



BioArctic AB

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Biotech & Money – Investival Showcase

Nasdaq Stockholm: BIOA B

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Helping Patients with Disorders in the Central Nervous System by Developing Innovative Treatments

Alzheimer's Disease



Three key areas with high unmet medical needs – all lacking effective treatments today

Disease modifying treatment in Alzheimer's and Parkinson's Disease – areas with huge and growing markets due to aging populations

BAN2401 Phase 2b study in early AD in collaboration with Eisai – first late stage study demonstrating potential disease modifying effect on both cognition and biomarkers

Parkinson's Disease



BAN0805 for PD in collaboration with AbbVie – preparing for clinical development and IND in the U.S.

SC0806 a unique regenerative treatment for patients with Complete Spinal Cord Injuries in Phase 1/2

Complete Spinal Cord Injury



Attractive combination of fully financed partner projects and innovative pipeline with substantial market and out-licensing potential

Strong science based research and highly educated engaged teams with vast experience in drug development and great track record of high quality deliverables

Strategic Partnerships and Cutting-Edge Proprietary R&D per September 30, 2018

	PRODUCT CANDIDATE	INDICATION	PARTNER	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
NEURODEGENERATIVE DISEASES	BAN2401 anti-A β antibody	Alzheimer's disease	 ¹⁾	[Progress bar from Discovery to Phase 2]				
	BAN2401 anti-A β antibody	Down's syndrome ²⁾ Traumatic Brain Injury	—	[Progress bar from Discovery to Phase 1]				
	BAN2401 back-up anti-A β antibody	Alzheimer's disease		[Progress bar from Discovery to Phase 1]				
	AD1801 undisclosed information	Alzheimer's disease	—	[Progress bar from Discovery to Phase 1]				
	AD1502 undisclosed information	Alzheimer's disease	—	[Progress bar from Discovery to Phase 1]				
	AD1503 undisclosed information	Alzheimer's disease	—	[Progress bar from Discovery to Phase 1]				
	BAN0805 anti- α -synuclein antibody	Parkinson's disease	abbvie	[Progress bar from Discovery to Phase 1]				
	PD1601 anti- α -synuclein antibody	Parkinson's disease	abbvie	[Progress bar from Discovery to Phase 1]				
	PD1602 anti- α -synuclein antibody	Parkinson's disease	abbvie	[Progress bar from Discovery to Phase 1]				
DIAGNOSTICS & TECHNOLOGY	Imaging and biochemical biomarkers A β	Alzheimer's disease	—	[Progress bar from Discovery to Phase 1]				
	Imaging and biochemical biomarkers α -synuclein	Parkinson's disease	abbvie	[Progress bar from Discovery to Phase 1]				
	BBB-technology blood-brain barrier	Multiple application areas	—	[Progress bar from Discovery to Phase 1]				
SPINE	SC0806 FGF1/medical device	Complete Spinal Cord Injury	—	[Progress bar from Discovery to Phase 2]				

¹⁾ Partner with Eisai on BAN2401 for treatment of AD. Since 2014, Eisai partnered with Biogen in AD

²⁾ Dementia and cognitive impairment associated with Down's syndrome and Traumatic Brain Injury

Source: company data

Long-standing and Extensive Partnerships

Eisai collaboration and license agreements Alzheimer's Disease



Description of agreements

- Two research collaborations – disease modifying therapies for AD – resulted in two licenses for A β oligomer/protofibril antibodies: BAN2401 and BAN2401 Back-up
- Third research collaboration – new target as a disease modifying therapy for AD

Milestone / royalty potential

- Total aggregated value of the research collaborations and license agreements is approx. EUR 218m in signing fee and milestones, plus high single digit royalties
- BioArctic has received approx. EUR 47m for the research collaborations, signing fees and milestones

AbbVie collaboration agreement Parkinson's Disease



Description of agreements

- Research collaboration – alpha-synuclein antibodies as disease modifying therapies for PD incl. BAN0805 to IND, follow-up compounds and diagnostic
- Option for AbbVie for a license to develop and commercialize the antibodies

