

BioArctic AB

Gunilla Osswald, CEO

Jan Mattsson, CFO

Interim Report Jan – Sep 2018

Nasdaq Stockholm: BIOA B

November 8, 2018



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.

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

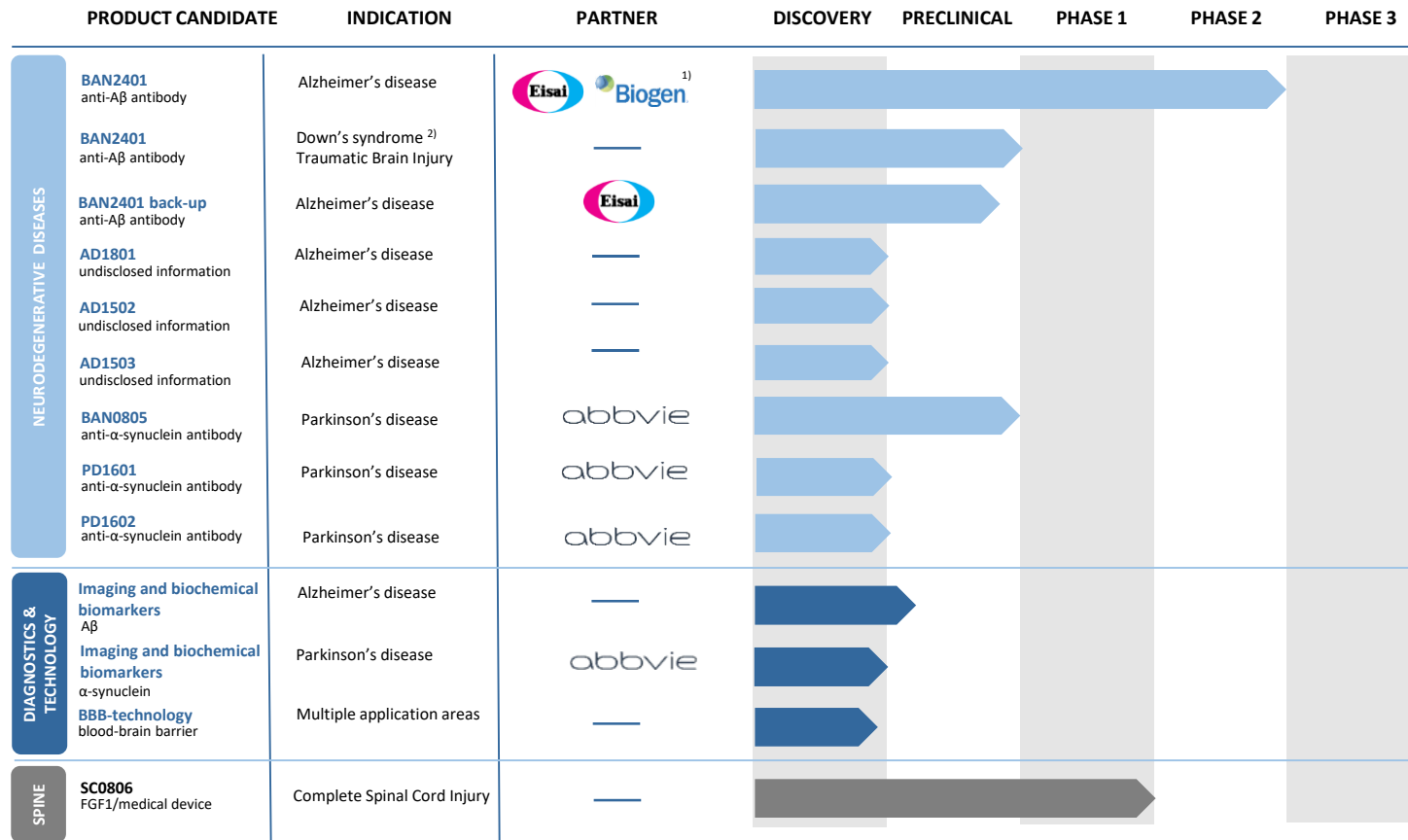
Complete Spinal Cord Injury



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



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

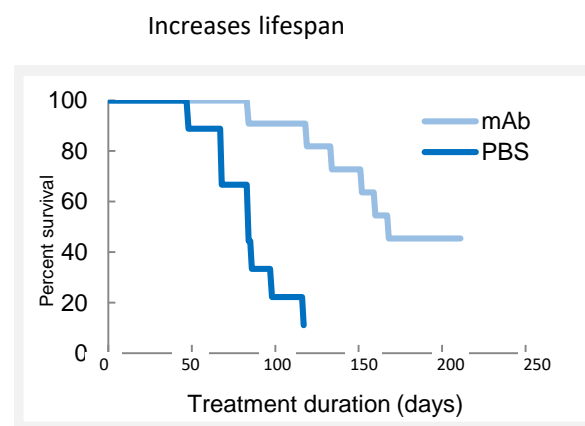
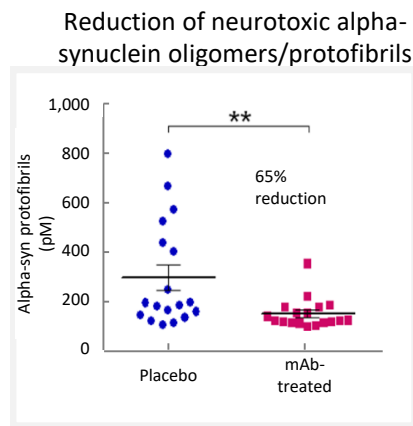
