

BIOARCTIC AB (PUBL)  
NASDAQ STOCKHOLM: BIOA B

# Interim Report January-June 2019

Stockholm, July 11, 2019

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*Gunilla Osswald, PhD, CEO*

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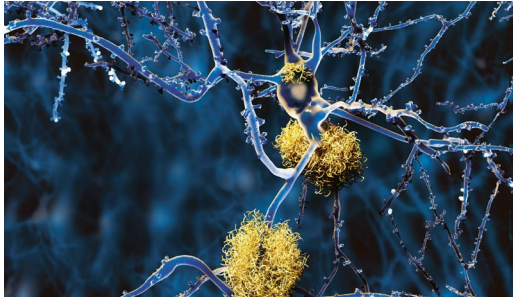
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# Significant progress in all areas 2019 year to date

## ALZHEIMER'S DISEASE



### BAN2401

- Phase 3 confirmatory study in early Alzheimer's disease started by Eisai (milestone received MEUR 15)
- Phase 2b open label extension study ongoing
- ACTC and Eisai prepare for secondary prevention study

### Discovery stage programs

- Progressed according to plan

## PARKINSON'S DISEASE



### ABBV-0805 (BAN0805)

- IND produced by BioArctic approved by FDA
- Phase 1 study started by AbbVie

### Discovery stage projects

- Progressed according to plan in AbbVie collaboration

## COMPLETE SPINAL CORD INJURY



### SC0806

- Phase 1 safety evaluated and Phase 2 started

## DIAGNOSTICS AND TECHNOLOGY



### Blood Brain Barrier Technology Platform

- Vinnova grant of MSEK 10 received together with Uppsala University
- Internationally renowned scientist recruited

# BioArctic – a unique Swedish biopharma company

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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** generating **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, **positive financial results** during the last six years and **valuable collaboration agreements** totaling BSEK 9.3 (BUSD ~1) plus royalties

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

	Product candidate	Indication	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	
Neurodegenerative Diseases	<b>BAN2401:</b> anti-A $\beta$ antibody	Alzheimer's Disease		→					
	<b>BAN2401:</b> anti-A $\beta$ antibody	Down's Syndrome <sup>2</sup> Traumatic Brain Injury <sup>2</sup>	—	→					
	<b>BAN2401 BACK-UP:</b> anti-A $\beta$ antibody	Alzheimer's Disease		→					
	<b>AD1801:</b> Undisclosed information	Alzheimer's Disease	—	→					
	<b>AD1502:</b> Undisclosed information	Alzheimer's Disease	—	→					
	<b>AD1503:</b> Undisclosed information	Alzheimer's Disease	—	→					
	<b>ABBV-0805<sup>3</sup>:</b> anti- $\alpha$ -synuclein antibody	Parkinson's Disease	abbvie	→					
	<b>PD1601:</b> anti- $\alpha$ -synuclein antibody	Parkinson's Disease	abbvie	→					
	<b>PD1602:</b> anti- $\alpha$ -synuclein antibody	Parkinson's Disease	abbvie	→					
Diagnostics & Technology	<b>IMAGING AND BIOCHEMICAL BIOMARKERS: A<math>\beta</math></b>	Alzheimer's Disease	—	→					
	<b>IMAGING AND BIOCHEMICAL BIOMARKERS: <math>\alpha</math>-synuclein</b>	Parkinson's Disease	abbvie	→					
	<b>BBB-TECHNOLOGY:</b> blood-brain barrier	Multiple application areas	—	→					
Spine	<b>SC0806:</b> FGF1/medical device	Complete Spinal Cord Injury	—	→					

as of June 30, 2019

- 1) Partner with Eisai on BAN2401 for treatment of Alzheimer's disease. Eisai partnered with Biogen on BAN2401 in 2014
- 2) Dementia and cognitive impairment associated with Down's syndrome and Traumatic Brain Injury
- 3) AbbVie in-licensed BAN0805 in late 2018 and will continue to develop BAN0805, now with the designation ABBV-0805

# Long-standing and extensive partnerships

## Alzheimer's disease

### Partner Track Record



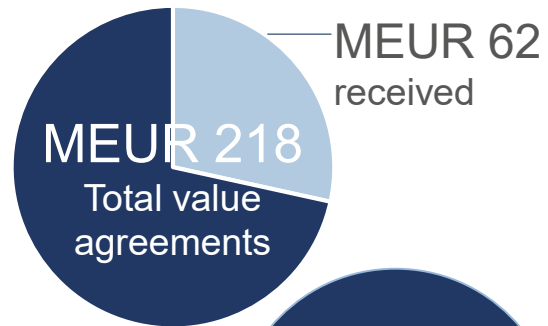
Discovered and developed world's best selling medicine for symptoms in Alzheimer's



