Q3 Report 2018

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Calliditas Therapeutics in brief

Company overview

- Calliditas is a specialty pharmaceutical company focused on developing high value pharmaceutical products for patients with IgA nephropathy – an orphan chronic autoimmune disease
- Lead product candidate Nefecon is an optimized oral formulation of budesonide with a unique and disease specific release profile
- Phase 3 study NefIgArd initiated and enrolling in H2 2018
- Top line read out and filing with regulatory agencies financed after successful IPO in June 2018
- Headquartered in Stockholm, 19 co-workers

Summary of key events Q3 2018

- Cash received from IPO and exercise of green shoe
  - SEK 650m before fees raised on main market of Nasdaq Stockholm, midcap list
  - Green shoe of SEK 89m before fees received end of July, 2018
- Phase 3 study initiated
  - Study approval requests to the remaining 10 countries sent out in July – 13 countries approved at end of Q3.
  - Inititation visits carried out at 17 sites during the quarter, required equipment being delivered to sites to enable sample collection as per protocol
  - Screening period is approximately 3-4 weeks
- IIgANN symposium in Buenos Aires saw over 210 attendants from China, North America, Japan and Europe. Several oral presentations relating to data from Phase 2b study. Mode of action supported by circulating complexes reduced in treatment arms – dose related response.
- Expecting to be able to publish additional biomarker data in 2019

Post period highlights

- Participated in Morgan Stanley bus trip in October
- Invited to present at Stifel New York conference in November
- Over 60 sites fully contracted to date
- Approvals from 15 countries received to date, approvals by all countries expected before the end of the year
- Initiation visits continuing; over 30 sites initiated as of end of October
- PIP initiated and work is progressing as planned
- ODD submission for a second indication progressing as planned

Our main indication: IgA nephropathy – large unmet medical needs

PROFILE

- Genetic predisposition – not sufficient but necessary. Environmental, bacterial, dietary triggers.
- Incidence estimated at 2.5 per 100,000 - For the US market corresponding to approximately 6,000-7,000 new cases each year
- Normally presents in the 20-30s – more prevalent in men than in women

ESTIMATED PREVALENCE

MAIN MARKET		**130,000-150,000**
		**200,000**
POTENTIAL MARKET OPPORTUNITIES		**~2,100,000**
		**~190,000**

Development program is regulatory agreed and de-risked

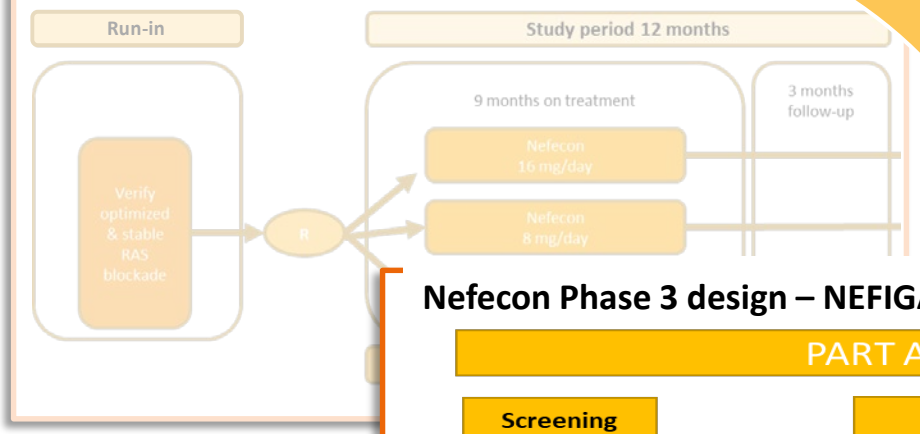
Proteinuria – Accepted by FDA as surrogate marker for Phase 3 and accelerated approval…

…supported with post-approval outcome data based on eGFR endpoint

- → Clear strategy for the further development and approval of Nefecon from end of Phase 2b meetings
- → The first company to receive acceptance by the FDA to use proteinuria as Phase 3 endpoint for approval
- → The opportunity to become the first drug to be approved for this indication – safe, efficient and convenient
- → FDA and all major European countries have accepted Phase 3 design and protocol

