BioArctic AB

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Full Year Report Jan – Dec 2018

Nasdaq Stockholm: BIOA B

February 14, 2019

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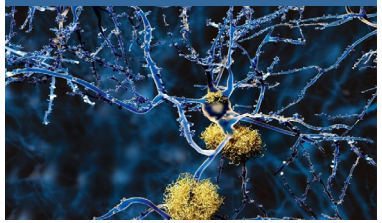
Helping Patients with Disorders in the Central Nervous System by Developing Innovative Treatments

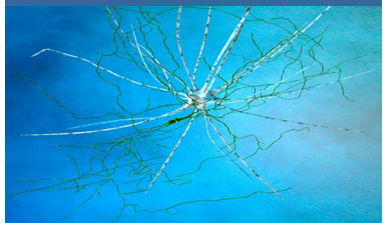
Three key areas with high unmet medical needs – all lacking effective treatments today
Disease modifying treatment in AD and PD – huge and growing markets due to aging populations

Alzheimer's Disease



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 with a good tolerability profile
Preparing for Phase 3 confirmatory study

Parkinson's Disease



BAN0805/ABBV-0805 for PD in collaboration with AbbVie
Preparing for Phase 1

Complete Spinal Cord Injury

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

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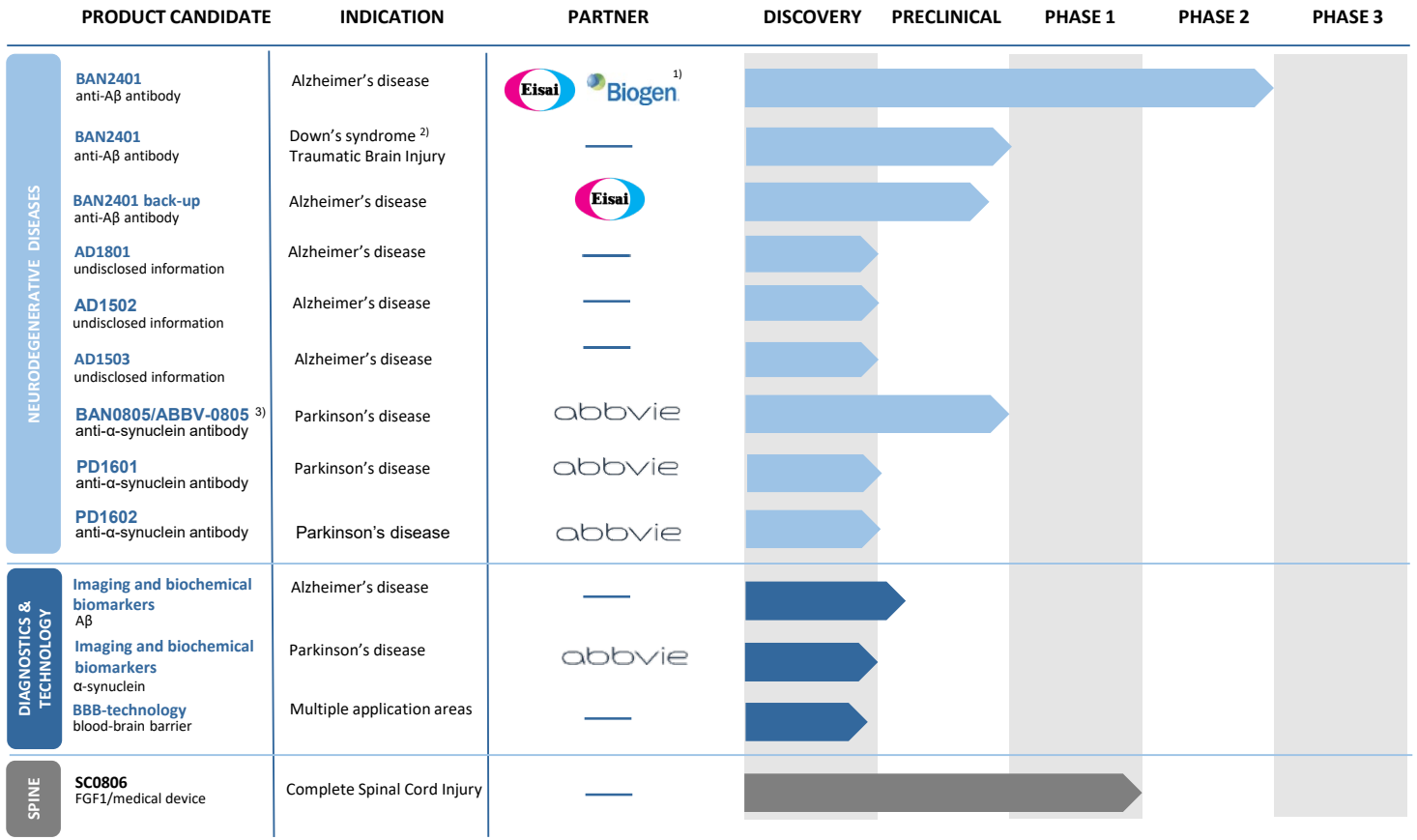
Strategic Partnerships and Cutting-Edge Proprietary R&D