Milestone / royalty potential

- Total potential value of the agreement is up to USD 755m incl. an up-front fee, option exercise fee, and success-based milestones plus tiered royalties
- BioArctic has received an USD 80m up-front payment for the research collaboration
- Payment of USD 50m to be received when exercising option to license, pending US antitrust legislation clearance

Strategic collaborations with pharmaceutical industry validating potential value and commercialization potential for BioArctic with proven track record of delivering on research collaborations

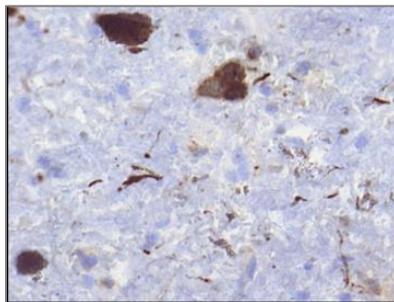
BAN0805 – Groundbreaking Disease Modifying Drug in PD with Rationale for Selective Targeting of Alpha-synuclein Oligomers/Protofibrils

Rationale for targeting alpha-synuclein

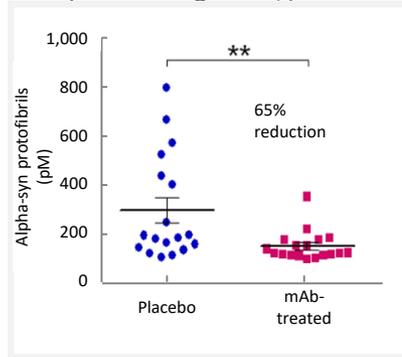
Human genetics

Pathology

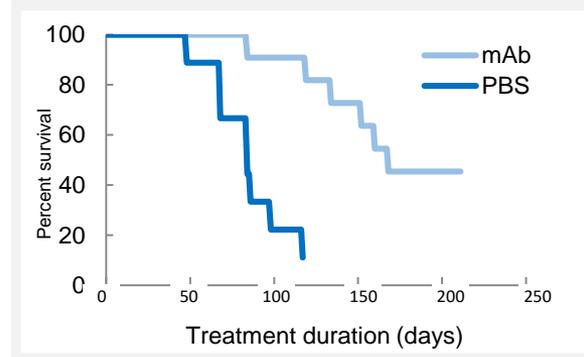
Pre-clinical proof of concept



Reduction of neurotoxic alpha-synuclein oligomers/protofibrils



Increases lifespan



Alpha-synuclein mutations lead to PD or Dementia with Lewy Bodies and are associated with increased oligomer/protofibril formation

Alpha-synuclein deposition is a hallmark of PD pathophysiology and alpha-synuclein oligomers/protofibrils are elevated in PD

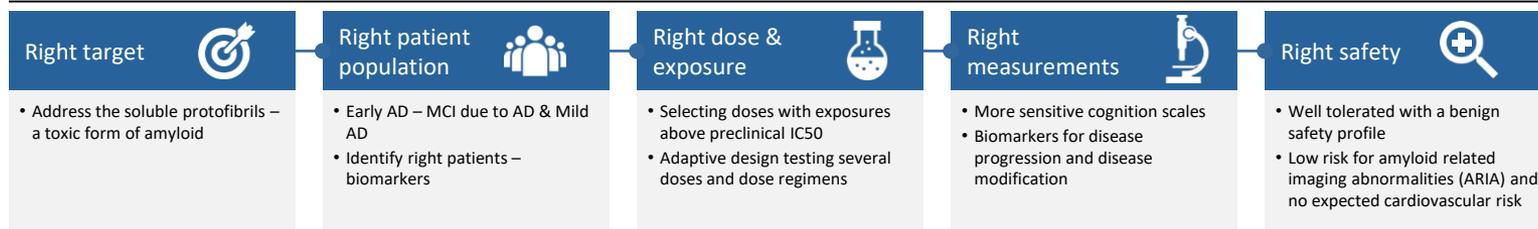
Oligomer/protofibril selective antibody reduces neurotoxic alpha-synuclein oligomer/protofibril levels, delays disease progression and increases life-span in a PD mice model