**10+ projects in dementia**

Currently in development

### Collaboration and license



Royalties  
High single digit %

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

## Parkinson's disease

### Partner Track Record



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

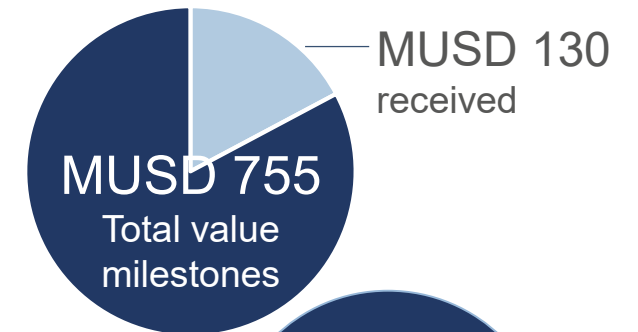


10 different indications in immunology

Approved product for symptoms associated with Parkinson's disease



### Collaboration and license



Royalties  
Tiered %

- AbbVie global rights to alpha-synuclein portfolio for all indications

Sources: Eisai, AbbVie and BioArctic corporate information

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

## High unmet medical need



No existing  
disease-  
modifying  
treatment

**TODAY**

>30 million  
people with Alzheimer's

**IN 20  
YEARS**  
doubling

## 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

## 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**

## Eisai announced three clinical trials underway

1. **Confirmatory Phase 3 study** ("Clarity AD") started
  - Primary endpoint final readout expected 2022
2. Phase 2b open label extension study ongoing
3. Secondary prevention study ("A45 Study") in planning to start 2020

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

## High unmet medical need



2nd most common neurodegenerative disease

6.2 million people with Parkinson's in 2015

Younger patient group, still at working age

## Unique profile

### Unique and targeted binding profile

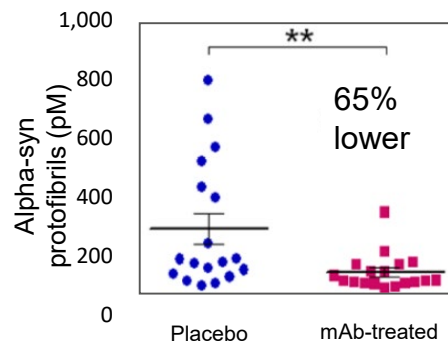
- Highly selective for toxic forms of misfolded alpha-synuclein (oligomers/protofibrils)

### Built on genetic and pathology rationale

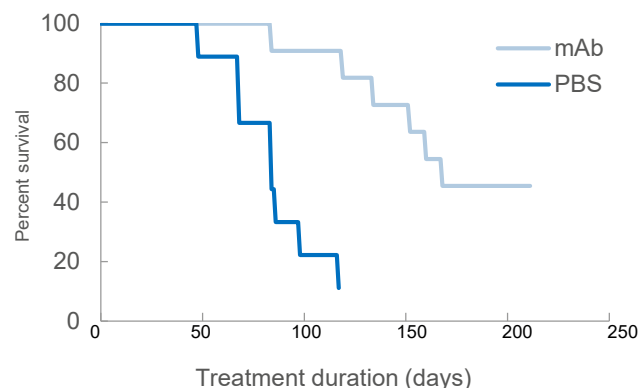
- Alpha-synuclein mutations lead to Parkinson's
- Alpha-synuclein oligomers/protofibrils are elevated in Parkinson's

## Preclinical proof of concept

Reduction of neurotoxic alpha-synuclein oligomers/protofibrils



Delays disease progression and increases lifespan



## ABBV-0805 in clinical development

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



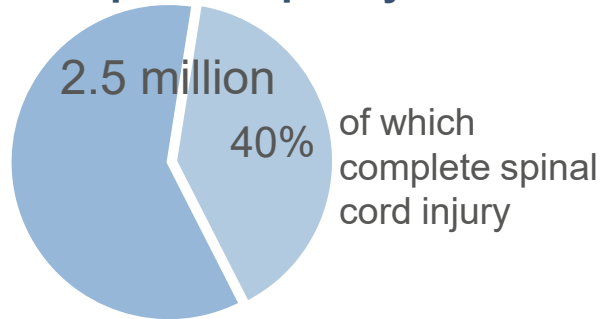
# SC0806: potential regenerative treatment for Complete Spinal Cord Injury in Phase 2

