnered with Eisai for lecanemab (BAN2401) for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding lecanemab (BAN2401) in 2014

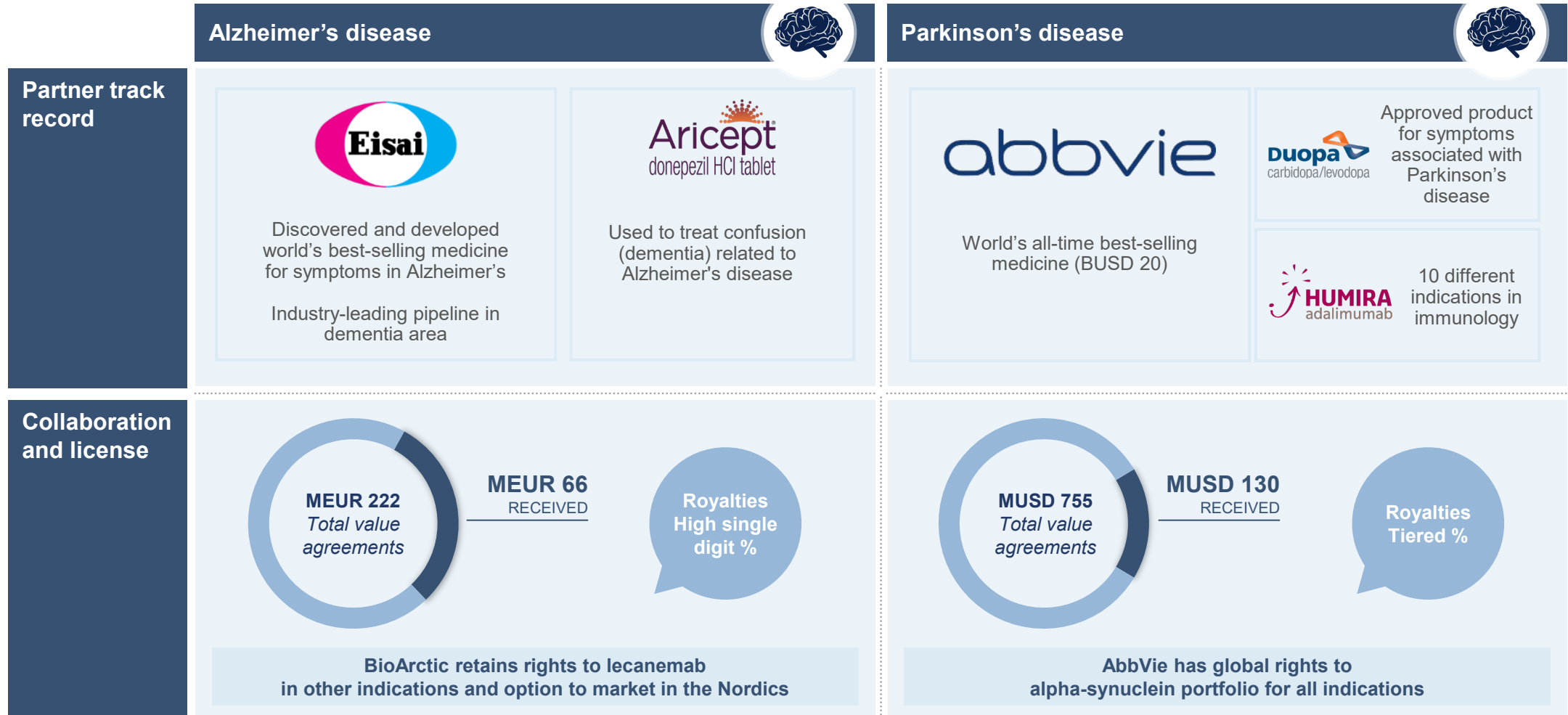
2) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805

3) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease

4) Normal cognitive function with intermediate or elevated levels of amyloid in the brain

