BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

# BioCapital

## Amsterdam, March 9, 2023

*Oskar Bosson, VP Investor Relations and Communications*

BIOARCTIC

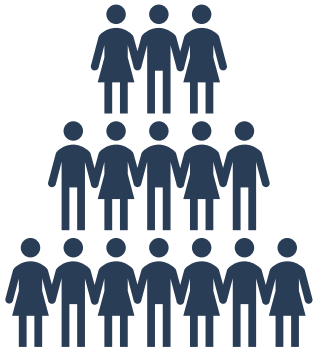
# Disclaimer

- 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.
- Investigational uses of an agent in development included in this presentation are not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.
- 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 unique Swedish biopharma company
# Improving life for patients with central nervous system disorders



**High unmet need**

**World-class research and development driven organization**

**Attractive project portfolio**

**Well-financed**



BIOARCTIC

# Attractive and well-balanced project portfolio

| | Project | Partner | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 | Regulatory & Market |
|---|---|---|---|---|---|---|---|---|
| ALZHEIMER'S DSEASE | 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 (Trunc Abeta) | | | | | | | |
| | AD-BT2802 | | | | | | | |
| | AD-BT2803 (Trunc Abeta with BT) | | | | | | | |
| | AD2603 | | | | | | | |
| PARKINSON'S DISEASE | BAN0805 (alpha-synuclein) | | | | | | | |
| | PD1601 (alpha-synuclein) | | | | | | | |
| | PD1602 (alpha-synuclein) | | | | | | | |
| | PD-BT2238 (alpha-synuclein with BT) | | | | | | | |
| OTHER CNS DISORDERS | Lecanemab (BAN2401) | | | | Down's syndrome[4], Traumatic brain injury[4] | | | |
| | ND3014 (TDP-43) | | | ALS | | | | |
| | ND-BT3814 (TDP-43 with BT) | | | ALS | | | | |
| | GD-BT6822 (GCase with BT) | | | Gaucher's disease | | | | |
| BLOOD BRAIN BARRIER | Brain Transporter (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



BIOARCTIC

# Great partnership with Eisai on lecanemab – preparing for co-promotion in the Nordics

## Alzheimer's disease

**Partner track record**

Eisai

Discovered and developed world's best-selling medicine for symptoms in Alzheimer's

Industry-leading pipeline in dementia area

Aricept donepezil HCl tablet

Used to treat confusion (dementia) related to Alzheimer's disease

**Collaboration and license**

Milestones of up to

**MEUR 136***

remains to be received

**Royalties High single digit %**

**BioArctic retains rights to lecanemab in other indications and option to market in the Nordics**

BioArctic has right to commercialize lecanemab in the Nordic under certain conditions and is currently preparing for commercialization in the Nordics together with Eisai.

***) including MEUR 35 to be paid to BioArctic in Q1 2023, based on regulatory approval and submissions**



BIOARCTIC

# Recent highlights relating to our lead drug candidate

- In the **U.S.**, lecanemab (brand name: LEQEMBI™) was granted accelerated approval as a treatment for Alzheimer's disease by the FDA on January 6, 2023. Eisai submitted a Supplemental Biologics License Application (sBLA) to the FDA for a full approval under the traditional pathway on the same day. Priority review granted with PDUFA date July 6, 2023
- In **Europe**, Eisai submitted marketing authorization application (MAA) to the European Medicines Agency (EMA) on January 9, 2023. The application was accepted for a standard review on January 26
- In **Japan**, Eisai submitted a marketing authorization application to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023. The application was granted priority review on January 30
- In **China**, Eisai initiated the Biologics License Application (BLA) for lecanemab in December 2022 and it was designated for priority review by the National Medical Products Administration (NMPA) on February 28, 2023