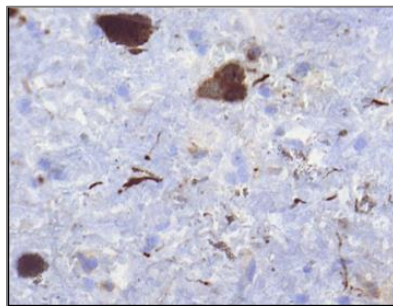
Milestone / royalty potential

- 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



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

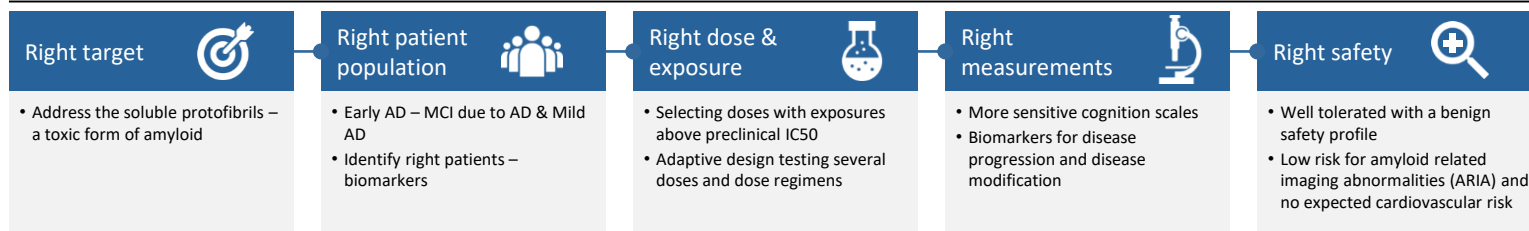
Oligomer/protofibril selective antibody reduces neurotoxic alpha-synuclein oligomer/protofibril levels, delays disease progression and increases life-span in a PD mice model

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

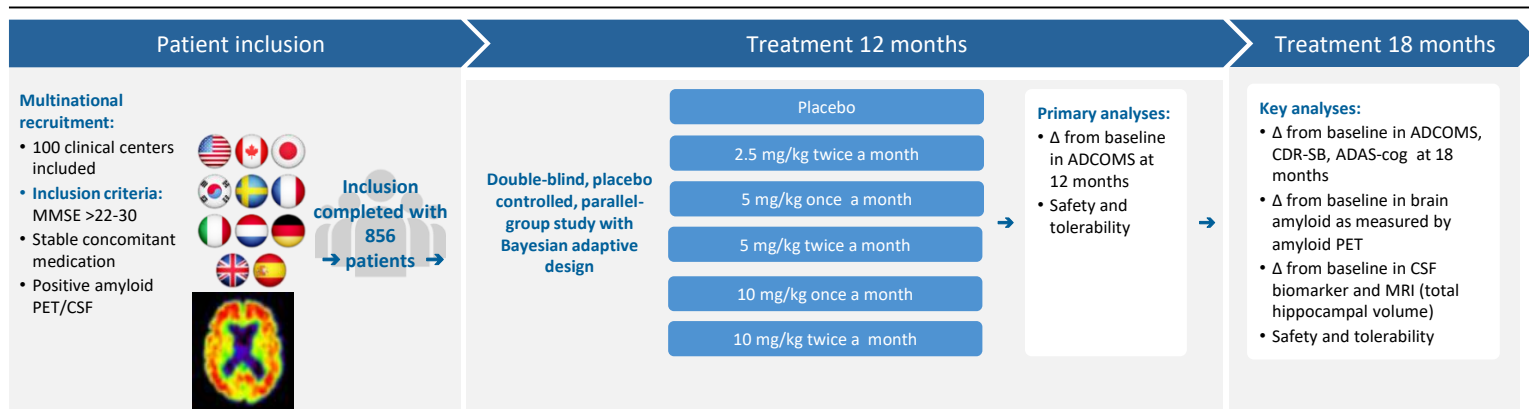
BAN2401 – Innovative Phase 2b Study Design