per December 31, 2018



[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

- **Attractive combination** of fully financed partner projects and cutting-edge, proprietary R&D pipeline with substantial market and out-licensing potential

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Long-standing and Extensive Partnerships

Eisai collaboration and license agreements Alzheimer's Disease

Description of agreements	Milestone/royalty potential
• Three research collaborations and two licenses for Abeta oligomer/protofibril antibodies BAN2401 and BAN2401 back-up as disease modifying treatments for Alzheimer's disease	• Total aggregated value of the research collaborations and license agreements is approx. EUR 218m in signing fee and milestones, plus high single digit royalties • Received approx. EUR 47m for the research collaborations, signing fees and milestones

AbbVie collaboration and license agreement Parkinson's Disease

Description of agreements	Milestone/royalty potential
• Research collaboration alpha-synuclein anti-bodies as disease modifying therapies for PD incl. BAN0805 to IND, follow-up compounds and diagnostic • AbbVie licensed project portfolio for development and commercialization	• Total pot. value of the agreement up to USD 755m incl. an up-front fee, option exercise fee, and success-based milestones plus tiered royalties • Received USD 80m up-front payment for the research collaboration • Received USD 50m for the license

BAN2401 – Innovative Phase 2b Study Design
Positive 18 Month Results Reported by Eisai

Important parameters

Right target
- Address the soluble protofibrils – a toxic form of amyloid

Right patient population
- Early AD – MCI due to AD & Mild AD
- Identify right patients – biomarkers

Right dose & exposure
- Selecting doses with exposures above preclinical IC50
- Adaptive design testing several doses and dose regimens

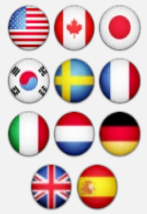
Right measurements
- More sensitive cognition scales
- Biomarkers for disease progression and disease modification

Right safety
- Well tolerated with a benign safety profile
- Low risk for amyloid related imaging abnormalities (ARIA) and no expected cardiovascular risk

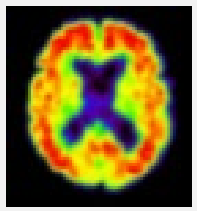
Phase 2b study design

Patient inclusion

Multinational recruitment:
- 100 clinical centers included
- **Inclusion criteria:** MMSE >22-30
- Stable concomitant medication
- Positive amyloid PET/CSF



Inclusion completed with 856 ➔ patients



Treatment 12 months

Double-blind, placebo controlled, parallel-group study with Bayesian adaptive design

- Placebo
- 2.5 mg/kg twice a month
- 5 mg/kg once a month
- 5 mg/kg twice a month
- 10 mg/kg once a month
- 10 mg/kg twice a month

Primary analyses:
- Δ from baseline in ADCOMS at 12 months
- Safety and tolerability

Treatment 18 months

Key analyses:
- Δ from baseline in ADCOMS, CDR-SB, ADAS-cog at 18 months
- Δ from baseline in brain amyloid as measured by amyloid PET
- Δ from baseline in CSF biomarker and MRI (total hippocampal volume)
- Safety and tolerability

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

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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

CFS 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

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BAN2401 – Next Steps – Eisai Reported that a Single Phase 3 Confirmatory Study Planned to Start Q1 2019

