BIOARCTIC AB (PUBL)
NASDAQ STOCKHOLM: BIOA B

SALSS

October 22, 2021

Gunilla Osswald, PhD, CEO

BIOARCTIC

Disclaimer

- This presentation has been prepared and produced by BioArctic AB (publ) (“BioArctic”) solely for the benefit of investment analysis of BioArctic and may not be used for any other purpose. Unless otherwise stated, BioArctic is the source for all data contained in this presentation. Such data is provided as at the date of this presentation and is subject to change without notice.
- This presentation includes forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause BioArctic’s actual results, performance, achievements or industry results to be materially different from those expressed or implied by these forward-looking statements. Forward-looking statements speak only as of the date of this presentation and BioArctic expressly disclaims any obligation or undertaking to release any update of, or revisions to, any forward-looking statement in this presentation, as a result of any change in BioArctic’s expectations or any change in events, conditions or circumstances on which these forward-looking statements are based.
- This presentation does not constitute or form part of, and should not be construed as, an offer or invitation for the sale of or the subscription of, or a solicitation of any offer to buy or subscribe for, any securities, nor shall it or any part of it or the fact of its distribution form, or be relied on in connection with, any offer, contract, commitment or investment decision relating thereto, nor does it constitute a recommendation regarding the securities of BioArctic.
- The information in this presentation has not been independently verified.
- No regulatory body in Sweden or elsewhere has examined, approved or registered this presentation.

BIOARCTIC

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

BIOARCTIC

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

BIOARCTIC

Long-standing and extensive partnerships

Alzheimer's disease

Partner track record

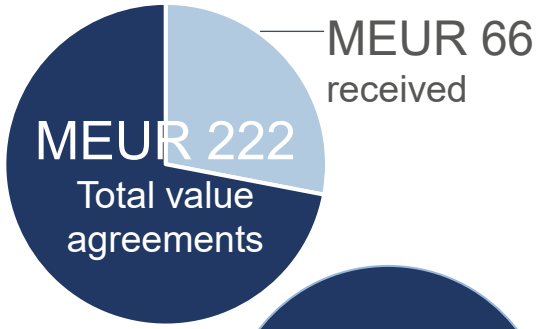
Eisai

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)

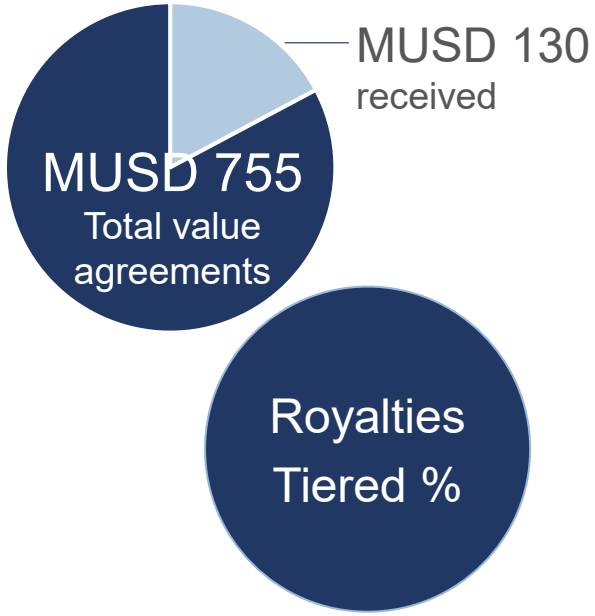
HUMIRA® adalimumab

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

BIOARCTIC

Alzheimer's disease – a global pandemic with a high unmet medical need and high costs to society

High unmet medical need

Today
> 30 MILLION
people have Alzheimer's disease

In 2050
> 80 MILLION
people are expected to have Alzheimer's disease

High cost to society

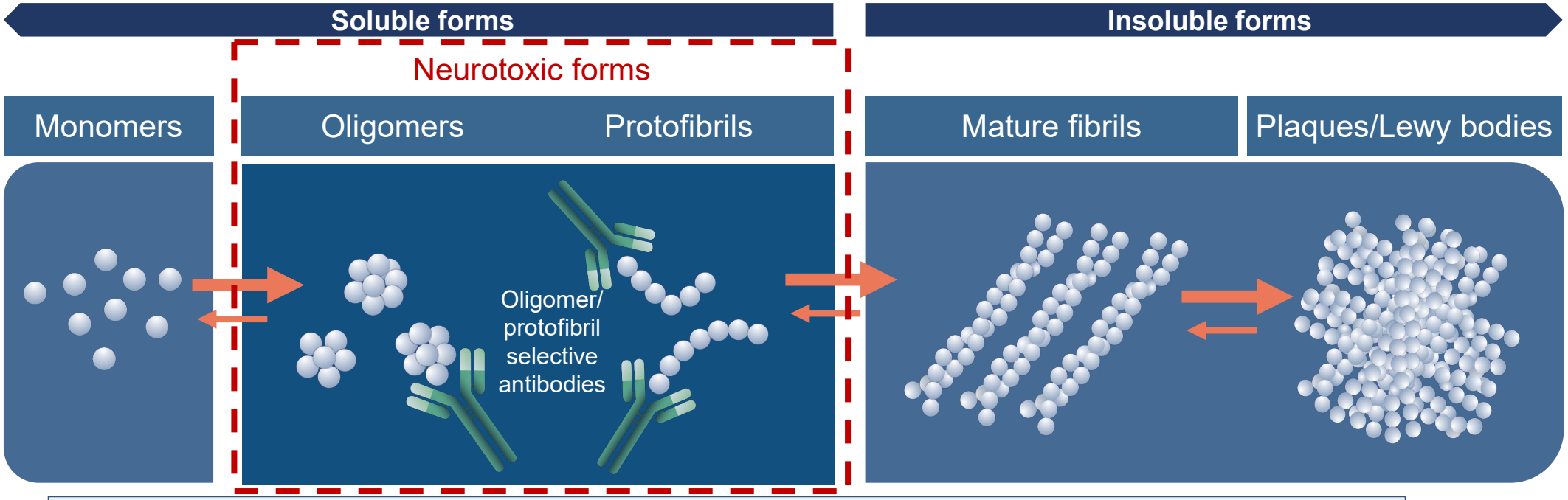
In 2019, estimated global societal cost of dementia was
$ 1.3 TRILLION

