BioArctic AB

Interim Report January - June 2018

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August 23, 2018

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Snapshot of BioArctic

Company overview

- **Research oriented biopharma company** focusing on development of drugs in areas with a large unmet medical need, such as Alzheimer's and Parkinson's Disease, and Complete Spinal Cord Injury
- **Founded in 2003** by Prof. Lars Lannfelt and Dr. Pär Gellerfors
- **Flexible organization** with approx. 30 FTEs complemented with consultants and close collaborations with external partners
- **Headquartered** in Stockholm, Sweden
- **Listed on Nasdaq Stockholm Mid Cap** since October 2017

Investment highlights

- **Highly educated organization** with proven track record of bringing drugs from idea to market
- **Innovative portfolio** of differentiated first-generation disease modifying agents in Alzheimer's and Parkinson's Disease, diagnostics and pioneering Complete Spinal Cord Injury treatment
- **Strategic collaborations** with Eisai and AbbVie validating highly innovative research organization and unique product candidates
- **Attractive combination** of fully financed partner projects and cutting-edge, well funded, 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

Description of agreements

- Two previous research collaborations regarding disease modifying therapies for Alzheimer's Disease that resulted in two licenses of the Aβ oligomer/protofibril antibodies BAN2401 and BAN2401 Back-up
- Third research collaboration ongoing regarding a new target as a disease modifying therapy for Alzheimer's Disease

Milestone / royalty potential

- The 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

Description of agreements

- Research collaboration (entered Sep 2016) regarding alpha-synuclein antibodies as disease modifying therapies for Parkinson's Disease incl. BAN0805 to IND, follow-up compounds and diagnostic
- BioArctic primarily responsible for performing all preclinical activities
- 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

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

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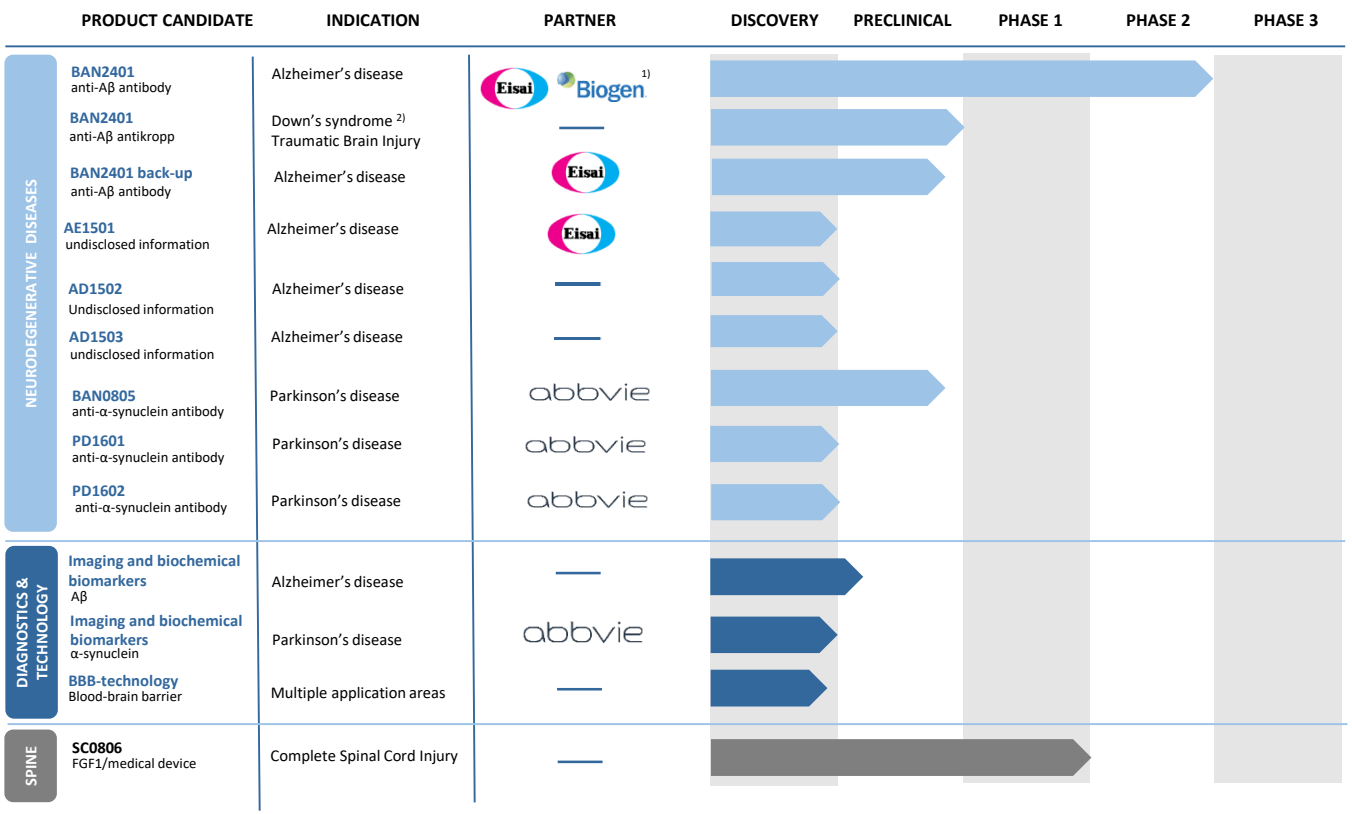
Strategic Partnerships and Cutting-Edge Proprietary R&D

