BioArctic AB

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Carnegie Healthcare Seminar

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BIOARCTIC

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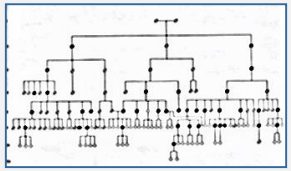
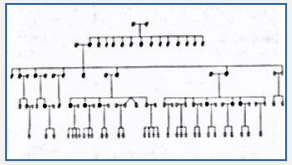
Long History of Research Achievements Within Disorders of the Central Nervous System (CNS)

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 (Aβ) peptide initiates the disease



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



Company history

2003
BioArctic founded

2004–2005
- mAb158 isolated
- New transgenic mouse model for AD developed
- Several AD patents filed

2005–2006
- BioArctic and Eisai entered research collaboration in AD

2007–2008
- BioArctic and Eisai entered partnership on BAN2401

2010–2012
- BAN2401 entered clinical development for AD
- PD Alpha-synuclein mAb patent filed
- SC0806 orphan drug designation in EU & US
- Vinnova grants

2013 – Today
- BAN2401 entered Phase 2b
- BAN2401 Back-up candidate developed
- Extended research collaboration with Eisai
- BAN0805 in pre-clinical development for PD
- BioArctic and AbbVie entered research collaboration on PD
- SC0806 entered clinical development
- Horizon 2020 grants
- Vinnova grants
- Listed on Nasdaq Stockholm Mid Cap

Partnerships & research collaborations: Eisai, Eisai, Eisai, abbvie

Soft money funding: VINNOVA, VINNOVA, Horizon 2020

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

Source: Company data.

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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 pre-clinical 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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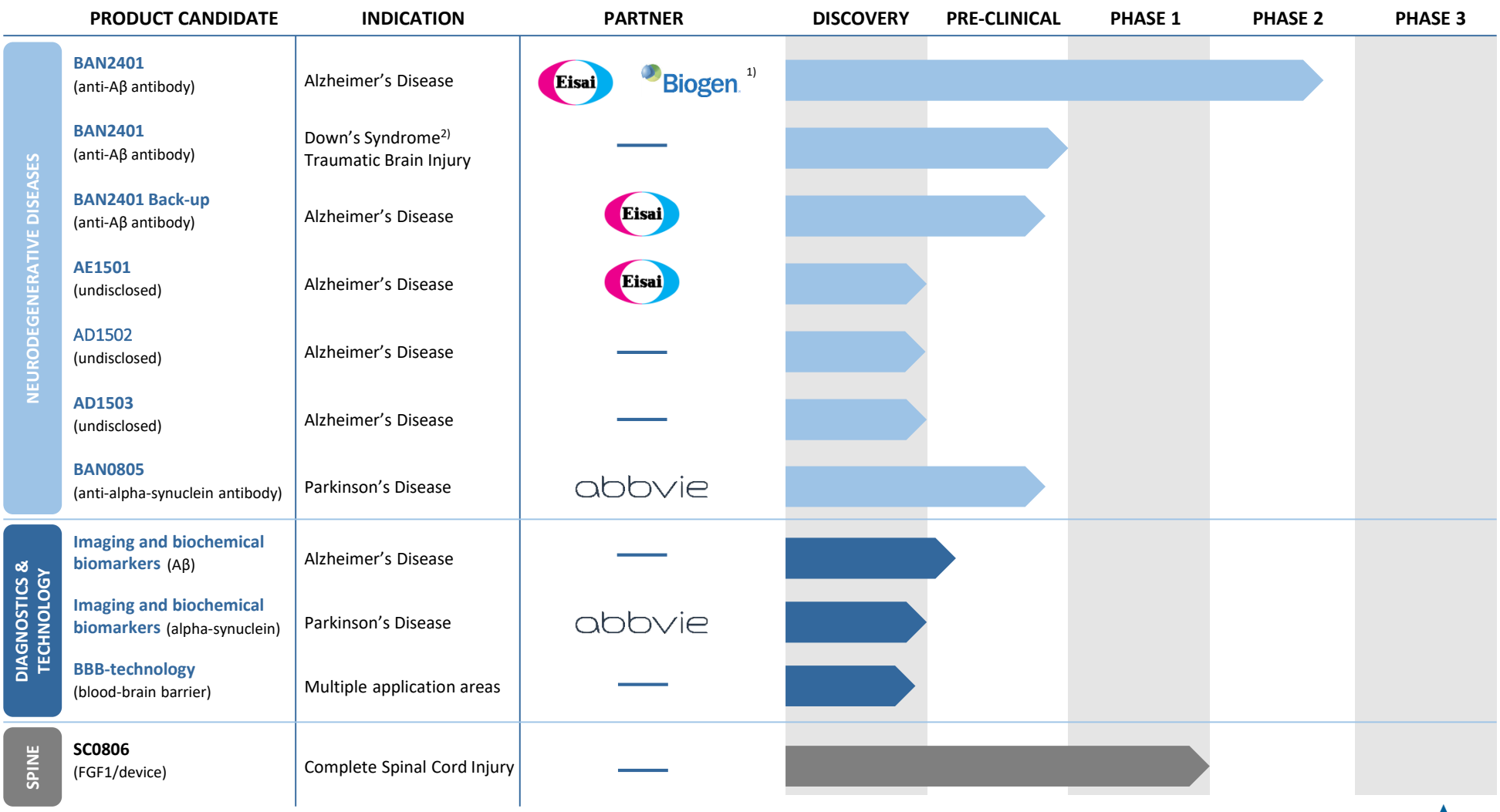
Strategic Partnerships and Cutting-Edge Proprietary R&D



