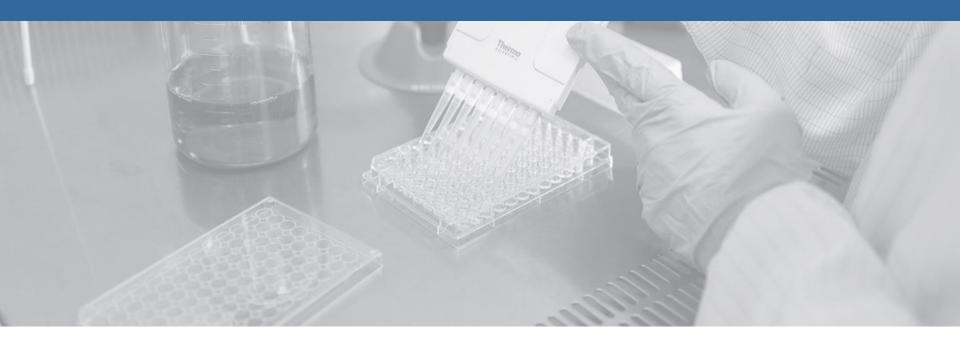


### BioArctic AB

Gunilla Osswald, PhD, President and CEO

# A Company Presentation

AGM 15th of May 2018



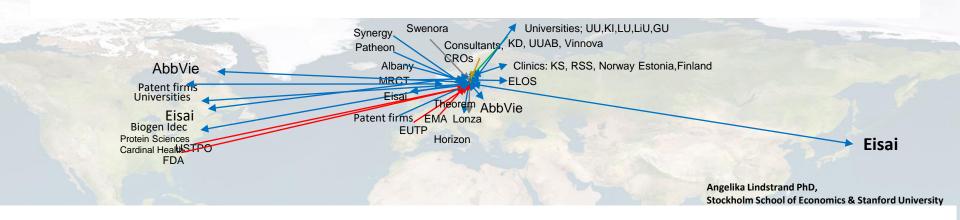


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# BioArctic AB



# Providing innovative effective treatments for patients with disorders in the Central Nervous System

- Alzheimer's disease: BAN2401 Phase 2b Partnership with Eisai
- Parkinson's disease: BAN0805 Preclinical Partnership with AbbVie
- Spinal Cord Injury: SC0806 Phase 1/2



### Long-standing and Extensive Partnerships

#### Eisai collaboration and license agreements



#### Description of agreements

- Two previous research collaborations regarding disease modifying therapies for Alzheimer's Disease that resulted in two licenses of the AB oligomer/protofibril antibodies BAN2401 and BAN2401 Back-up
- Third research collaboration ongoing regarding a new target as a disease modifying therapy for Alzheimer's Disease

#### Milestone / royalty potential

- The total aggregated value of the research collaborations and license agreements is approx. EUR 218m in signing fee and milestones plus high single digit royalties
- BioArctic has received approx. EUR 47m for the research collaborations. signing fees and milestones

### AbbVie collaboration agreement

# abbyie

#### Description of agreements

- Research collaboration (entered Sep 2016) regarding alpha-synuclein antibodies as disease modifying therapies for Parkinson's Disease incl. BAN0805 to IND, follow-up compounds and diagnostic
- BioArctic primarily responsible for performing all preclinical activities
- Option for AbbVie for a license to develop and commercialize the antibodies