BAN0805 in preparation for IND to start clinical trials in the US 2019

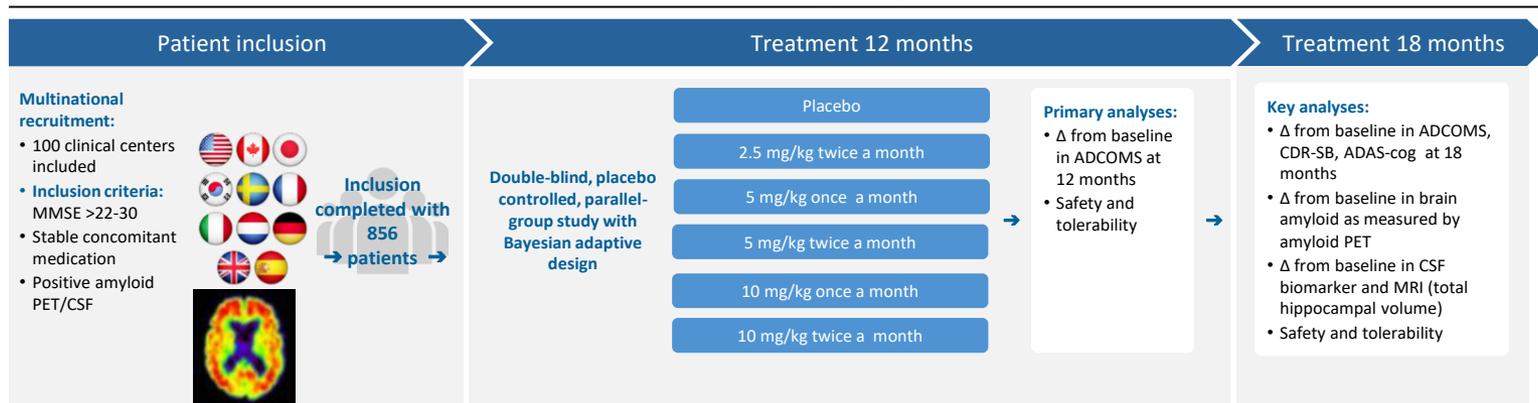
BAN2401 – Innovative Phase 2b Study Design

Positive 18 Month Results Reported

Important parameters



Phase 2b study design



BAN2401 18 months treatment demonstrated an effect on both cognition and biomarkers with a good tolerability profile

Completion of study after 18 months treatment and 3 months follow-up - Q4 2018

Source: Company information

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

Positive Phase 2b Study Results Support BAN2401 as a Potential Treatment for a Broad Population of Early Alzheimer Patients

BAN2401 Treatment Effect in Early AD

Clinical Outcome Measures

- Slowing of disease progression observed across clinical outcome measures at the highest dose, including 30 % on ADCOMS
- Slowing of disease progression observed across sub-groups

Brain Amyloid PET

- Pronounced dose-dependent amyloid clearance across the dose range
- 81% of subjects converted to amyloid negative state
- Consistent and pronounced amyloid clearance across all sub-groups

CSF Biomarkers

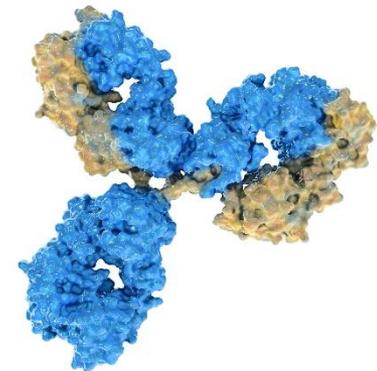
- Elevated Abeta demonstrates target engagement
- Impact on AD pathophysiology with benefits on neuro-degeneration markers: t-tau, p-tau, neurogranin and NfL

BAN2401 was well tolerated with < 10% ARIA-E at any dose

Selectively targeting Abeta protofibrils with low affinity to monomers confer an advantageous benefit risk profile