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

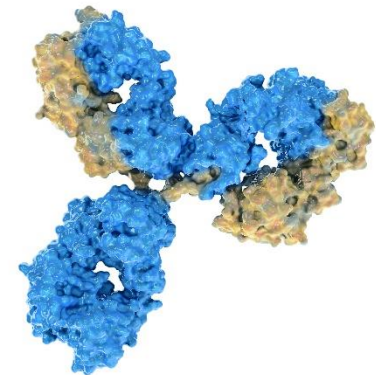
- Elevated Abeta demonstrates target engagement
- Impact on AD pathophysiology with benefits on neuro-degeneration markers: t-tau, p-tau, neurogranin and NfL

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

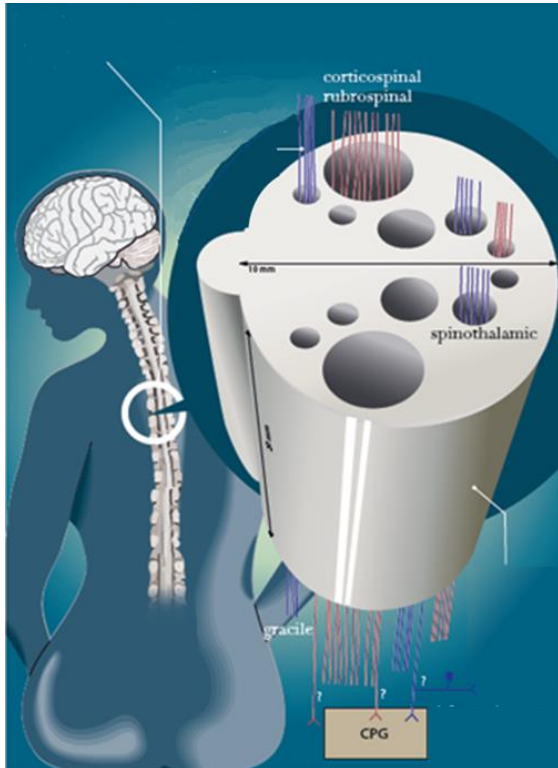
- Eisai is currently conducting interactions with regulatory agencies regarding the future BAN2401 program
- The study will be completed in Q4 2018 and includes a further 3 months follow-up after completion of 18 months of treatment (at 21 months)
- Open-label extension study with BAN2401, without placebo,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



SC0806 – Unique Regenerative Treatment of Complete SCI

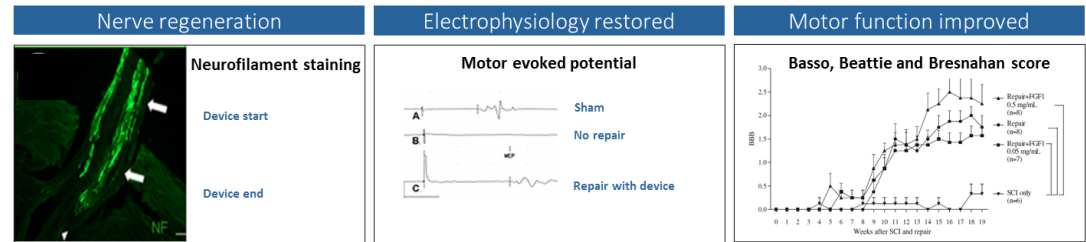
SC0806 – Regenerative Treatment of Complete SCI

