

Q3 Report 2019

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Summary of key events Q3 2019

- FDA approved revised design for the confirmatory part of Phase 3 – Part B
 - More sensitive endpoint
 - Reduced size and duration of the Part B of the study – now 360 patients required in total
 - Overall study reduced from a maximum of 6 years to under 4 years
 - All patients will only need to stay in the study for 2 years
 - Possibility to offer a roll-over study for patients completing Part A
 - Part A unchanged, read out expected in 2H 2020; full approval in 2022
- Directed share issue completed for SEK 210 million.
 - Included Biotechnology Value Fund, BVF Capital Partners, a US based specialist life sciences investor
 - Provides company with the flexibility to fund additional clinical trials
 - A total of 3.5 million shares issued at SEK 60

Summary of key events Q3 2019

- Roll over study planned to initiate in Q4 2020
 - First patient exits the trial and become eligible for enrollment in Q4 202
 - Ability for all eligible patients to receive treatment with Nefecon, subject to the recommendation by physician
 - Allows placebo patients to be treated with the study drug
 - Ability to collect additional data regarding re-treatment interval
- Recruitment for Phase 3 study continuous to be on plan
 - Over 140 clinical sites activated and recruiting across 19 countries
 - Based on average screening numbers and conversion rates seen in the study to date, recruitment can be completed before the end of the year

Post quarter events

- EMA issues advice which is supportive of conditional approval
 - Significant step forward in Europe
 - Market access planned for 2022
 - Orphan indication with no approved medications; positioned to be first approved drug on the market
- IQVIA report on US market completed
 - Third party survey of KOLs and nephrologists
 - Reimbursement / Payor information
- Capital markets day on November 4th
 - Broad agenda covering the main events announced by the company year to date
 - KOL attendance with focus on disease pathogenesis and treatment paradigms

Market Landscape Research – conducted with IQVIA



- Qualitative interviews:
 - 8 payers covering MCO, PBM, IDN, and FFS for organizations/plans covering over 225 million US lives
 - Major national and regional payer organizations representing commercial, Medicare, and Medicaid lives
 - 12 Nephrologists representing academic centers, community hospitals and private practices that treat a minimum of 10 IgAN patients per month
- Quantitative research/survey:
 - 102 Nephrologists that, on average, treat 14 IgAN patients per month
 - Geographically diverse/spread throughout the US
 - Academic centers, community hospitals, and private practice – all well represented