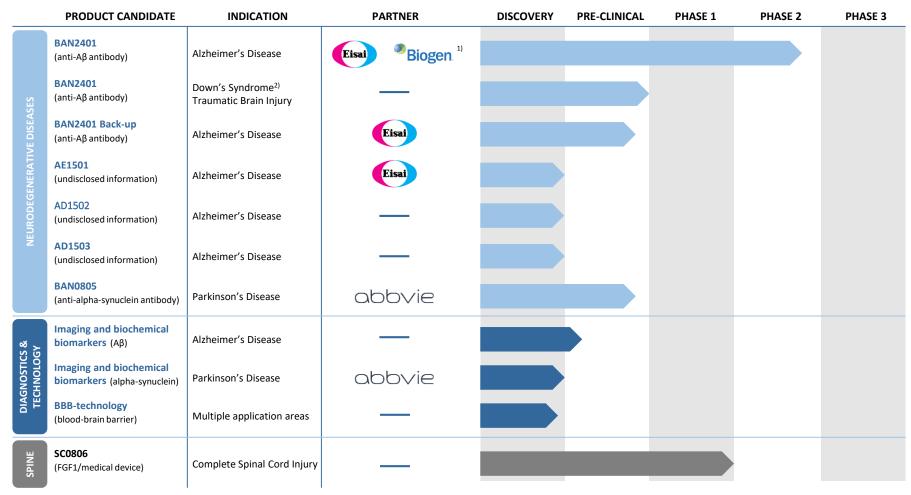
#### Milestone / royalty potential

- Total potential value of the agreement is up to USD 755m incl. an up-front fee, option exercise fee, and success-based milestones plus tiered royalties
- BioArctic has received an USD 80m up-front payment for the research collaboration

Strategic collaborations with pharmaceutical industry validating potential value and commercialization potential for BioArctic with proven track record of delivering on research collaborations



# Strategic Partnerships and Cutting-Edge Proprietary R&D



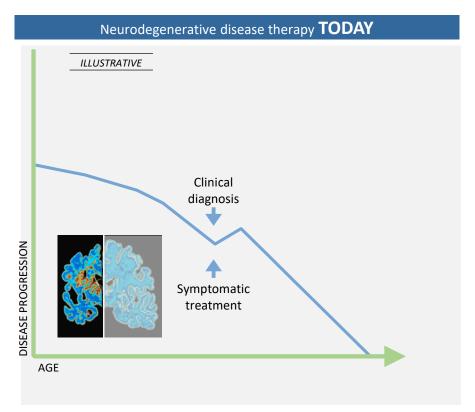
<sup>1)</sup> Partner with Eisai on BAN2401 for treatment of AD. Since 2014, Eisai partnered with Biogen in AD.

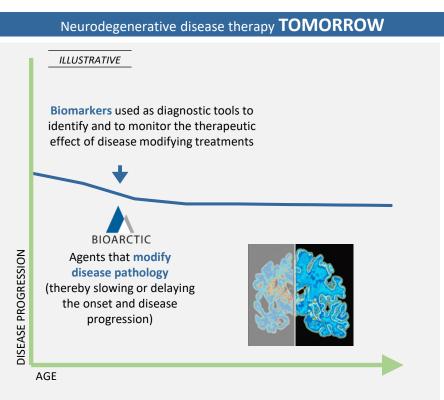


<sup>&</sup>lt;sup>2)</sup> Dementia and cognitive impairment associated with Down's syndrome and Traumatic Brain Injury

### Disease Modifying Agents and Reliable Diagnostics/Biomarkers for Neurodegenerative Diseases

New therapy focus on disease pathogenesis – efforts to delay the neurodegenerative process

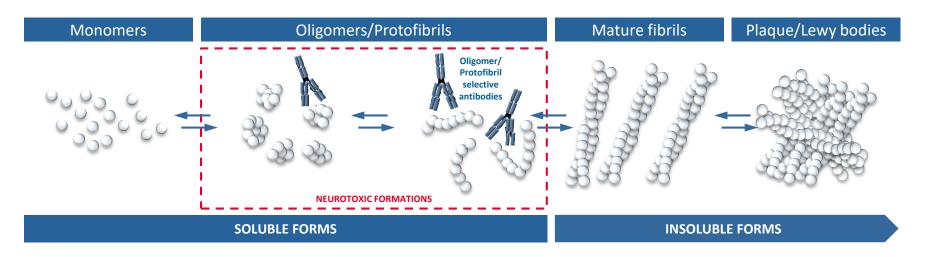


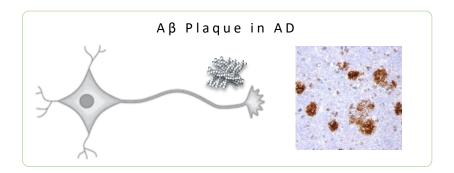


Significant unmet medical need to be addressed by disease modifying agents and reliable diagnostics/biomarkers



# Protein Misfolding is Disease Causing in a Number of Neurodegenerative Diseases Including AD and PD





Alpha-synuclein Lewy bodies in PD

Source: Company information.



