

BIOARCTIC AB (PUBL)  
NASDAQ STOCKHOLM: BIOA B

# First Quarter Report January-March 2020

Stockholm, April 22, 2020

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*Jan Mattsson, CFO*



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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**



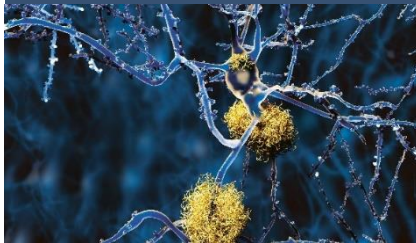
**Attractive and well-balanced project portfolio** with projects from discovery through Phase 3 and combination of both proprietary projects with substantial marketing and out-licensing potential and partnered projects generating income



**Well-financed** with 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

# Operations progressing according to plan

## Alzheimer's disease



### BAN2401

- 3 clinical studies underway or in planning
- Including Phase 3 confirmatory study ("Clarity AD") underway



### Discovery stage programs

- 4 fully-owned disease modifying programs

## Parkinson's disease



### ABBV-0805

- Second stage of Phase 1 study in patients with Parkinson's disease now underway by partner

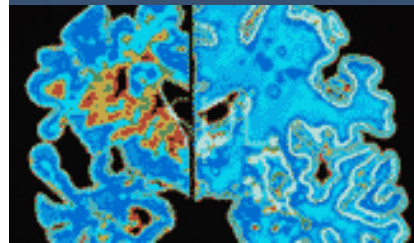


### Discovery stage projects

- Progressing according to plan in research collaboration with



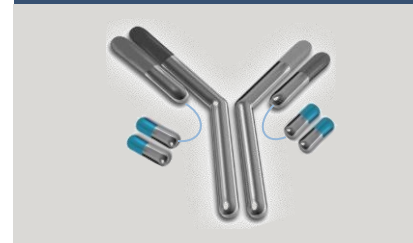
## Other CNS disorders



### Neurodegeneration research

- Working on new indications and new targets
- New research program - potential in various neurodegenerative disorders

## Blood-brain barrier technology



### Blood-brain barrier technology platform

- Continuing development

## Diagnostic tools



### Diagnostic tools

- Continuing development of imaging and biochemical biomarkers

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

as of March 31, 2020

- 1) Partnered with Eisai for BAN2401 for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding BAN2401 in 2014
- 2) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805
- 3) Dementia and cognitive impairment associated with Down's syndrome



# Long-standing and extensive partnerships

## Alzheimer's disease

### Partner track record

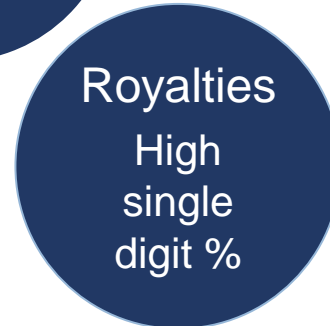
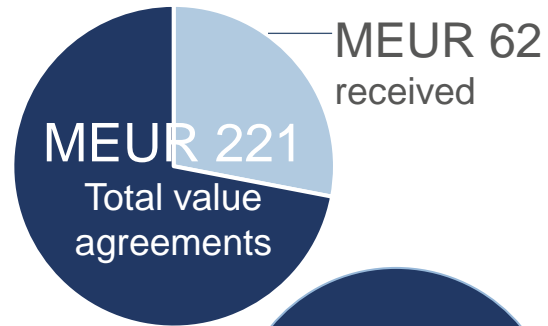


Discovered and developed world's best-selling medicine for symptoms in Alzheimer's