BAN2401 – Next Steps

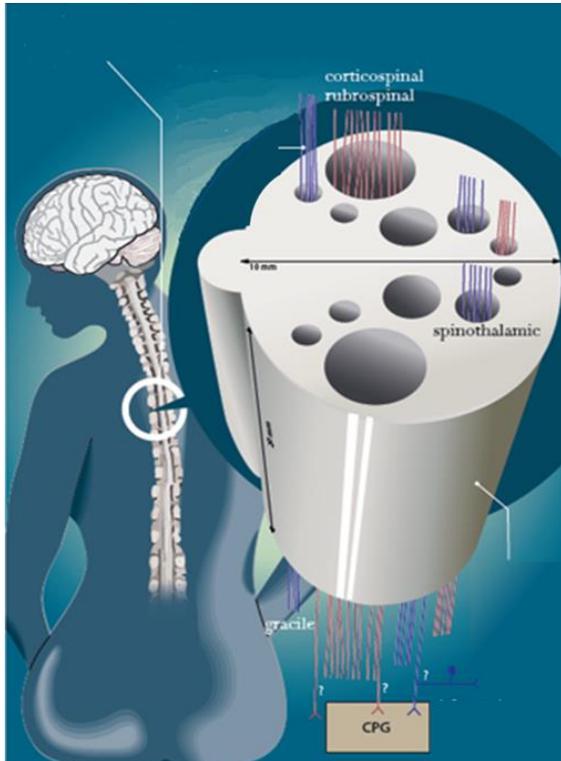
- Eisai is currently conducting interactions with regulatory agencies regarding the future BAN2401 program
- The study will be completed in Q4 2018 and includes a further 3 months follow-up after completion of 18 months of treatment (at 21 months)
- Open-label extension study with BAN2401, without placebo, for patients from the Phase 2b study will be initiated Q4 2018



SC0806 – Unique Regenerative Treatment of Complete SCI

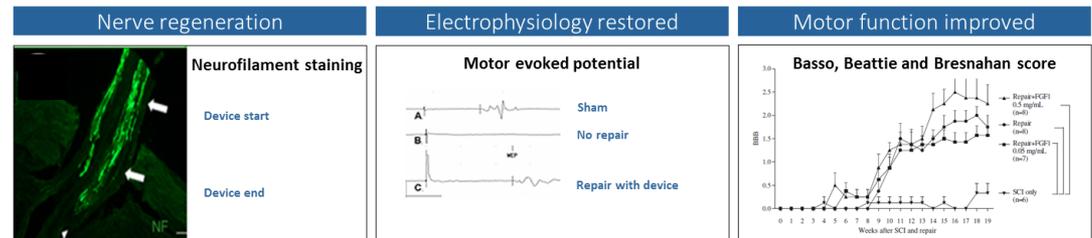
SC0806 – Regenerative Treatment of Complete SCI

Treatment Rationale



SC0806 makes nerve regeneration possible

FGF1 activated by heparin	<ul style="list-style-type: none"> Stimulation of central axon outgrowth Decreases gliosis
Peripheral nerve autografts	<ul style="list-style-type: none"> Optimal regeneration environment
Biodegradable device	<ul style="list-style-type: none"> Provides sustained release of FGF1 Positioning of nerve grafts from white to gray matter



Preclinical Proof of Concept shown in rats

- Rat experiments demonstrate nerve regeneration, restored electrophysiology and motor function
- The motor evoked potential (MEP) has been restored in rats with resected spinal cords