per June 30, 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

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BAN2401 – Learnings from Previous Clinical Trials in AD Incorporated in Phase 2b Study Design
Final 18 Month Results in July 2018

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

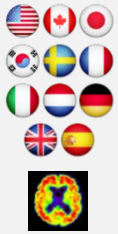
Right measurements
- More sensitive cognition scales
- Biomarkers for disease progression and disease modification

Right safety
- Well tolerated with a benign safety profile
- Low cardiovascular risks and amyloid related imaging abnormalities (ARIA) etc.

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 bi-weekly
- 5 mg/kg bi-weekly
- 10 mg/kg bi-weekly
- 5 mg/kg once every four weeks
- 10 mg/kg once every four weeks

→

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

Detailed results after 18 months treatment incl. biomarker and cognition – July 2018
A positive scenario includes an effect on both cognition and a biomarker
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

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BAN2401 Phase 2b Study Demonstrated Positive Results at 18 Months in Early Alzheimer's Disease

- BAN2401 Phase 2b study is the first late stage study demonstrating potential disease-modifying effects on both cognition and biomarkers

- In the final 18-month analyses of BAN2401 Phase 2b clinical study with 856 early Alzheimer patients BAN2401 demonstrated dose-dependent, clinically meaningful and statistically significant slowing in clinical decline and reduction of amyloid beta accumulated in the brain with a good tolerability profile

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BAN2401 Showed Effect on Clinical Parameters and Biomarkers with Good Tolerability in Early AD Patients - I

Clinical effect:
- ADCOMS
- ADAS-Cog
- CDR-SB

- **ADCOMS,** cognition scale (the key efficacy parameter) showed statistically significant slower decline of 30% (p=0.034) with 10 mg/kg twice a month (highest dose) at 18 months
- ADCOMS showed effect already at 6 months – as well as after 12 and 18 months treatment – with the highest dose
- **ADAS-Cog** (well-known cognition scale) showed statistically significant slower decline of 47% (p=0.017) with 10 mg/kg twice a month at
- 18 months
- **CDR-SB** (cognition and function scale) showed slower decline of 26% (p>0.05) with 10 mg/kg twice a month at 18 months

