Q2 Report 2020

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Summary of key events Q2 2020

- In June, Calliditas completed an initial public offering on The Nasdaq Global Select Market in the United States for gross proceeds of approximately USD 90 million (SEK 828 million).
  - Became the first Swedish life science company to raise capital in an IPO on NASDAQ Select
  - Significant demand
    - multiple times oversubscribed
    - high quality US investors
  - Upsized deal from USD 75 M to 90M due to demand
  - 90% of deal placed with US investors
- In April, Calliditas appointed Dr. Richard Philipson as Chief Medical Officer (CMO)
  - Strong background in orphan drug development
  - Over 16 years at GSK, including Head and Acting CMO of GSK rare disease unit
  - Recently managed the FDA filing process of an orphan drug candidate for Trizell Ltd
  - 25 years of professional experience: combination of big pharma experience and smaller biotech environment
- Change in Board composition at the AGM in June; election of Molly Henderson to the Board of Directors.

Covid-19

- COVID-19 continues to create havoc across the globe
  - The World Health Organization (WHO) on March 11, 2020, declared the novel coronavirus (COVID-19) outbreak a global pandemic.
  - The virus has continued to spread across North and South America as well as in India
    - At the time of our last quarterly report we quoted numbers of 4 million cases; today this is in excess of 20 million
    - Total Deaths Worldwide at the same time were 290,000; today the tally stands at over 730,000
    - In May the US reported over a million cases and over 80,000 deaths; today those numbers are 5 million and over 160,000 respectively
  - The new virus seems to be more of a clotting disorder rather than a respiratory disease in general and continues to baffle the medical community, despite enormous resources being thrown at it.
  - However, slowly but surely science is making progress, and there has been a significant reduction in mortality.
    - Government backed initiatives into vaccines have exceeded $8bn already with an expectation that towards the end of the year, early next year, some parts of the world will have some kind of vaccine
    - Over 700 clinical trials are presently underway and more are being added on a daily basis

Covid-19 business impact in Q2

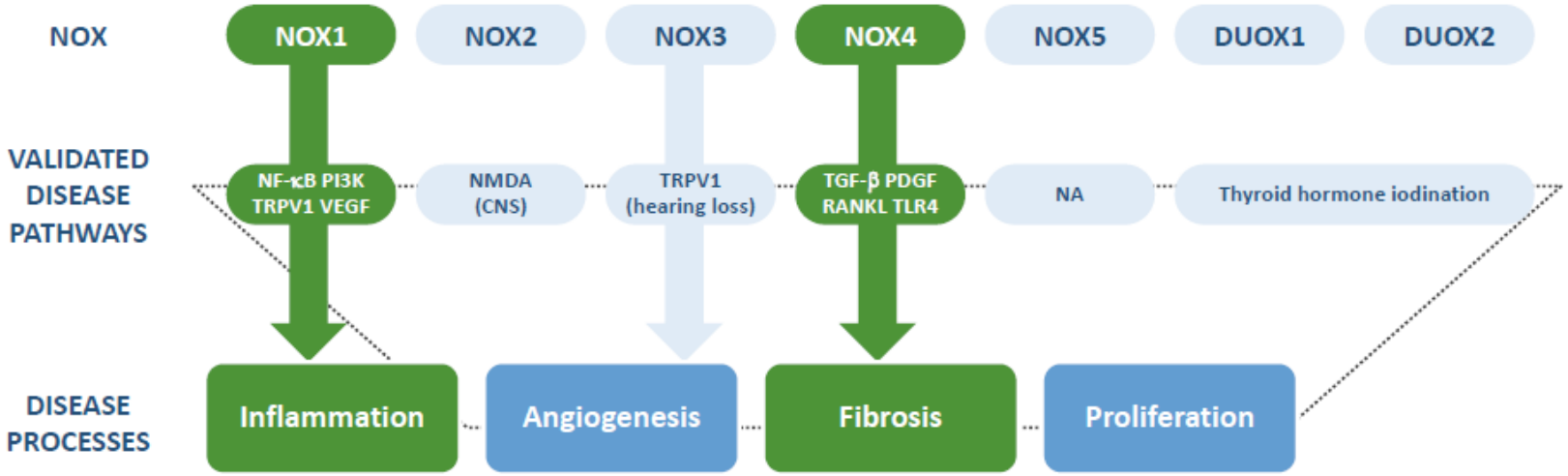
- Phase 3 study continues to be on plan
  - Over 146 clinical sites activated and recruiting across 19 countries
  - In Q2 continued focus on analyzing potential impact of the virus across different geographic regions and crafting mitigating solutions to ensure patient safety and trial integrity.
    - Significant improvement seen in June compared to April
  - 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:
    - Recruitment rate has been impacted in Q2, but improvements seen across Europe and Asia
    - Completion of recruitment still possible before the end of the year with China contribution, however the ongoing situation in the US is still a concern