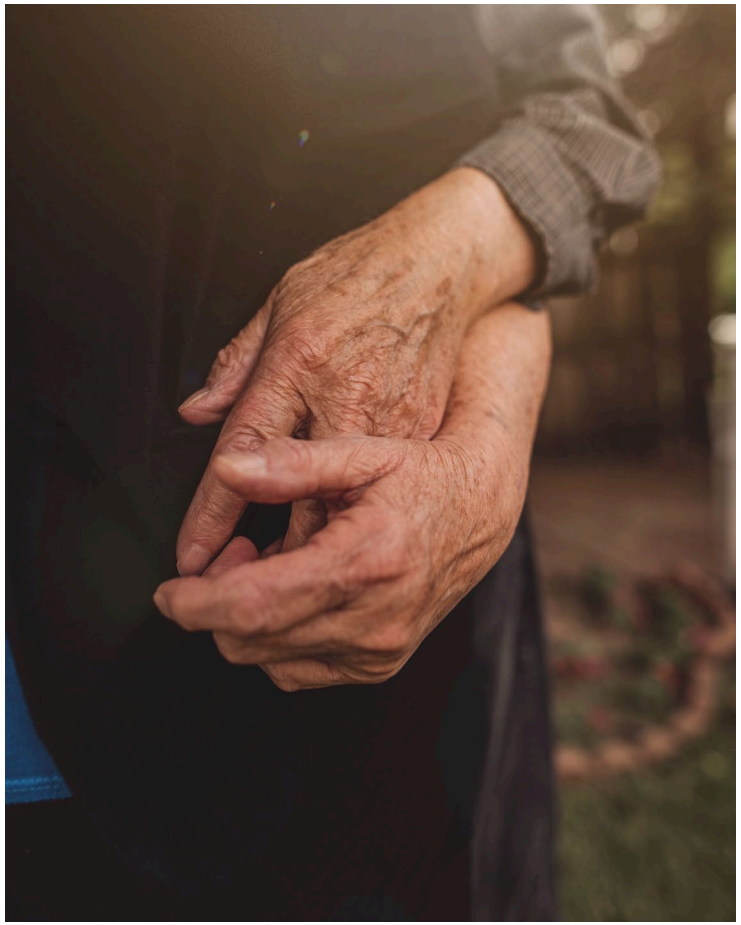



BIOARCTIC

# Early portfolio also developing well

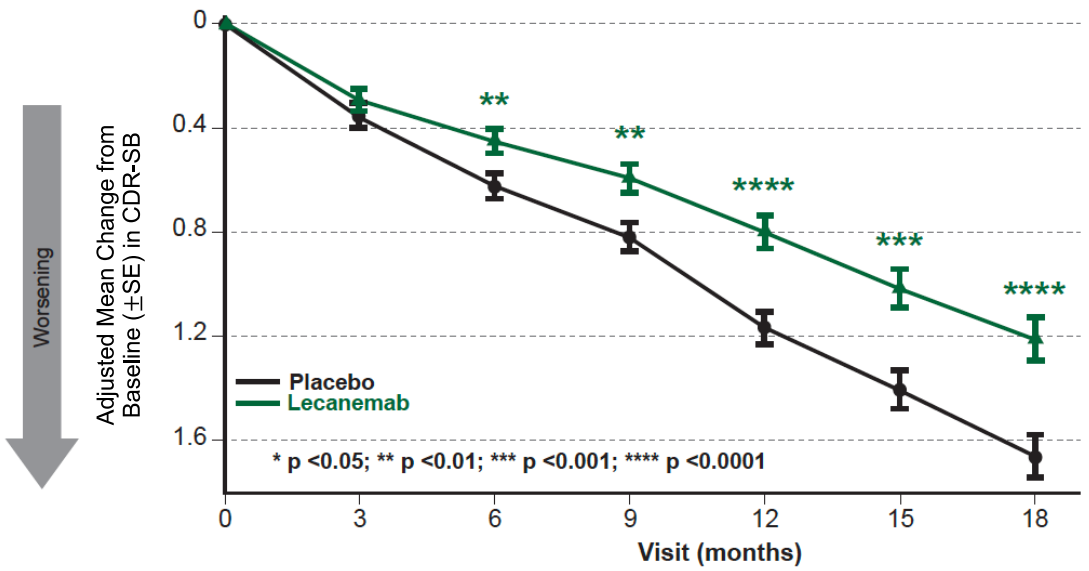
## Early portfolio

- Project AD1803 – data-driven decision to stop the project
- Project AD1503 CD nominated, now called BAN1503 and combined with BT technology in project AD-BT2803
- BioArctic started two new projects, both combined with the company's Brain Transporter technology;
    - PD-BT2238, a selective antibody against soluble alpha-synuclein aggregates (oligomers/protofibrils), and
    - GD-BT6822, an enzyme replacement therapy for Gaucher’s disease