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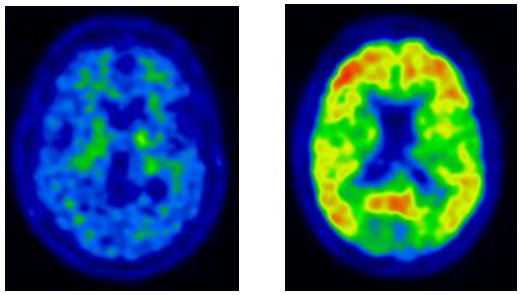
BAN2401 Showed Effect on Clinical Parameters and Biomarkers with Good Tolerability in Early AD Patients - II

Biomarkers:
- Amyloid PET
- CSF Abeta, t-tau

- **Amyloid PET:** BAN2401 reduced brain amyloid-beta dose-dependent and statistically significant, amyloid decreased ~70 units (from 74.5 at baseline to 5.5 at 18 months for the top dose) with Centiloid scale ($p<0.0001$)
- Amyloid PET visual read showed dose-dependent and statistically significant improvements and 81% of the patients in the BAN2401 top dose converted from amyloid positive to amyloid negative
- **CSF:** Abeta increased dose-dependent and statistically significant and t-tau decreased for the two top doses
- Biomarkers support a disease modifying effect of BAN2401



Brain images provided by PET-Centre, Uppsala University Hospital, Sweden, showing a normal brain (left) and an Alzheimer brain (right).
The images are illustrative examples of PET scans and are not images from the BAN2401 Phase 2b study.

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BAN2401 Showed Effect on Clinical Parameters and Biomarkers with Good Tolerability in Early AD Patients - III

Safety & tolerability

- BAN2401 was **well-tolerated** with infusion reactions and ARIA as the most common side effects (mostly mild to moderate)
- ARIA-E incidence:
  - <10% at any dose
  - <15% in APOE4 carriers at the highest dose
  - ~ 90% of ARIA-E cases were asymptomatic

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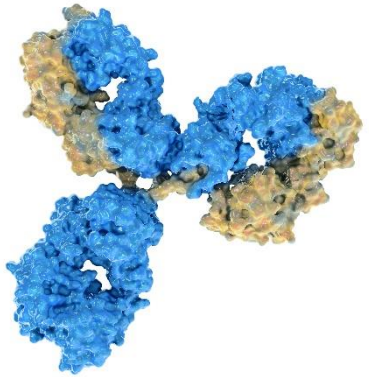
BAN2401 – Next Steps

- Eisai is currently preparing for interactions with regulatory agencies regarding the future BAN2401 program
- Further analyses are on-going and will be presented by Eisai at CTAD (11th Clinical Trials on Alzheimer's Disease) on Oct 24-27, 2018 in Barcelona, Spain
- 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)



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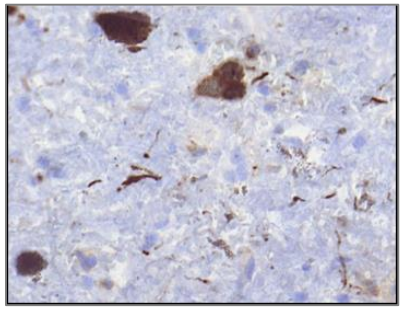
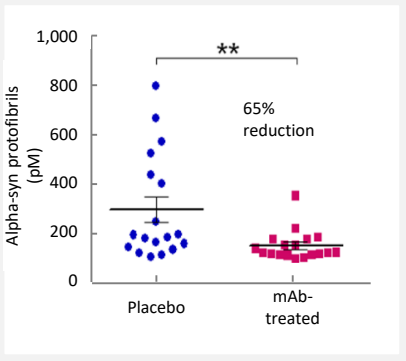
BAN0805 – Groundbreaking Disease Modifying Drug in PD with Rationale for Selective Targeting of Alpha-synuclein Oligomers/ Protofibrils