Post quarter events

- Partial exercise of the greenshoe resulting in an additional capital infusion of USD 6.9 million (SEK 63 million)
- Research coverage initiated by Citi, Jefferies and Stifel in the US, significantly expanding research coverage
- Expansion of pipeline:
  - Announcement of agreement to acquire controlling stake in Genkyotex SA, followed by a mandatory simplified tender offer subject to closing of the controlling stake
  - €20.3m in total consideration at €2.80/share for 62.7% of the company
  - Contingent rights amounting to a total of €55M related to regulatory approvals of setanaxib within a 10 year period:
    - €30M for FDA approval,
    - €15M for EMA approval,
    - €10M for either IPF or type 1 diabetes approval by either FDA or EMA (unless milestone paid out as per above).
  - Following the closing of the control transaction, a simplified cash tender offer will be launched on the same terms for the remaining outstanding shares. The off-market block trade is expected to close in early October 2020.
  - Delivering on our communicated strategy; acquiring a late stage asset with orphan focus
    - Genkyotex's lead clinical candidate, setanaxib (GKT831), is in development for Primary Biliary Cholangitis (PBC), and in a Phase 2 trial demonstrated evidence of anti-fibrotic activity and significant impact on fatigue
    - Broad platform with potential to address inflammatory / fibrotic disease across a variety of indications
    - No significant impact on cash runway

NOX enzymes

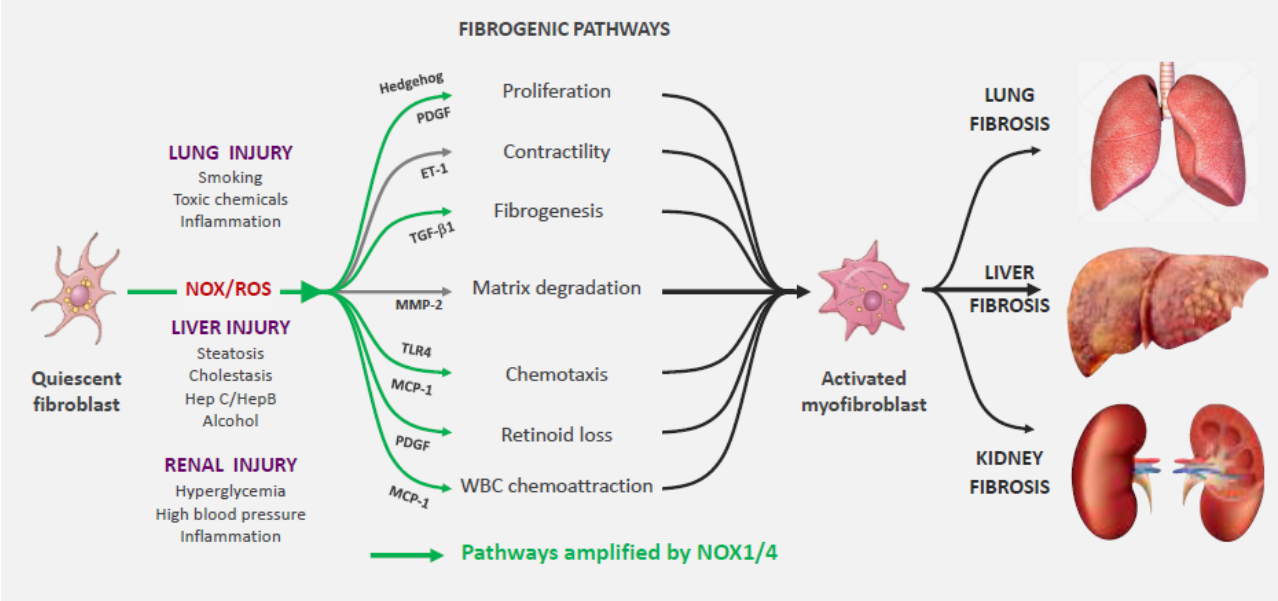
- NADPH oxidases (NOX enzymes) are critical mediators of both physiologic and pathophysiologic processes
- NOX enzymes catalyze NADPH-dependent generation of reactive oxygen species (ROS), including superoxide and hydrogen peroxide
- NOX enzymes are a family of seven (7) enzymes that amplify signalling pathways
- NOX 1 and NOX 4 are involved in inflammatory and fibrotic pathways, respectively