**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



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

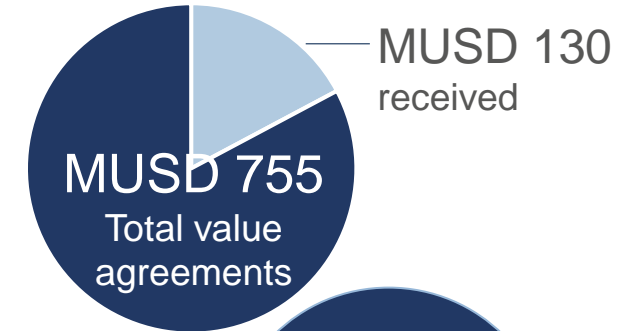


10 different indications in immunology

Approved product for symptoms associated with Parkinson's disease



### Collaboration and license

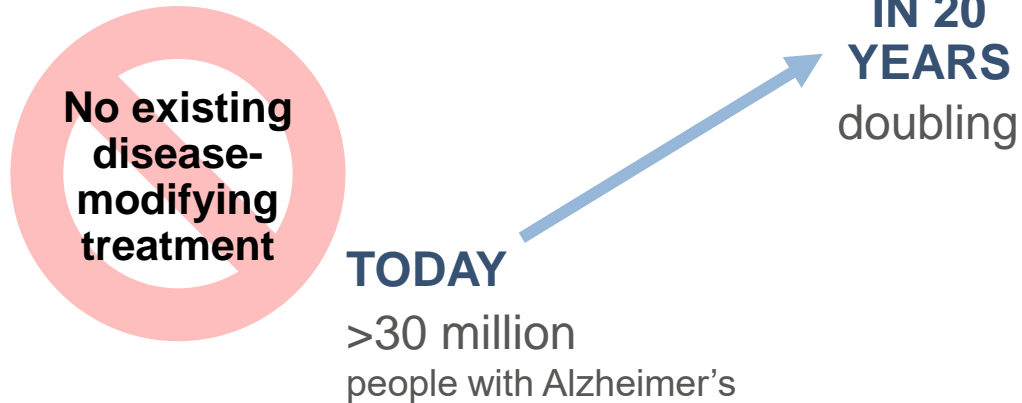


- AbbVie global rights to alpha-synuclein portfolio for all indications

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



## 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**

## 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

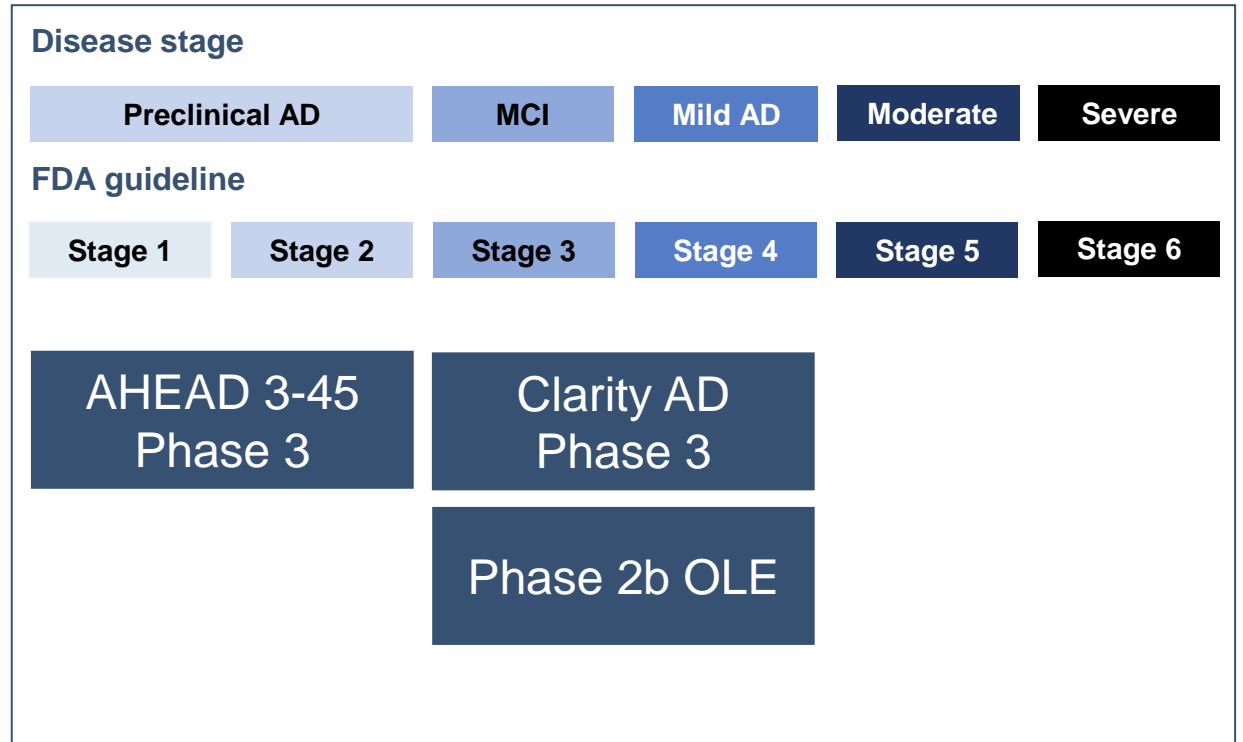
- Started May 2019, MEUR 15 milestone to BioArctic
- Study ongoing with target of 1566 early AD patients
- Primary endpoint readout expected 2022