- Eisai has interactions with regulatory authorities regarding the future BAN2401 program
  - Eisai reported that authorities have acknowledged that the BAN2401 Phase 2b study showed robust data demonstrating dose dependent reduction of amyloid plaque in the brain and slowing of clinical decline
  - Eisai reported that they have confirmed with health authorities that a single Phase 3 study would meet the requirements for the approval as a confirmatory study
  - A global confirmatory study with BAN2401 will be initiated in patients with early Alzheimer´s disease in Eisai's FY 2018, that is first quarter 2019
  - Eisai reported that they continue to seek opportunities for potential earlier approval for BAN2401
- Open-label extension study with BAN2401, without placebo, for patients from the Phase 2b study has been initiated Q4 2018

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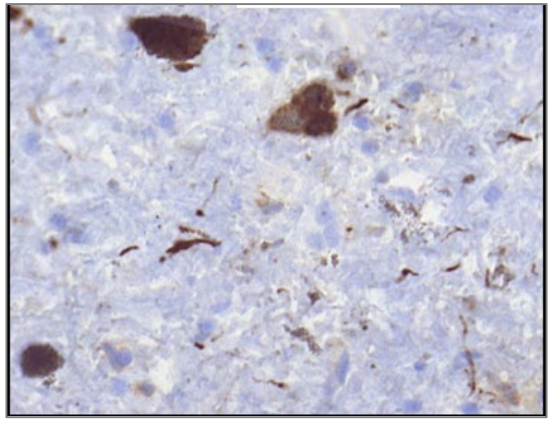
BAN0805 – Groundbreaking Disease Modifying Drug in PD with Rationale for Selective Targeting of Alpha-synuclein Oligomers/Protofibrils

Rationale for targeting alpha-synuclein

Human genetics → **Pathology** → **Pre-clinical proof of concept**

Alpha-synuclein mutations

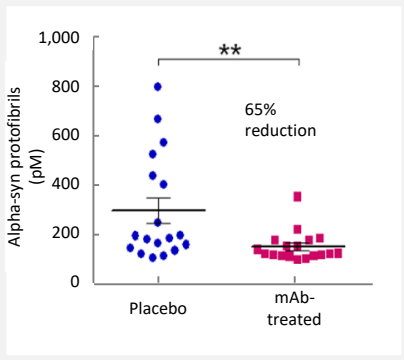
lead to PD or Dementia with Lewy Bodies and are associated with increased oligomer/ protofibril formation



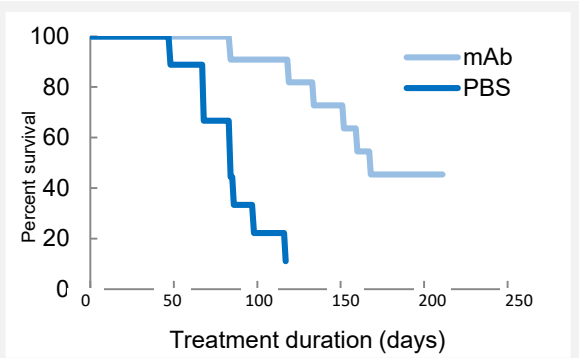
Alpha-synuclein deposition

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

Reduction of neurotoxic alpha-synuclein



Increases lifespan



Oligomer/protofibril selective antibody

reduces neurotoxic alpha-synuclein oligomer/protofibril levels, delays disease progression and increases lifespan in a PD mice model

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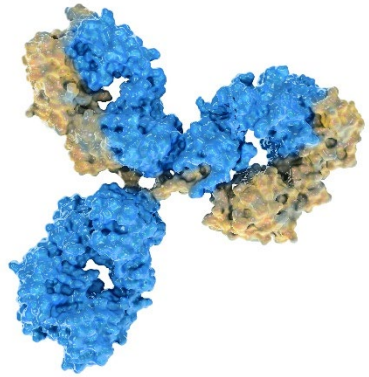
BAN0805/ABBV-0805

- Alpha-synuclein antibody portfolio licensed by AbbVie December 14, 2018
- Received a milestone payment of USD 50m for the license
- BAN0805/ABBV-0805 IND-application has been approved by FDA
- AbbVie is responsible for the clinical development and plans to start clinical trials 2019
- BioArctic will deliver follow-up compounds in the continued collaboration with AbbVie