Rationale for targeting alpha-synuclein

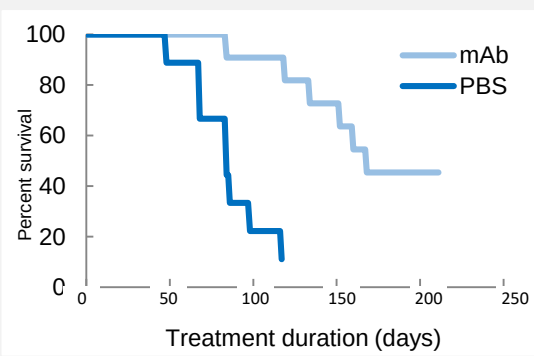
Human genetics → Pathology → Pre-clinical proof of concept



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

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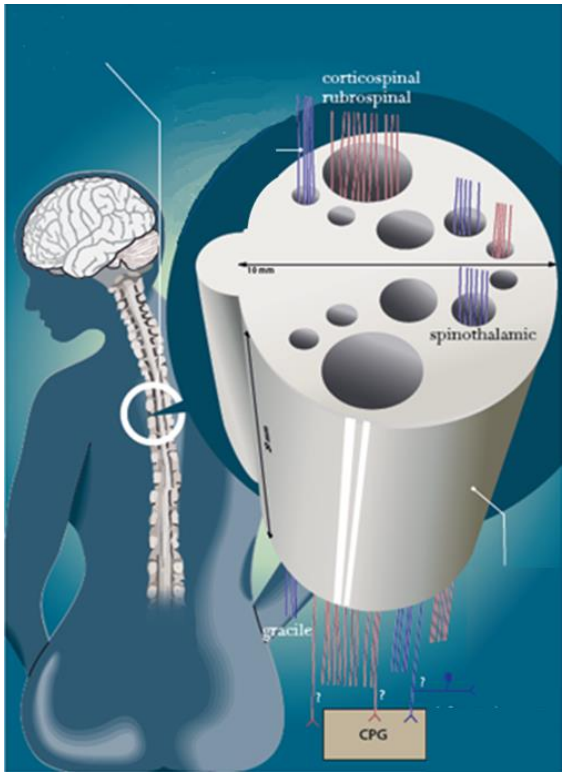
SC0806 – Unique Regenerative Treatment of Complete SCI

SC0806 – Regenerative Treatment of Complete SCI

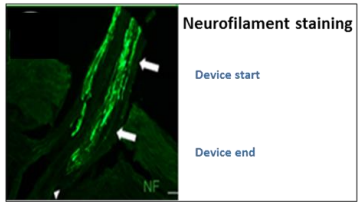


Treatment Rationale and Project Status

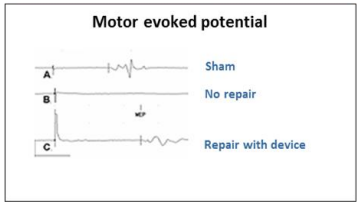
SC0806 makes nerve regeneration possible

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

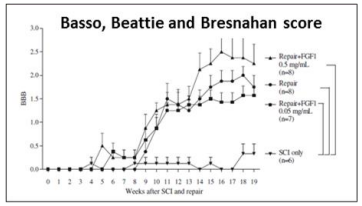
Nerve regeneration



Electrophysiology restored



Motor function improved



Preclinical Proof of Concept shown in rats

- 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

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SC0806 – Unique Regenerative Treatment of Complete SCI

The Lokomat™ used in the Rehabilitation

Treatment Rationale and Project Status

- Surgical implantation of biodegradable SCI device with recombinant Fibroblast Growth Factor 1 (FGF1) and nerve grafts
  - Combination of medical device and new drug from a regulatory perspective
  - Orphan Drug designation in US and EU – granting 7 and 10 years exclusivity, respectively
- Clinical Phase 1/2 trial ongoing with SC0806 in patients with Complete Spinal Cord Injury
  - Surgery in Sweden
  - Rehabilitation for 18 months with Lokomat™ in Sweden and preparations to include patients in Estonia, Finland and Norway
  - Patients receiving SC0806 treatment are given the option of 12 months additional participation in an extension study
  - 9 patients included (6 treated with SC0806 and 3 control patients)
- EU Horizon 2020 research and innovative programme Grant Agreement No. 643853 of MEUR 6.4