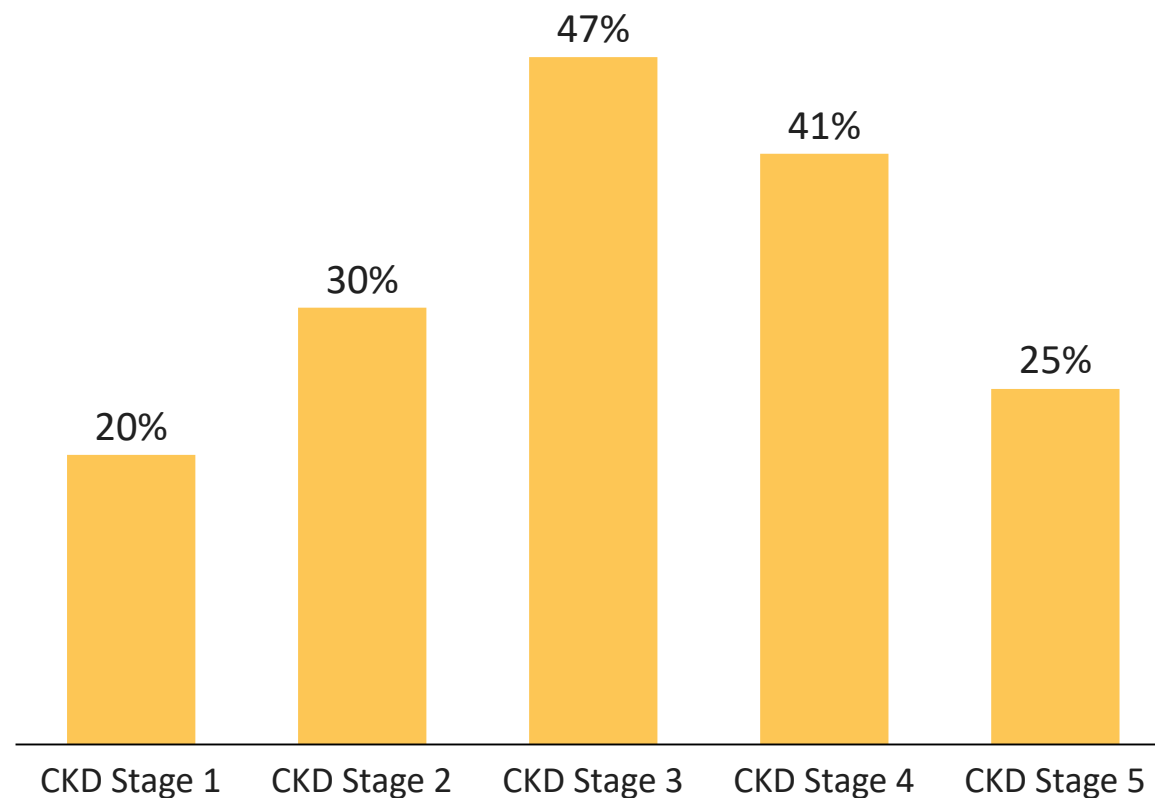
Nephrologist Summary: Opportunity

- Very favorable opinion of Nefecon upon exposure to Phase 2B trial results across settings of care
- Survey results suggest that the introduction of Nefecon treatment paradigm reduces share of glucocorticoids and immunosuppressives
- Nephrologist perceptions of Nefecon improve with knowledge that budesonide is the active ingredient
- Opportunity to further educate Nephrologists on the connection between Peyer's Patches and IgA Nephropathy
- There is a disconnect between patient experienced impact of adverse events of systemic steroids and Nephrologist perceptions
- Education can lead to earlier diagnosis and treatment

Nephrologist Summary: Perception of Nefecon

- Product profile shown to Nephrologists reflected the Phase 2B, Nefigan Trial, results
- The majority of Nephrologists indicated they would:
 - Prescribe Nefecon for their IgAN patients within the first year of being on the market (68%)
 - Prescribe Nefecon as the first agent after, or in conjunction with, ACEs/ARBs
- 75% of Nephrologists indicated a neutral or more favorable opinion when learning the active ingredient in Nefecon was budesonide
- Assuming no tolerability issues, half of nephrologists indicate an interest in continuing use of Nefecon past its initial 9 month course

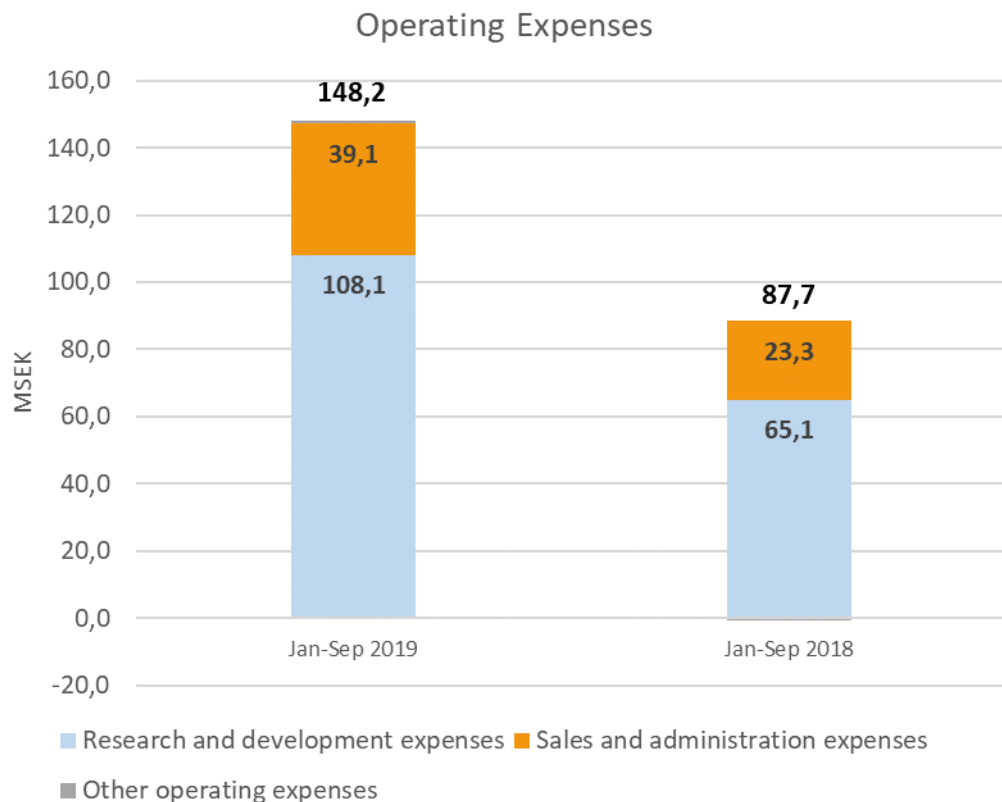
- Of existing patients, Nephrologist anticipate Nefecon would be appropriate for:



