BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

Third Quarter Report July-September 2021

Stockholm, October 21, 2021

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BIOARCTIC

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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 close to MSEK 900 (MUSD ≈100[1]) in cash, **net profitable** during seven of the last eight years and **valuable collaboration agreements** totaling BSEK 8.9[2] (BUSD ~1) plus royalties

1) FX as per September 30, 2021
2) FX as per September 30, 2021

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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
ALZHEIMER'S DISEASE	Lecanemab (BAN2401) *(Clarity AD)*	Eisai[1]	Early Alzheimer's disease[3]				
	Lecanemab (BAN2401) *(AHEAD 3-45)*	Eisai[1]	Preclinical (asymptomatic) Alzheimer's disease[4]				
	BAN2401 back-up	Eisai					
	AD1801						
	AD1502						
	AD1503						
	AD-BT2802						
	AD-BT2803						
	AD2603						
PARKINSON'S DISEASE	ABBV-0805[2]	AbbVie					
	PD1601	AbbVie					
	PD1602	AbbVie					
OTHER CNS DISORDERS	Lecanemab (BAN2401)		Down's syndrome[5] Traumatic brain injury[5]				
	ND3014						
BLOOD BRAIN BARRIER	Brain Transporter (BT) technology platform						
DIAGNOSTICS	Imaging and biochemical biomarkers – Alzheimer's disease						
	Imaging and biochemical biomarkers – Parkinson's disease	AbbVie					

as of September 30, 2021

1) Partnered with Eisai for lecanemab (BAN2401) for treatment of Alzheimer's disease. Eisai entered partnership with Biogen regarding lecanemab (BAN2401) in 2014
2) AbbVie in-licensed BAN0805 in late 2018 and develops the antibody with the designation ABBV-0805
3) Mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease
4) Normal cognitive function with intermediate or elevated levels of amyloid in the brain
5) Dementia and cognitive impairment associated with Down´s syndrome and with traumatic brain injury

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Long-standing and extensive partnerships

Alzheimer's disease

Partner track record

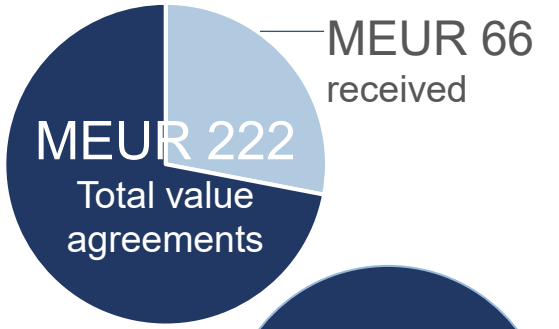
Eisai

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

Aricept® donepezil HCl tablet

Industry-leading pipeline in dementia area

Collaboration and license



- BioArctic retains rights to lecanemab 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)