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

# Long-standing and successful partnerships – de-risking clinical development and optimizing commercialization



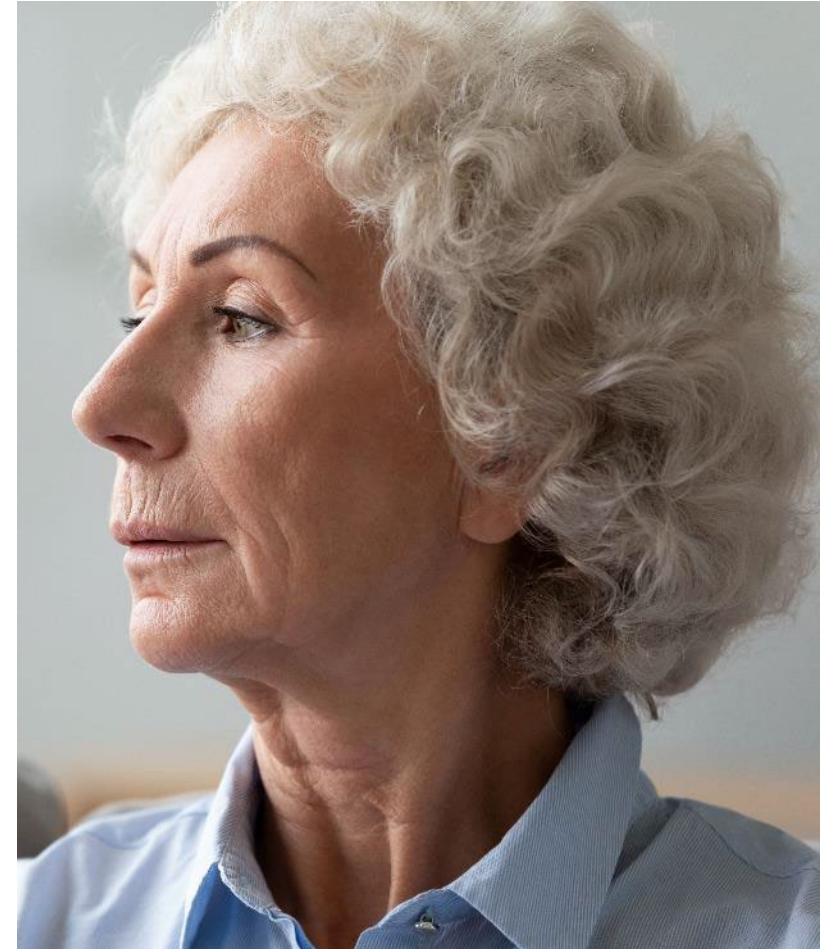
# Q4 highlights

## Alzheimer's disease – Lecanemab

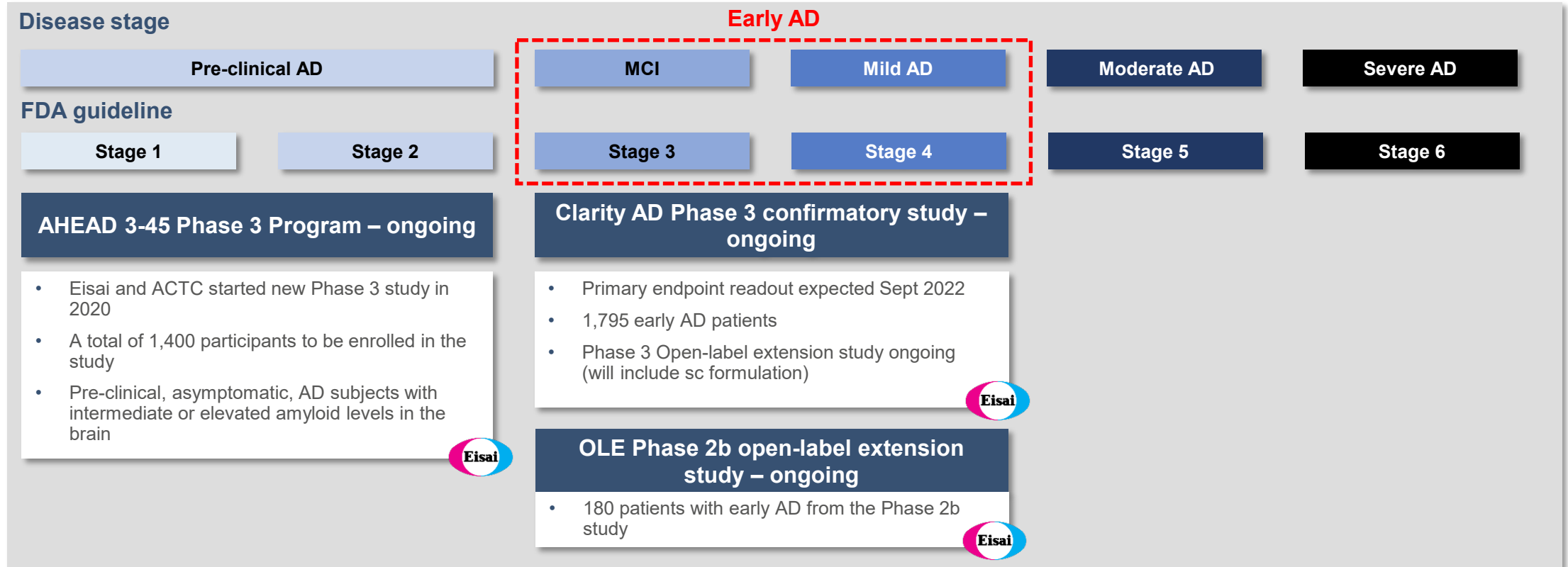
- Eisai initiated a rolling BLA submission under the accelerated approval pathway in September 2021.
  - In December, the second of three parts of the file was submitted
  - The submission is expected to be completed during H1 2022
- Lecanemab was granted Fast Track designation by the FDA in December 2021
- Data presented at CTAD congress in November continue to further strengthen and differentiate lecanemab towards competitors
- Lecanemab selected by DIAN-TU as backbone anti-amyloid therapy in combination with tau therapies in the NexGen study in dominantly inherited Alzheimer's disease
  - First patient enrolled in January 2022

## Other

- Expanding into new indications and treatment target (TDP-43)
- Continuing to build Nordic commercial organization
  - four new recruits with vast industry experience



