Q1 Report 2020

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Summary of key events Q1 2020

- EMA Paediatric Committee (PDCO) adopted a positive opinion on the Paediatric Investigation Plan (PIP) for Nefecon for the treatment of primary IgA nephropathy (IgAN).
- Board of Directors decided to explore a potential offering of the Company's securities in the US, via an IPO on NASDAQ
- The Company welcomes two new significant shareholders; Vivo Capital and Sofinnova Partners by way of a secondary purchase of shares from existing shareholders
- The Company held an Extra General Meeting where authorization for the board of directors to issue new shares for a potential equity offering and listing in the United States, adoption of new articles of association and adoption of a new incentive program were approved.

Covid-19

- A new coronavirus (Covid-19) is reported from Wuhan, China, showing lethal respiratory syndrome
  - In early January cases are reported from China, followed by Japan, Thailand, South Chorea, Hong Kong and Taiwan.
  - On January 30th the WHO declares the coronavirus outbreak as a Public Health Emergency of International Concern (PHEIC).
  - The virus spreads to the US and Europe and continues to sweep across the globe. Status on February 20th:
    - Total Countries With Confirmed Cases: 27 / Total Cases Confirmed Globally: 75,386
    - Total Deaths Worldwide: 2,129 / Deaths Outside of China: 11
  - Three weeks later on March 13th, status is:
    - Total Countries With Confirmed Cases: 121 / Total Cases Confirmed Globally: 142,095
    - Total Deaths Worldwide: 5,373 / Deaths Outside of China: 2,197
  - Italy becomes the largest cluster outside of China with devastating impact on death rate, followed by Spain and France.
  - The World Health Organization (WHO) on March 11, 2020, declared the novel coronavirus (COVID-19) outbreak a global pandemic.
  - In May the US reports over a million cases and over 80,000 deaths
  - Today there are over 4m cases established world-wide with over 290,000 deaths reported
  - The new virus seems poorly characterized understood with regards to its mode of action and has a very varied impact