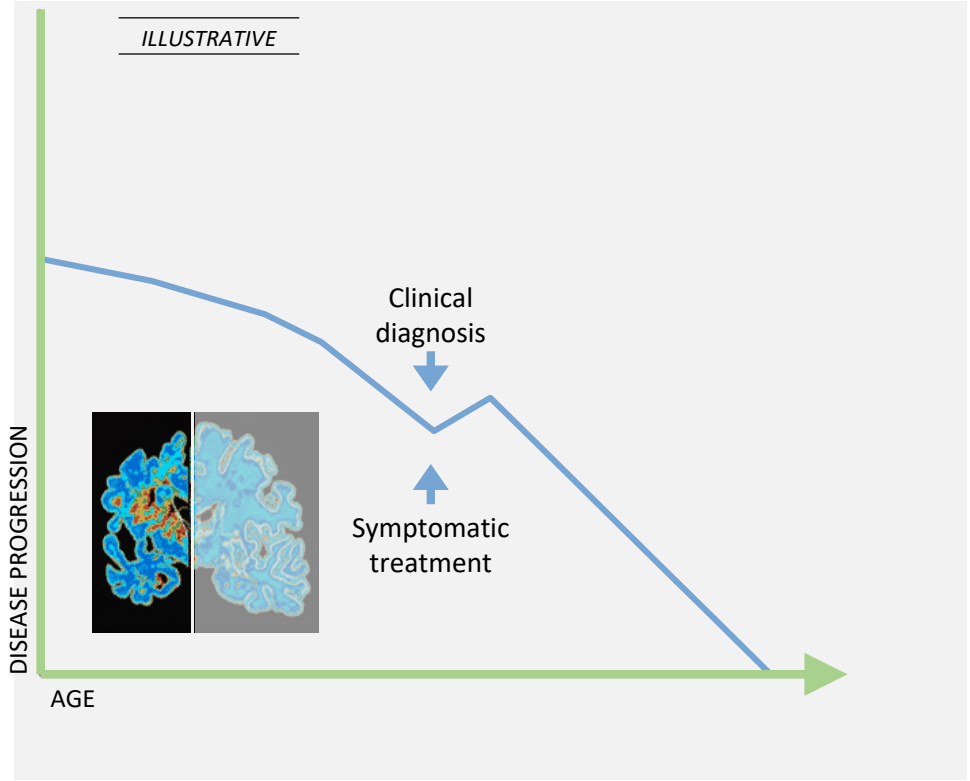
1) Partner with Eisai on BAN2401 for treatment of AD. Since 2014, Eisai partnered with Biogen in AD.
2) Dementia and cognitive impairment associated with Down's syndrome.