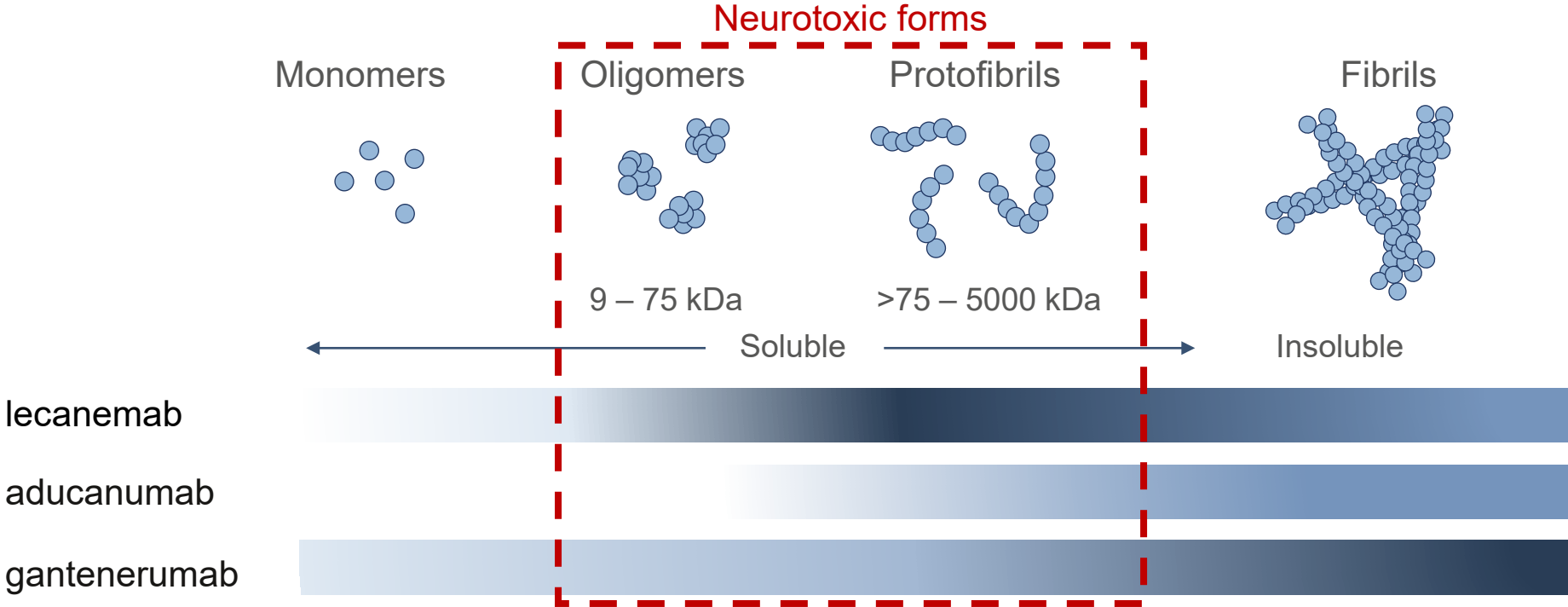
# Lecanemab – broad late-stage clinical program