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

Positive Progress of the Project Portfolio – Highlights

▶ Alzheimer's disease: Positive results of the BAN2401 Phase 2b study in early AD

- 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 (Jul)
- Sub-group analyses presented at CTAD 2018 on demonstrate effects across sub-groups (Oct)

▶ Research collaborations

- Extended the research collaborations with Uppsala University regarding new antibody technology for increased passage across the BBB (May) and PET imaging (Sep)
- Obtained exclusive rights to develop antibody treatments for AD from a research project jointly owned with Eisai (Aug)
- Signed research agreement with Brain Biomarker Solutions in Gothenburg AB to develop new diagnostics for AD (Sep)

▶ Parkinson's disease: BAN0805 Preclinical phase

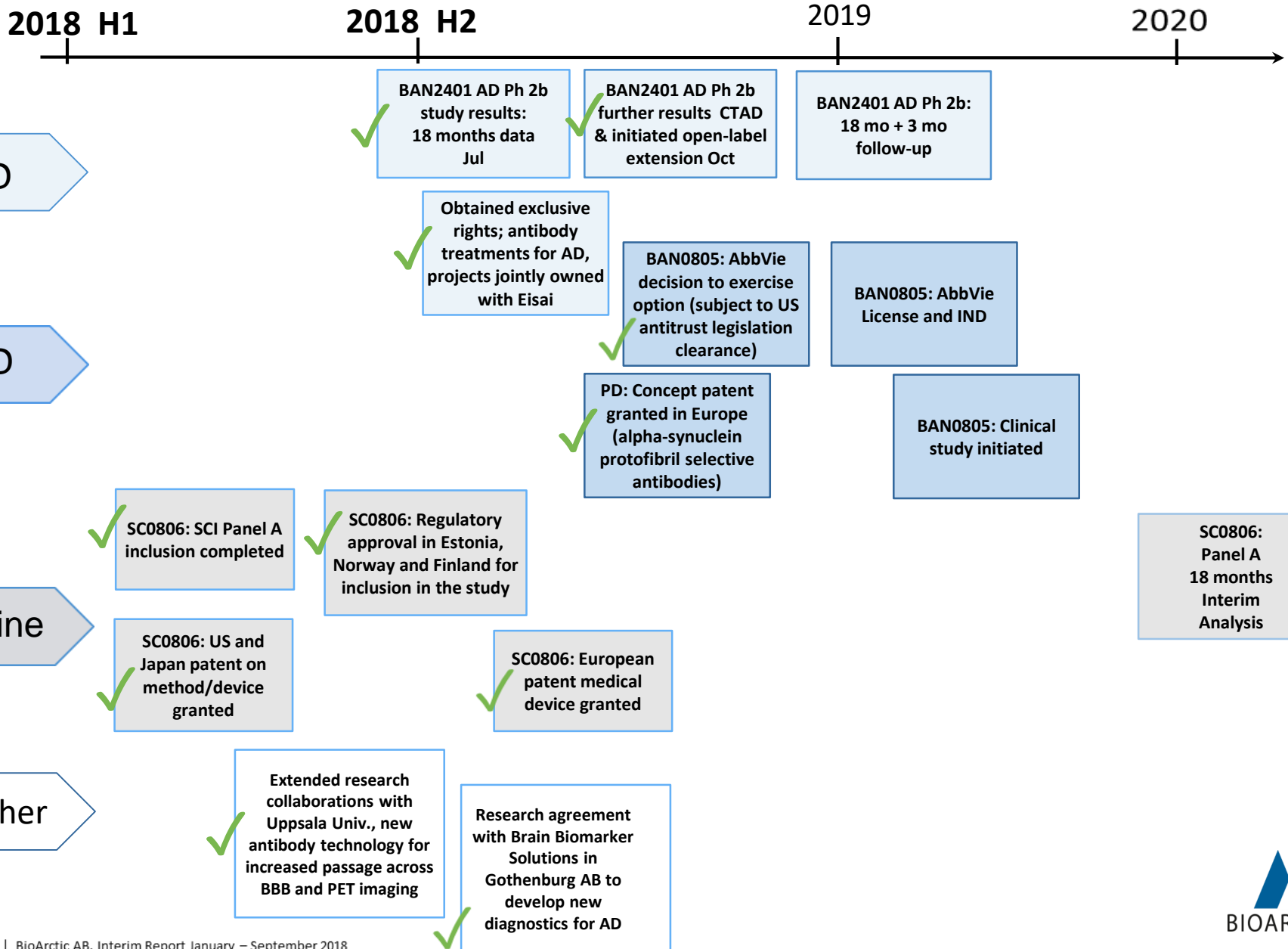
- Program progressing well including preparations for BAN0805 IND in the U.S. to start clinical trials
- Concept patent for alpha-synuclein protofibril selective antibodies granted in Europe (Oct)
- AbbVie to exercise its option to license alpha-synuclein antibody portfolio subject to U.S. antitrust legislation clearance (Nov)