## High unmet medical need



No treatment for chronic injury

### People with paralysis



- Significant quality of life issues
- More common among younger men
- Orphan Drug designation in US and EU for SC0806

## Preclinical proof of concept and initial clinical safety

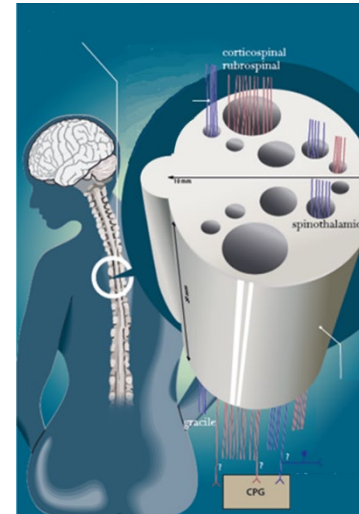
Preclinical model showed <sup>1)</sup>:

- Nerve regeneration
- Electrophysiology restored
- Motor function improved

Phase 1 in patients:

- Safety evaluation supported progression into Phase 2

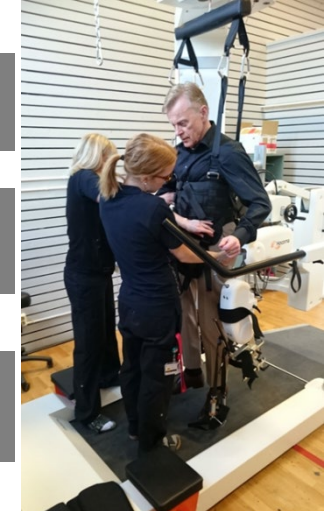
## SC0806 makes nerve regeneration possible



Growth factor FGF1

Peripheral nerve autografts

Biodegradable device

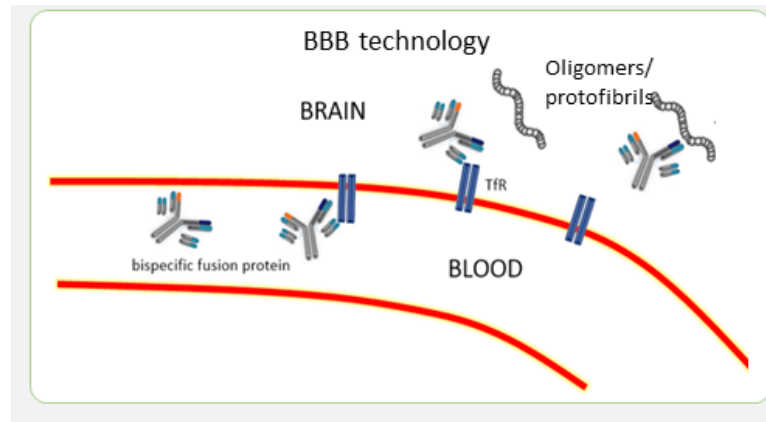
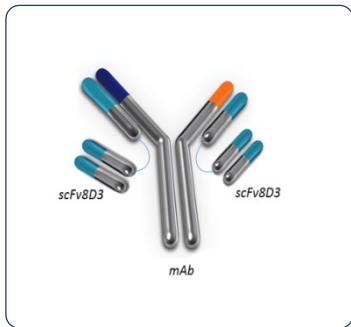


## SC0806 in Phase 2

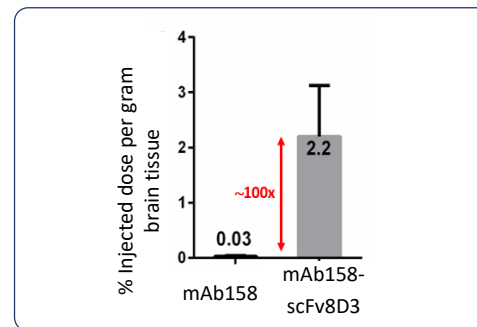
- Phase 2 ongoing in patients with Complete Spinal Cord Injury
  - Interim analysis expected 1H2020
- EU Horizon 2020 research and innovative program <sup>2)</sup>