**Sub cutaneous (sc) formulation – Phase 1 study – select optimal dose for OLE Q1 2022**

**Selected as background treatment in DIAN-TU Tau NexGen study – first patient enrolled in January 2022**

# Lecanemab – unique selectivity towards toxic soluble species of Aβ

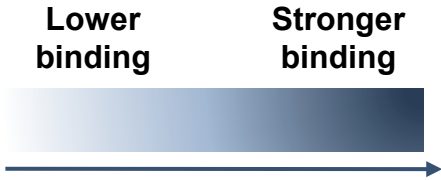


**Lecanemab** had the highest preference for soluble protofibrils/oligomers versus monomeric and fibrillar forms of Aβ

**Aducanumab and gantenerumab** had a preferences for the insoluble fibrils

**Aducanumab** showed a lower binding to all Aβ species

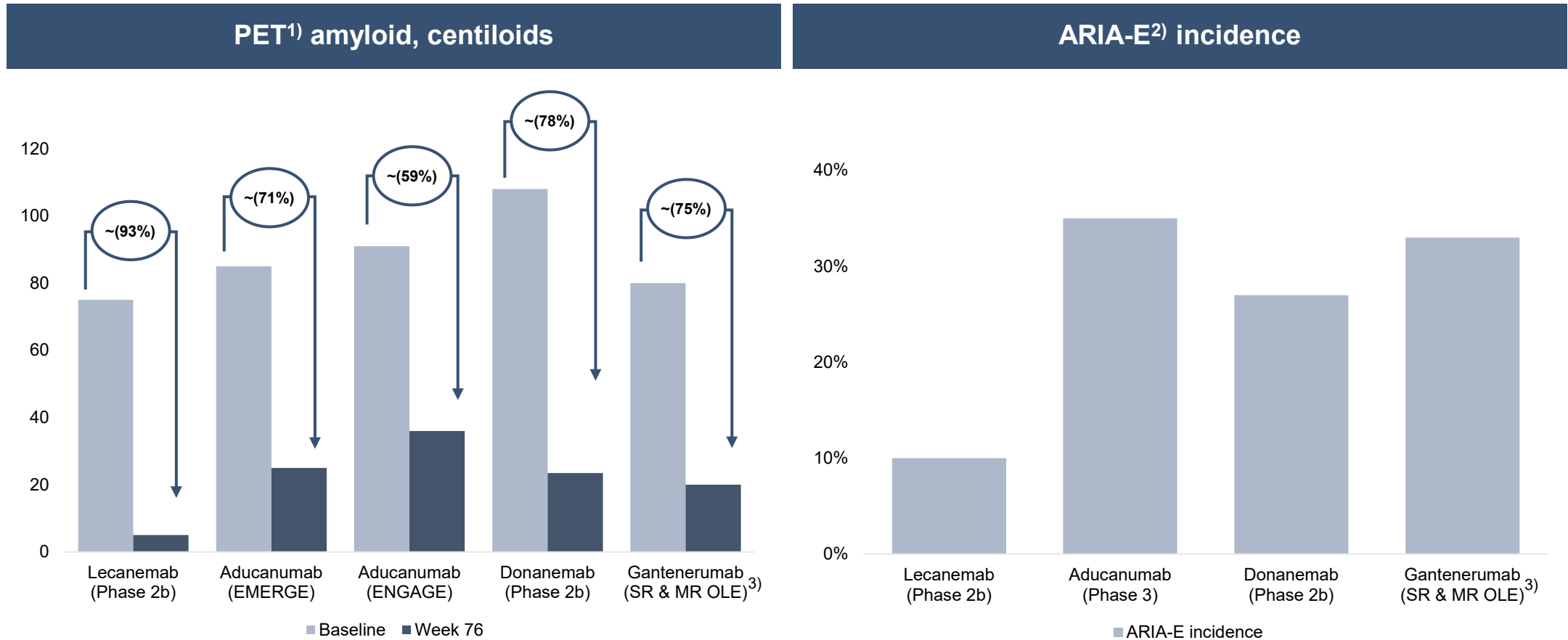
**Gantenerumab** had somewhat higher binding to monomers and prefers fibrils



Source: Presented at CTAD 2021. Note: Illustration is based on data from Biacore, inhibition ELISA and immunoprecipitation



# Lecanemab – strongest reduction of brain amyloid and lowest ARIA-E incidence among competitors



Note: 1) PET: positron emission tomography, 2) Amyloid related imaging abnormalities edema, 3) Week 104  
 Curtesy Carnegie research

# Lecanemab – potential to lead the paradigm shift in the treatment of Alzheimer’s disease

## Increased likelihood for lecanemab success

- Positive and consistent Phase 2b results
- Phase 2b OLE further strengthens the Phase 2b results
- Phase 3 study “Clarity AD” designed to confirm the positive Phase 2b results



## Opportunity to be first with full approval in US and EU

- Accelerated approval pathway ongoing in the US and submission is expected to be completed H1 2022
- Submission for full approval in the US, EU and Japan planned by Q1 2023, pending topline Phase 3 data expected Sept 2022



## Opportunity to differentiate

- Rapid and profound brain amyloid clearance
- Early onset of clinical effect in slowing cognitive decline
- Better tolerability profile than competition
- Full dose from day one



## Further development programs

- Subcutaneous injection
- Blood biomarkers utilized to explore reduced dosing frequency for maintenance treatment
- Expanded Alzheimer’s disease populations:
  - Selected for AHEAD in pre-symptomatic individuals
  - Selected as background treatment for DIAN-TU NexGen study – dominantly inherited Alzheimer disease



# The next step on a transformational journey for BioArctic

Establish commercial organization in the Nordic countries, with stepwise and timely recruitment, including support functions and IT infrastructure

- Increase awareness about;
  - early Alzheimer's disease,
  - current and future diagnostics incl blood-based biomarkers,
  - the possibility of future paradigm-shifting disease modifying treatments
- Build and prepare pricing and market access strategies to demonstrate value of potential products
- Build a solid case for the positioning of potential products in a competitive market
- Prepare patient centric infrastructure to support launch based on the patient journey and digital education initiatives
- Prepare for Life Cycle Management (subcutaneous formulation, indication expansions)



# Significant progress and expansion of the pipeline

## Parkinson's disease



### ABBV-0805

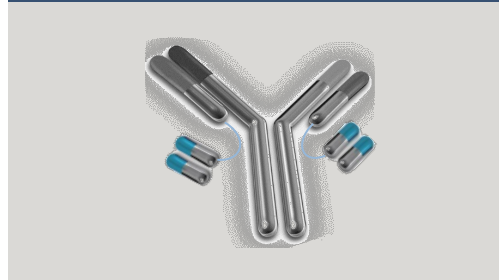
- Potential disease modifying antibody in Phase 1. Phase 2 expected to start in 2022

### Discovery stage projects

- Pre-clinical stage alpha-synuclein projects

abbvie

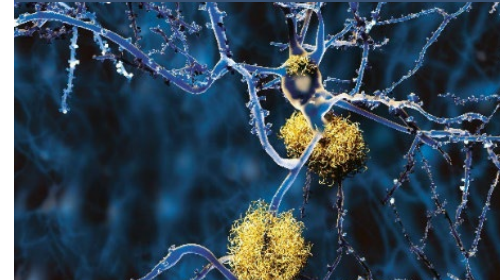
## Blood-brain barrier



### Brain Transporter (BT)

- Continued development of Brain Transporter (BT) technology platform
- 2<sup>nd</sup> generation under development