Source: Company data

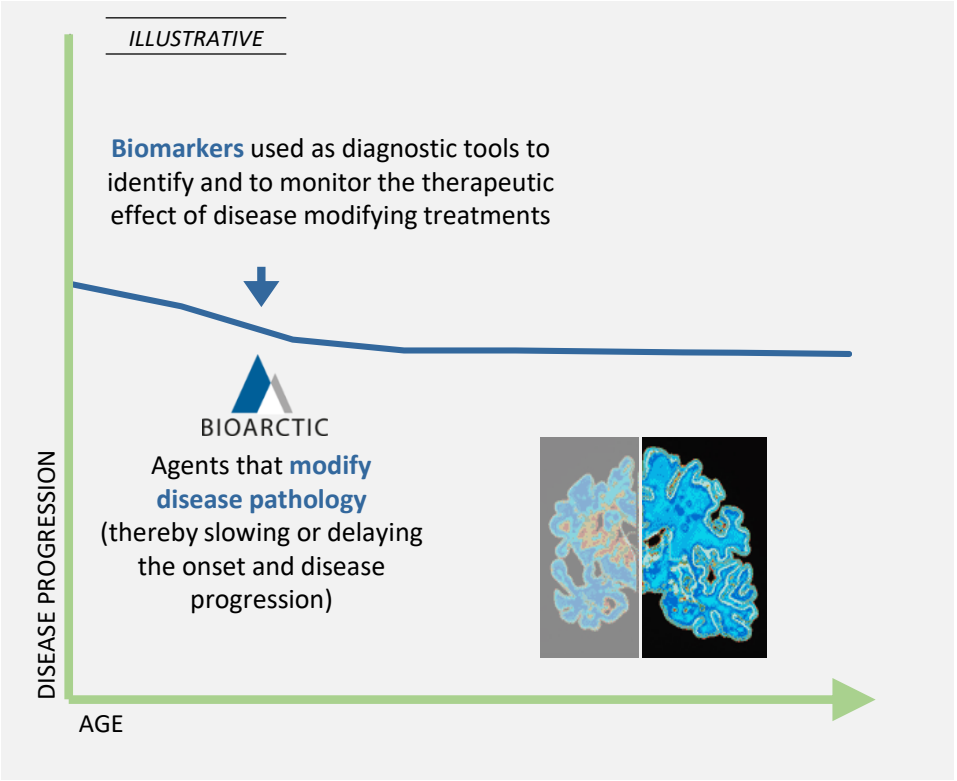
Disease Modifying Agents and Reliable Diagnostics/Biomarkers for Neurodegenerative Diseases

New therapy focus on disease pathogenesis – efforts to delay the neurodegenerative process

Neurodegenerative disease therapy **TODAY**



Neurodegenerative disease therapy **TOMORROW**



Significant unmet medical need to be addressed by disease modifying agents and reliable diagnostics/biomarkers