### About Alzheimer's Disease

### Neurons with Amyloid Plaques in Alzheimer's Disease



#### Alzheimer's Disease (AD)

- AD is an irreversible neurodegenerative brain disease of the elderly, which, through the death of brain cells, leads to a progressive decline in memory and cognitive abilities, such as thinking, language, and learning capacity
- MCI (mild cognitive impairment) with a slight but noticeable and measurable decline in cognitive abilities, including memory and thinking skills, but no dementia
- Prodromal AD or MCI due to AD are MCI subjects with biomarkers showing AD disease pathology
- Early AD encompass mild AD and MCI due to AD
- 47 million people worldwide suffer from dementia and by 2050 expected to be 130 million. >50 % of dementia diagnosed as AD
- 25 million people worldwide suffer from Alzheimer's disease today and the number is expected to double in 20 years
- Future disease modifying drugs will be used earlier in the disease and in combination with symptomatic drugs used today
- New guidelines from FDA and EMA focus on the value of early diagnosis and treatment of Alzheimer's disease patients and the importance of biomarkers and cognition data. This is well in line with the development program of BAN2401 and the upcoming analyses of the study

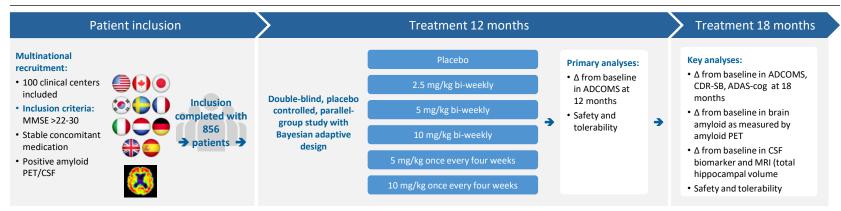


### BAN2401 – Learnings from Previous Clinical Trials in AD Incorporated in Phase 2b Study Design Final Results in H2 2018

#### Important parameters



#### Phase 2b study design



Top line results after 18 months treatment incl. biomarker and cognition - Q3 2018 Full read-out of study after 18 months treatment and 3 months follow-up - Q4 2018 A positive scenario includes an effect on both a biomarker and cognition

Source: Company information.

Note: ADCOMS = Alzheimer's Disease Composite Score, an evaluation tool developed by Eisai.



### About Parkinson's Disease

#### **Network of Neurons in Parkinson's Disease**



#### Parkinson's Disease (PD)

- Tremor is the best known sign of the disease. The disease develops gradually and can start with hardly noticeable tremor in one hand or symptoms related to disturbances in the REM sleep, smell and bowel function. The disease often also leads to stiffness and slow movements
- PD is the second most common neurodegenerative disease
- Compared to AD it affects a younger patient group, which means that many who fall ill are still at working age
- From 1990 to 2015 the prevalence of PD has doubled
- In 2015 it was estimated that 6.2 million people suffered from PD worldwide
- There is currently no disease modifying treatment for PD



### BAN0805 – Groundbreaking Disease Modifying Drug in PD with Rationale for Selective Targeting of Alpha-synuclein Oligomers/Protofibrils

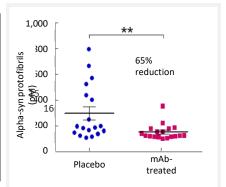
Rationale for targeting alpha-synuclein

**Human** genetics

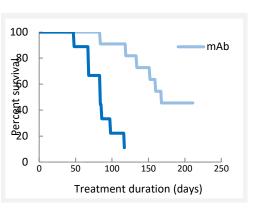
**Pathology** 

### Pre-clinical proof of concept

Reduction of neurotoxic alphasynuclein oligomers/protofibrils



Increases lifespan



### Alpha-synuclein mutations

lead to PD or Dementia with Lewy Bodies and are associated with increased oligomer/protofibril formation