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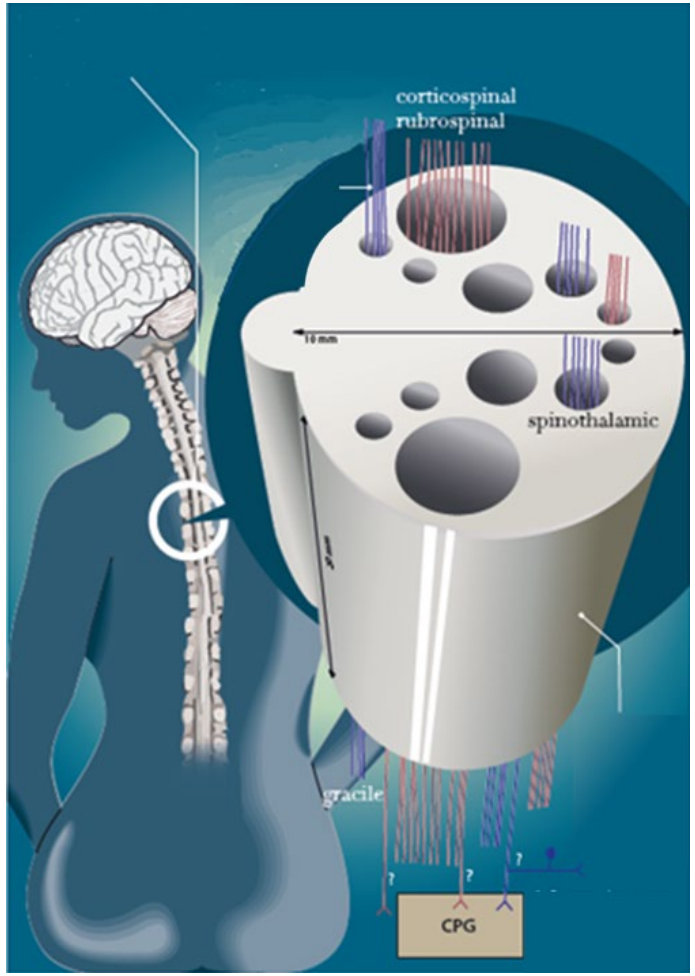
SC0806 – Unique Regenerative Treatment of Complete Spinal Cord Injury

SC0806 – Regenerative Treatment of CSCI

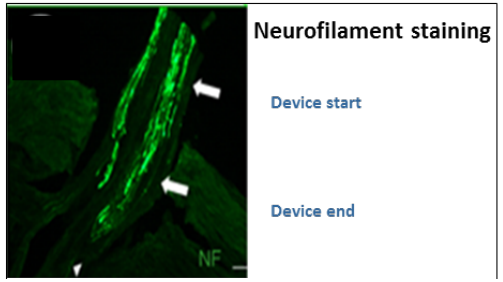


Treatment Rationale

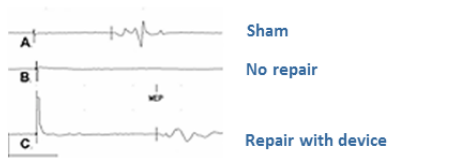
SC0806 makes nerve regeneration possible

FGF1 activated by heparin	•Stimulation of central axon outgrowth •Decreases gliosis
Peripheral nerve autografts	•Optimal regeneration environment
Biodegradable device	•Provides sustained release of FGF1 •Positioning of nerve grafts from white to gray matter

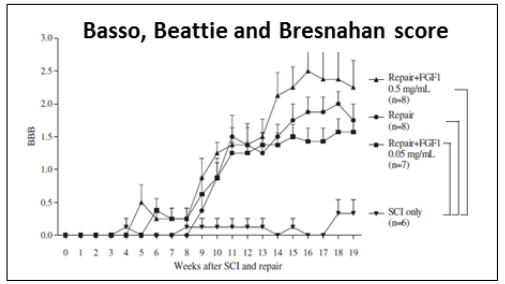
Nerve regeneration



Electrophysiology restored



Motor function improved



Preclinical Proof of Concept shown in rats with resected spinal cords

- Rat experiments demonstrate nerve regeneration, restored electrophysiology and motor function after SC0806 treatment

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

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SC0806 – Unique Regenerative Treatment of Complete SCI