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Positive Progress of The Project Portfolio – Highlights

- **Alzheimer's disease: Positive results of the BAN2401 Phase 2b study in early Alzheimer's disease in July**
  - The 18 months analyses of BAN2401 Ph 2b study with 856 patients demonstrated consistent dose-dependent, clinically meaningful and statistically significant effects of BAN2401 on several clinical endpoints as well as dose-dependent and significant effects on PET and other biomarkers with a good tolerability profile

- **Research collaborations**
  - BioArctic extended the research collaboration with Uppsala University regarding new antibody technology for increased passage across the blood-brain barrier in May
  - BioArctic obtained exclusive rights to develop antibody treatments for AD from a research project jointly owned with Eisai in August

- **Parkinson's disease: BAN0805 Preclinical phase**
  - Program progressing well including preparations for BAN0805 IND in the U.S. to start clinical trials

- **Spinal Cord Injury: SC0806 Phase 1/2**
  - The inclusion of patients with Complete SCI in the first panel of three was completed in BioArctic's ongoing Phase 1/2 study with SC0806 in April
  - Regulatory approvals in Finland to include patients in the clinical study in May

- **Expansion of the patent portfolio**
  - More than 150 granted patents and 55 pending patent applications within 12 patent families

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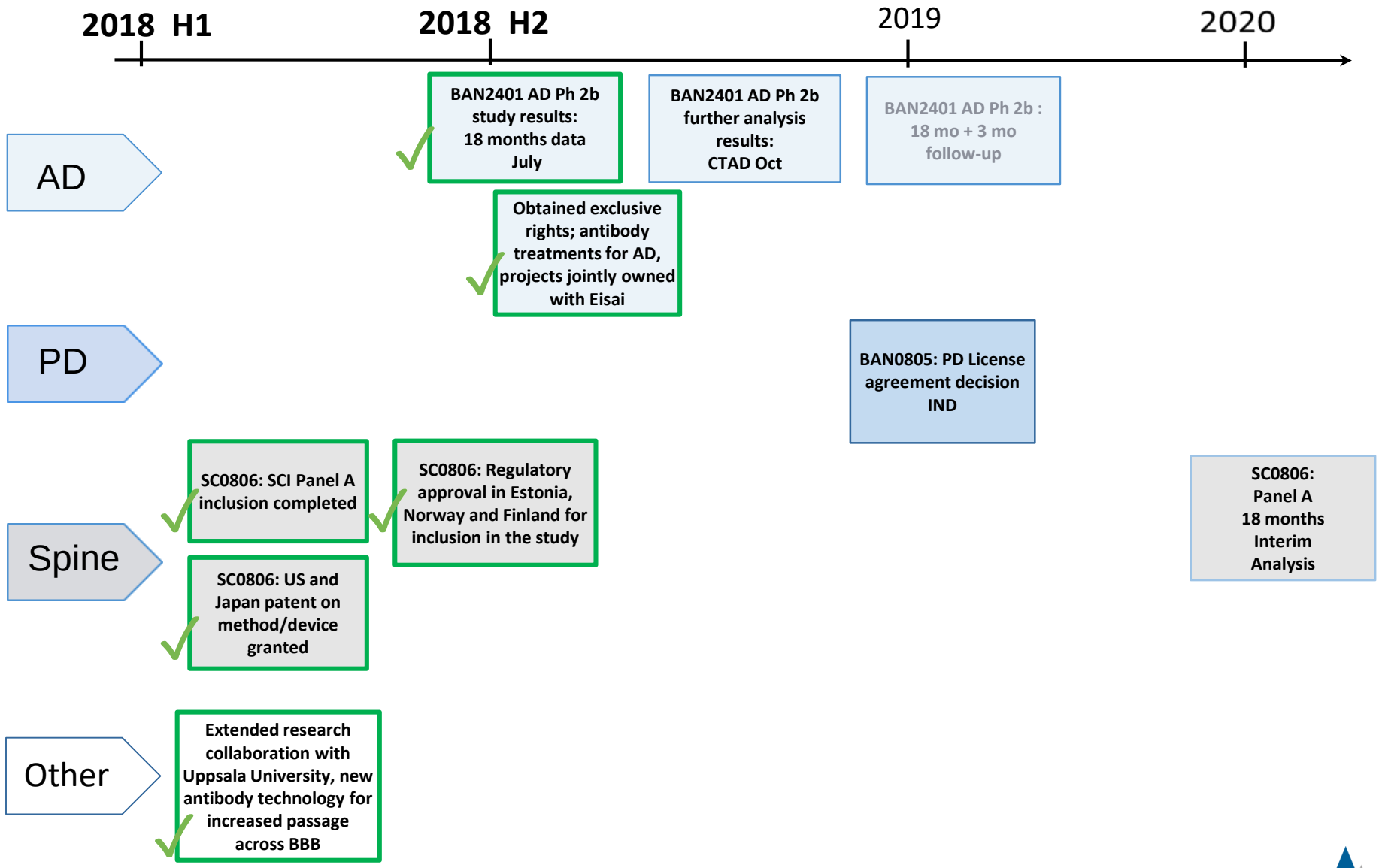
Recent & Anticipated News Flow