▶ Spinal Cord Injury: SC0806 Phase 1/2

- European patent protection for the medical device for treatment of patients with CSCI (Oct)
- Screening of patients for Panel B initiated in Sweden and Estonia (Aug)

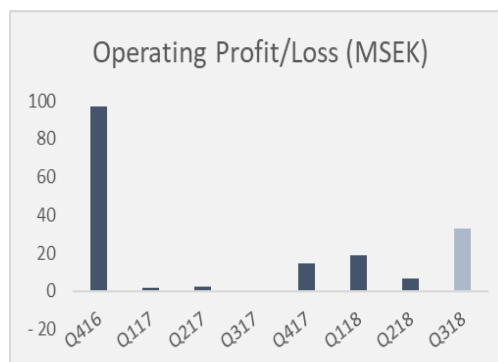
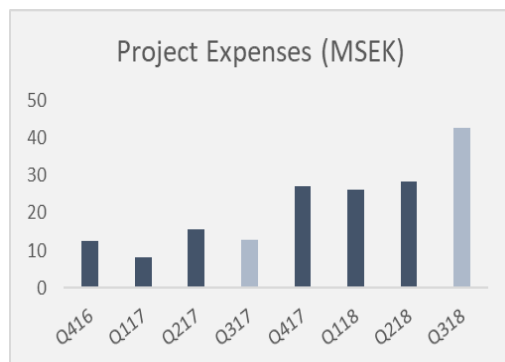
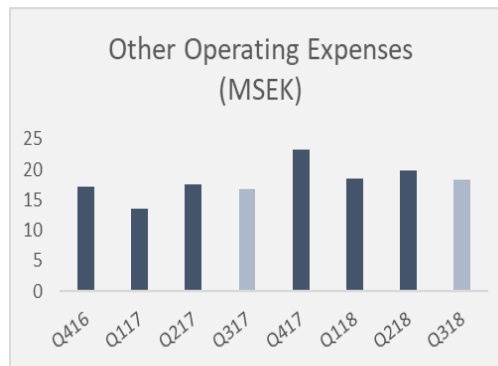
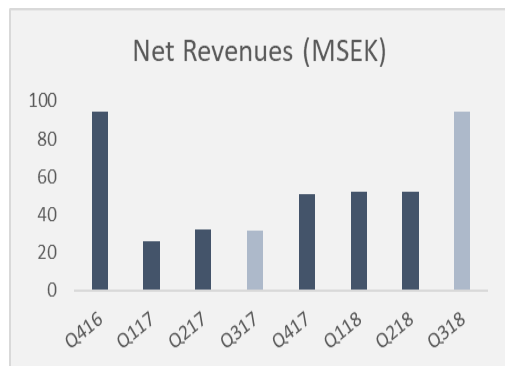


Recent & Anticipated News Flow



Financial Overview Q3 2018

By Quarters



Q3 2018 – Comments

- ▶ **Net revenues** increased to SEK 94.0m (31.5) mainly due to an intensive period in the AbbVie research collaboration regarding the Parkinson program. This included a positive one-off effect of SEK 20.1m related to higher efficiency in the Parkinson program
- ▶ **Project expenses** increased to SEK 42.7m (12.7) mainly due to activities related to the Parkinson program
- ▶ **Other operating expenses** was SEK 18.3m (13.8), excluding IPO costs in 2017. The increase is related to expanded activities in the research organization and being a listed company
- ▶ **Operating profit** increased to SEK 33.1m (0.6)

BioArctic changed from income statement by function to income statement by nature of expense starting from the previous interim report.