The Lokomat™ used in the Rehabilitation

Project Status

- Clinical Phase 1/2 trial ongoing in patients with Complete Spinal Cord Injury
  - Surgery in Sweden
  - Rehabilitation 18 months with Lokomat™ in Sweden, Estonia, Finland and Norway
  - Patients receiving SC0806 has an option of 12 months additional participation in an extension study
  - 9 patients included in Panel A (6 treated with SC0806 and 3 control patients)
  - Safety evaluation of patients in Panel A performed and support progression into Panel B i.e. Phase 2
  - First patient included in Phase 2
  - Interim analysis planned no later than first half 2020
- Orphan Drug designation in US and EU – may grant 7 and 10 years exclusivity, respectively
- EU Horizon 2020 research and innovative program Grant Agreement No. 643853 of MEUR 6.4

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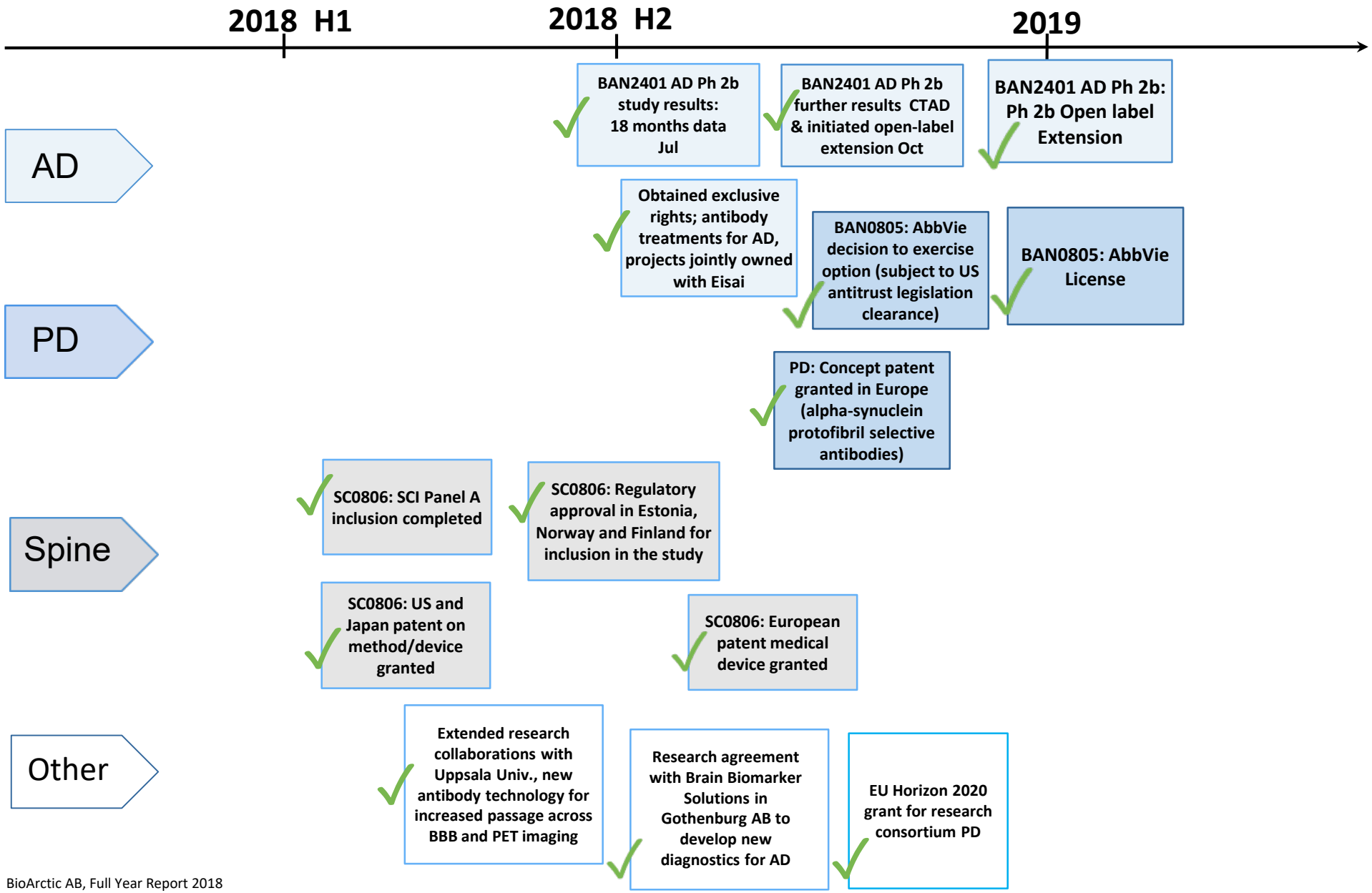
News Flow 2018