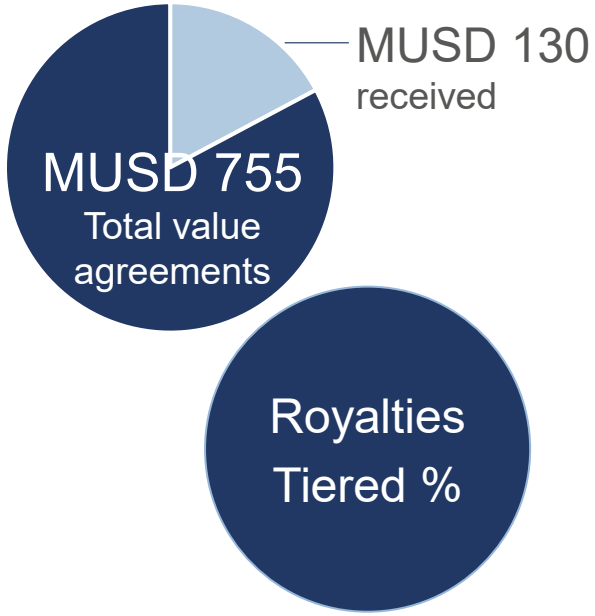
HUMIRA® adalimumab

10 different indications in immunology

Approved product for symptoms associated with Parkinson's disease

Duopa carbidopa/levodopa

Collaboration and license



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

Sources: Eisai, AbbVie and BioArctic corporate information

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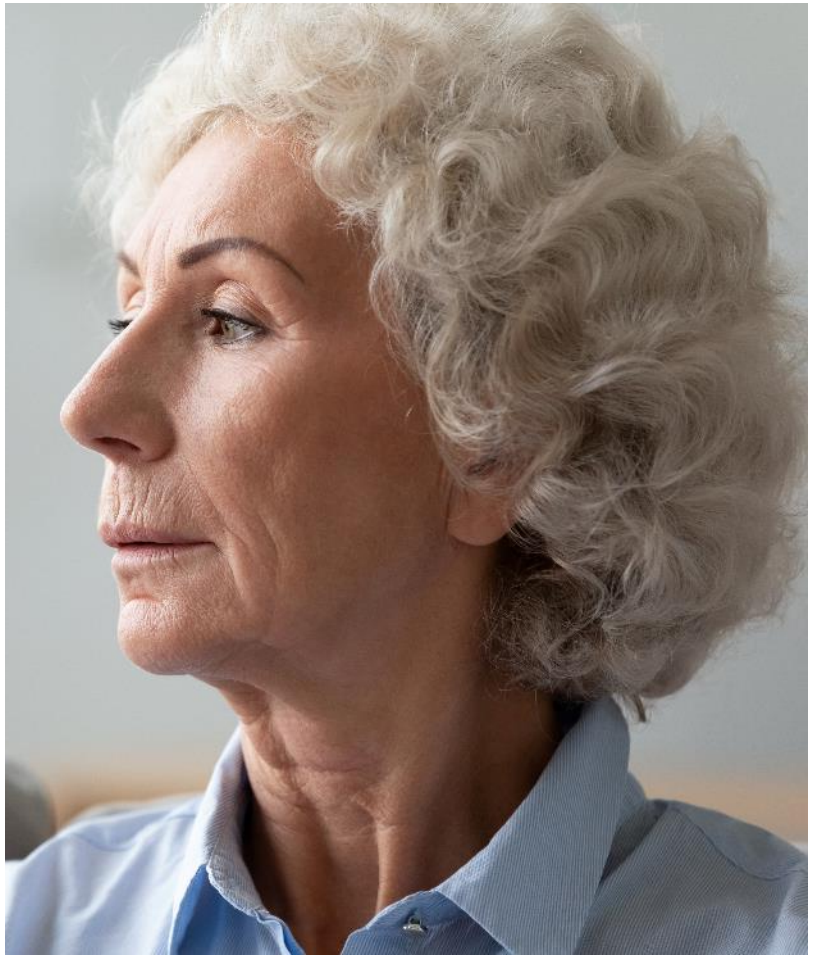
Q3 highlights

Alzheimer's disease – Lecanemab

- Eisai has agreed with the FDA to submit the Biologic License Application for lecanemab as a rolling submission utilizing the accelerated approval pathway
- Data presented at AAIC congress in July from the lecanemab clinical program:
  - continue to confirm the encouraging Phase 2b results and support continued development of lecanemab
  - explore the possibility of using specific blood biomarkers to monitor the effects of the drug in individual patients.