In 2030, these costs are expected to surpass
$ 2.8 TRILLION

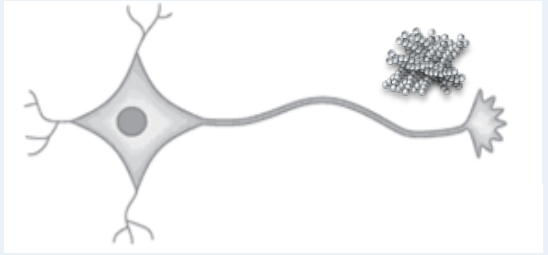
Sources: WHO, https://www.who.int/news-room/fact-sheets/detail/dementia

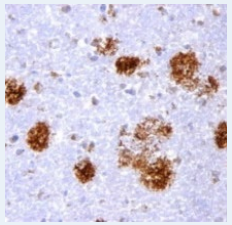
BIOARCTIC

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

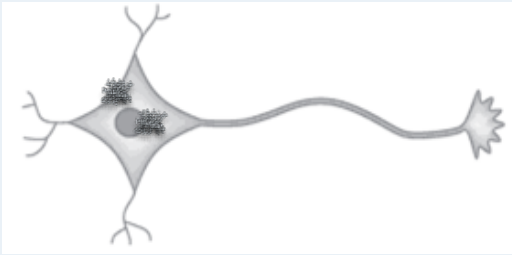


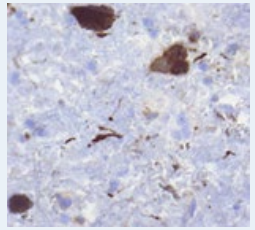
Alzheimer's disease: misfolded amyloid beta results in amyloid plaques





Parkinson's disease: misfolded alpha-synuclein results in Lewy Bodies





BIOARCTIC

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

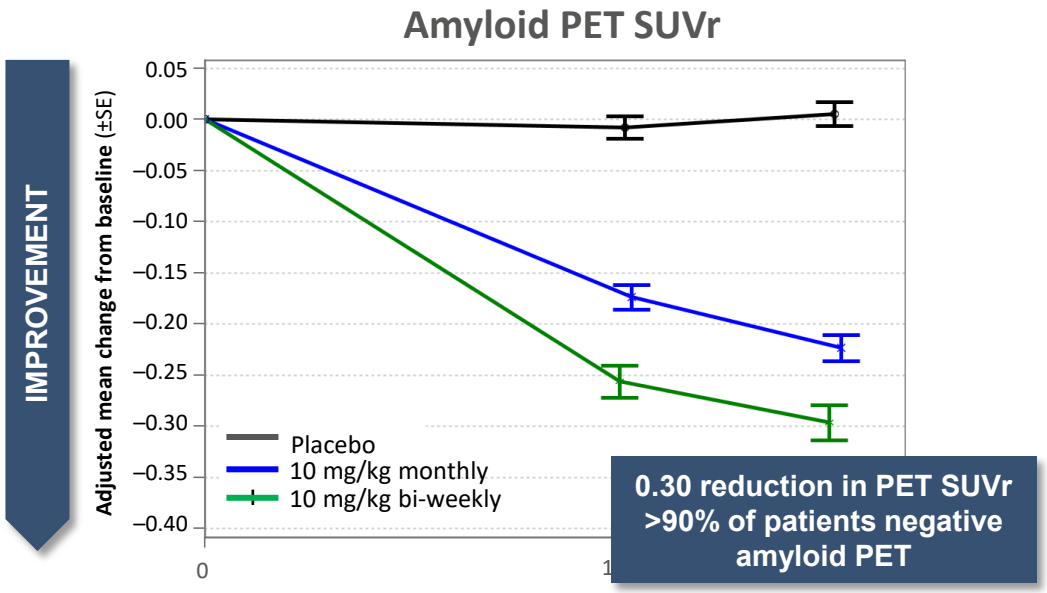
OLE Phase 2b open-label extension study – ongoing