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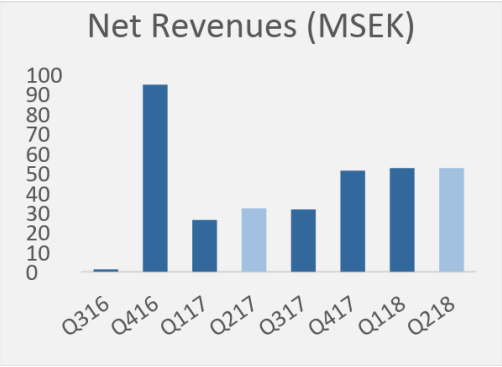
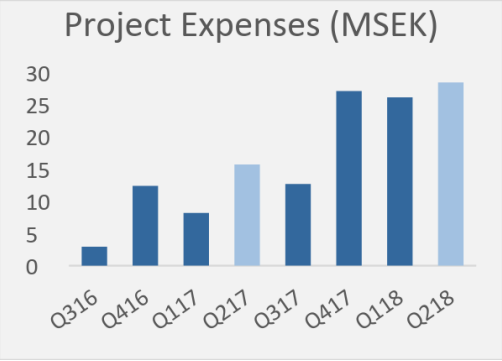
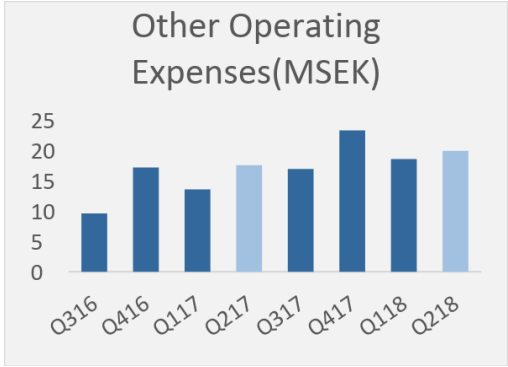
Financial Overview Q2 2018