# Advancing technology platforms and diagnostics to fuel pipeline

## BLOOD-BRAIN BARRIER TECHNOLOGY PLATFORM

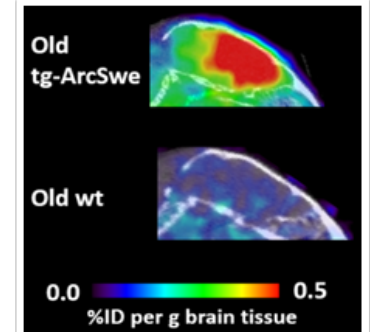


Substantially increased antibody brain uptake by BioArctic's brain shuttle technology



## DIAGNOSTICS

### Antibody-based imaging (PET)



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

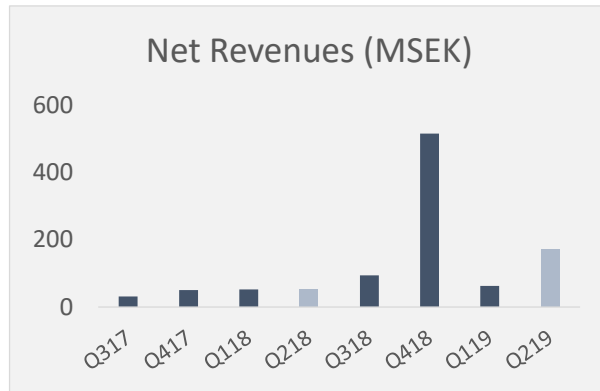
### Biochemical biomarkers



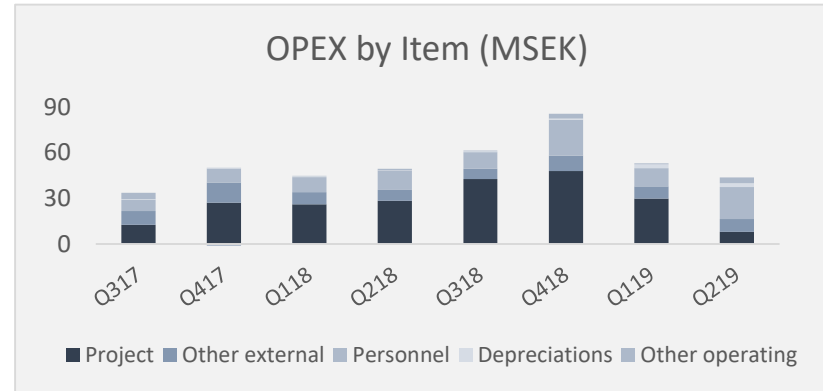


## Financial summary

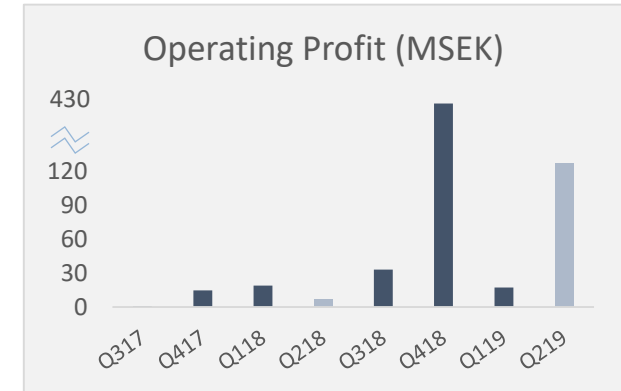
# Revenues and operating profit Q2 2019



- Net revenues increased to 171.3 MSEK (52.3)
- Mainly related to the Eisai 15 MEUR milestone payment linked to the start of Phase 3 for BAN2401



- Project expenses decreased to 8.0 MSEK (28.5) due to lower external expenses in the Parkinson's project this quarter
- Personnel costs increased to 21.1 MSEK (12.5), mainly related to one-time incentive payments

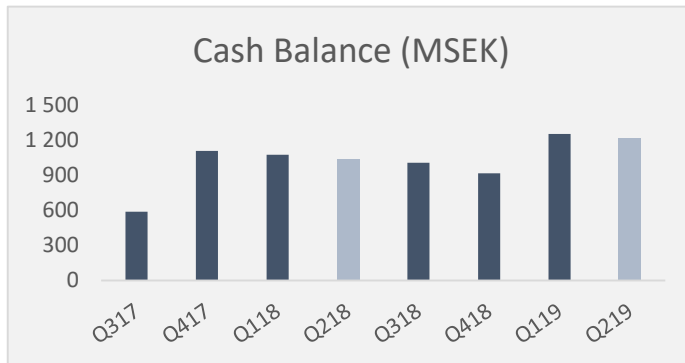


- Operating profit increased to 126.8 MSEK (6.4)