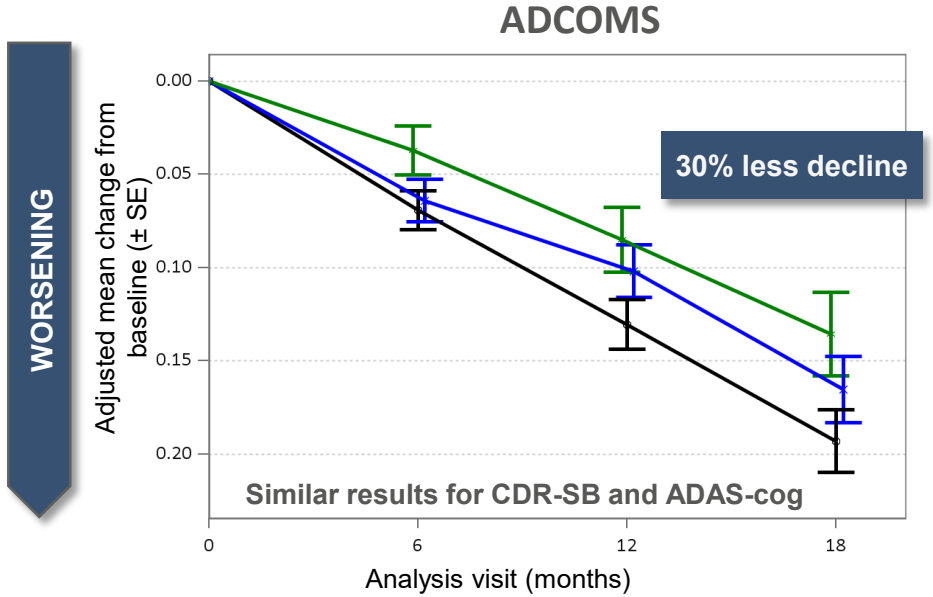
- 180 patients with early AD from the Phase 2b study

Sub cutaneous formulation Phase 1 study initiated

BIOARCTIC

Lecanemab: potential disease modifying antibody for Alzheimer's disease with positive Phase 2b results





Lecanemab has positive Phase 2b results

- **Large trial:** 856 early Alzheimer's patients
- **Consistent effects** on clinical outcomes, imaging and neurodegenerative biomarkers
- **Rapid onset** of clinical effect
- **Effect increases over time**
- **Good safety profile –** no titration required due to low frequency of ARIA–E (<10%)

PET: positron emission tomography

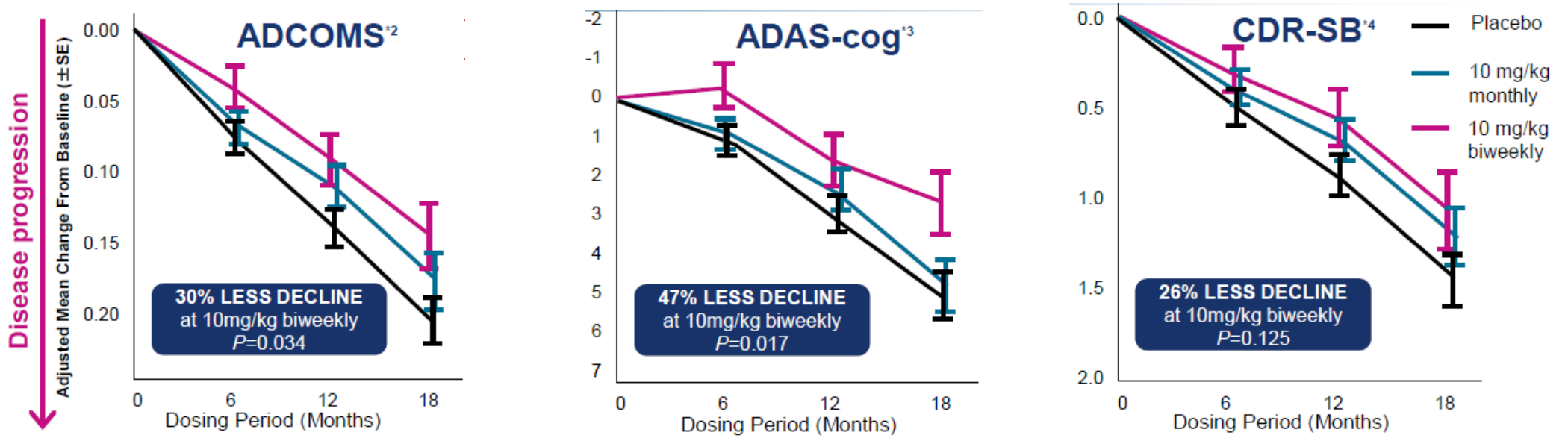
Presented at the Clinical Trials on Alzheimer's Disease Conference 2018; Barcelona, Spain. October 25, 2018