Payer Summary: Perception of Nefecon

- Clinical results (Phase 2B) were strong and make sense to get approval on surrogate marker
- Would like to know what treatment to expect after the first 9 months, eager to see longer term effect
- Didn't anticipate managing too differently – as long as the price remained within the broad range of \$55 – 85k per year. Restrictions are standard to specialty products and include:
 - Prior authorization to label
 - Prescribed by Nephrologist
 - Confirmation of IgAN diagnosis through renal biopsy
 - Step to ACE/ARB
 - Tier 3~4 placement
- Opportunity to strengthen Nefecon's value proposition by leveraging:
 - KOL guidance and endorsements
 - Health-economic benefit related to cost effectiveness of Nefecon vs. cost of dialysis/kidney transplant
 - Additional clinical data related to the degree of sustained efficacy and tolerability post course of Nefecon

Financial overview of the period Jan-Sept 2019



- Revenues of SEK 138.2 M (-) from the upfront payment of the China out-licensing deal (USD 15m) in Q2.
- Operating profit (loss) of SEK -10.0 M (-87,7)
 - Research and development expenses increased to SEK 108.1 M (65.1), representing 73% of total operating expenses
 - Sales and administrative expenses increased to SEK 39.1 M (23.3), due to pre-commercial activities in the US and China deal related transaction cost.
- Cash flow from operating activities of SEK 83.1 M (-25.6). The USD 15 M payment from the China out-licencing deal was received during Q3.
- The cash position per end of September 2019, was SEK 805.1 M (685.9), since net SEK 200.1 M was received from the Q3 direct share issue.

Going forward: focus on Nefecon program & project pipeline

Ongoing updates regarding commercial strategy and plans

H1 2018	H2 2018	H1 2019	H2 2019	H1 2020	H2 2020	2021	2022
<ul style="list-style-type: none"> • IPO raising \$82m on Nasdaq OMX <input checked="" type="checkbox"/> 	<ul style="list-style-type: none"> • NEFIGARD first patient in <input checked="" type="checkbox"/> • Application for ODD for second indication submitted <input checked="" type="checkbox"/> • Application for ODD for third indication submitted <input checked="" type="checkbox"/> 	<ul style="list-style-type: none"> • Filing of Pediatric Investigational Plan submitted to EMA <input checked="" type="checkbox"/> • Approval of ODD designation for second indication <input checked="" type="checkbox"/> • Approval of ODD designation for third indication <input checked="" type="checkbox"/> 	<ul style="list-style-type: none"> • EMA meeting to discuss surrogate marker <input checked="" type="checkbox"/> • 200 patients recruited • In-licensing of additional product <input checked="" type="checkbox"/> • Out-licensing of major territory rights <input checked="" type="checkbox"/> • FDA interaction enhancing Part B design <input checked="" type="checkbox"/> 	<ul style="list-style-type: none"> • Clinical trial initiation of chronic dosing study with Nefecon • EMA decision regarding pediatric pathway • FDA meeting regarding regulatory pathway for AIH indication • Response from NMPA re: China clinical trial 	<ul style="list-style-type: none"> • Top line read out for 200 patients • Study fully recruited • Initiation of roll-over study for re-treatment 	<ul style="list-style-type: none"> • Filing with regulatory agencies for market approval • Open study results of chronic / repeat dosing trials 	<ul style="list-style-type: none"> • Commercial launch of Nefecon in H1 • Analysis based on 360 patients for validation of surrogate marker

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 2bn market opportunity in USA alone, no approved drugs in Europe or the US



Questions