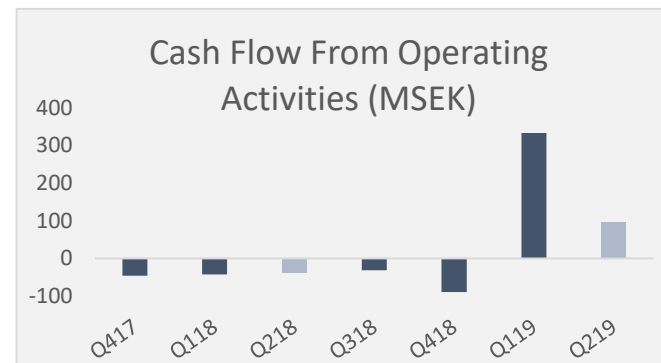
Operating expenses are expected to be in the range of 190 - 250 MSEK for the fiscal year January - December 2019



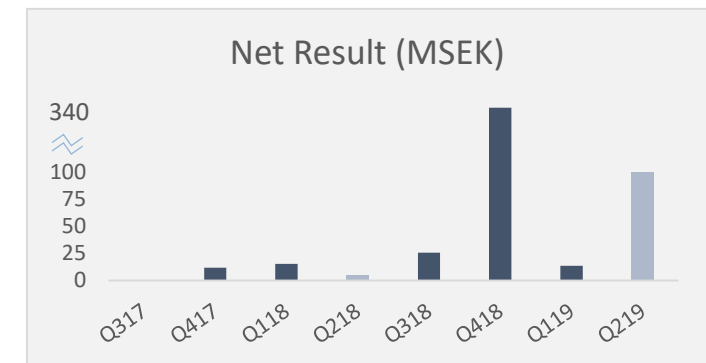
# Cash related and net profit Q2 2019



- Cash balance amounted to 1,218.4 MSEK (1,041.7) at the end of the quarter
- The two main items during the quarter were the dividend to shareholders and the incoming milestone payment from Eisai



- Operating cash flow amounted to 97.2 MSEK (-37.3) during Q2
- The reason for the positive number in Q2 is related to the 15 MEUR milestone payment from Eisai



- Profit for the period increased to 100.3 MSEK (5.1) during Q2

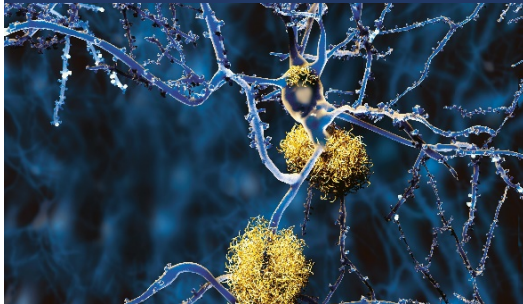
To sum up, BioArctic showed another quarter with positive net results and a strong cash balance



**Upcoming news and  
closing remarks**

# Upcoming news flow

## ALZHEIMER'S DISEASE



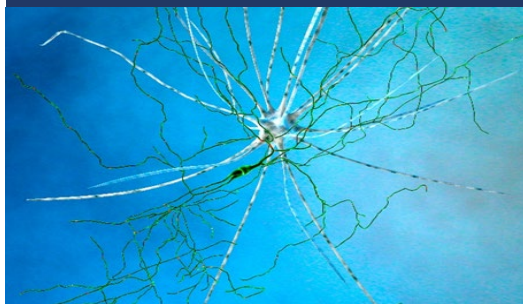
### **BAN2401** (Eisai)

- Present data at international congresses incl. AAIC in July
- Phase 3 confirmatory study results 2022
- Phase 2b open label extension study results
- Secondary prevention study start 2020

### **Discovery stage programs**

- Advance into preclinical development

## PARKINSON'S DISEASE



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

- Complete Phase 1 study

### **Discovery stage projects**

- Continue development in AbbVie collaboration

## COMPLETE SPINAL CORD INJURY



### **SC0806**

- Phase 1/2 study interim analyses of safety and efficacy

## DIAGNOSTICS AND TECHNOLOGY



### **Blood-Brain Barrier Technology Platform**

- Expansion and continued development



**GUNILLA OSSWALD, CEO**



**JAN MATTSSON, CFO**



**NEXT REPORT & IR CONTACT**

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Q3 2019, October 24, 2019
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