Alpha-synuclein deposition is

a hallmark of PD pathophysiology and alpha-synuclein oligomers/ protofibrils are elevated in PD

### Oligomer/protofibril selective antibody

reduces neurotoxic alpha-synuclein oligomer/protofibril levels, delays disease progression and increases life-span in a PD mice model



### About Complete Spinal Cord Injury



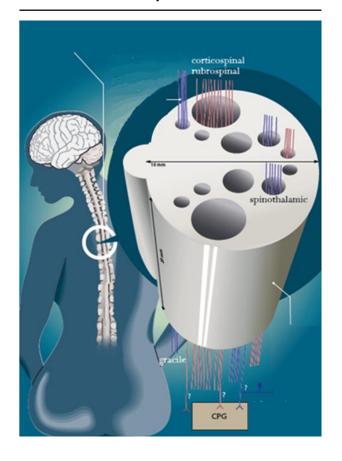
#### **Spinal Cord Injuries (SCI)**

- A complete spinal cord injury is defined as an injury where the patient can accomplish no voluntary movement or sensory feedback below the injury
- A spinal cord injury causes degeneration of the nerve fibers below the site of the injury as nerve cells do not regenerate
- Besides paralysis patients with complete spinal cord injury suffer from other serious symptoms, including neuropathic pain, bowel and bladder incontinence, sensory loss, pressure sores, infertility and sexual dysfunction
- Increasing stability, restoring bowel and bladder control, reducing pain or enabling sexual functionality would constitute a major improvement of the patient's quality of life
- 40 percent have complete spinal cord injuries
- Complete spinal cord injuries are more common among younger persons, primarily men injured in accidents
- 2.5 million people live with paralysis
- Today there is no effective treatment for complete spinal cord injury
- The patients require life-long treatment and care, which means high costs for healthcare systems and societies



# SC0806 – Unique Regenerative Treatment of Complete SCI

# SC0806 – Regenerative Treatment of Complete SCI



### **Treatment Rationale and Project Status**

### SC0806 makes nerve regeneration possible

FGF1 activated by heparin

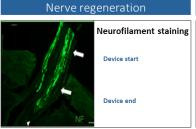
- Stimulation of central axon outgrowth
- Decreases gliosis

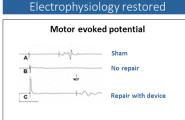
Peripheral nerve autografts

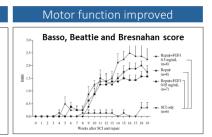
• Optimal regeneration environment

Biodegradable device

- Provides sustained release of FGF1
- Positioning of nerve grafts from white to gray matter







#### Preclinical Proof of Concept shown in rats

- Rat experiments demonstrate nerve regeneration, restored electrophysiology and motor function
- The motor evoked potential (MEP) has been restored in rats with resected spinal cords



### SC0806 – Unique Regenerative Treatment of Complete SCI

#### The Lokomat™ used in the Rehabilitation



#### **Treatment Rationale and Project Status**

- Surgical implantation of biodegradable SCI device with recombinant Fibroblast Growth Factor 1 (FGF1) and nerve grafts
  - Combination of medical device and new drug from a regulatory perspective
  - Orphan Drug designation in US and EU granting 7 and 10 years exclusivity, respectively
- Clinical Phase 1/2 trial ongoing with SC0806 in patients with complete spinal cord injury
  - Surgery at Karolinska University Hospital in Sweden
  - Rehabilitation for 18 months with Lokomat™ in Sweden and preparations to include patients in Norway, Estonia and Finland
  - Patients receiving SC0806 treatment are given the option of 12 months additional participation in an extension study
  - 9 patients included (6 treated with SC0806 and 3 control patients)
- EU Horizon 2020 research and innovative programme Grant Agreement No. 643853 of MEUR 6.4