Sources: Altenhöfer et al Antioxid Redox Signal 2015 23(5):406-27; Genkyotex 2020 investor presentation; Xu et al, Bioorg Med Chem 2018 26(5):989-998

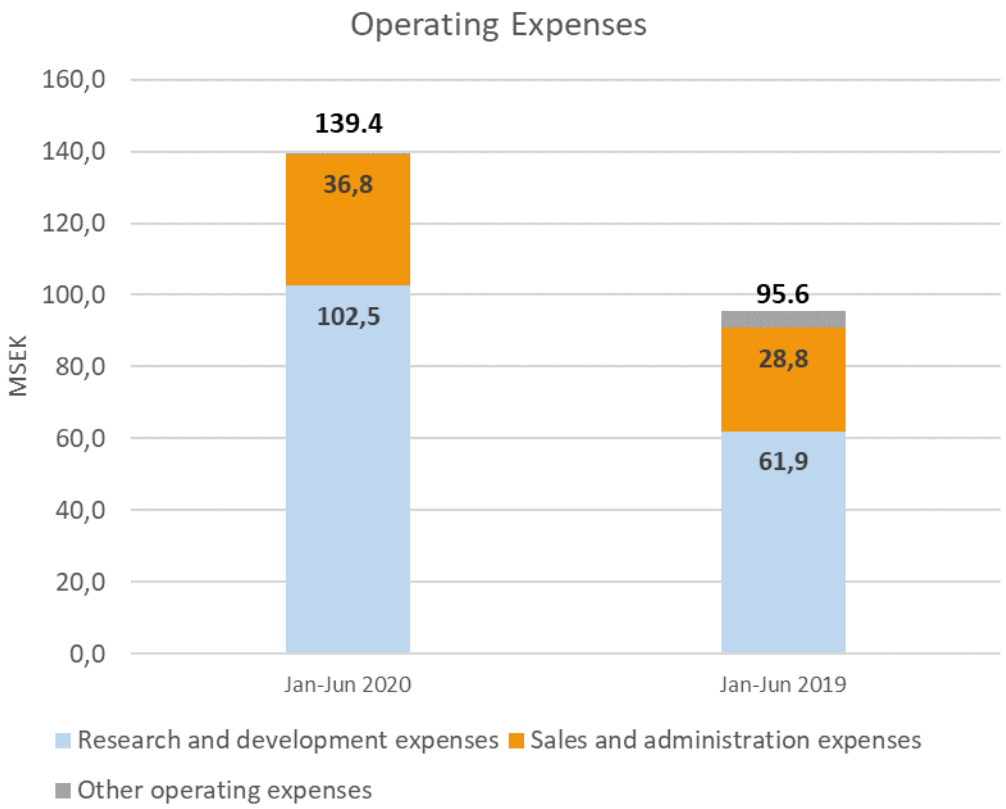
NOX enzymes and drug development

- Oxidative stress, an excess of ROS production vs. consumption, is involved in the pathogenesis of different diseases
- At appropriate concentrations ROS serve essential functions in cellular signalling processes of eg proliferation, differentiation, migration, vascular tone, immune response etc
- Enhanced activity of ROS production may cause systems to overreact and drive eg pathogenic inflammation and fibrosis
- NOX enzyme inhibitors are a class of very promising novel experimental drugs in redox pharmacology
- Inhibitors of NOX 1 and NOX 4 are relevant therapeutic agents for inflammatory and fibrotic diseases, an area of high unmet medical need
- NOX pharmacology is a developing field with approx 1,500 peer reviewed reports the past 10 years (PubMed)



Sources: Altenhöfer et al Antioxid Redox Signal 2015 23(5):406-27; Genkyotex 2020 investor presentation; Xu et al, Bioorg Med Chem 2018 26(5):989-998

Financial overview – First six months of 2020



- Revenues of SEK 0.5M vs SEK 138.2M for the same period last year.
- Operating profit/(loss) of (SEK 138.9M) vs SEK 42.7M
  - Research and development expenses increased to SEK 102.5M vs SEK 61.9M, 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 36.8M vs SEK 28.8M, mainly due to increase in pre-commercial activities and expenses in connection with the June NASDAQ listing.
- Cash flow used in operating activities was SEK 85.8M vs SEK 108.7M, due to receipt of USD 5M payment in Q1 for Q4 2019 China milestone.
- Cash position per end of June 2020 was SEK 1,459.6M vs SEK 534.9M. The increase is due to the cash flow from financing activities of SEK 777.7 M primarily from the Nasdaq IPO.

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*

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

2021

- NDA / MAA filings with FDA and EMA for accelerated / conditional approval of Nefecon in IgAN (1H 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 the 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