Parkinson's disease – ABBV-0805

- Data presented at MDS congress in September
  - Phase 1 results support Phase 2 development with dosing once a month
  - ABBV-0805 highly selectively targets soluble toxic α-synuclein aggregates vs physiological monomers, preventing α-synuclein to spread, delaying motor-symptoms and prolonging the lifespan

Other

- Starting to build commercial organization

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Eisai has agreed with the US FDA to initiate a rolling BLA submission under the accelerated approval pathway for lecanemab for early AD

- In June 2021, the FDA granted **Breakthrough Therapy designation** for lecanemab in Alzheimer's disease
- Eisai has interacted with the FDA to seek the **most optimal regulatory pathway** and has agreed with the FDA to submit the BLA for lecanemab as a **rolling submission**
- Eisai is utilizing the **accelerated approval pathway** after discussion with the FDA
- The BLA submission for lecanemab is primarily based on
  - the results from the Phase 2b study in 856 early AD patients with confirmed amyloid pathology,
  - the Open label extension study with 180 patients all receiving lecanemab 10mg/kg biweekly, and
  - blinded safety data from Clarity AD
- The Phase 3 Clarity AD study in 1795 early AD patients **can serve as the confirmatory study to verify the clinical benefit** of lecanemab

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Broad lecanemab clinical program – driven by BioArctic's partner Eisai

Disease stage

Preclinical AD	MCI	Mild AD	Moderate	Severe

FDA guideline

Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6

AHEAD 3-45 Phase 3 Program – ongoing

- Eisai and ACTC started new Phase 3 study in 2020
- A total of 1,400 participants to be enrolled in the study.
- Pre-clinical, asymptomatic, AD subjects with intermediate or elevated amyloid levels in the brain

Clarity AD Phase 3 confirmatory study – ongoing

- Primary endpoint readout expected 2022
- 1,795 early AD patients

OLE Phase 2b open-label extension study – ongoing

- 180 patients with early AD from the Phase 2b study

Sub cutaneous formulation Phase 1 study initiated

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Our view on current developments in the Alzheimer's disease field

ABBV-0805: potential disease modifying antibody for Parkinson's disease (PD) – in Phase 1 preparing for Phase 2

High unmet medical need

No existing disease-modifying treatment

Younger patient group, still at working age

TODAY

>6 million[1]
people with Parkinson's

Unique profile

Unique and targeted binding profile

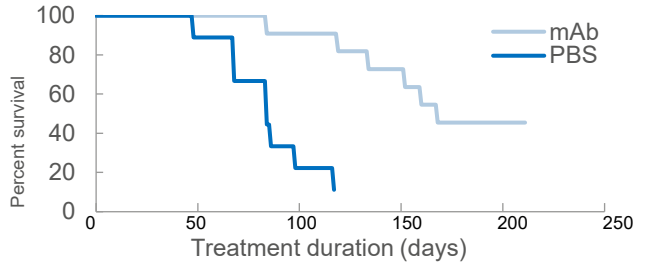
- Highly selective (>100.000) for pathological forms of misfolded alpha-synuclein (oligomers/protofibrils) vs physiological forms (monomers)

Built on genetic and pathology rationale

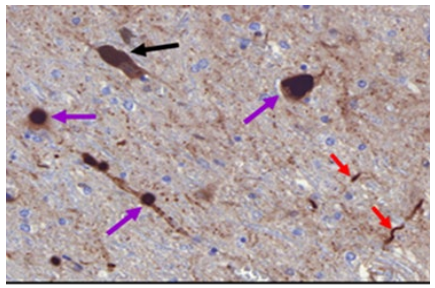
- Alpha-synuclein mutations lead to PD
- Alpha-synuclein oligomers/ protofibrils are elevated in PD

Preclinical proof of concept

- Reduction of neurotoxic alpha-synuclein oligomers/protofibrils
- Delays disease progression and increases lifespan



Human target binding of ABBV-0805 in PD brain



Black: neuromelanin ,Purple: Lewy bodies, Red:Lewy neurites

Phase 1 results presented at MDS congress in Sept 2022 support Phase 2 development with dosing once a month

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

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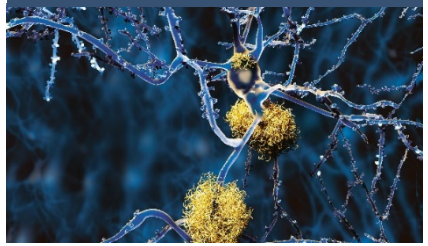
Early-stage portfolio continues to develop well