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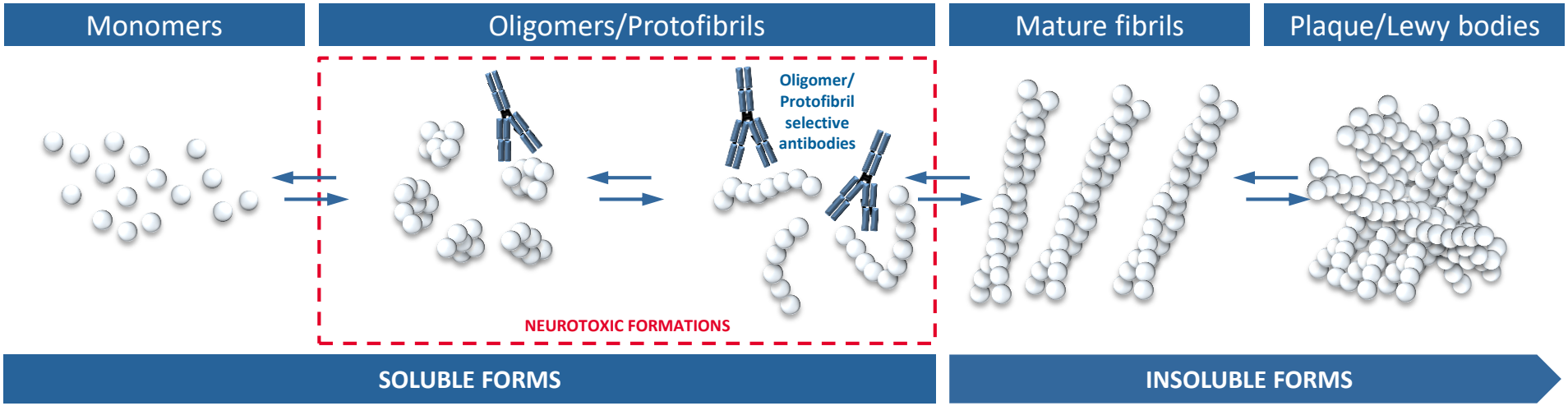
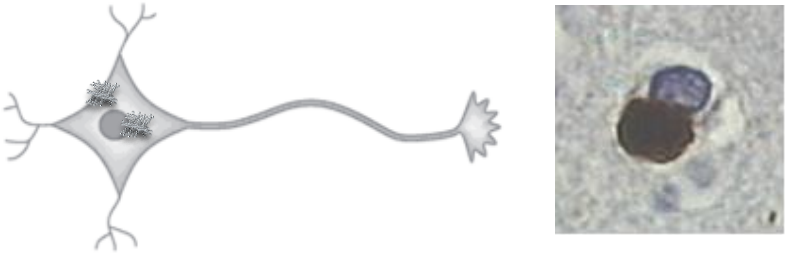
Protein Misfolding is Disease Causing in a Number of Neurodegenerative Diseases Including AD and PD



Aß Plaque in AD

Alpha-synuclein Lewy bodies in PD



Source: Company information.

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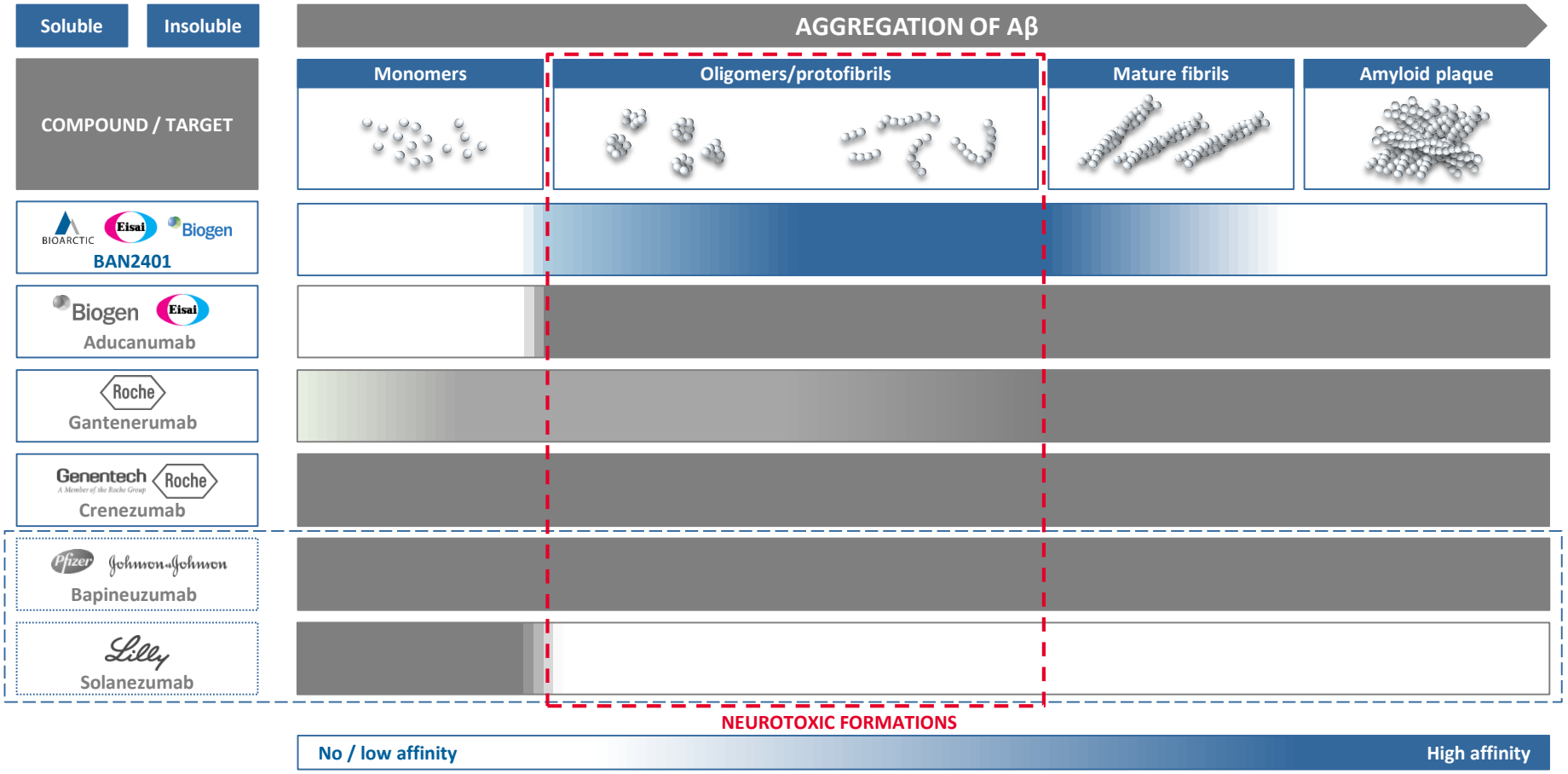
BAN2401 – Unique Aβ Treatment Concept Selectively Targeting and Reducing Neurotoxic Oligomers/Protofibrils in AD