# Clarity AD: lecanemab demonstrates Clinically Meaningful Effect

**Lecanemab met primary and all key secondary endpoints in Phase 3 Clarity AD study in 1795 early AD subjects with highly statistically significant results, reducing disease progression by 27% as measured by the primary endpoint CDR-SB* with relatively low frequency of the side effect ARIA**




**Clarity AD shows consistent highly statistically significant effects and confirms Phase 2b results**

**Safety profile confirmed in Phase 3 with low rates of ARIA, despite no titration and full dose from day 1**

**Slowing down disease progression means more time in less severe stages of Alzheimer's disease[1]**

**Lecanemab modifies the underlying disease pathology[2]**



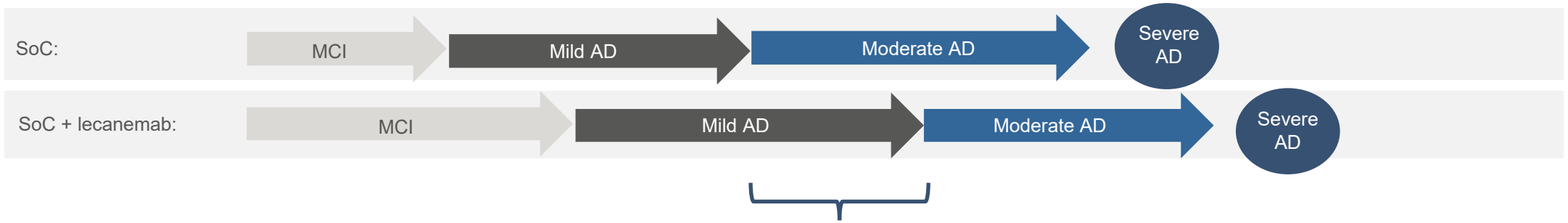
*CDR-SB: Clinical Dementia Rating Scale Summary of Boxes, measures key cognitive and functional symptoms in Alzheimer's Disease

Source: *1. Monfared et al. "Long-Term Health Outcomes of Lecanemab in Patients with Early Alzheimer's Disease Using Simulation Modeling". Neurol Ther. 2022.*
*2. van Dyck et al. "Lecanemab in Early Alzheimer's Disease" N Engl J Med 2023; 388:9-21.*

BIOARCTIC

# Disease modeling suggests that lecanemab could delay progression to moderate Alzheimer´s Dementia by several years

*Estimated progression time to moderate Alzheimer's Disease (AD) for patients completing the full lecanemab dosing regime compared with patients subject to standard of care (SOC) only*