Alzheimer's Research & Therapy volume 13, Article number: 80 (2021)

BIOARCTIC

Lecanemab Showed Effect on Clinical Parameters in Phase 2b

ADCOMS cognition scale (the key efficacy parameter)	ADAS-Cog (well-established cognition scale)	CDR-SB (cognition and function scale)



- Showed effect already at 6 months – as well as after 12 and 18 months of treatment
- Slowing of disease progression observed across sub-groups[1]
- Clinical effect increased over time

1) MCI due to AD – mild AD, ApoE4 carriers – non-carriers, with or without symptomatic treatment
2) ADCOMS – Alzheimer's Disease Composite Score
3) ADAS-Cog – Alzheimer's Disease Assessment Scale, cognitive subscale
4) CDR-SB – Clinical Dementia Rating – sum of boxes

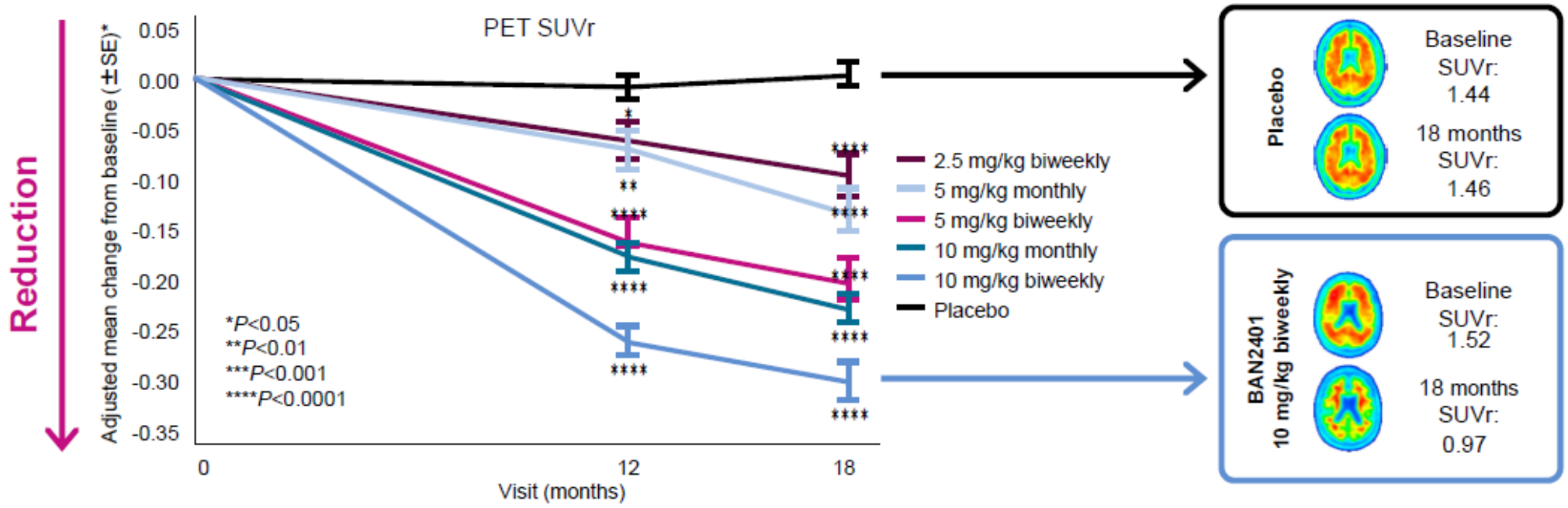
Presented at CTAD October 2018 by Eisai

BIOARCTIC

Profound clearance of brain amyloid with lecanemab in Phase 2b

Amyloid reductions measured by PET imaging assessments: PET SUVr, centiloid and visual read

PET SUVr



Level for being amyloid positive: > 1.15 (SUVr)

Amyloid reduction – PET centiloid scale

>90% reduction from base-line at highest dose
From 74.5 at base-line to 5.5 after 18 months