## 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

## Unique profile

### Unique and targeted binding profile

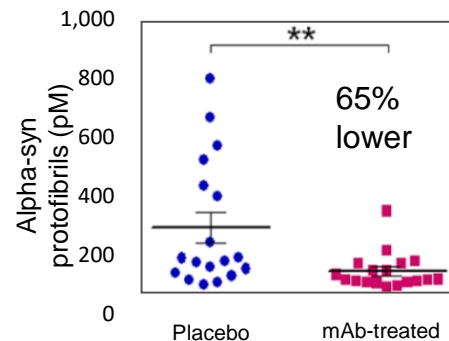
- Highly selective for toxic forms of misfolded alpha-synuclein (oligomers/protofibrils)

### Built on genetic and pathology rationale

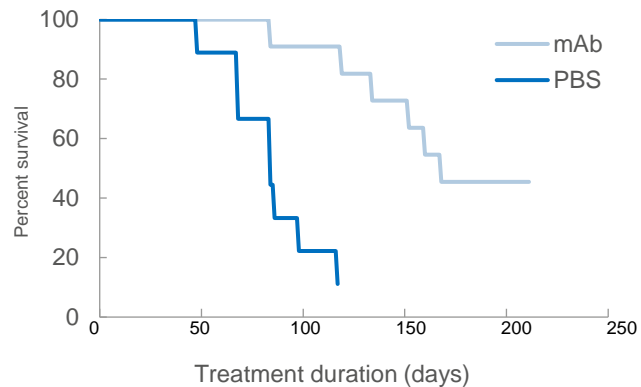
- Alpha-synuclein mutations lead to Parkinson's
- Alpha-synuclein oligomers/protofibrils are elevated in Parkinson's

## 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 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 alpha-synuclein plays a role
- AbbVie is responsible for clinical development
- BioArctic delivers follow-up antibodies in the continued collaboration with AbbVie

## ABBV-0805 advancing in clinical trials



Alpha-synuclein antibody portfolio licensed by AbbVie

Milestone of 50 MUSD for the license

ABBV-0805 IND-application 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

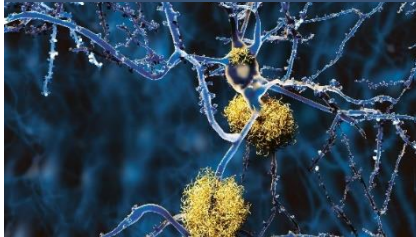
### How partnership should work to bring innovative medicines to patients

Janice M. Twombly<sup>1</sup>, jan@rhythmofbusiness.com, Johanna Färling<sup>2</sup>, Marco Giorgetti<sup>3</sup>, Anna C. Maroney<sup>4</sup> and Gunilla Osswald<sup>5</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.

# Early stage portfolio continues to develop well

## Alzheimer's disease



### Discovery stage programs

- 4 disease modifying antibody projects in Alzheimer's disease
- Each project has a different mechanism from the others
- All fully-owned by BioArctic