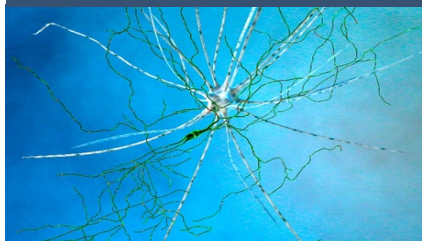
Alzheimer's disease



Discovery stage programs

- Expanded early-stage portfolio with 2 new AD+BT projects
- 6 fully-owned disease modifying antibody projects in Alzheimer's disease
- BAN2401 back-up in collaboration with Eisai

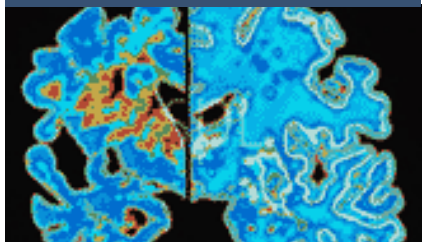
Parkinson's disease



Discovery stage projects

- Preclinical stage alpha-synuclein projects in research collaboration with abbvie

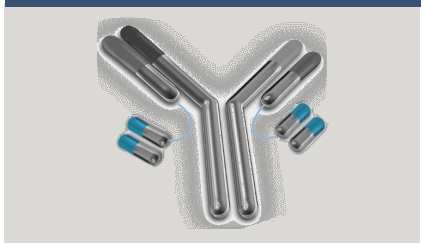
Other CNS disorders



Neurodegeneration research

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

Blood-brain barrier



Brain Transporter (BT)

- Continued development of our Brain Transporter (BT) technology platform
- Collaboration with Uppsala University under Vinnova grant

Diagnostics

Diagnostics

- Continued development of imaging and biochemical biomarkers

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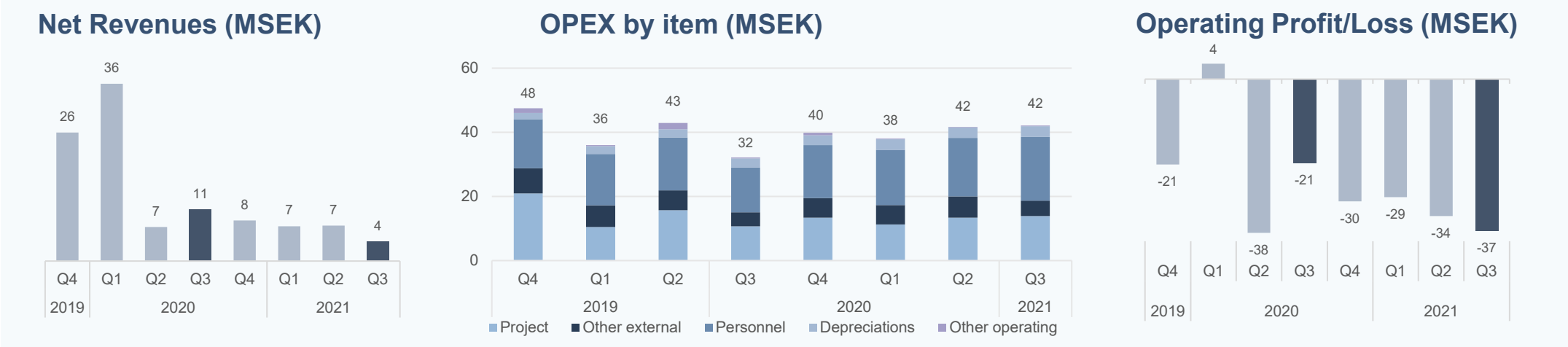
Financial Summary

Net revenues and operating profit/loss Q3 2021



- Net revenues were 4 MSEK (11) for the third quarter

- Total costs in the quarter were higher than the same period previous year
- Costs will increase going forward as we start building a commercial organization and further progressing our expanded project portfolio