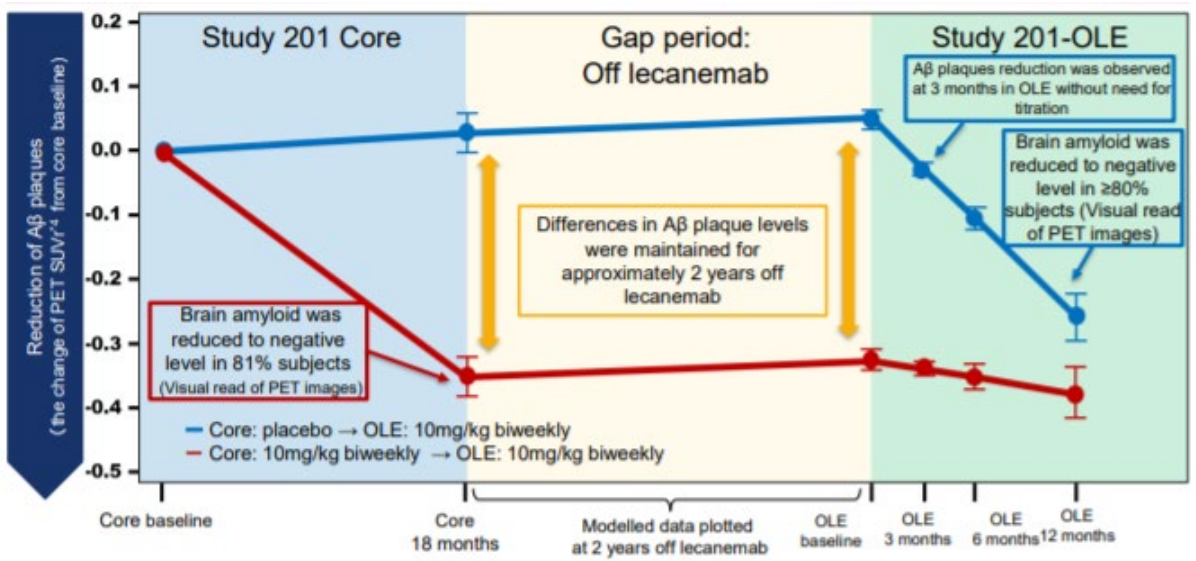
Amyloid conversion – PET SUVr/Visual read

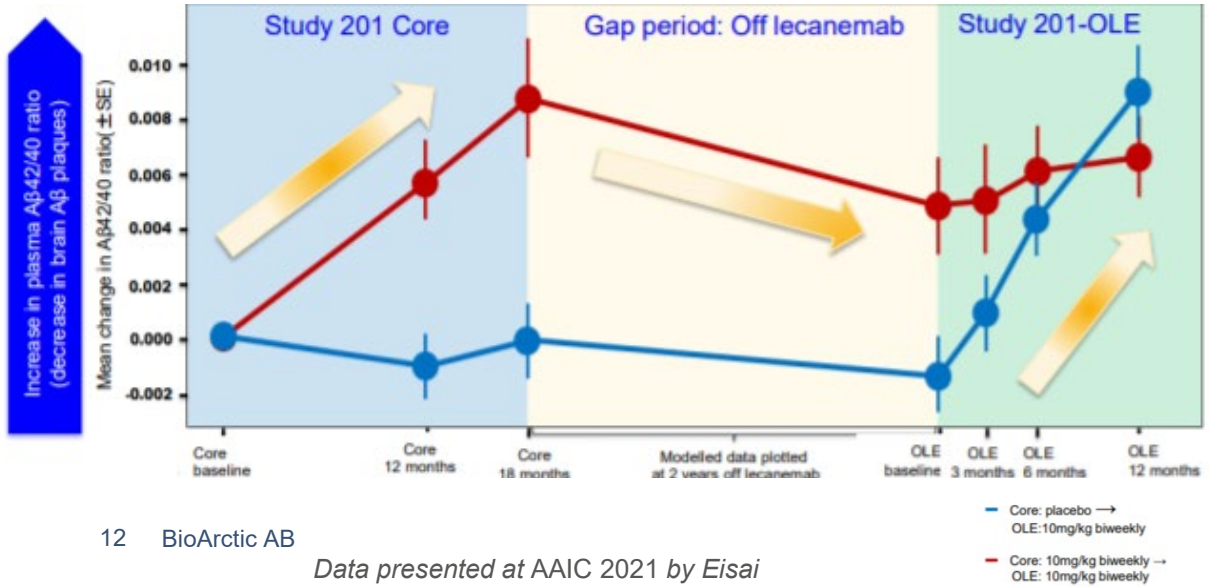
>90% of amyloid positive converted to negative at highest dose (PET SUVr)
>80% converted to negative at highest dose (PET visual read)

Data presented at AAIC 2018 and *AD/PD March 2019 by Eisai*

BIOARCTIC

Fast and profound clearance of brain amyloid with lecanemab, correlating with Ab42/4 blood biomarker and contiuned low frequency of ARIA-E in Phase 2b OLE





Amyloid PET- visual read

>80% were amyloid negative after 18 months in Ph 2b study

>80% were amyloid negative after 12 months in OLE study

Blood biomarker Ab42/40

Blood biomarker Ab42/40 correlate with Ab PET and clin effect

Could potentially be used to monitor clin effect in patients

ARIA-E

9.9% for top dose in Phase 2b study

8.9% for the same dose in OLE study for newly treated subjects

Data presented at AAIC 2021 *by Eisai*

Lecanemab – Eisai's Phase 3 study "Clarity AD" designed to confirm the positive Phase 2b results

IMPORTANT PARAMETERS

Right target

- Address the soluble protofibrils – a toxic form of amyloid

Right patient population

- Early Alzheimer's – MCI due to AD & Mild AD
- Identify right patients – biomarkers

Right dose & exposure

- Top dose in Phase 2b study demonstrated positive effects

Right measurements

- Cognition scales
- Biomarkers for disease progression and disease modification

Right safety

- Well tolerated with a benign safety profile
- Low levels of amyloid related imaging abnormalities (ARIA), reversible and mostly without symptoms