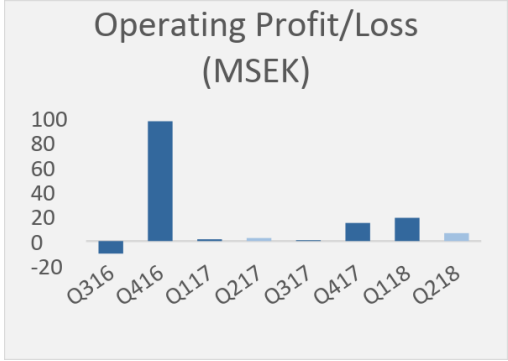
By Quarters





By Quarters





Q2 2018 – Comments

- **BioArctic** has decided to change from income statement by function to income statement by nature of expense
- **Net revenues** increased to SEK 52.3m (32.0) mainly due to an intensive period in the AbbVie research collaboration regarding the Parkinson program
- **Project expenses** increased to SEK 28.5m (15.7) mainly due to activities related to the Parkinson program
- **Other operating expenses** was SEK 19.9m (17.5). The increase is related to a larger research organization and being a listed company
- **Operating profit** increased to SEK 6.4m (2.5), mainly due to increased activities in the AbbVie collaboration

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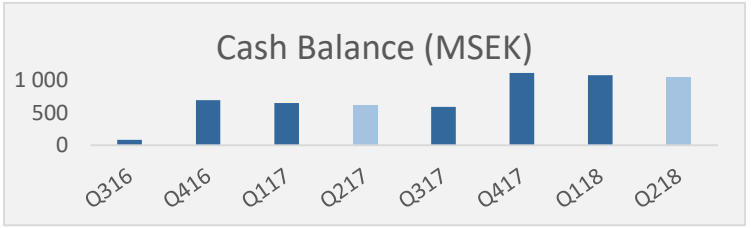
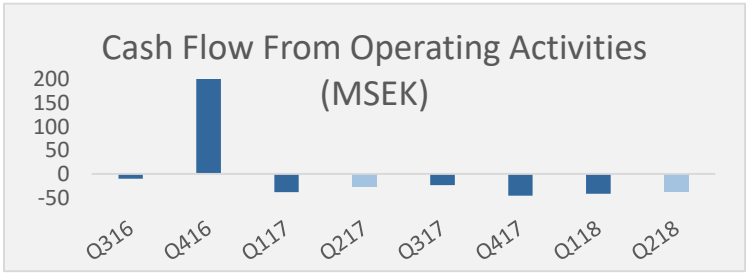
Financial Analysis Q2 2018

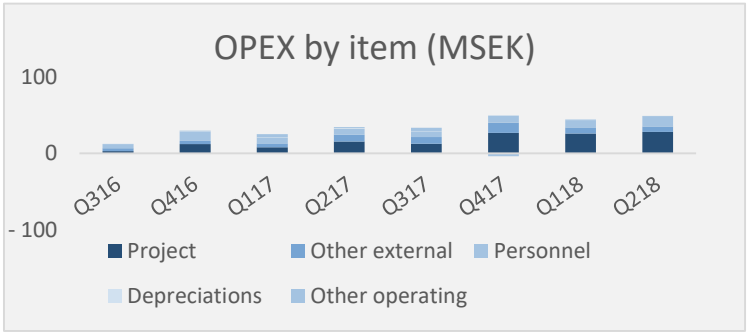
Q2 2018 – Items of Importance

- **Cash balance and Cash flow**
  - Cash balance amounted to SEK 1,041.7m (622.1) at the end of the quarter
  - Operating cash flow depends on the development activities in the projects and amounted to SEK -37.3m (-27.6) during Q2
- **FX impact on earnings**
  - Payment commitments in foreign currency are handled by holding corresponding cash amounts in foreign currency (FX). This FX exposure may have an impact on earnings as currency rates fluctuate over time. In Q2, the FX impact on earnings amounted to a total result of SEK -0.2m (-0.2). For the January-June period the FX impact on earnings amounted to SEK 10.1m (-3.9)
- **Expenses**
  - About 80% of the costs are related to R&D
- **Positive results**
  - All in all, BioArctic showed another quarter with positive net results that amounted to SEK 5.1m (2.3)

Q2 2018 Comments







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Q&A

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Jan Mattsson, CFO

Next report & IR Contact

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  Q3 November 8, 2018
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Thank you for your attention!

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