calliditas
THERAPEUTICS

Q2 2021 REPORT

August 19, 2021

Disclaimers

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Clinical Activities

Clinical Candidate	Indication / Trial	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Phase 4 / Marketed[1]
Nefecon	IgAN/ NefIgArd					
Setanaxib	PBC					
Setanaxib	Oncology					
	Kidney					
Setanaxib (ILS)	IPF					
	DKD					
Nefecon	IgAN Open Label Extension[1]					

Depicts ongoing/planned clinical trial stage: Depicts ongoing/planned clinical trial stage in an Investigator Lead Study:

1. Clinical study primarily supporting healtheconomic and / or treatment related considerations

Q2 Highlights - Regulatory Interactions

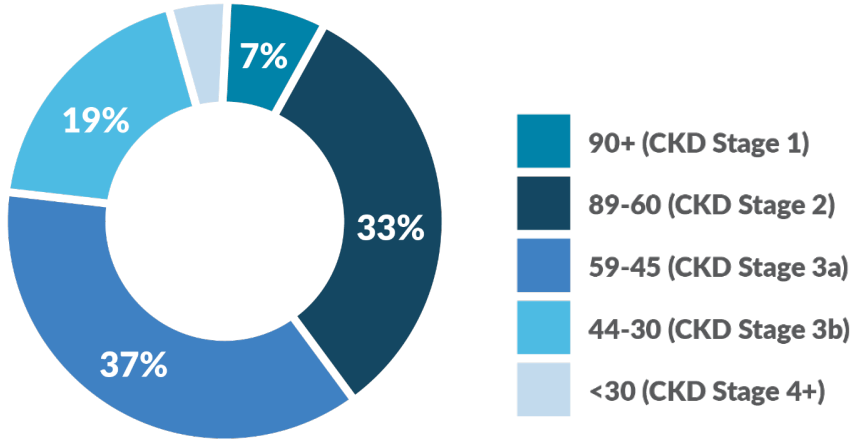
- Filed an MAA with EMA for conditional approval on May 28th
  - Were granted accelerated review on April 23rd
  - First round of questions expected in Q3
- Ongoing Q&A with the FDA regarding NDA filed in Q1, PDUFA target date is September 15th, 2021
- First ever submission for approval in IgAN, both regulatory processes on accelerated basis
- Looking forward to engaging with EMA

Other Activities in Q2, 2021

- Significant investments in resources and pre-commercial activities in the US
  - Continuing to prepare for commercial readiness by PDUFA date – medical affairs, market access, marketing & commercial
- Execution focus across all divisions of the business
  - Medical & Clinical - NefIgArd, OLE, preparations for Phase 2/3 study in PBC & head and neck cancer proof of concept trial in 2H
  - CMC & Supply - commercial supply of Nefecon for Q4 & study supply of setanaxib in 2H
  - Regulatory - interactions with regulators
  - G&A - recruitment & training, systems and processes, contracting etc
- Competitive processes to secure non-dilutive access to capital and European commercial partnership.

Market Opportunity

- Spherix Global Insights – 468 IgAN patient chart audit conducted this year; encouraged by the market size
- IgAN patients, on average:
  - **70% :** Arrive upon referral in CKD stage 2 or 3a
  - At most recent visit, the majority have progressed to CKD stage 3a or 3b



- The majority of patients are on Supportive Care (ACE / ARB):
  - **>50% :** Already on ACE/ARBs at the time of referral
  - **88% :** Are on an optimal dose, per nephrologists
- Physicians
  - See patients on average **3.1 times a year**
  - Conduct at least one lab test annually (eGFR and urinalysis) for **99.8% of patients**
  - Prescribe on average **4.9** medications concomitantly
  - Consider **proteinuria and especially eGFR** to have the most value in clinical trials

Commercial Launch Readiness

MARKET ACCESS PREPARATIONS

- Minimizing barriers to market access
- Trade/distribution partners are established
- National Account Managers calling on payers

DISEASE AWARENESS CAMPAIGN LAUNCH

SALES FORCE READINESS

- Sales leadership onboarded
- In preparation for 40 sales territories to provide appropriate reach and frequency