PHASE 3 STUDY DESIGN

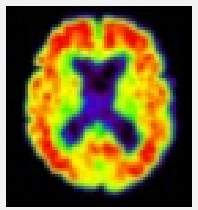
Patient inclusion

Global recruitment:
US, EU, Asia

Inclusion criteria:

- MCI due to AD or mild AD
- Positive amyloid PET/CSF

1795 Early Alzheimer patients



Treatment 18 months

Randomized, double-blind, placebo controlled, parallel-group study

- Lecanemab 10 mg/kg twice a month
- Placebo

Read-outs at 18 months

Primary analysis:
Change from baseline in CDR-SB

Key analyses:

- Change from baseline in ADCOMS, ADAS-cog
- Change from baseline in brain amyloid measured by amyloid PET
- Change from baseline in CSF biomarkers: t-tau, p-tau, neurogranin, Neurofilament light
- Safety and tolerability

Followed by an open label extension part when all patients receive lecanemab

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

BIOARCTIC

Q3 highlights

Alzheimer's disease – Lecanemab

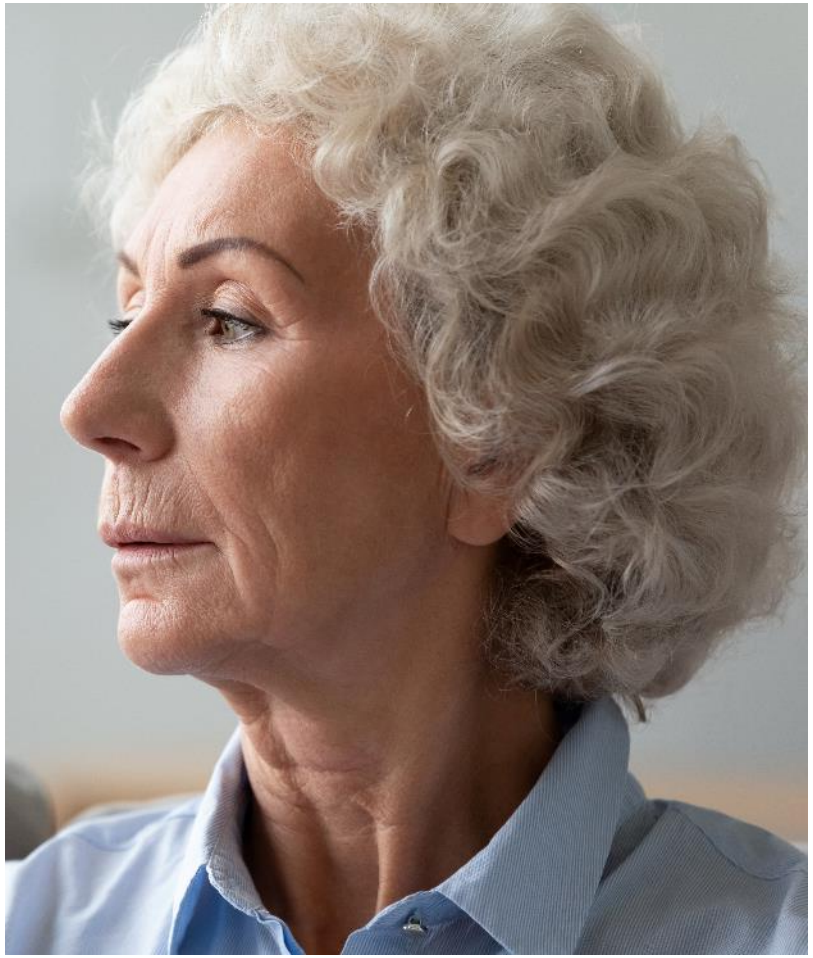
- Eisai has agreed with the FDA to submit the Biologic License Application for lecanemab as a rolling submission utilizing the accelerated approval pathway
- Data presented at AAIC congress in July from the lecanemab clinical program continue to confirm the encouraging Phase 2b results and support continued development of lecanemab

Parkinson's disease – ABBV-0805

- New 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



BIOARCTIC

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.

BIOARCTIC

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

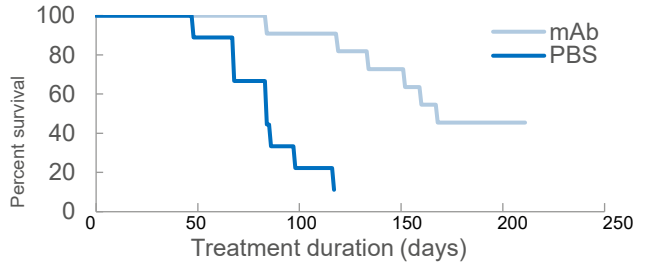
- Highly selective (>100.000) for pathological forms of misfolded alpha-synuclein (oligomers/protofibrils) vs physiological forms (monomers)