Source: Binding profiles of Aducanumab, Gantenerumab, Crenezumab, Bapineuzumab and Solanezumab are Company interpretations based on information disclosed by competitors.

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BAN2401 – Learnings from Previous Clinical Trials in AD Incorporated in Phase 2b Study Design
Last interim analyses performed and final results in H2 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

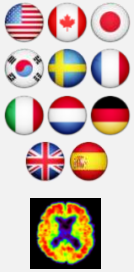
Right measurements
- More sensitive cognition scales
- Biomarkers for disease progression and disease modification

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

Treatment 18 months

Secondary endpoints:
- Δ from baseline in ADCOMS at 18 months
- Δ from baseline in brain amyloid as measured by amyloid PET at 12 and 18 months
- Δ from baseline in total hippocampal volume at 6, 12 and 18 months

Full read-out of study after 18 months treatment in H2 2018

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

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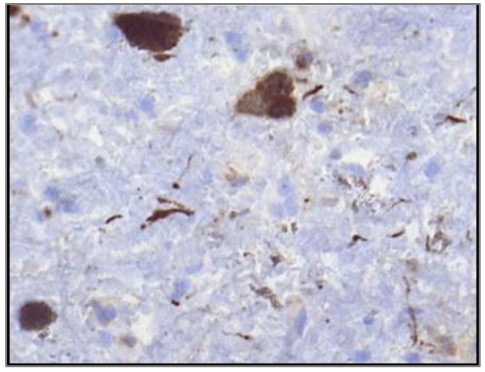
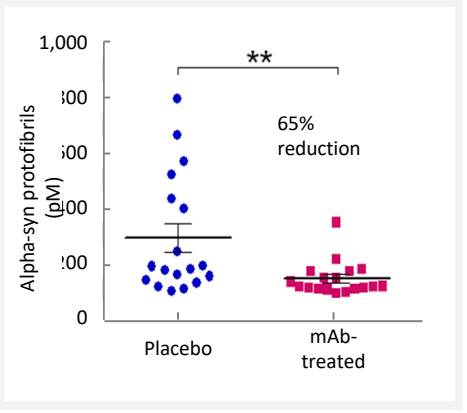
BAN0805 – Groundbreaking Disease Modifying Drug in PD with Rationale for Selective Targeting of Alpha-synuclein Oligomers/Protofibrils

