Q4 Report 2019

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Summary of key events Q4 2019

- NeflgArd pivotal study Part A fully recruited on time
  - FPI on November 18, 2018; LPI on December 22nd, 2019.
  - 200 patients; dosing once daily for 9 months. Top line readout in Q4, 2020.
  - Primary endpoint; reduction in proteinuria. Key supportive secondary eGFR endpoint
  - Withdrawal rate observed in Phase 2b not reflected in Phase 3 to date
  - Continued recruitment into Part B (160 patients) progressing on plan
- NMPA accepts IND application filed by Everest Medicines
  - Rapid turnaround of all required regulatory documentation, questions etc
  - Good collaboration between the organizations
  - In December 2019 the NMPA accepted the IND, which can provide for an approval of Nefecon in China based on the global data set, complemented by a limited number of Chinese subjects
  - Expectation that China will assist with recruitment of patients into Part B of the study

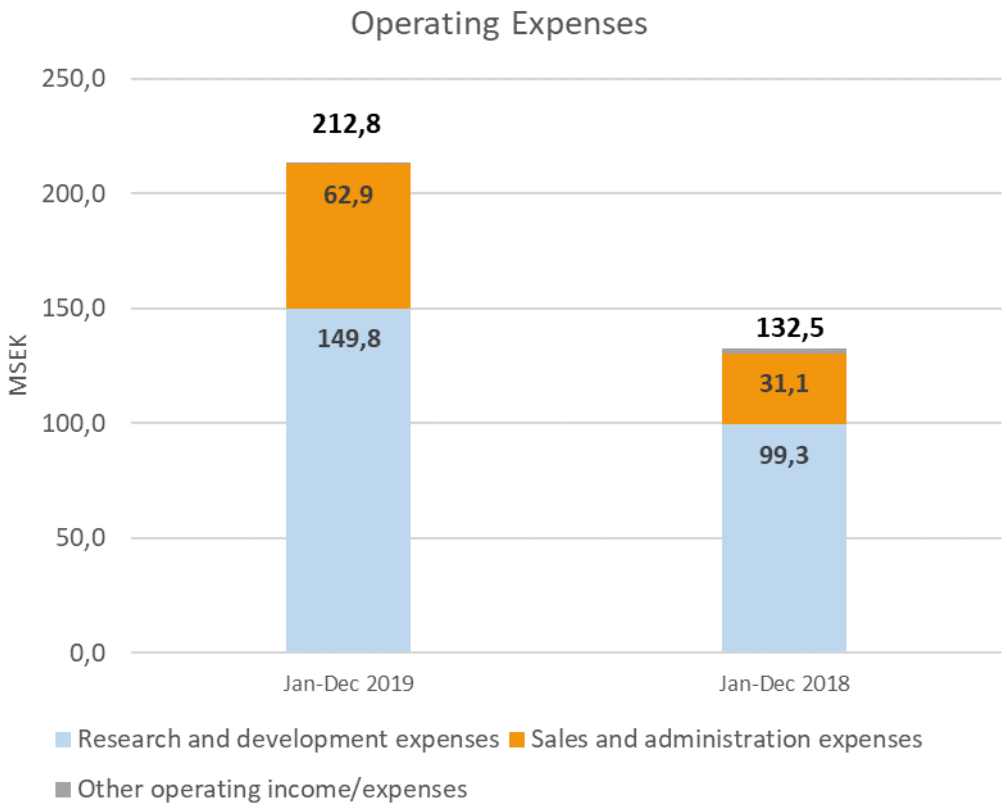
Summary of key events Q4 2019

- Capital Markets Day on November 4th
  - The first capital markets day held in Stockholm with significant local and web based participation
  - Professor Jonathan Barratt provided KOL input on the disease, pathophysiology and treatment paradigms
  - Review of updated Part B design and summary output from IQVIA US market research of nephrologists and payors
  - Review of select auto immune liver diseases
  - General business update

Post quarter events

- Positive opinion from PDCO received regarding PIP
  - Interactions with PDO during Q4. Agreement is a requirement for filing of MAA of Nefecon with EMA
  - Provides basis for potential orphan protection extension of 2 years in Europe
  - Company commitment to address the adolescent IgAN population
- Sofinnova Partners and Vivo Capital become shareholders
  - Secondary transaction of $17.5m (SEK 166m) with Industrifonden and Investinor in January, 2020
  - Validation of the company's strategy to clearly communicate its position relative to the industry framework in the US and drive commercialization in the US
  - Broadens the share holder base and brings onboard highly regarded specialist investors and related networks
- Press release of ITF
- EGM announced for March 3rd

Financial overview of the full year 2019



- Revenues of SEK 184.8 M (-) from USD 15 M upfront payment and USD 5 M IND milestone from China out-licensing deal.
- Operating profit (loss) of SEK -28.0 M (-132.5)
  - Research and development expenses increased to SEK 149.8 M (99.3), representing 70% of total operating expenses
  - Sales and administrative expenses increased to SEK 62.9 M (31.1), due to pre-commercial activities in the US, China deal related transaction costs and an organizational growth.
- Cash flow from operating activities of SEK -71,0 M (-128.2).
- Cash position per end of December 2019, was SEK 753.5 M (646.2), since net SEK 199.4 M was received from the Q3 direct share issue.

Anticipated milestones

Anticipated milestones regarding Calliditas' clinical, regulatory and commercial plans

1H 2018

- IPO raising $82m on Nasdaq OMX ✓

2H 2018

- NefIgArd first patient in ✓
- Application for Orphan Drug Designation (ODD) for PBC submitted ✓
- Application for ODD for AIH submitted ✓

1H 2019

- Filing of Pediatric Investigational Plan submitted to EMA ✓
- Approval of ODD designation for PBC ✓
- Approval of ODD designation for AIH ✓

2H 2019

- EMA meeting to discuss surrogate marker ✓
- Fully recruited Part A of NefIgArd with 200 patients ✓
- China IND approval for Nefecon in IgAN, triggering $5mm milestone ✓
- EMA positive opinion regarding pediatric pathway for Nefecon in IgAN ✓

2020

- Topline readout of Part A of NefIgArd for 200 patients (4Q 2020)
- Initiate open-label extension trial for Nefecon in IgAN (4Q 2020)
- Complete recruitment of Part B of NefIgArd trial of additional 160 patients (2020)
- Initiate open-label chronic dosing trial for Nefecon in IgAN (2020)
- FDA meetings regarding regulatory pathway for PBC and AIH (2020)
- China part of phase 3 recruitment initiated (2020)
- In-licensing of a new project to the pipeline (2020)

2021

- NDA / MAA filings with FDA and EMA for accelerated / conditional approval of Nefecon in IgAN (1H 2021)
- Late stage clinical program initiated

2022

- Assuming regulatory approval, commercial launch of Nefecon for IgAN in U.S. (1H 2022)
- Readout of Part B of NefIgArd trial based on 360 patients for validation of surrogate marker to support full approval (2022)

Investment Overview

1. Novel treatment of IgA nephropathy (IgAN) with potential **disease modifying** effect
2. Clear path to market – FDA & EMA **supportive of accelerated / conditional approval**
3. Mode of action targets the **origin** of the disease – corroborated by Ph2b data analysis
4. **Only successful** placebo controlled, randomized Ph2b study in IgA nephropathy (150 patients)
5. Design of ongoing clinical Phase 3 study NEFIGARD **replicates Phase 2b**
6. Additional potential for **pipeline** development, in-licensing targeting orphan disease
7. Significant **unmet medical need** with USD 9-10bn market opportunity in USA alone, no approved drugs in Europe or the US

Questions