Clinical Phase 3 study NEFIGARD to confirm Phase 2b results

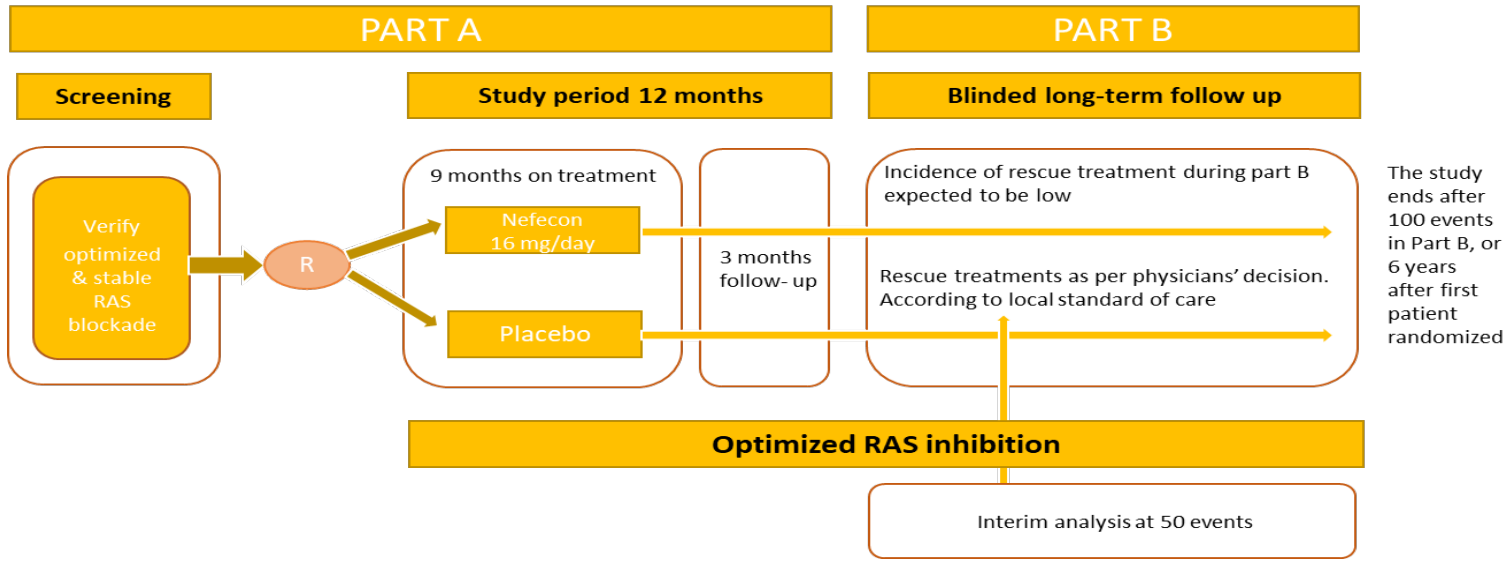
Nefecon Phase 2b design



Key highlights

- Phase 3 study design replicates successful Ph2b
- 200 versus previous 150 patient population
- Fixed 16mg Nefecon once daily oral dose
- Only Phase 2b study to be successful in this indications