Post period events

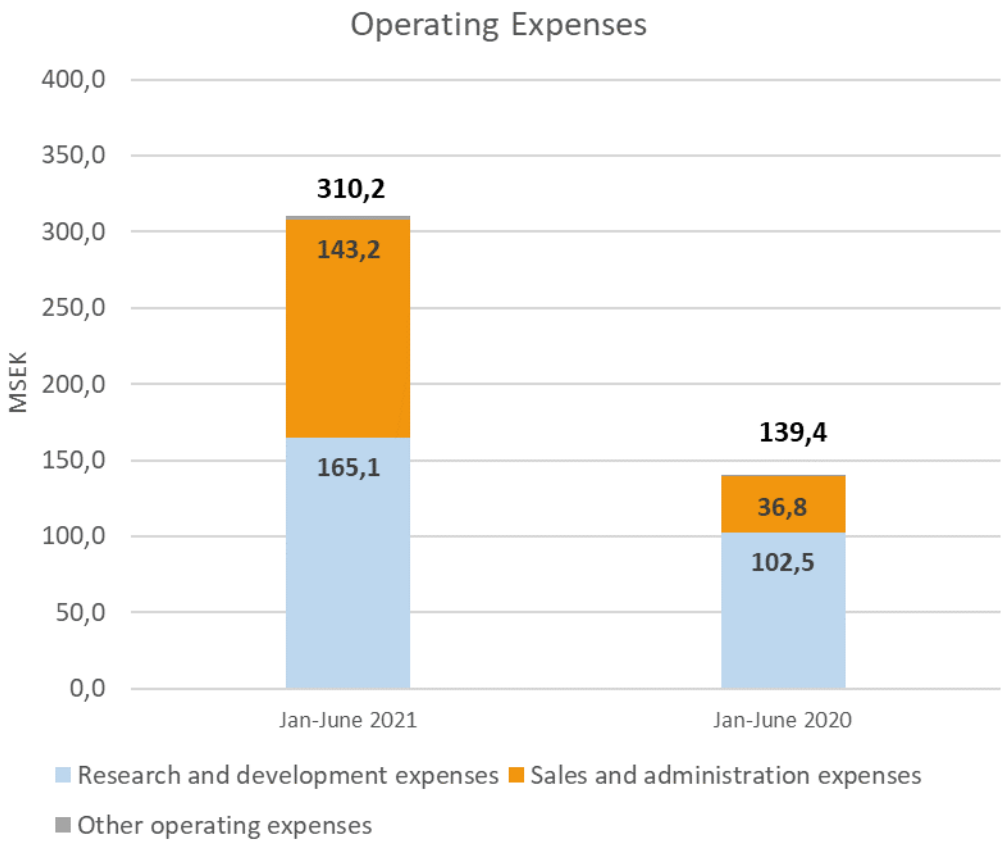
- **JULY 15th –** Signed agreement with Kreos Capital regarding credit line of $75m
  - Initial $25m available post signing
- **JULY 21st –** European partnership of €97.5m announced with STADA Arzneimittel AG
  - €20m upfront payment
- **AUGUST 13th –** Accelerated book build, raising SEK 324m of gross proceeds ($37m), less than 5% dilution and less than 5% discount to close, 90 day lock up
- Collectively ensures that the company has access to significant capital both on a pre commercial, as well as a post launch basis
  - Strong financial position mitigates potential concern regarding need to raise capital in conjunction with potential approval on target PDUFA date as well as any macro impact / market risk in 2H

Summary Overview

- **Successful Phase 3 study -** Read out positive Phase 3 data in November, 2020.
  - Presented overall profile of study population, primary endpoint (reduction of proteinuria) and secondary endpoint (eGFR) as well as overall safety profile.

- **Regulatory –** Filings for approval accepted by both the FDA and EMA
  - Filed for accelerated approval in March 2021, with priority review granted in April, 2021. Presently engaged in regulatory review. Target PDUFA date September 15, 2021.
  - Filed with EMA for conditional approval in May, 2021. Accelerated assessment granted. Target date for opinion Q4, 2021.
    - Both filings accepted and being reviewed on an accelerated basis
    - FDA has communicated need for supportive eGFR data
    - Differentiated mode of action, targeting the origin of the disease – potential for disease modification
    - Robust data package addressing a significant unmet medical need
    - Significant lead over other development programs

Financial overview – first six months 2021



- No revenues during the period vs SEK 0.4 M for the same period last year.
- Operating loss of SEK 310.2 M vs SEK 138.9 M
  - Research and development expenses increased to SEK 165.1 M vs SEK 102.5 M, representing 53% of total operating expenses. Increase due to higher activity in the NefIgArd studies and preparations for the setanaxib trials.
  - Administration and selling expenses increased to SEK 143.2 M vs SEK 36.8 M, mainly due to intensified preparations for commercial and medical affairs activities in the US.
- Cash flow used in operating activities was SEK 267.1 M vs SEK 85.8 M.
- The cash position per end of June 2021 was SEK 709,3 M vs SEK 1,459.6 M.
- Additional capital made available after the close of the period