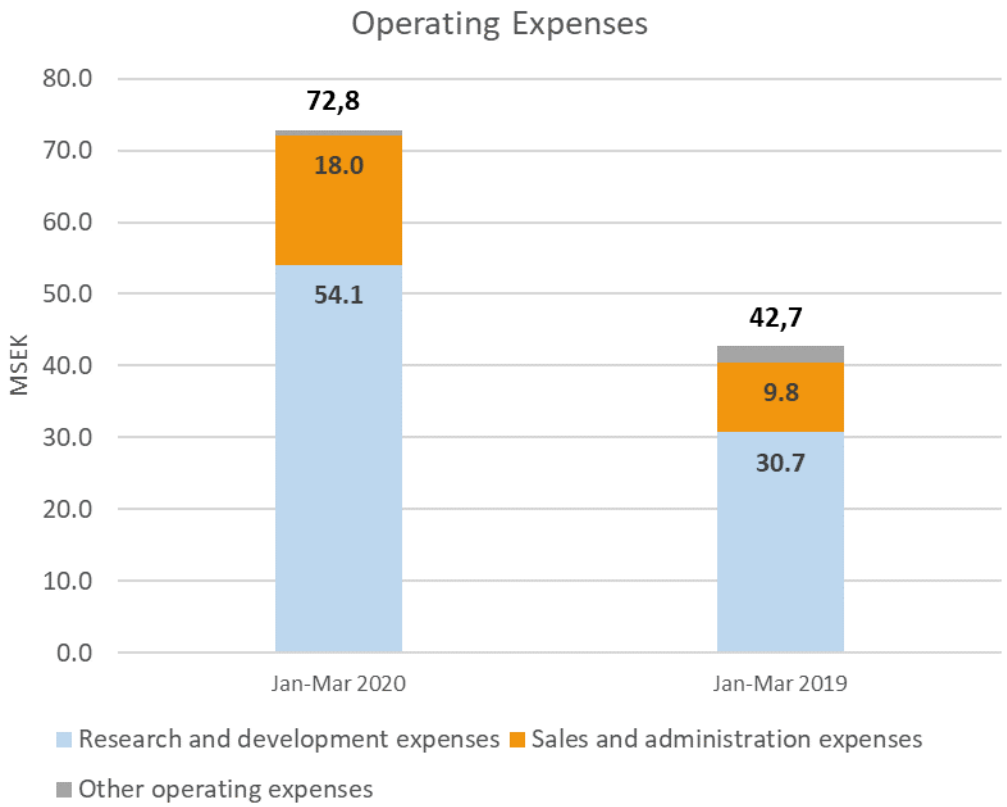
Covid-19 business impact in Q1

- Phase 3 study continuous to be on plan
  - Over 146 clinical sites activated and recruiting across 19 countries
  - Significant part of Q1 focused on analyzing potential impact of the virus across different geographic regions and putting mitigating solutions in place to ensure patient safety and trial integrity
  - Limited impact to date on NefIgArd:
    - Part A fully recruited in December 2019
    - Oral medication
    - Limited interaction with healthcare system
    - Successful implementation of strategy encompassing CRO, national co-ordinators and site staff to minimize potential impact
  - Helpful guidance received from regulatory bodies
  - Part B - based on recruited number of patients to date and recent increase in activities in China; full recruitment still planned to be completed before the end of the year

Post quarter events

- Dr Philipson recruited for CMO position, starting in early July
  - Strong background in orphan drug development (Head of GSK rare disease unit)
  - Recently managed FDA filing process of orphan drug candidate
  - Combination of big pharma experience and smaller biotech environment
- Press release issued on May 14th; company publicly files registration statement with SEC for proposed initial public offering in the United States
  - The potential Global Offering will not commence until the SEC and Nasdaq Global Market complete their respective review processes, and any such offering remains subject to market conditions and investor demand

Financial overview - first quarter 2020



- Revenues of SEK 0.5 M (-) from the delivery of Nefecon to China as part of the license agreement with Everest Medicines.
- Operating loss of SEK 72.3 M (42.7)
  - Research and development expenses increased to SEK 54.1 M (30.7), representing 74% of total operating expenses. Increase due to higher activity in the NeflgArd study and product development.
  - Sales and administrative expenses increased to SEK 18.0 M (9.8), mainly due to pre-commercial activities and related personnel costs in US.
- Cash flow from operating activities of SEK -18.8 M (-49.4) due to received 5 MUSD payment for Q4-19 China milestone.
- Cash position per end of March 2020, was SEK 728.6 M (596.9).

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
- FDA meeting regarding regulatory pathway for AIH
- China part of phase 3 recruitment initiated
- In-licensing of a new project to the pipeline

2021

- NDA / MAA filings with FDA and EMA for accelerated / conditional approval of Nefecon in IgAN (1H 2021)
- FDA meeting regarding regulatory pathway for PBC (Q1 2021)
- Late stage clinical program initiated
- Initiate open-label extended dosing trial for Nefecon in IgAN

2022

- 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)*

* Subject to uncertainty due to Covid-19 outbreak

Investment highlights

1. Nefecon is a proprietary, novel treatment for IgAN intended to be **disease modifying**
2. Nefecon targets the presumed **origin** of the disease – the area of the ileum where the highest concentration of Peyer's patches are located
3. Nefecon is the **most advanced** product candidate for IgAN. The **only successful** randomized, double-blind, placebo-controlled Phase 2b clinical trial carried out in IgAN to date
4. Ongoing pivotal Phase 3 clinical trial (NefIgArd) **using the same primary endpoint** as previous successful Phase 2b trial
5. Regulatory pathway based on discussions with FDA and EMA of our seeking accelerated / conditional approval based on proteinuria as **surrogate marker** for IgAN
6. **Significant unmet medical need** in IgAN with no currently approved treatments; total market opportunity of US$9-10bn in the U.S alone.
7. Additional potential for **pipeline development** and **in-licensing** of product candidates targeting orphan diseases

Questions