**Estimated time gained before reaching moderate AD: + 3.13 years**

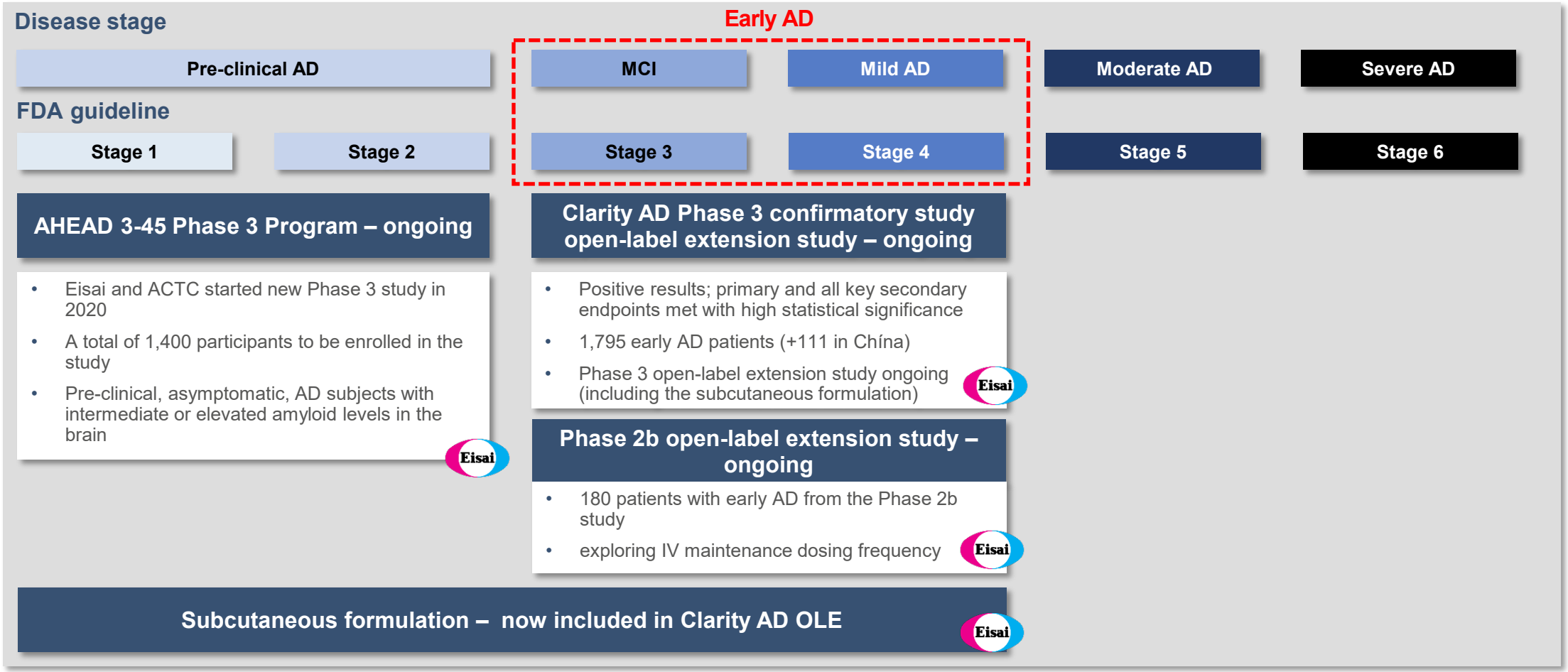
**The results from the modeling show the potential clinical value of lecanemab for patients with early Alzheimer's disease and how it can slow the rate of disease progression, delay progression to moderate Alzheimer's dementia with several years and consequently reduce the need for institutionalized care**

1. Monfared et al. "Long-Term Health Outcomes of Lecanemab in Patients with Early Alzheimer's Disease Using Simulation Modeling". Neurol Ther. 2022. 2.Swanson et al. " A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody". Alzheimer's Res Ther. 2021. 3. ADNI (Alzheimer's Disease Neuroimaging Initiative) study.