Rationale for targeting alpha-synuclein

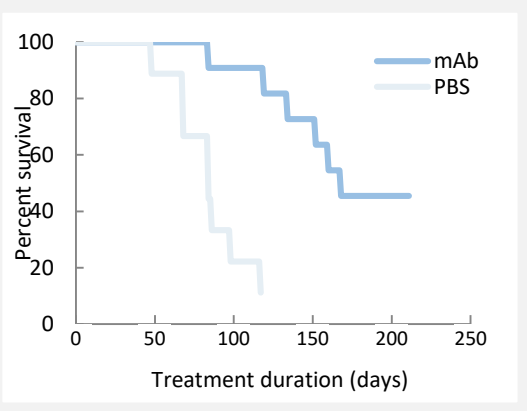
Human genetics → Pathology → Pre-clinical proof of concept



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, delay disease progression and increase life-span in a PD mice model

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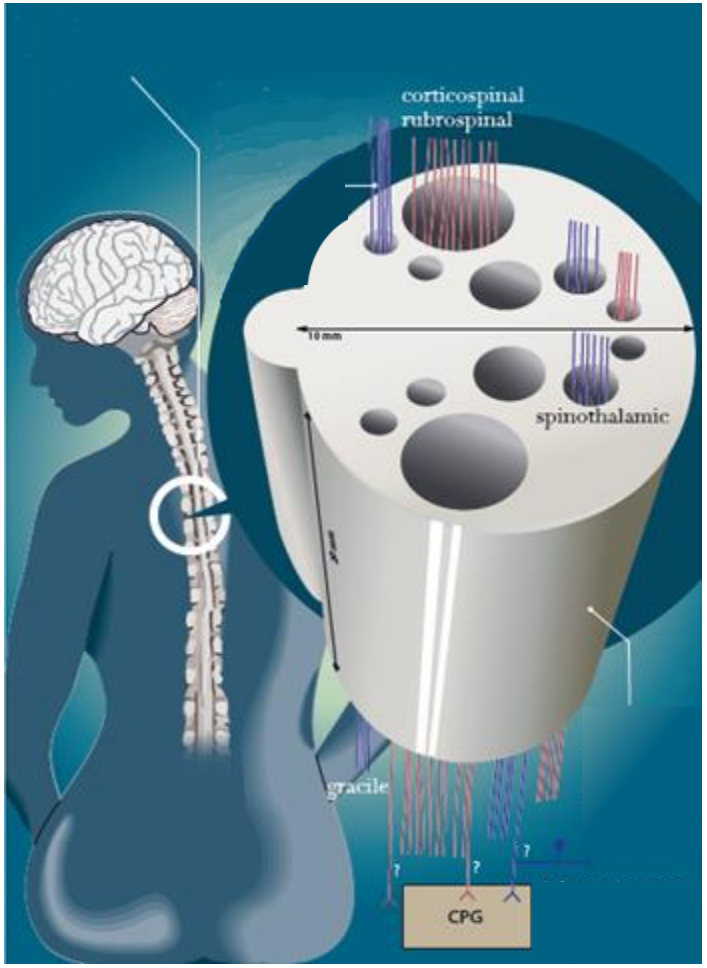
SC0806 – Unique Regenerative Treatment of Complete SCI

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

- 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
- 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
- Clinical Phase 1/2 trial ongoing with SC0806 in patients with complete spinal cord injury
  - Surgery at Karolinska University Hospital in Sweden
  - Rehabilitation for 18 months with Lokomat in Sweden and preparations to include patients in Norway, Estonia and Finland
  - Patients receiving SC0806 treatment are given the option of 12 months additional rehabilitation in an extension study
  - 8 patients included (5 treated with SC0806 and 3 control patients)

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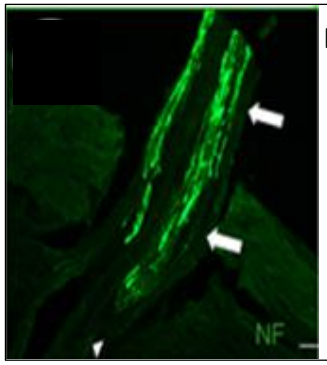
SC0806 – Pre-clinical Proof of Concept

