BIOARCTIC AB (PUBL) NASDAQ STOCKHOLM: BIOA B

# **BioArctic Company Presentation**

Redeye Growth Day 2 June 2020 Gunilla Osswald, PhD, CEO



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# BioArctic – a unique Swedish biopharma company Improving life for patients with central nervous system disorders



**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



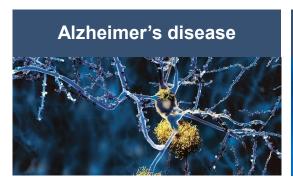
Attractive and well-balanced project portfolio with projects from discovery through Phase 3 and combination of both proprietary projects with substantial marketing and out-licensing potential and partnered projects generating income



**Well-financed** with BSEK >1 (MUSD >100) in cash, **net profitable** during the last seven years and **valuable collaboration agreements** totaling BSEK 9.6 (BUSD ~1) plus royalties



# BioArctic R&D focuses on improving life for patients with Central Nervous System disorders



#### **BAN2401**

- Strong clinical Phase 2b results in early Alzheimer's
- 3 clinical trials underway or in planning
- Phase 3 confirmatory study ongoing by

### **Discovery stage programs**

 4 fully-owned preclinical stage disease modifying antibody programs with different mechanisms



#### **ABBV-0805**

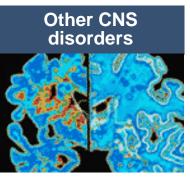
 Second part of Phase 1 study ongoing by partner



# Discovery stage projects

 Preclinical stage projects in research collaboration partnered with





## Neurodegeneration research

 New indications and new targets





# Blood-brain barrier technology platform

 Facilitate the passage of biologics over the blood-brain barrier

### **Diagnostics**



### **Diagnostics**

 Imaging and biochemical biomarkers



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

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	BAN2401	Eisai, Biogen <sup>1</sup>					
	BAN2401 back-up	Eisai					
	AD1801						
	AD1502						
	AD1503						
	AD2603						
PARKINSON'S DISEASE	ABBV-0805 <sup>2</sup>	AbbVie					
	PD1601	AbbVie					
	PD1602	AbbVie		•			
OTHER CNS DISORDERS	BAN2401 Down's syndrome <sup>3</sup> Traumatic brain injury						
	ND3014						
BLOOD-BRAIN BARRIER TECHNOLOGY	BBB technology platform						
DIAGNOSTICS	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

as of March 31, 2020

<sup>1)</sup> Partnered with Eisai for BAN2401 for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding BAN2401 in 2014

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

<sup>3)</sup> Dementia and cognitive impairment associated with Down's syndrome

### Long-standing and extensive partnerships

### Alzheimer's disease

#### Partner track record

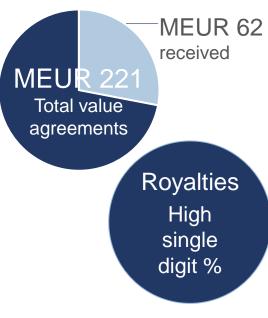


Discovered and developed world's best-selling medicine for symptoms in Alzheimer's



Industry-leading pipeline in dementia area

### **Collaboration and license**



 BioArctic retains rights to BAN2401 in other indications and option to market in the Nordics

### Parkinson's disease

#### Partner track record

### abbvie

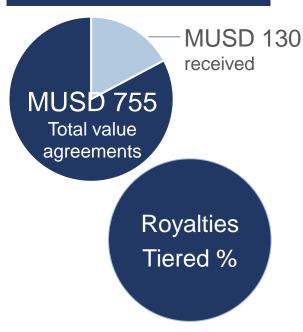
World's all-time best-selling medicine (BUSD 20)



Approved product for symptoms associated with Parkinson's disease



#### **Collaboration and license**



 AbbVie global rights to alphasynuclein portfolio for all indications

Sources: Eisai, AbbVie and BioArctic corporate information



# Experienced management, innovative scientists and collaborations with universities to bring forward the next groundbreaking therapy

Experienced R&D Leadership

Gunilla Osswald, PhD CEO

Former VP AstraZeneca (portfolio, projects, clinical, marketing)

30+ years relevant experience

Tomas Odergren, MD, PhD CMO

Senior positions in clinical development at AstraZeneca and H Lundbeck

20+ years relevant experience

Christer Möller, PhD

CSO

Extensive experience from small biotech (research & development)

20+ years relevant experience

Johanna Fälting, PhD VP Head of Research

Former AstraZeneca R&D (discovery & drug projects)