## Parkinson's disease

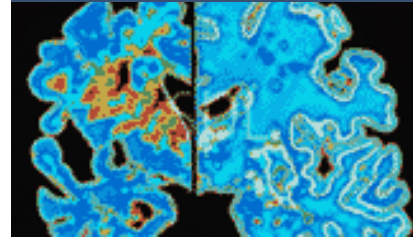


### Discovery stage projects

- Preclinical stage alpha-synuclein projects in research collaboration with

abbvie

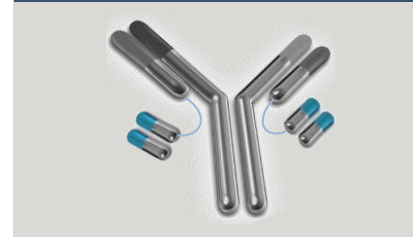
## Other CNS disorders



### Neurodegeneration research

- BAN2401 in indications other than Alzheimer's disease
- Research project in neurodegeneration ("ND") with potential in various CNS disorders

## Blood-brain barrier technology



### Blood-brain barrier technology platform

- Continued development with expanded and enhanced capabilities
- Collaboration with Uppsala University under Vinnova grant

## Diagnostic tools



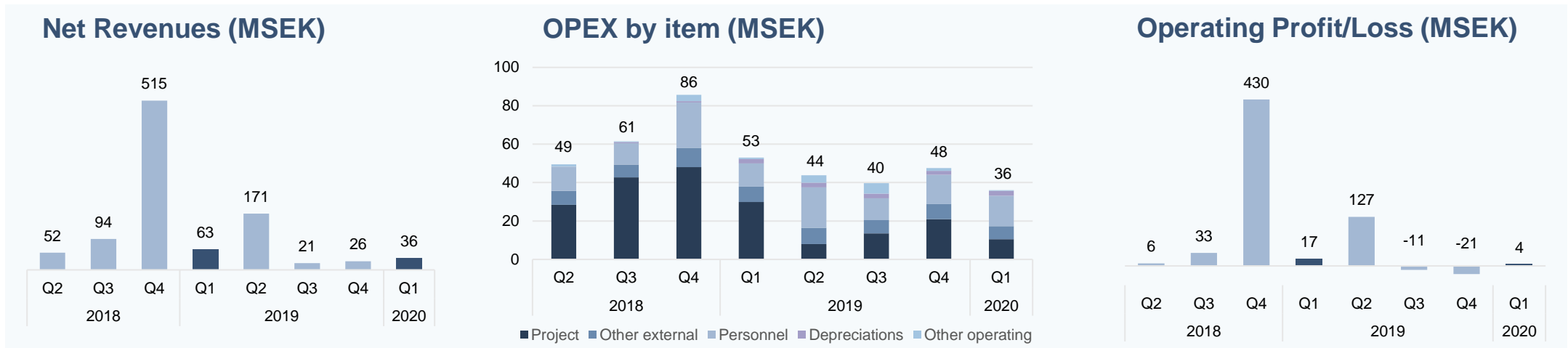
### Diagnostic tools

- Continued development of imaging and biochemical biomarkers



## Finance Summary

# Net revenues and operating profit Q1 2020



- Net revenues were 36.4 MSEK (63.4) for the first quarter
- The change is primarily due to lower activity in the Parkinson's program as planned

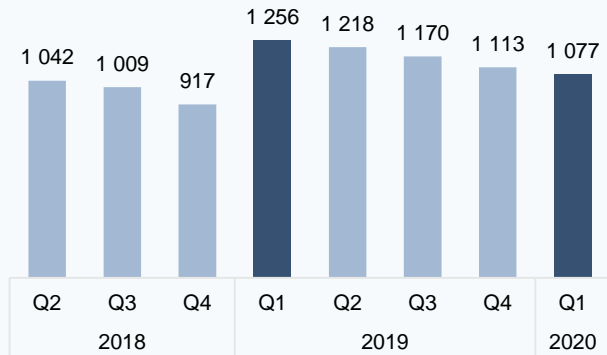
- Project expenses decreased to 10.5 MSEK (30.0) due to lower external expenses in the Parkinson's project versus previous year
- The personnel expenses increased to 16.0 MSEK (12.0) primarily attributable to an increase in the number of employees

- Operating profit was 3.8 MSEK (17.3) for the first quarter
- The change is attributable to lower activity in the Parkinson's program as planned

Operating expenses are expected to be in the range of 180 - 230 MSEK for the financial year January - December 2020