Nefecon Phase 3 design – NEFIGARD

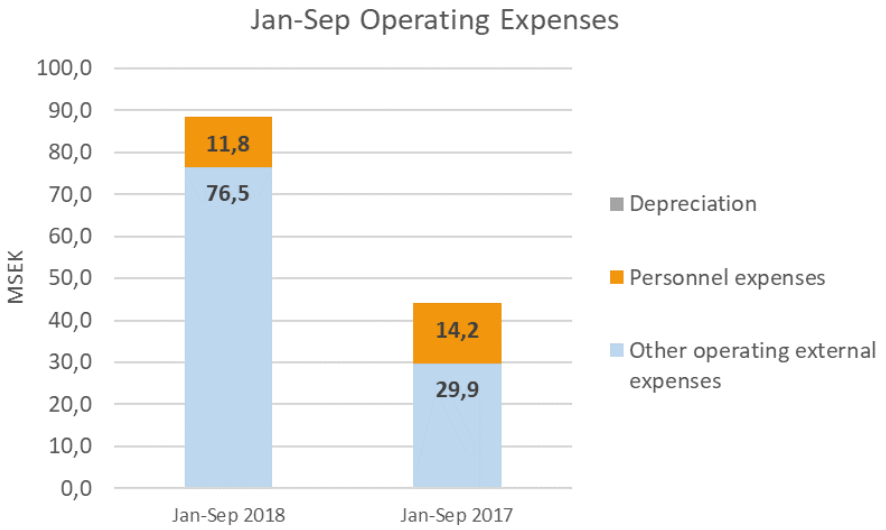


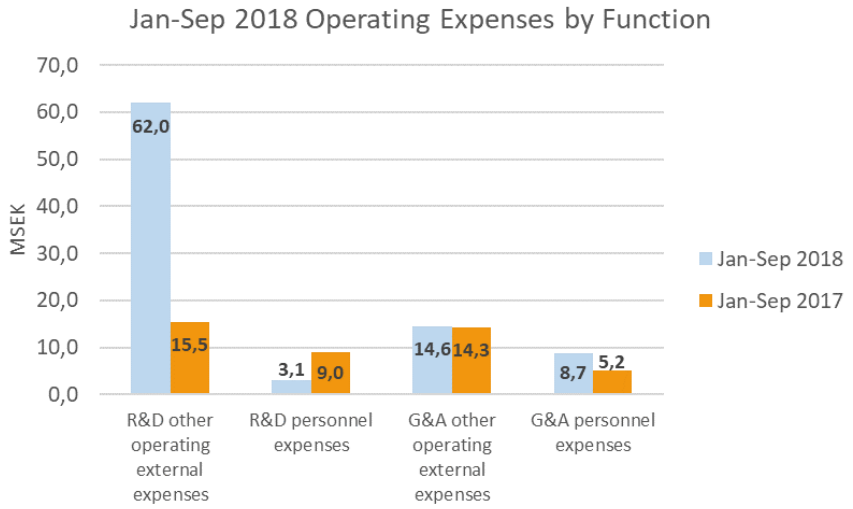
Going forward: full focus on the Nefecon program

Ongoing updates regarding commercial strategy and plans

H1 2018	H2 2018	H1 2019	H2 2019	H1 2020	H2 2020	H1 2021	H2 2021
• Filing of new patent application related to Nefecon ☑	• NEFIGARD first patient • Pediatric investigational plan submitted to EMA • Application for ODD for second indication submitted	• FDA response regarding regulatory path proposal for pipeline asset • Publication of new data from exploratory studies from Phase 2b in major scientific publication • Approval of ODD designation for second indication	• EMA decision regarding pediatric pathway • FDA / EMA meetings regarding regulatory pathway for second indication	• Part A fully recruited	• Top line data 200 patients • Study fully recruited • Filing with regulatory agencies	• Enrolment first patient in treatment modality trials / label expansion	• Interim analysis based on 450 patients

Financial overview of the period Jan-Sep 2018





- Operating loss increased to SEK -87.7 M (loss: -44.0)
  - Personnel expenses decreased to SEK 11.8 M (14.2). Credit received in Q1 of SEK 1.5 M on payroll tax attributable to R&D.
  - Other operating expenses increased to SEK 76.5 M (29.9) due to the initiation of the NeflgArd study.
- Cash flow from operating activities decreased to SEK -85.7 M (- 41.4).
- Net cash from IPO of SEK 684.2 M received in July.
- Net cash flow for 9m was SEK 628.6 M (-2.2).
- The cash position per end of Sep 2018, was SEK 685.9 M (22.0).

Calliditas Summary

1. Novel disease modifying treatment of IgA nephropathy (IgAN)
2. Clear path to market – FDA acceptance of proteinuria as surrogate marker
3. Mode of action targets the origin of the disease – supported by biomarker data
4. Only successful Ph2b study in IgA nephropathy (150 patients)
5. Design of upcoming clinical Phase 3 study NefIgArd replicates Phase 2b to maximize probability of success
6. Strong product protection and product exclusivity position
7. USD 1bn orphan market opportunity with no approved treatments today
8. Additional potential for Nefecon in liver disease

Questions