15+ years relevant experience

Mikael Moge, PhD

VP CMC

Former AstraZeneca (Pharmaceutical

Development) and Syntagon (Head Development & Pilot Plant) 20+ years relevant experience Nora Sjödin

VP Regulatory Affairs Former Pharmalink, NDA Regulatory Service, AstraZeneca

20+ years relevant experience

Per-Ola Freskgård, PhD

Distinguished Scientist
Former Roche Head of
Neurovascular Biology,
AstraZeneca, Novo Nordisk
20+ years relevant experience

Lars Lannfelt, Professor, MD

Co-founder, SVP University Collaborations

Senior Professor, Uppsala University Discovered the Swedish and Arctic mutations in Alzheimer's Disease 35+ years relevant experience

Innovative Scientists









Collaboration with Universities















## BAN2401: potential disease modifying antibody for Alzheimer's disease with positive Phase 2b results now in Phase 3

### High unmet medical need **IN 20** YEARS No existing doubling diseasemodifying treatment **TODAY** >30 million people with Alzheimer's

### **BAN2401** has positive Phase 2b results

- **Large trial:** 856 early Alzheimer's patients
- **Consistent effects** on clinical outcomes. imaging and neurodegenerative biomarkers
- Effect increase over time
- Good safety profile

### **BAN2401** unique profile

### Unique and targeted binding profile

Highly selective for toxic forms of misfolded Abeta (oligomers/protofibrils)

### **Unique clinical fingerprint**

- Rapid onset of clinical effect
- Consistent effects
- No titration required due to low frequency of ARIA–E

### **Broad clinical program**

- Confirmatory Phase 3 study ("Clarity AD") ongoing
  - Primary endpoint final readout expected 2022
- Phase 2b open label extension study ongoing
- Phase 3 prevention program ("AHEAD 3-45" comprised of 2 groups "A3" and "A45") in even earlier stages of AD
  - Preparing to start 2020

### **Broad BAN2401 clinical program**

### **Clarity AD Phase 3 confirmatory study**

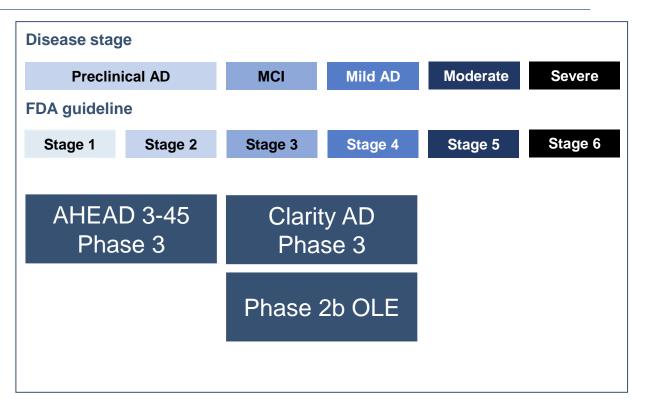
- Started May 2019, MEUR 15 milestone to BioArctic
- Study ongoing with target of 1566 early AD patients
- Primary endpoint readout expected 2022

### Phase 2b OLE open-label extension study

- Ongoing with approx. 200 patients with early AD
- Baseline data presented at CTAD December 2019 showed maintenance of benefit after BAN2401 treatment conclusion

### **AHEAD 3-45 Program**

- Eisai and ACTC planning to start A3 and A45 prevention study in 2020
- A45: ~1000 subjects with preclinical AD, little to no cognitive impairment and elevated levels of amyloid in the brain
- A3: ~400 subjects with early preclinical AD, cognitively normal with intermediate amyloid levels in the brain
- Biomarkers on amyloid, tau and neurodegeneration
- Clinical evaluation scale PACC5<sup>1</sup> for A45



Clinical program driven by:





# ABBV-0805: potential disease modifying antibody for Parkinson's disease with strong preclinical results now in Phase 1

### High unmet medical need

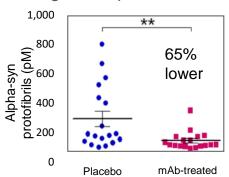
No existing disease-modifying treatment

- 2nd most common neurodegenerative disease
- 6.2 million people with Parkinson's<sup>1</sup>
- Younger patient group, still at working age

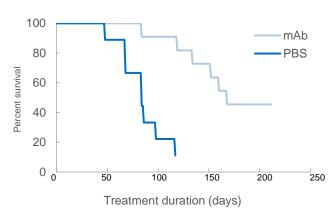
1) Dorsey and Bloem, JAMA Neurology 2018;75:9-10