Pre-clinical results

Nerve regeneration



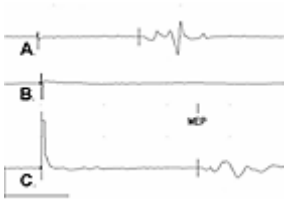
Neurofilament staining

Device start

Device end

Electrophysiology restored

Motor evoked potential



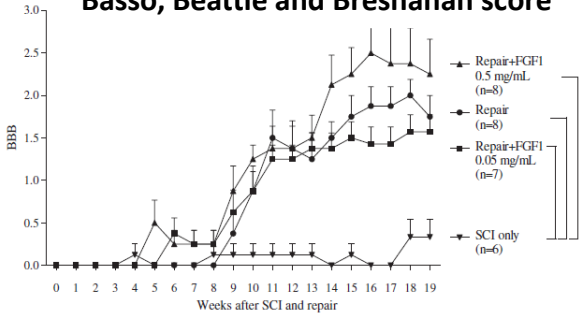
Sham

No repair

Repair with device

Motor function improved

Basso, Beattie and Bresnahan score



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

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

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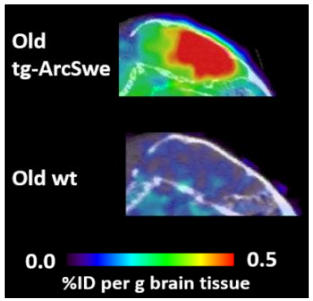
Several Novel Approaches to Improve Diagnostics and Treatment

Imaging and biochemical biomarkers in AD

Aβ protofibril PET tracer

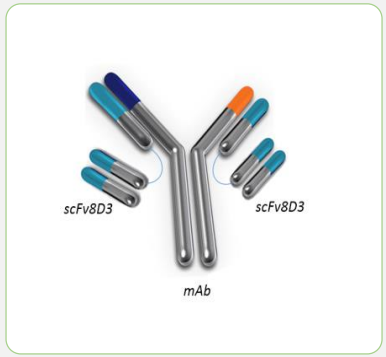


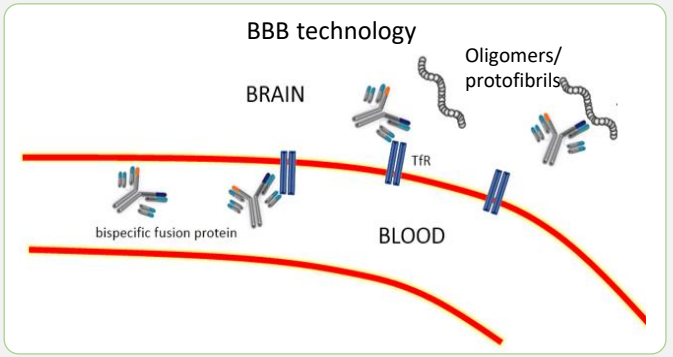
- PET with an antibody-based ligand
- Binding to Aβ oligomers/protofibrils
- Has short half-life
- Improved BBB penetration

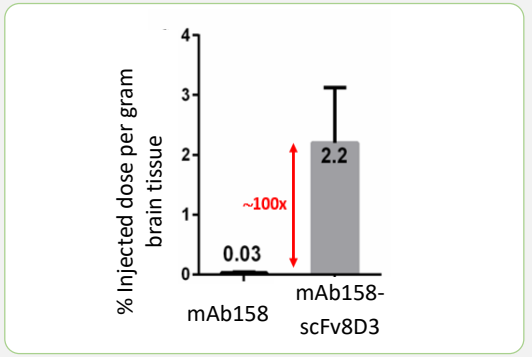
Aβ protofibril biochemical biomarker

- Sensitive biochemical method for Aβ measurement in development is of great clinical importance

Blood-brain barrier technology







Source: Sehlin et al 2016 Nature Communications. Hultqvist et al 2017, Theranostics.

Substantially increased antibody brain uptake by BioArctic´s brain shuttle technology

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Successful IPO in October 2017

IPO and new share issue in October

- **IPO on Nasdaq Stockholm**. BioArctic's B-share started trading on Nasdaq Stockholm main list, Mid Cap, on October 12
- **New share issue** of 25 million B-shares resulted in proceeds of SEK 600m
- **Largest total offering in Swedish biotech since 2000.** Total offering value of SEK 805m
- **Widening the shareholder base.** Following the IPO, BioArctic has around 2,400 shareholders
- **Attracting renowned institutional shareholders.** A number of well renowned international institutional investors, among them HBM Healthcare Investments, as well as Swedish institutional investors such as AP2, AP3, AP4, Handelsbanken Fonder and Swedbank Robur are shareholders in BioArctic
- **Funding of own R&D projects secured.** The new share issue rendered approx. SEK 549m in funding for BioArctic's own R&D projects