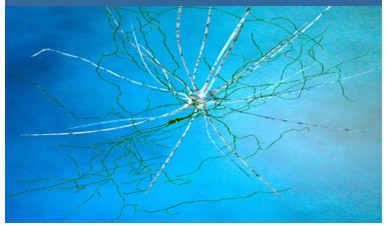
Planned Key Events Next 18 Months

Alzheimer's Disease

BAN2401

Phase 3 confirmatory study started in early AD initiated by Eisai

Parkinson's Disease



BAN0805/ABBV-0805

Phase 1 study initiated by AbbVie

Preparing for further clinical development in PD

Complete Spinal Cord Injury

SC0806

Phase 2 started in patients with Complete Spinal Cord

Interim analysis first half 2020 at the latest

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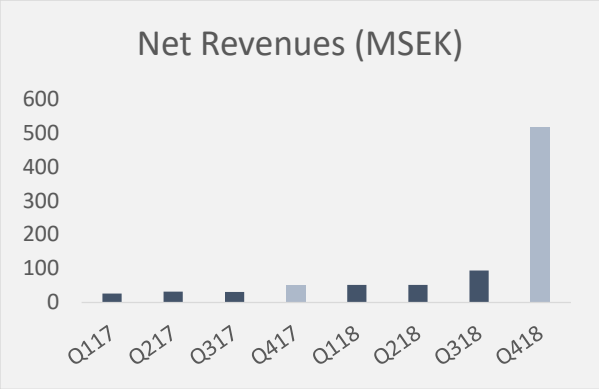
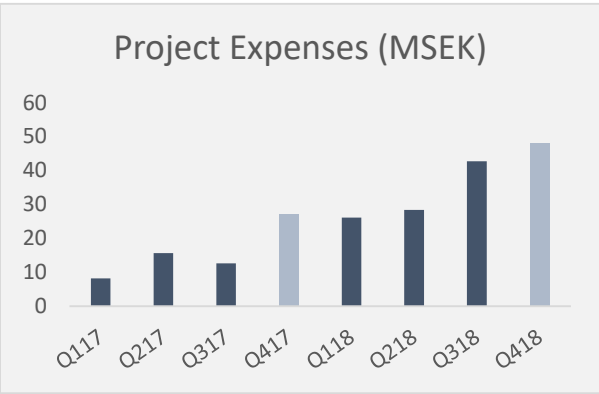
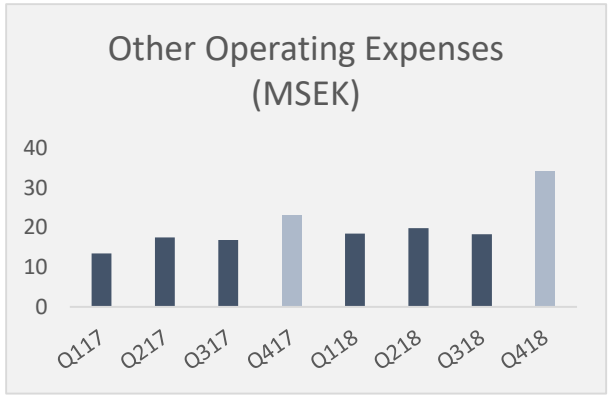
Financial Overview Q4 2018

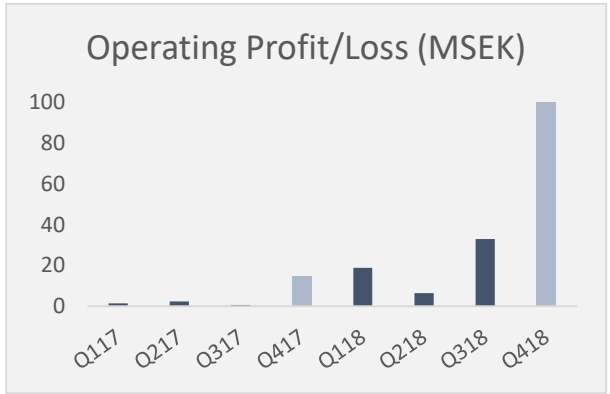
By Quarters





By Quarters





Q4 2018 – Comments

- **Net revenues** increased to SEK 515.3m (51.0) mainly due to the USD 50m milestone payment from AbbVie attributable to AbbVie's in-licensing of the Parkinson portfolio. The milestone payment was fully recognized as revenue in 2018.
- **Project expenses** increased to SEK 48.0m (27.1) mainly due to activities related to the Parkinson program.
- **Other operating expenses** was SEK 34.3m (23.2). The increase is mainly related to costs for expanded activities in the research organization and to expenses related to the AbbVie milestone payment.
- **Operating profit** increased as a consequence of the milestone payment to SEK 430.3m (14.7)