### **Preclinical proof of concept**

Reduction of neurotoxic alpha-synuclein oligomers/protofibrils



Delays disease progression and increases lifespan



### **Unique profile**

### Unique and targeted binding profile

 Highly selective for toxic forms of misfolded alpha-synuclein (oligomers/protofibrils)

### Built on genetic and pathology rationale

- Alpha-synuclein mutations lead to Parkinson's
- Alpha-synuclein oligomers/protofibrils are elevated in Parkinson's

### ABBV-0805 in clinical development

- Phase 1 with ABBV-0805 ongoing by AbbVie
- BioArctic delivers follow-up antibodies in the continued collaboration with AbbVie



## Continued progress in collaboration with AbbVie on alpha-synuclein

### **Collaboration highlights**

- ABBV-0805 targeting disease modification in Parkinson's disease
- Potential to expand to earlier stage Parkinson's disease patients and other diseases where alphasynuclein plays a role
- AbbVie is responsible for clinical development
- BioArctic delivers followup antibodies in the continued collaboration with AbbVie

### ABBV-0805 advancing in clinical trials

December 2018

January 2019 February 2019 March 2019

2020

Alpha-synuclein antibody portfolio licensed by AbbVie

Milestone of 50 MUSD for the license ABBV-0805 INDapplication approved by the US FDA AbbVie started Phase 1 with ABBV-0805

Phase 1 study ongoing

- Aim to evaluate safety and tolerability
- Second stage of Phase 1 study in patients with Parkinson's disease now underway

Collaboration featured in *Drug Discovery Today* (March 2020)

Drug Discovery Today



feature

How partnership should work to bring innovative medicines to patients

Janice M. Twombly<sup>1</sup>, jan@rhythmofbusiness.com, Johanna Fälting<sup>2</sup>, Marco Giorgetti<sup>3</sup>, Anna C. Maroney<sup>3</sup> and Gunilla Osswald<sup>2</sup>

Scientists increasingly find themselves working in bilateral drug development alliances. Alliances are conceptually simple, but operationally challenging, resulting in the value-eroding misalignment and delays that alliances often experience. This case study of an exemplary collaboration between a small biotech and a global biopharmaceutical company is based on 15 interviews and a lessons-learned workshop conducted with the principal alliance team members. We outline five repeatable practices identified as contributing to their success that other alliance teams can follow.



## BioArctic has a strong financial profile

• Listed on Nasdaq Stockholm Mid Cap, market capitalization of SEKbn 6.1<sup>1</sup> (~650 MUSD)<sup>2</sup>



 More than 1 billion SEK (100 MUSD) in cash



- Net profit during the last 7 years
- Expected 2020 operating costs 180-230 MSEK



- Significant funding from partner research collaborations and license agreements, as well as grants
- Total potential collaboration deal value<sup>3</sup> of ~SEKbn 9.6 (~1 BUSD) of which ~SEKbn 1.9 (~0.2 BUSD) received
- Additional future royalties potential
- Milestone payments one-time nature explain fluctuations in financial results







- 1) As of April 21, 2020.
- 2) Calculated using relevant exchange rate as of April 21, 2020.
- 3) Calculated using relevant exchange rate as of December 30, 2019.



## **Upcoming news flow**



### BAN2401 (Eisai)

- To present data at international congresses
- Phase 3 confirmatory study results 2022
- Phase 2b open label extension study results
- Phase 3 prevention study to start 2020

## Discovery stage programs

 Advance into preclinical development

### Parkinson's disease



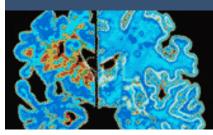
#### ABBV-0805 (AbbVie)

- Complete Phase 1 and start Phase 2
- Publications on the collaboration

## Discovery stage projects

 Development in AbbVie collaboration

### **Other CNS disorders**



## Neurodegeneration research

- New project development
- New indications and new targets

## Blood-brain barrier technology



# Blood-brain barrier technology platform

 Continue development of platform

### **Diagnostics**



### **Diagnostics**

 Continue development of imaging and biochemical biomarkers

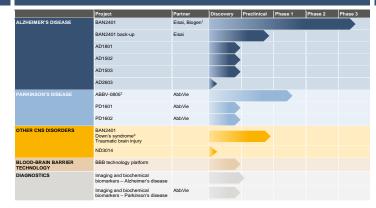


### **BioArctic: With Patients in Mind**

### **Built on science**



### **Projects in focus**



### Value-driven leadership





## Targeting neurotoxic forms of aggregated misfolded proteins is important when designing therapies for neurodegenerative diseases