### Several Novel Approaches to Improve Diagnostics and Treatment

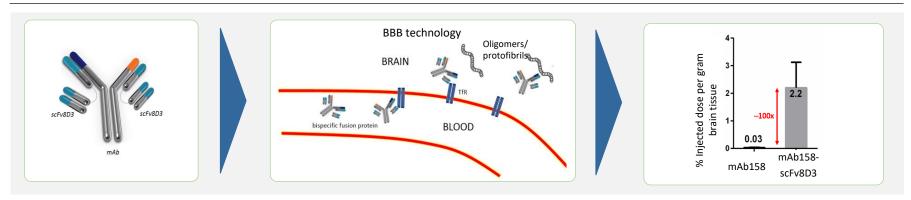
### Imaging and biochemical biomarkers in AD

### Aβ protofibril PET tracer PET with an antibody-based ligand Old tg-ArcSw Binding to AB oligomers/protofibrils Has short half-life Improved BBB penetration Old wt %ID per g brain tissue



 Sensitive biochemical method for AB measurement in development is of great clinical importance

### Blood-brain barrier technology



Source: Sehlin et al 2016 Nature Communications. Hultqvist et al 2017, Theranostics.

Substantially increased antibody brain uptake by BioArctic's brain shuttle technology



# Successful IPO on Nasdaq Stockholm Mid Cap in October 2017

#### IPO and new share issue October 12

- Largest total offering in Swedish biotech since 2000.
  Total offering value of SEK 805m (USD 97m)
- Attracting renowned institutional shareholders
  - A number of well renowned international institutional investors among others HBM Healthcare Investments, as well as Swedish institutional investors such as AP2, AP3, AP4, Handelsbanken Fonder and Swedbank Robur are shareholders in BioArctic
- Funding of own R&D projects secured
  The new share issue rendered approx. SEK 550m (USD 66m) in funding for BioArctic's own R&D projects





### Highlights 2017



#### 2017

- All projects progressed well according to plan
- Listing on Nasdaq Stockholm Mid Cap on October 12
- BioArctic's patent for its product candidate antibody BAN0805, for Parkinson's disease, granted in Europe
- Patent for the BAN2401 Back-up was granted in the US
- BioArctic announced that the Phase 2b study of BAN2401 in early Alzheimer's disease continues toward 18 months endpoint



### 2018 to Date

#### **Highlights**

#### Alzheimer's disease BAN2401 Phase 2b

- Top line results after completion of 18 months treatment with BAN2401 are expected in Q3 2018
- Final results after completed study with 18 months treatment including 3 months follow-up of the patients are expected in Q4 2018

### Parkinson's disease BAN0805 Preclinical phase

- Program progressing well including preparations for BAN0805 IND in the U.S. to start clinical trials

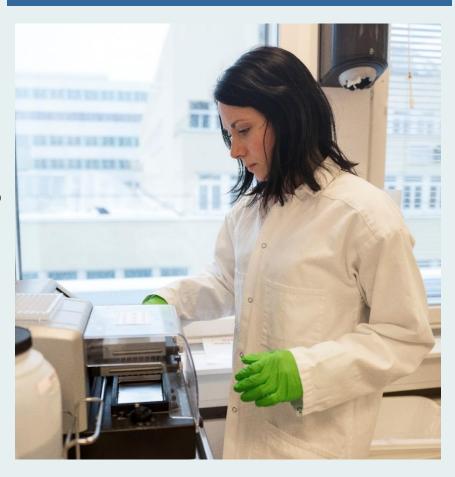
### Spinal Cord Injury SC0806 Phase 1/2

- Patient inclusions completed in the first panel of three in the ongoing SC0806 study
- Regulatory and ethic committee approvals in Estonia and Norway to include patients in the clinical study
- Patents were granted in the U.S. and Japan for treatment of SCI patients with the medical device, which is one of the components in SC0806
- Extended research collaboration with Uppsala University regarding **BBB** technology

### **Expansion of the patent portfolio**

- More than 150 granted patents and 55 pending patent applications within 12 patent families

### **BioArctic Laboratory**





### Highly Educated and Research-oriented Organization with Vast Experience of Bringing Drugs from Idea to Market

#### **GUNILLA OSSWALD**

PhD, CEO, former VP AstraZeneca (Portfolio, Projects, Clinical, Marketing)

30 years of relevant experience



HANS BASUN

Professor, MD, CMO, Geriatrician at Memory Clin in Uppsala, former AstraZeneca (Clinical Development)