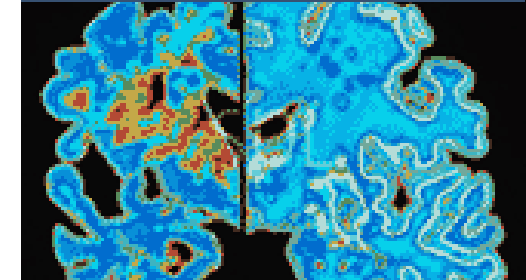
## Alzheimer's disease



### Discovery stage programs

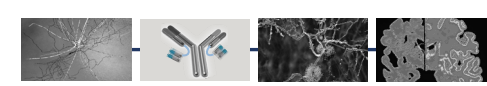
- Expanded early-stage portfolio with two new AD+BT projects
- Six internal disease modifying antibody projects in Alzheimer's disease

## Other CNS disorders



### Neurodegeneration research

- Lecanemab in indications outside of Alzheimer's disease
- Research project in neurodegeneration ("ND") with potential in various CNS disorders, including orphan indications such as ALS



# Brain Transporter (BT) technology delivers biotherapeutics to the brain

*Novel platform achieves high exposure and broad brain distribution*

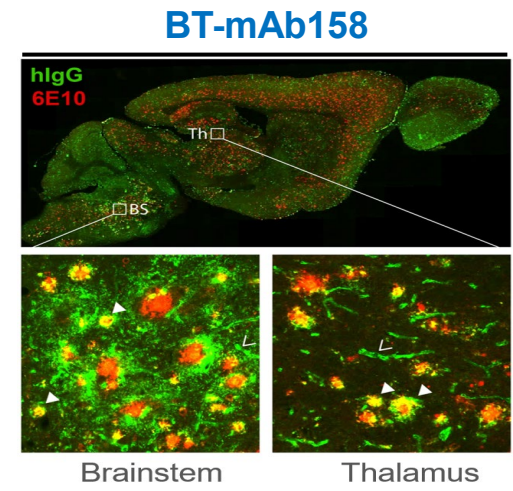
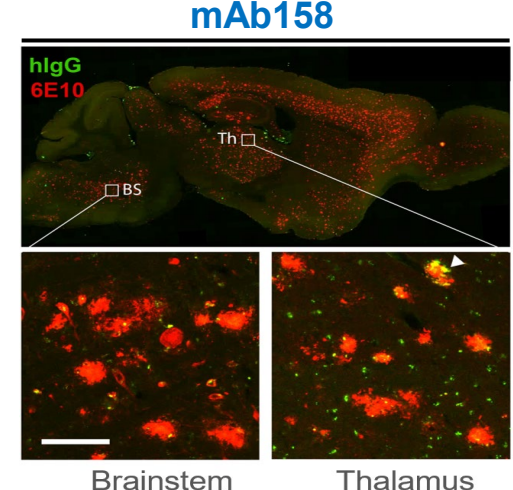
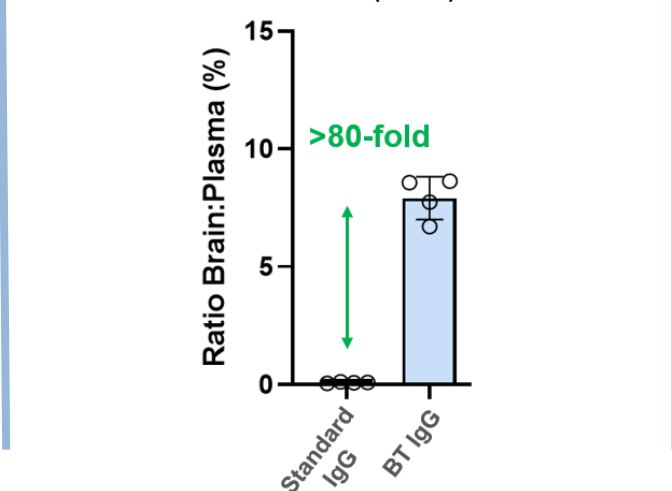
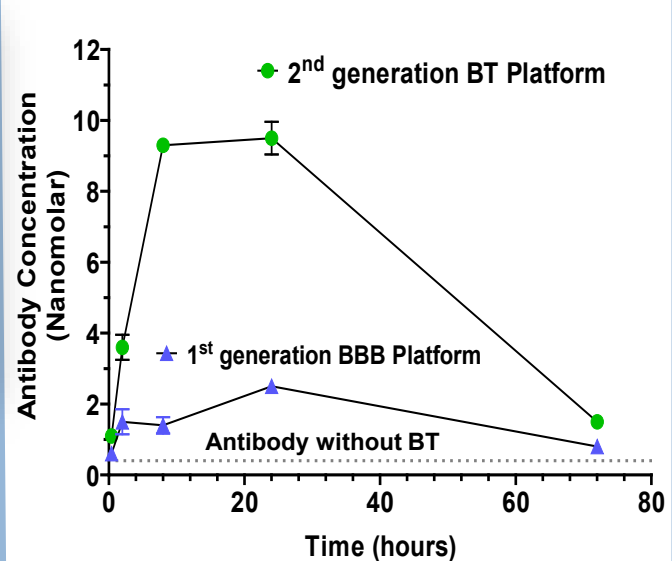
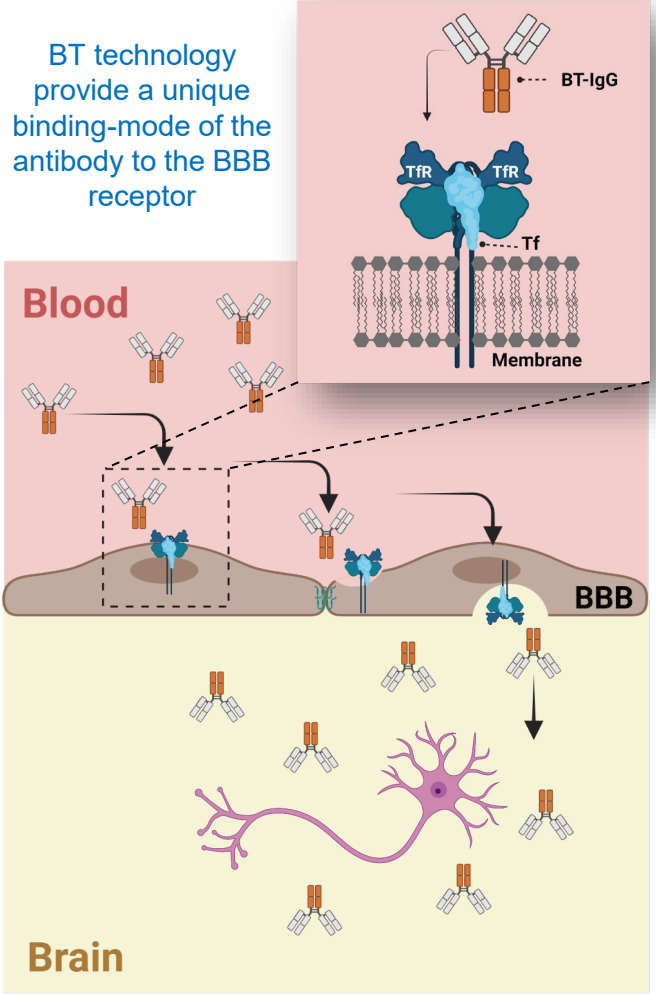
**BT**