Financial Analysis Q3 2018

Q3 2018 – Items of Importance

▶ Cash balance and Cash flow

- Cash balance amounted to SEK 1,008.5m (590.7) at the end of the quarter
- Operating cash flow depends on the development activities in the projects and amounted to SEK -31.5m (-23.6) during Q3

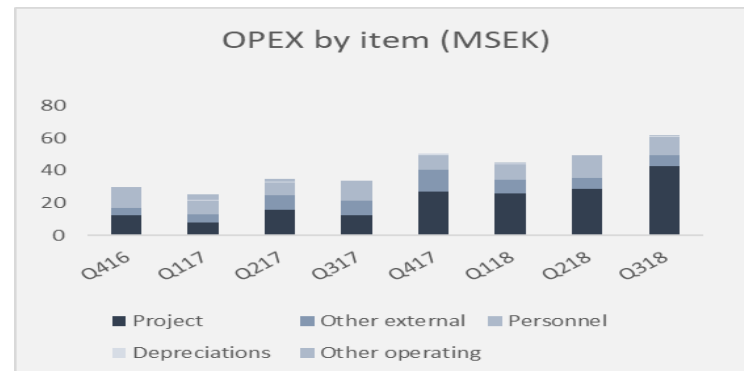
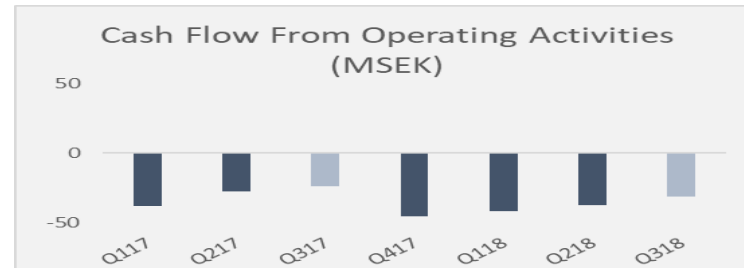
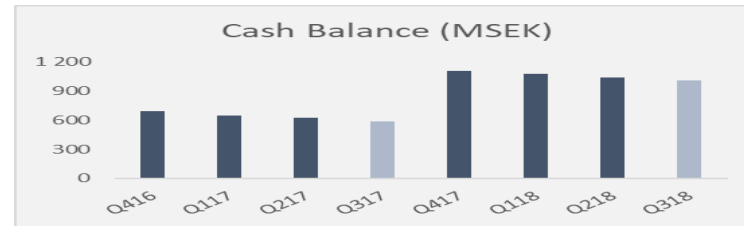
▶ Expenses

- About 85% 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 25.9m (-0.1)

Q3 2018 Comments



Q&A

Gunilla Osswald, CEO



Jan Mattsson, CFO



Next Report & IR Contact

- ▶ **Next report:**
Full Year Report 2018
Feb 14, 2019
- ▶ **IR contact:**
Christina Astrén
+46 8 695 69 30
ir@bioarctic.se

For subscription of financial reports/press releases
and more information, please visit
www.bioarctic.com

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

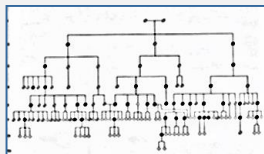
Investment highlights

- ▶ **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

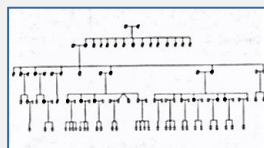
Long History of Research Achievements Within Disorders of the Central Nervous System (CNS)