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Financial Analysis Q4 2018

Q4 2018 Comments

Cash balance and Cash flow

- Cash balance amounted to SEK 917.3m (1,110.4) at the end of the quarter. The AbbVie USD 50m milestone payment was received February 2019
- Operating cash flow depends on the development activities in the projects and amounted to SEK -89.3m (-45.7) during Q4
- The Board of Directors proposes a dividend of SEK 1.50 per share, a total of SEK 132m, for the fiscal year 2018. The board has concluded that the company's financial resources are sufficient to finance its projects and programs as planned without additional share issue

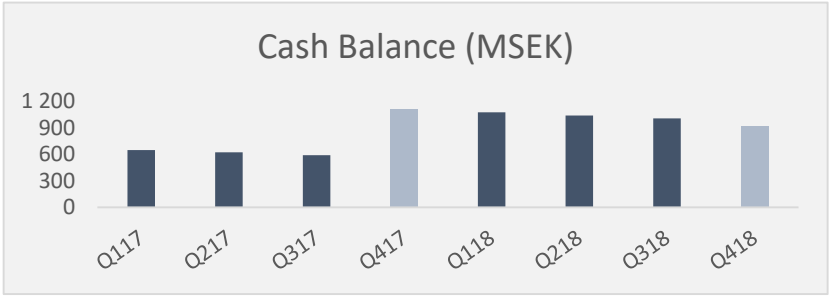
Expenses

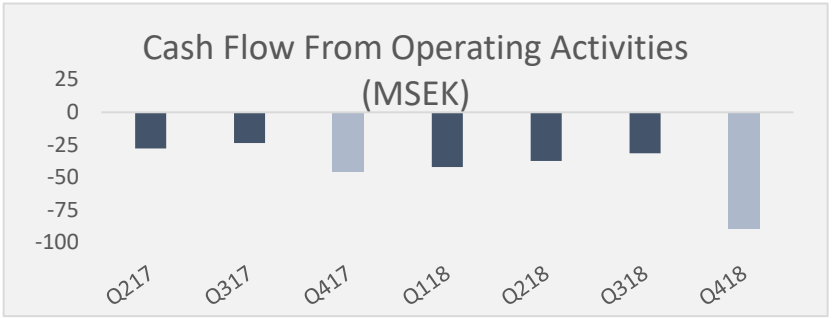
- About 80% of the costs are related to R&D

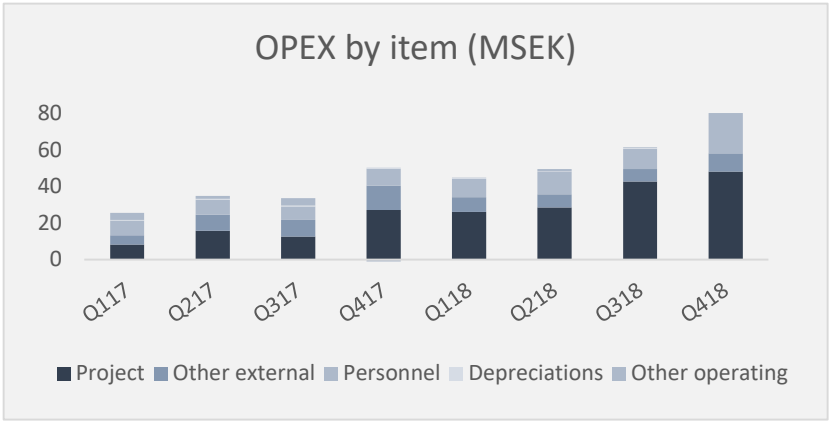
Positive results

- All in all, BioArctic's net result amounted to SEK 335.2m (11.8)

Q4 2018 – Items of Importance







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Q&A

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Jan Mattsson, CFO

Next Report & IR Contact

- **Next report:**
  Interim Report Jan-Mar
  May 9, 2019
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