Built on genetic and pathology rationale

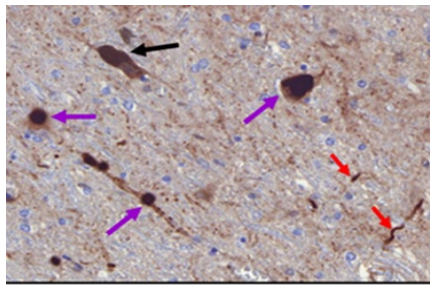
- Alpha-synuclein mutations lead to PD
- Alpha-synuclein oligomers/ protofibrils are elevated in PD

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



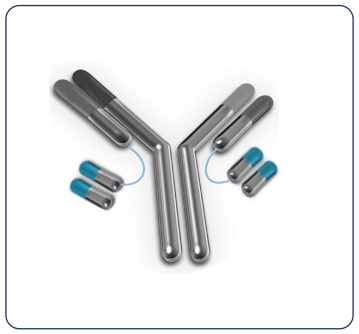
Black: neuromelanin ,Purple: Lewy bodies, Red:Lewy neurites

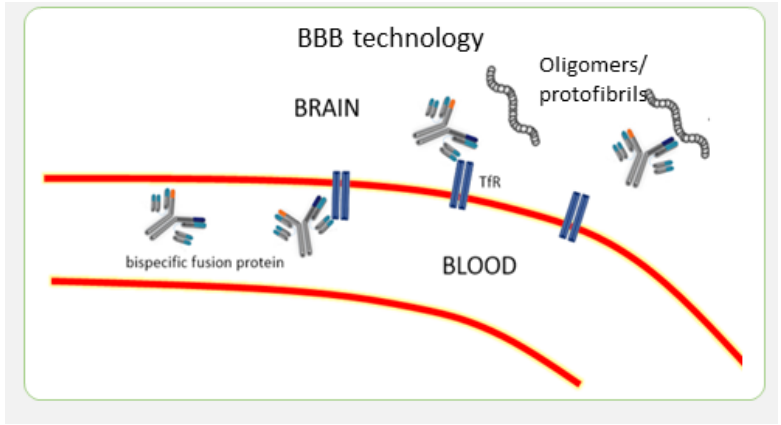
Phase 1 results presented at MDS congress in Sept 2022 support Phase 2 development with dosing once a month

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

BIOARCTIC

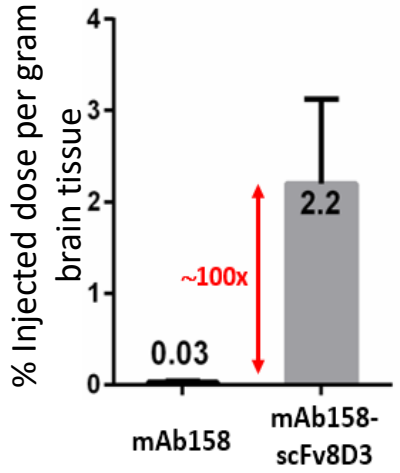
Blood-brain barrier transporter technology platform potential across multiple diseases with promising preclinical results



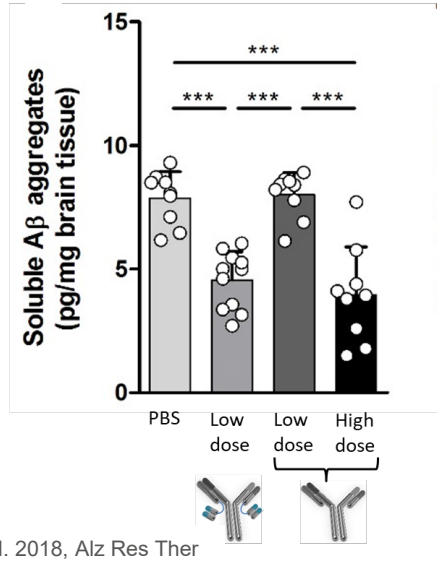


- Development of multi-specific antibodies with a transporter to facilitate passage across the blood brain barrier
- Collaboration with Uppsala University with a grant from Sweden's Innovation Agency, Vinnova
- Further investment in our Brain Transporter technology incl. recruitment of Distinguished Scientist Peo Freskgård and other senior scientists
- 2nd generation Brain Transporter platform under development

Substantially increased antibody brain uptake by BioArctic's Brain Transporter technology



Hultqvist et al 2017, Theranostics.