Background to founding

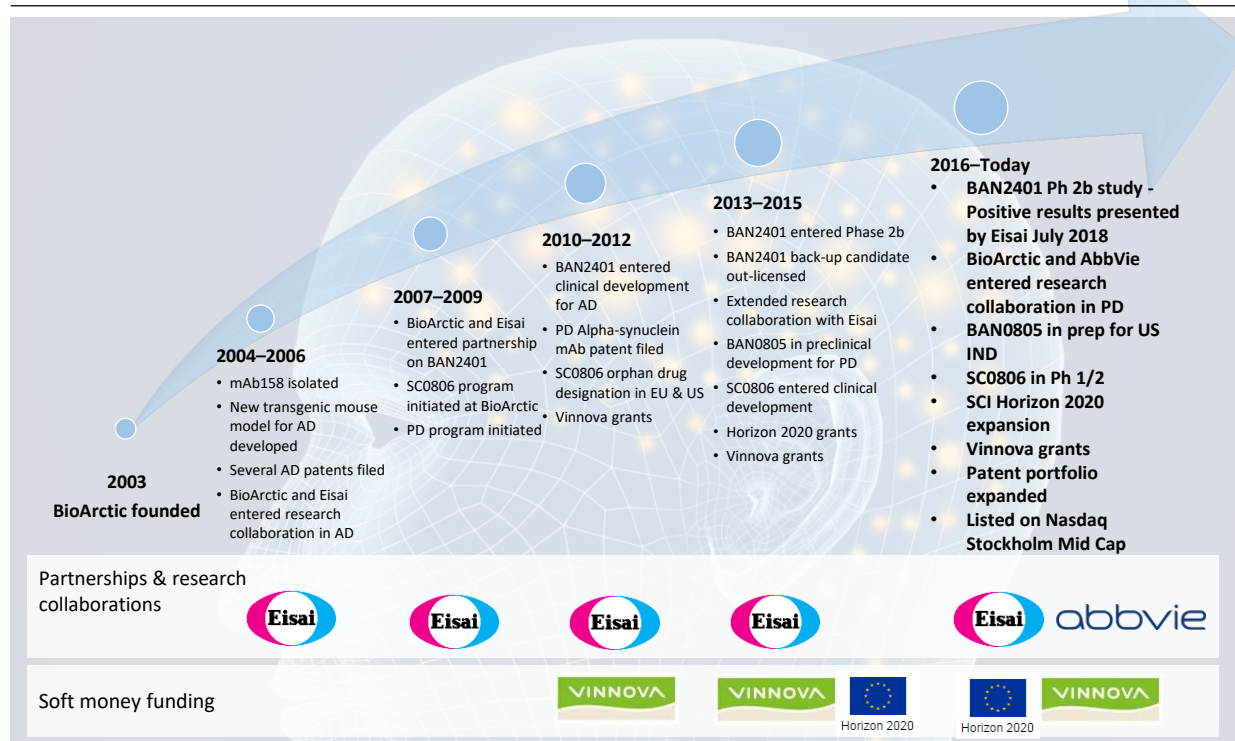
- ▲ Scientific discoveries by Professor Lars Lannfelt laid the foundation for BioArctic
- ▲ **The Swedish mutation** demonstrated for the first time in a clinical setting that amyloid-beta (A β) peptide initiates the disease



- ▲ **The Arctic mutation** revealed that soluble aggregated forms of A β , oligomers and protofibrils, are toxic and likely driving the disease



Company history



Source: Company data

Successful collaborations with pharmaceutical industry validating potential value and commercialization potential for BioArctic

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 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 of clinical decline and reduction of amyloid beta accumulated in the brain with a good tolerability profile

BAN2401 Showed Effect on Clinical Parameters and Biomarkers with Good Tolerability in Early AD Patients at the Highest Dose at 18 Months - 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)
 - ADCOMS showed effect already at 6 months – as well as after 12 and 18 months of treatment
 - Slowing of disease progression observed across sub-groups*
 - The clinical effect increased over time
- **ADAS-Cog** (well-established cognition scale) showed statistically significant slower decline of 47% ($p=0.017$)
- **CDR-SB** (cognition and function scale) showed slower decline of 26% ($p=0.125$)

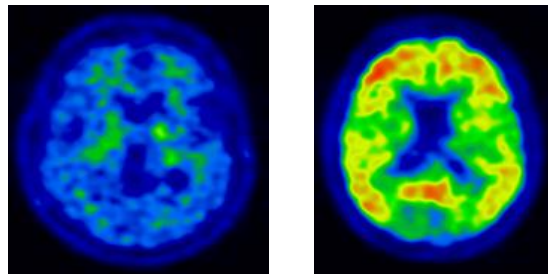
*MCI due to AD – mild AD, ApoE4 carriers – non-carriers, with or without symptomatic treatment

BAN2401 Showed Effect on Clinical Parameters and Biomarkers with Good Tolerability in Early AD Patients at the Highest Dose at 18 Months - II

Biomarkers:

- Amyloid PET

- **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 ($p < 0.0001$)
 - Amyloid PET demonstrated consistent and pronounced reduction of amyloid in the brain across all clinical sub-groups*



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.