35 years of relevant experience



20 years of relevant experience

PhD, CSO, extensive experience

(Research & development)



JOHANNA FÄLTING

PhD, Director Immunology & Pharmacology, former AstraZeneca R&D (Discovery & Drug Projects)



15 years of relevant experience

LARS LANNFELT

#### **MIKAEL MOGE**

PhD, Director Biochemistry & Molecular Biology, former AstraZeneca (Pharmaceutical Development), Syntagon (Head Development & Pilot Plant)

20 years of relevant experience



**NORA SJÖDIN** 

Vice President Regulatory Affairs, former Pharmalink, NDA Regulatory Service, AstraZeneca



**PÄR GELLERFORS** 

**CHRISTER MÖLLER** 

from small biotech

Co-founder, Associate Professor, Senior Advisor, KabiVitrum/Pharmacia (R&D & Marketing), co-founder Zymenex AS

35 years of relevant experience



MD, discovered the Swedish and the Arctic mutations in Alzheimer's Disease

Professor, Uppsala University.

Co-founder, Senior Advisor, Senio

35 years of relevant experience

25 years of relevant experience

Highly educated staff with 80% PhDs with background from

















Above 80% of BioArctic employees have a doctors degree in relevant research areas Significant in-house experience combined with collaborations with Universities, Hospitals, consultants, CDMOs/CROs and pharmaceutical industry



### BioArctic encourages Curiosity and Innovation



#### **Our Core Values**

### Science driven

We are driven by our desire to understand the diseases in order to be able to develop new treatment strategies

### Respect

We act respectfully

### Commitment

We are highly engaged in everything we do

### **Teamwork**

We collaborate to achieve our common goals

### Responsibility

We deliver high quality science



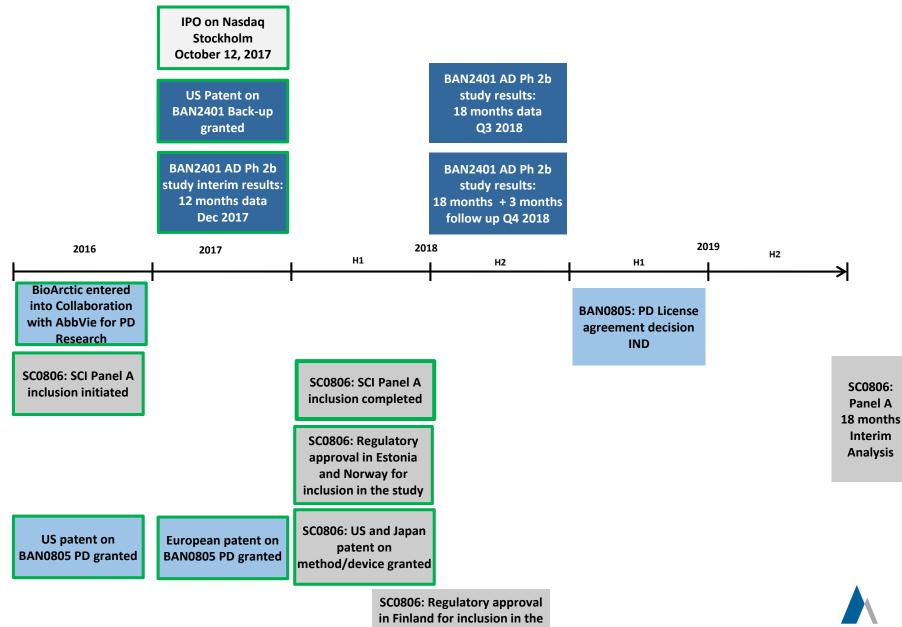
### BioArctic has a Strong Financial Position



- BioArctic has a successful business-model with research collaborations and license agreements with big pharma
- Close collaboration with universities
- Grants from Vinnova and EU Horizon2020
- External validation of high quality deliverables
- Positive results last 5 years and all years but 3 since start
  15 years ago
- Solid cash position with more than SEK 1 billion



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study

# Q&A



Thank you for your attention!