Source: Nordblom et al. Restorative Neurology and Neuroscience 30 (2012) 91–102

SC0806 – Unique Regenerative Treatment of Complete SCI

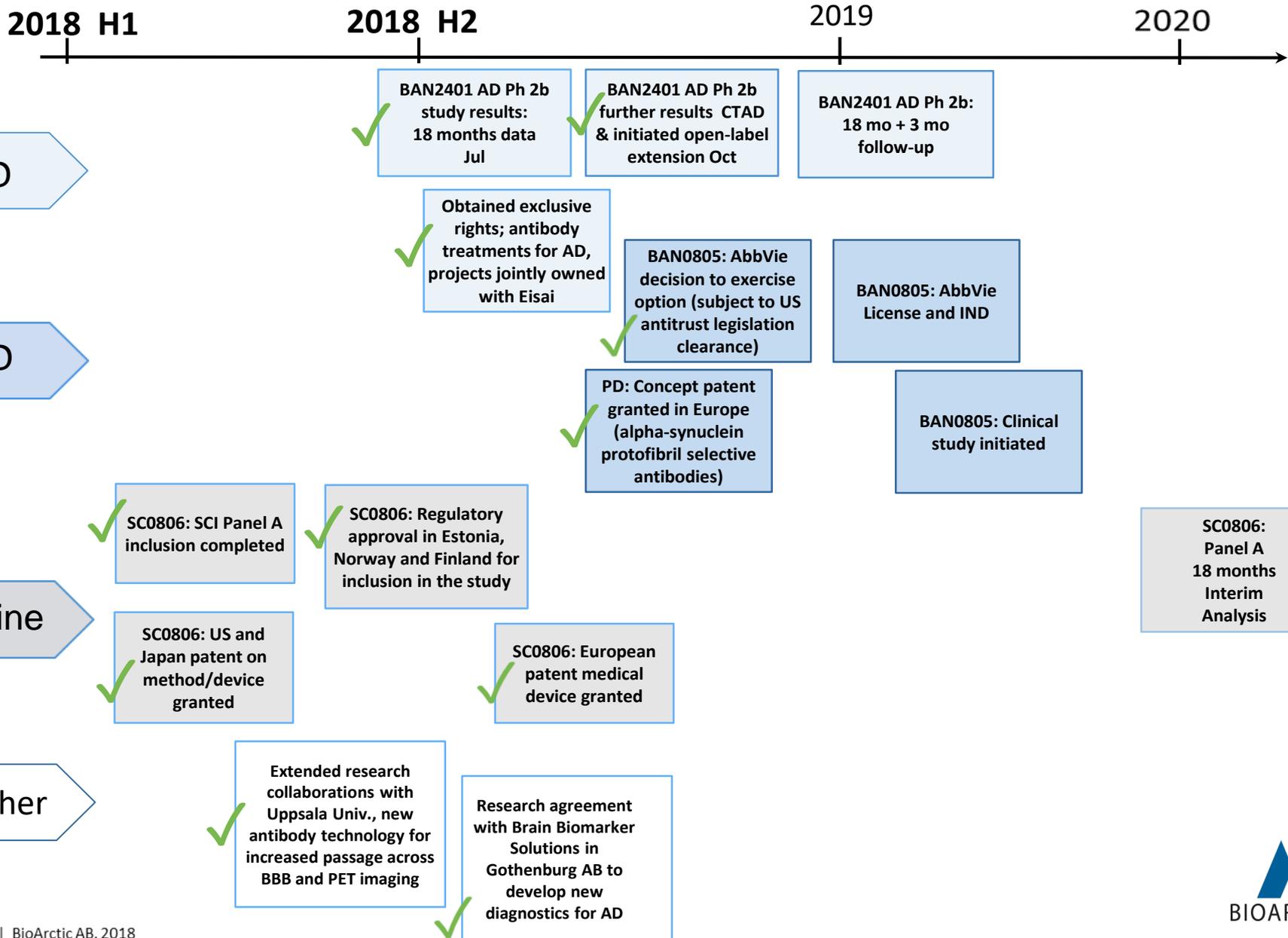
The Lokomat™ used in the Rehabilitation



Project Status

- Clinical Phase 1/2 trial ongoing with SC0806 in patients with Complete Spinal Cord Injury
 - Surgery in Sweden
 - Rehabilitation 18 months with Lokomat™ in Sweden, Estonia, Finland and Norway
 - Patients receiving SC0806 treatment are given the option of 12 months additional participation in an extension study
 - 9 patients included in Panel A (6 treated with SC0806 and 3 control patients)
 - Screening of patients for Panel B on-going
 - Interim analysis planned Q4 2019/Q1 2020
- Orphan Drug designation in US and EU – granting 7 and 10 years exclusivity, respectively
- EU Horizon 2020 research and innovative program Grant Agreement No. 643853 of MEUR 6.4

Recent & Anticipated News Flow



Thank you for your attention

Q&A

Gunilla Osswald, CEO, PhD



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Full Year Report 2018
Feb 14, 2019
- ▶ **IR contact:**
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