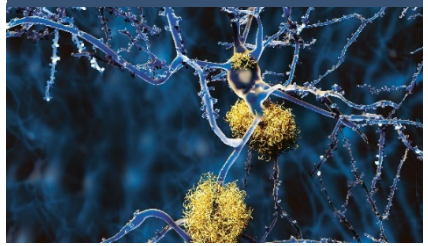


Syvänen et al. 2018, Alz Res Ther

BIOARCTIC

Early-stage portfolio continues to develop well

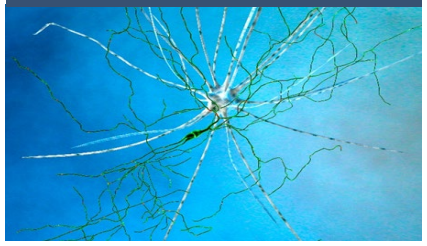
Alzheimer's disease



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

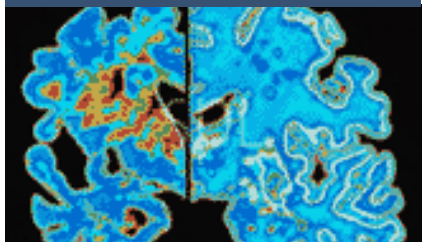
Parkinson's disease



Discovery stage projects

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

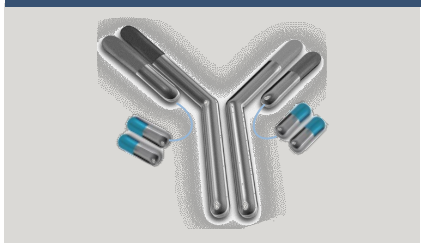
Other CNS disorders



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

BIOARCTIC

Strong IP Position in BioArctic's Business Areas

- More than 230 granted patents and 40 pending patent applications within 14 patent families
- Solid patent position for Alzheimer's Disease including BAN2401, with patent coverage until 2032, taking Patent Term Extension into account where available. Regulatory biologics data and market exclusivity 12 years in US and 10-11 years in Europe.
- Solid patent position for Parkinson's Disease including ABBV-0805, with patent coverage at least until 2036, taking Patent Term Extension into account where available. Regulatory biologics data and market exclusivity 12 years in US and 10-11 years in Europe.
- BioArctic holds a generally broad geographical patent coverage, including major markets (US, Canada, Australia, Europe, Japan and China)
- BioArctic's strategic partners also have active patent strategies with worldwide coverage

Current as per 30 September 2021

BIOARCTIC

BioArctic has a strong financial profile

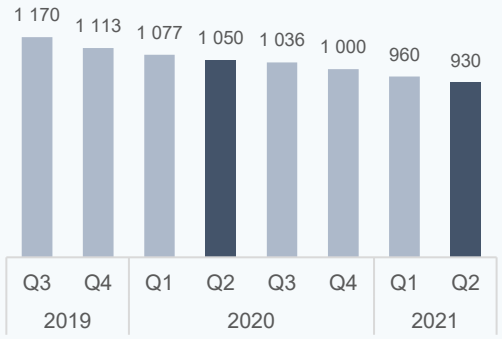
- Listed on Nasdaq Stockholm Mid Cap, market capitalization of BSEK 14.3 (~1.6 BUSD)[1]

- Close to MSEK 900 (100 MUSD) [1] in cash

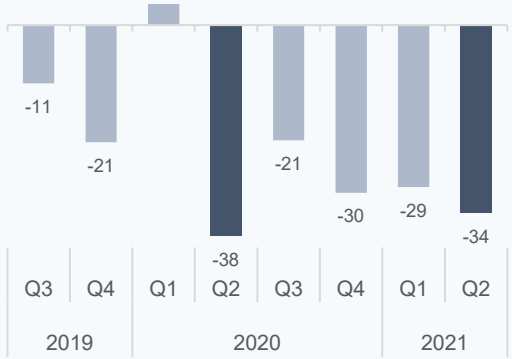
- Expected 2021 operating costs 160-190 MSEK

- Significant funding from partner research collaborations and license agreements, as well as grants
- Total potential collaboration deal value[1] of ~BSEK 8.9 (~1 BUSD)[1] of which ~BSEK 1.8 (~0.2 BUSD)[1] received
- Additional future royalty potential
- Milestone payments one-time nature explain fluctuations in financial results

Cash Balance (MSEK)



Operating Profit/Loss (MSEK)



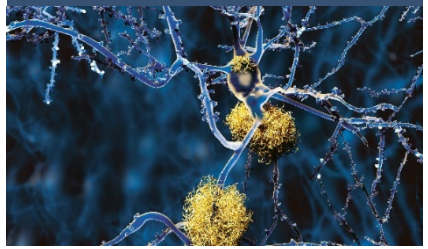
Net Revenues (MSEK)

1) As of September 30, 2021

BIOARCTIC

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

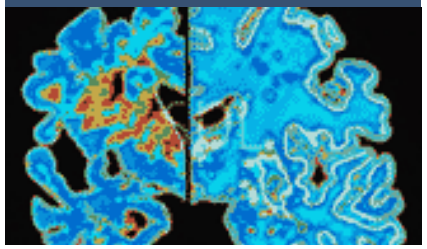
Discovery stage programs
- Advance into preclinical development

Parkinson's disease

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

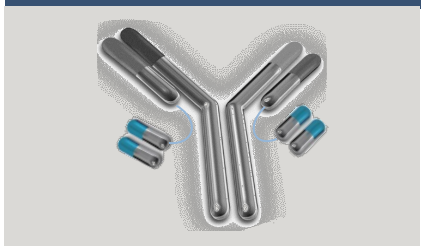
Discovery stage projects
- Development in AbbVie collaboration

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

BIOARCTIC

BioArctic: With Patients in Mind

Great science

Great projects

Great partners

Great people

BIOARCTIC