Brain Transporter technology mediate transport across the BBB

2nd – generation technology provide superior brain exposure

Rapid and global brain distribution

**Short summary**



Red: Amyloid-β plaque in the brain  
Green: Antibody in the brain at the Amyloid-β target  
8-hour post-dose

- BT technology based on a novel approach using the Transferrin receptor (TfR) at the blood-brain barrier (BBB) (patent submitted)
- BT technology currently utilized in two portfolio projects (AD-BT2802, AD-BT2803)

**Opportunity**

- Drug delivery across the BBB remains a key obstacle for the development of efficient neurological disease therapies
- Opportunity to combine BT technology with internal projects as well as external antibodies or proteins through several non-exclusive license deals



# TDP-43 – opportunity for ALS and other neurodegenerative disorders

Amyotrophic lateral sclerosis (ALS) – a debilitating rare disease

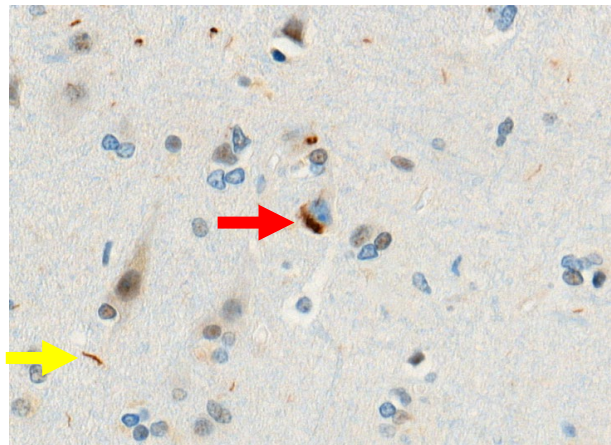
- Progressive neurodegenerative disease characterized by motor neuron degeneration

TDP-43 a promising target for ALS – an orphan disease indication

Several mutations in TARDBP (encoding TDP-43) are linked to familial ALS<sup>1)</sup> and FTD<sup>2)</sup>

Pathological aggregation of TDP-43 is found in multiple neurodegenerative diseases

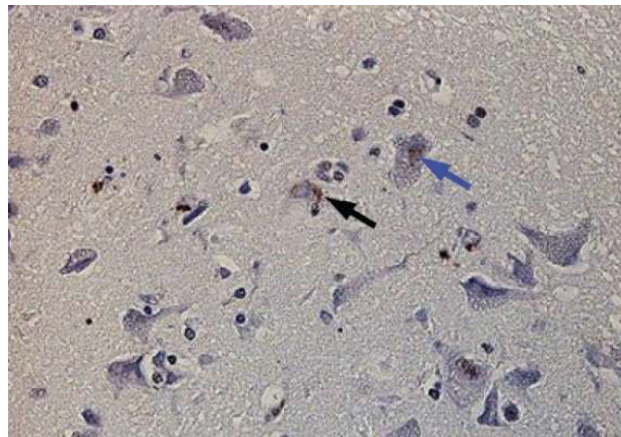
- 97% of **ALS**<sup>1)</sup> cases (orphan drug indication)
- 50% **AD**<sup>2)</sup> cases
- 45% **FTD**<sup>3)</sup> cases