- Operating loss was -37 MSEK (-21) for the third quarter

Operating expenses are now expected to be in the range of 160 - 190 MSEK for the financial year January - December 2021 (previously 170 - 200 MSEK)

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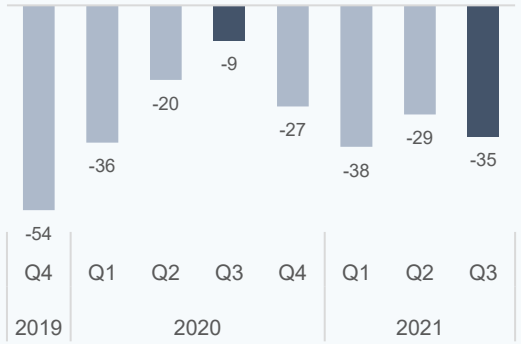
Cash and net result Q3 2021

Cash Balance (MSEK)

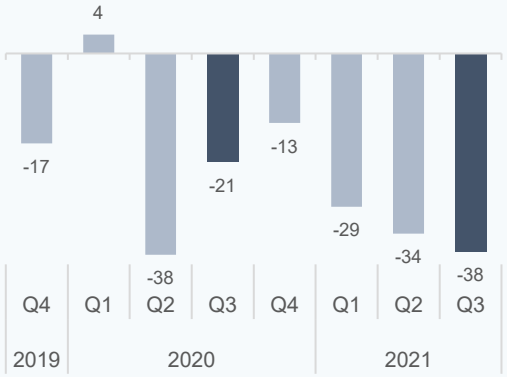
- Cash balance amounted to 892 MSEK at the end of the third quarter

Cash Flow From Operating Activities (MSEK)



- Operating cash flow amounted to -35 MSEK (-9) during Q3

Net Result (MSEK)



- Net result for the period was -38 MSEK (-21)

In summary, BioArctic continues to have a strong financial position

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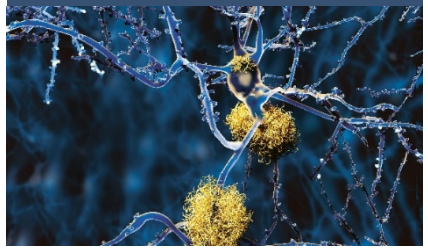
Upcoming news and closing remarks

Upcoming news flow

Alzheimer's disease



Lecanemab (Eisai)
- Data presented at international congresses
- Phase 3 confirmatory study in early AD results 2022
- Phase 2b open label extension study results
- Phase 3 study in pre-symptomatic AD
- Sub cutaneous formulation
- Update on the progress of rolling BLA in the USA

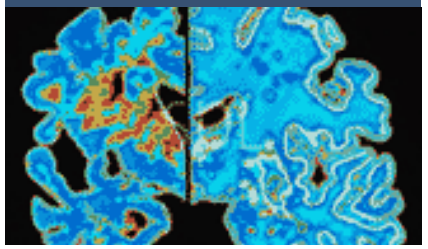
Discovery stage programs
- Advance into preclinical development

Parkinson's disease

ABBV-0805 (AbbVie)
- Complete Phase 1 and start Phase 2
- Data presented at international congresses

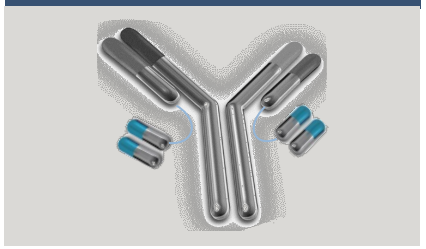
Discovery stage projects
- Development in AbbVie collaboration

Other CNS disorders



Neurodegeneration research
- New project development
- New indications and new targets

Blood-brain barrier



Brain Transporter (BT) technology platform
- Continue development of platform

Diagnostics

Diagnostics
- Continue development of imaging and biochemical biomarkers

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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:**
  Q4 Jan-Dec 2021 on February 3, 2022
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