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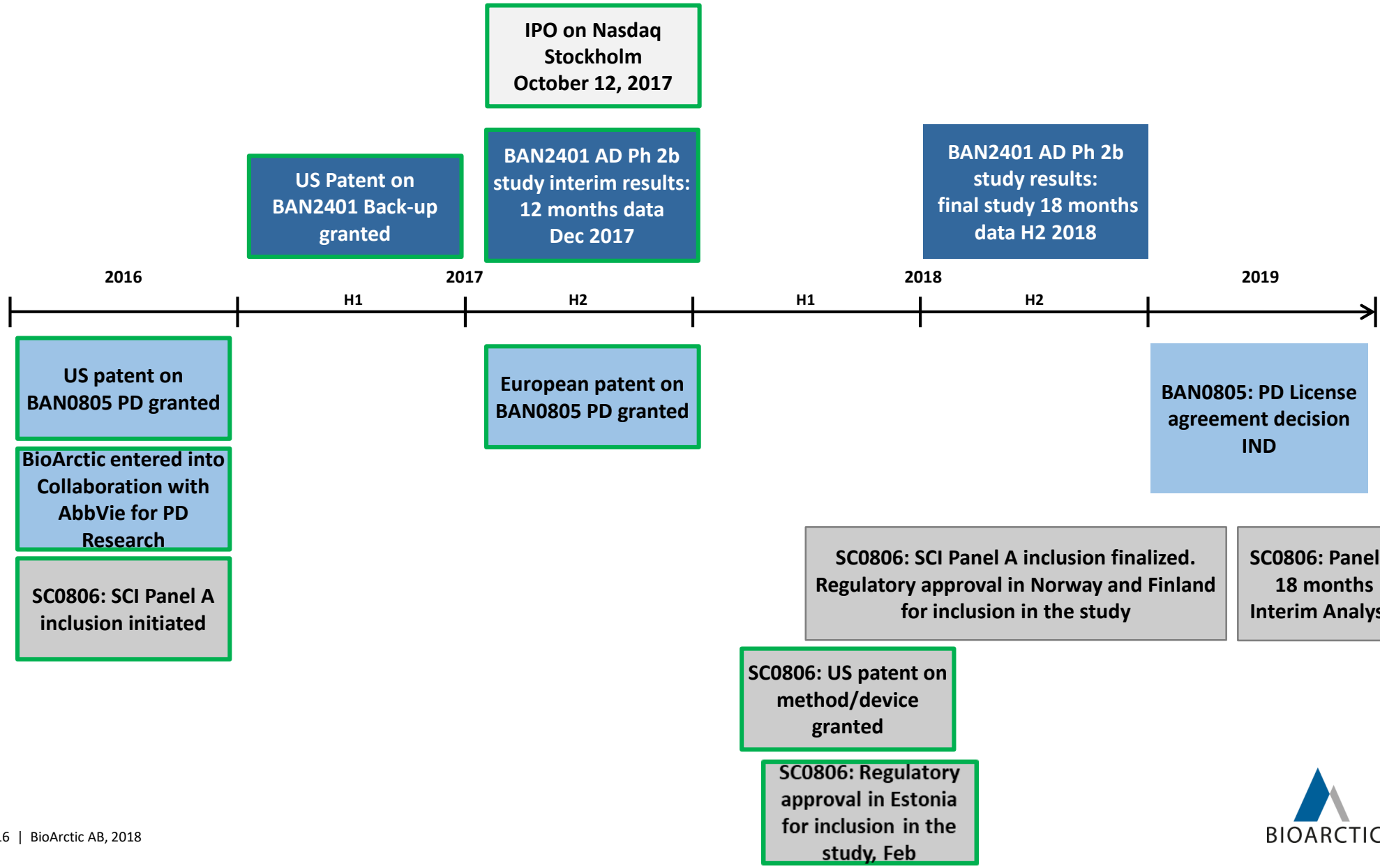
Recent & Anticipated News Flow



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Q&A

Thank you for your attention!

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