BIOARCTIC

# Lecanemab – broad late-stage clinical program




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

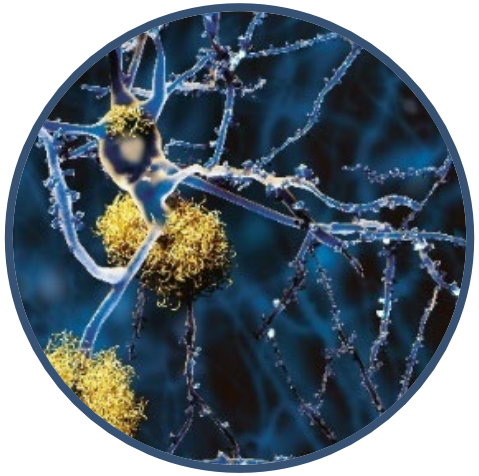
Eisai



BIOARCTIC

# Upcoming news flow

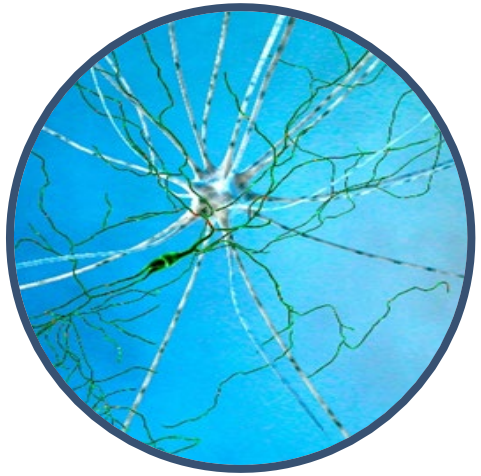
## Alzheimer's disease



**Lecanemab** (Eisai)
- Data to be disclosed at international congresses, including AD/PD in Gothenburg in March/April
- Regulatory progress

**Discovery stage programs**
- Advancement of projects

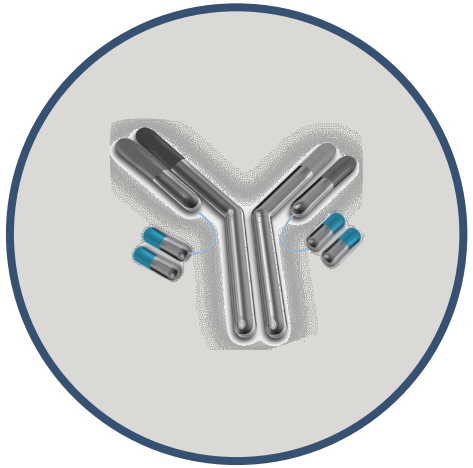
## Parkinson's disease



**BAN0805**

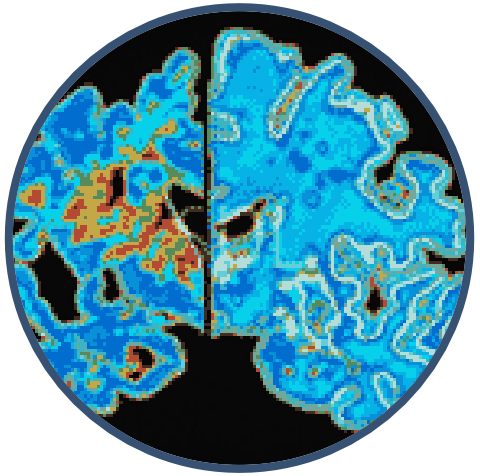
Data presented at international congresses

## Blood-brain barrier



**Brain Transporter (BT) technology platform**
- Further development of the technology platform
- Data to be disclosed at international congresses
- BT supporting the expansion of the project portfolio

## Other CNS disorders



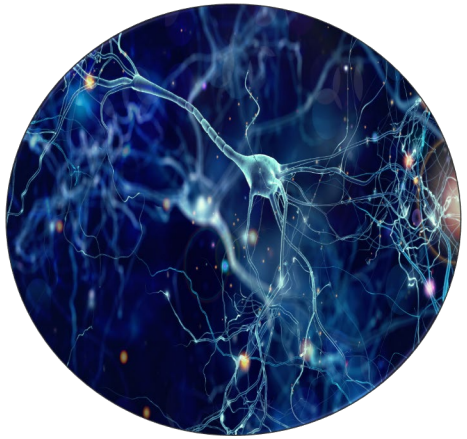
**Neurodegeneration**
- Data to be disclosed at international congresses



BIOARCTIC

# BioArctic: With Patients in Mind

Great science



Great projects

Great partners

Great people




BIOARCTIC

## GUNILLA OSSWALD, CEO

## JAN MATTSSON, CFO

## OSKAR BOSSON, VP COMMUNICATIONS & IR

## NEXT REPORT & IR CONTACT

- **Next Report:**
  Q1 Report
  Jan-Mar 2023
  on Apr 27, 2023
- **Contact:**
  Oskar Bosson,
  VP Communications & IR
  +46 704 10 71 80
  ir@bioarctic.se

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



BIOARCTIC