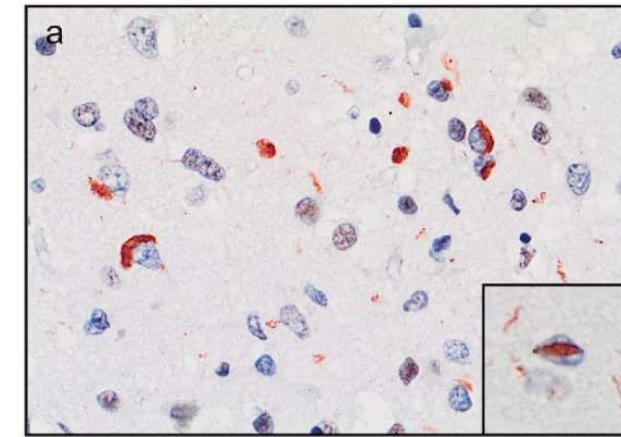
TDP-43 pathology very common in **ALS**<sup>1)</sup>

Source: Ling et. al. 2013

Note: 1) Amyotrophic lateral sclerosis, 2) Alzheimer's disease, 3) Fronto temporal dementia



Abnormal TDP-43 immunoreactivity is common in **AD**<sup>2)</sup>

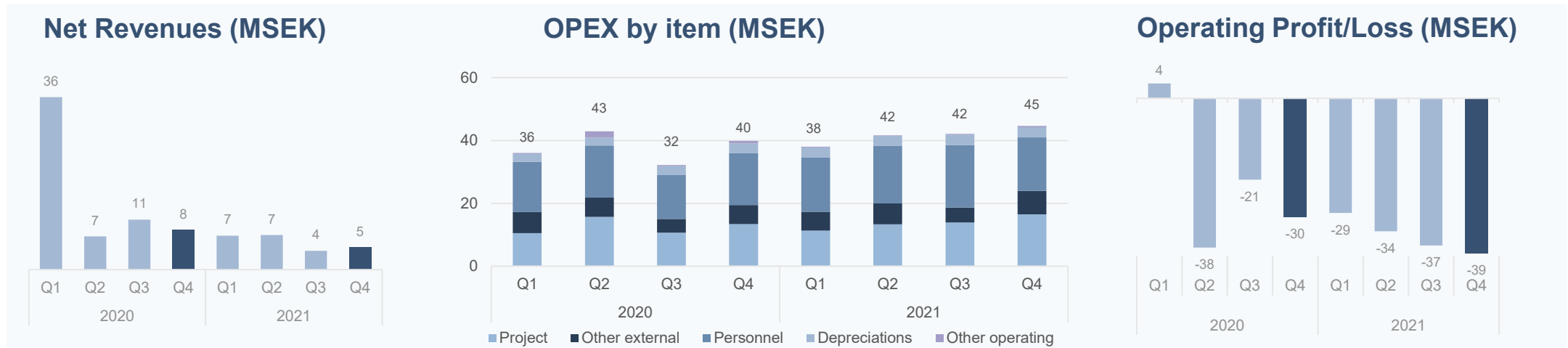


Abnormal TDP-43 immunoreactivity is common in **FTD**<sup>3)</sup>



## Financial Summary

# Net revenues and operating profit/loss Q4 2021



- Net revenues were 5 MSEK (8) for the fourth quarter

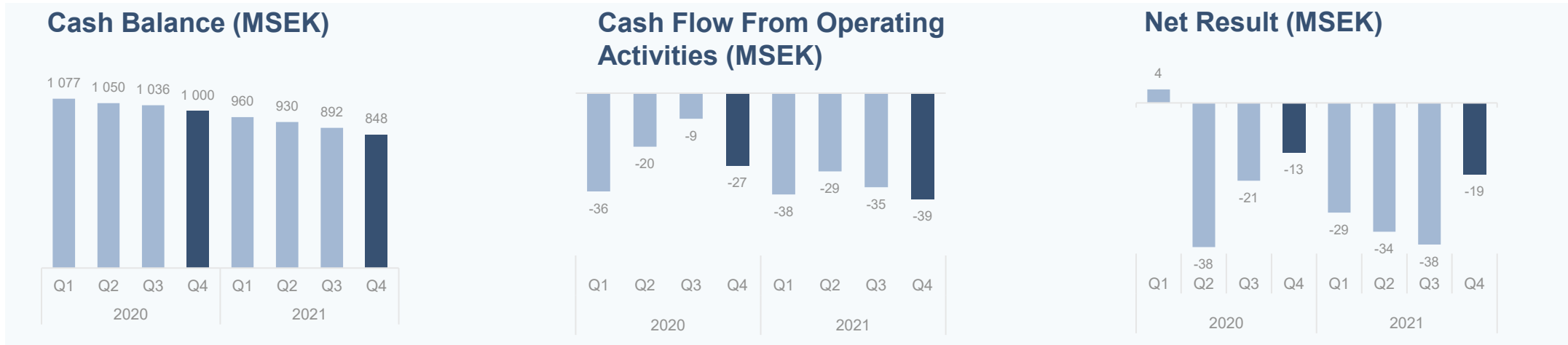
- Total costs in the quarter were higher than the same period previous year
- Costs will increase going forward as we continue to build a commercial organization and further progress our expanded project portfolio