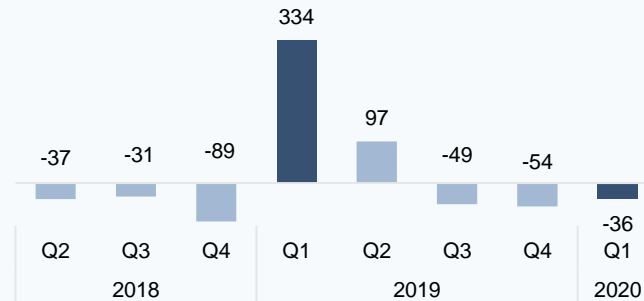
# Cash related and net profit Q1 2020

## Cash Balance (MSEK)



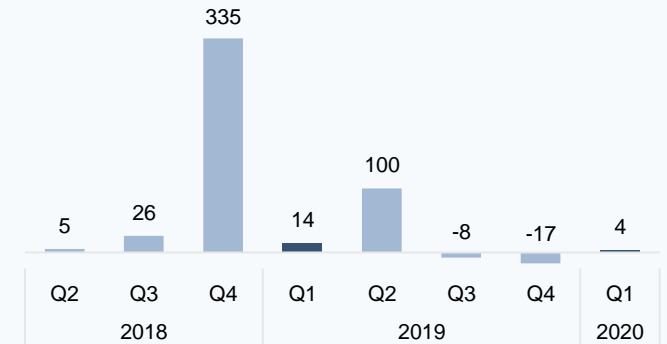
- Cash balance amounted to 1,077.3 MSEK (1,255.6) at the end of the first quarter

## Cash Flow From Operating Activities (MSEK)



- Operating cash flow amounted to -36.3 MSEK (333.6) during Q1

## Operating Profit/Loss (MSEK)



- Net result for the period was 3.6 MSEK (13.6)

To sum up, BioArctic showed positive net result for the first quarter and continues to have a strong financial position





**Upcoming news and  
closing remarks**

# Upcoming news flow

## Alzheimer's disease



### **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



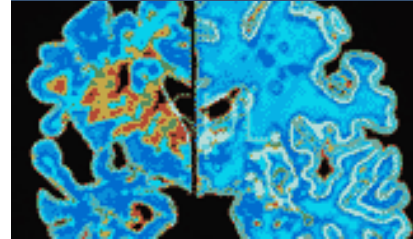
### **ABBV-0805** (AbbVie)

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

### **Discovery stage projects**

- Development in AbbVie collaboration

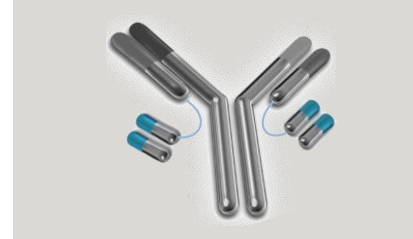
## Other CNS disorders



### **Neurodegeneration research**

- New project development
- New indications and new targets

## Blood-brain barrier technology



### **Blood-brain barrier technology platform**

- Continue development of platform

## Diagnostic tools



### **Diagnostic tools**

- Continue development of imaging and biochemical biomarkers

# BioArctic: With Patients in Mind

## Built on science



## Projects in focus

	Project	Partner	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ALZHEIMER'S DISEASE	BAN2401	Eisai, Biogen <sup>1</sup>	[Progress bar]				
	BAN2401 back-up	Eisai	[Progress bar]				
	AD1801		[Progress bar]				
	AD1502		[Progress bar]				
	AD1503		[Progress bar]				
PARKINSON'S DISEASE	AD2803		[Progress bar]				
	ABBV-0805 <sup>2</sup>	AbbVie	[Progress bar]				
	PD1801	AbbVie	[Progress bar]				
OTHER CNS DISORDERS	PD1802	AbbVie	[Progress bar]				
	BAN2401 Down's syndrome <sup>3</sup> Traumatic brain injury ND3014		[Progress bar]				
BLOOD-BRAIN BARRIER TECHNOLOGY	BBB technology platform		[Progress bar]				
DIAGNOSTIC TOOLS	Imaging and biochemical biomarkers – Alzheimer's disease		[Progress bar]				
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie	[Progress bar]				

## Value-driven leadership



GUNILLA OSSWALD, CEO



JAN MATTSSON, CFO



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Interim report Jan-Jun 2020  
on July 10, 2020
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