* MCI due to AD – mild AD, ApoE4 carriers – non-carriers, with or without symptomatic treatment

BAN2401 Showed Effects on Amyloid and CSF Markers of Neurodegeneration Consistent with Impact on Underlying Disease Pathophysiology - III

CSF
Biomarkers:

- Abeta
- t-tau
- p-tau
- neurogranin
- NfL

- Abeta increase shows target engagement
- Neurodegenerative markers show effect of BAN2401 on underlying pathophysiology
 - Reduction in t-tau (downstream tau pathway)
 - Reduction in p-tau (downstream tau pathway)
 - Reduction in neurogranin (synaptic damage)
 - Reduction in increase of Neurofilament Light (NfL) (axonal degeneration)

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

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
 - Generally occurred within the first 3 months of treatment

ARIA-E, Alzheimer's Related Imaging Abnormality-Edema

Consolidated Income statement

kSEK	Jul-Sep 2018	Jul-Sep 2017	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Net revenues (note 4)	94,045	31,493	198,650	89,685	140,706
Other operating income	556	2,764	15,552	8,678	19,044
Total operating income	94,602	34,257	214,202	98,363	159,750
Operating expenses					
Project related expenses	-42,738	-12,667	-97,327	-36,556	-63,641
Other external expenses	-6,675	-8,959	-21,907	-22,869	-36,197
Personnel expenses	-11,039	-7,408	-33,410	-23,651	-32,936
Depreciations of tangible assets	-624	-507	-1,392	-1,399	-1,993
Other operating expenses	-402	-4,097	-1,692	-9,326	-5,689
Operating profit	33,125	619	58,474	4,563	19,294
Financial income	453	-401	2,283	138	1,043
Financial expenses	-342	-295	-1,067	-307	-647
Profit before tax	33,236	-77	59,689	4,394	19,690
Tax	-7,379	-39	-13,292	-1,073	-4,534
Profit for the period	25,856	-116	46,397	3,321	15,157
Earnings per share					
Earnings per share, SEK ^{2,3}	0.29	0.00	0.53	0.05	0.22

¹ BioArctic has decided to change to income statement by nature of expense and the comparative periods have been changed accordingly

² There are no potential shares. Thus; there is no dilutive effect

³ The comparative figures have been recalculated as a result of the 15:1 split executed on August 1, 2017

Consolidated Balance sheet

kSEK	Sep 30, 2018	Sep 30, 2017	Dec 31, 2017
ASSETS			
Tangible fixed assets	7,065	7,580	7,093
Deferred tax assets	180	215	230
Other financial assets	2,675	2,675	2,675
Current assets excluding cash and cash equivalents	13,824	9,774	20,119
Cash and cash equivalents	1,008,522	590,677	1,110,367
TOTAL ASSETS	1,032,266	610,921	1,140,483
EQUITY AND LIABILITIES			
Equity	682,531	64,080	636,134
Deferred tax liabilities	5,487	4,136	5,487
Other current liabilities	18,538	9,837	12,160
Accrued expenses and deferred income	325,710	532,868	486,702
EQUITY AND LIABILITIES	1,032,266	610,921	1,140,483

Consolidated Cash flow statement

kSEK	Jul-Sep 2018	Jul-Sep 2017	Jan-Sep 2018	Jan-Sep 2017	Jan-Dec 2017
Operating profit	33,125	619	58,474	4,563	19,294
Adjustment for non-cash items	-93,925	-27,911	-211,526	-80,273	-143,453
Interest received/paid	-342	-305	-1,067	-307	-582
Income tax paid	-2,067	-163	-8,822	-7,353	-7,739
Cash flow from operating activities before changes in working capital	-63,209	-27,761	-162,942	-83,371	-132,481
Change in working capital	31,752	4,150	52,139	-6,257	-2,846
Cash flow from operating activities after changes in working capital	-31,456	-23,611	-110,803	-89,628	-135,327
Cash flow from investing activities	-498	-2,781	-1,364	-3,334	-2,813
Cash flow from financing activities	-	-	-	-	560,218
Cash flow for the period	-31,954	-26,392	-112,168	-92,962	422,078
Cash and cash equivalents at beginning of period	1,041,740	622,063	1,110,367	692,530	692,530
Exchange rate differences in cash and cash equivalents	-1,264	-4,994	10,323	-8,891	-4,241
Cash and cash equivalents at end of period	1,008,522	590,677	1,008,522	590,678	1,110,367