- Operating loss was -39 MSEK (-30) for the fourth quarter

Operating expenses are expected to be in the range of 220 - 260 MSEK for the financial year January - December 2022, compared to MSEK 166 in 2021



# Cash and net result Q4 2021



- Cash balance amounted to 848 MSEK at the end of the fourth quarter

- Operating cash flow amounted to -39 MSEK (-27) during Q4

- Net result for the period was -19 MSEK (-13)

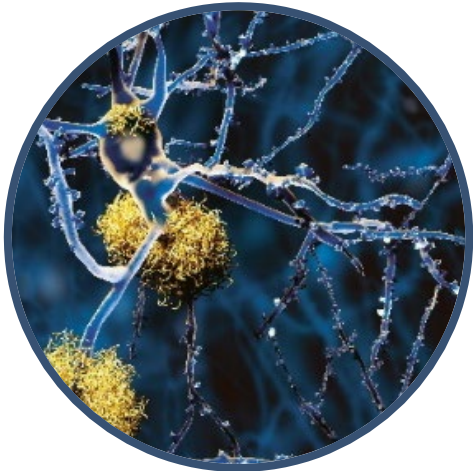
In summary, BioArctic continues to have a strong financial position



**Upcoming news and  
closing remarks**

# Upcoming news flow

## Alzheimer's disease



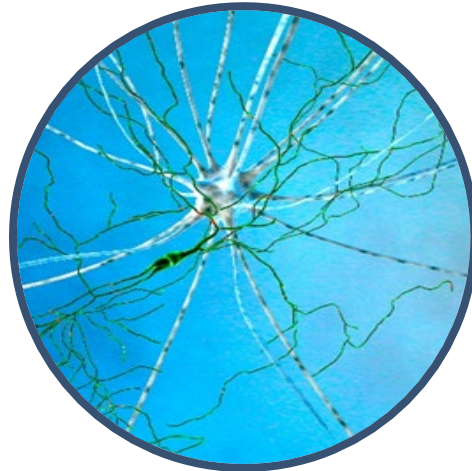
### **Lecanemab** (Eisai)

- Rolling submission for accelerated approval in the US expected to be completed H1 2022
- Clarity AD topline data expected in September 2022
- Data to be disclosed at international congresses

### **Discovery stage programs**

- Advancement of projects

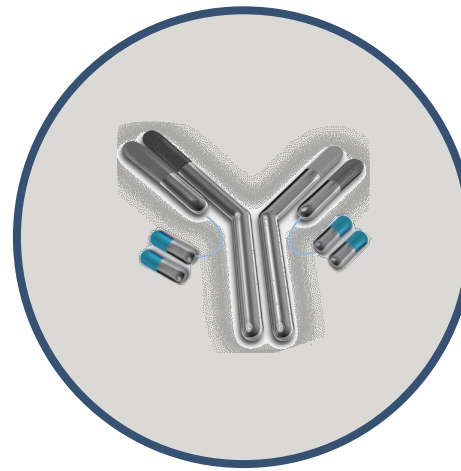
## Parkinson's disease



### **ABBV-0805** (AbbVie)

- Start Phase 2
- Data presented at international congresses

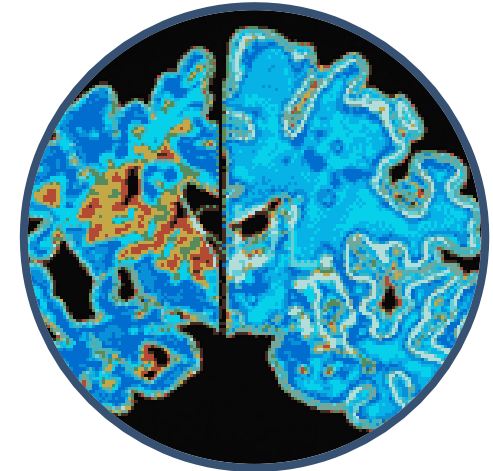
## Blood-brain barrier



### **Brain Transporter (BT) technology platform**

- Further development of the technology platform
- Data to be disclosed at international congresses

## Other CNS disorders



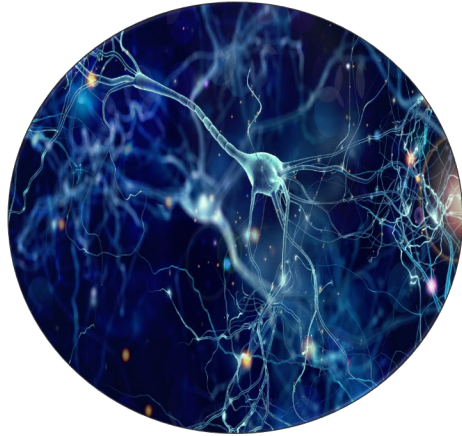
### **Neurodegeneration**

- Data to be disclosed at international congresses

# BioArctic: With Patients in Mind

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Great science



Great projects



Great partners



Great people



**GUNILLA OSSWALD, CEO**



**JAN MATTSSON, CFO**



**OSKAR BOSSON, VP  
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