

Q4 Report 2018

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Investment Overview Calliditas

- 1 Novel treatment of IgA nephropathy (IgAN) with potential **disease modifying** effect
- 2 Clear path to market – FDA acceptance of proteinuria as **surrogate marker**
- 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 The 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 1bn market opportunity, no approved drugs



Summary of key events Q4 2018

- First patient enrolled in the global Phase 3 study, Nefigard
 - No clear impact to date of competing studies recruiting in the indication
 - Site initiations on plan
- Phase 3 study on plan
 - Sites initiated – 84 in total
 - Screening pipeline building according to plan
- Competition: read-out of Omeros Phase 2 placebo controlled trial did not meet primary end point / Reata selected to take ADPKD into Phase 3 / Retrophin initiated its Phase 3 trial with hypertension agent

Post period highlights

- Received ODD in AIH from the FDA
- Study approval in 18 of the 19 countries; Over 60% of the global sites activated
- PIP related work is progressing, filing expected in Q1
- Dr Bringstrup, VP regulatory, and Mr Udell, VP commercial North America, joined the leadership team
- National co-ordinators in place

Autoimmune Hepatitis (AIH)

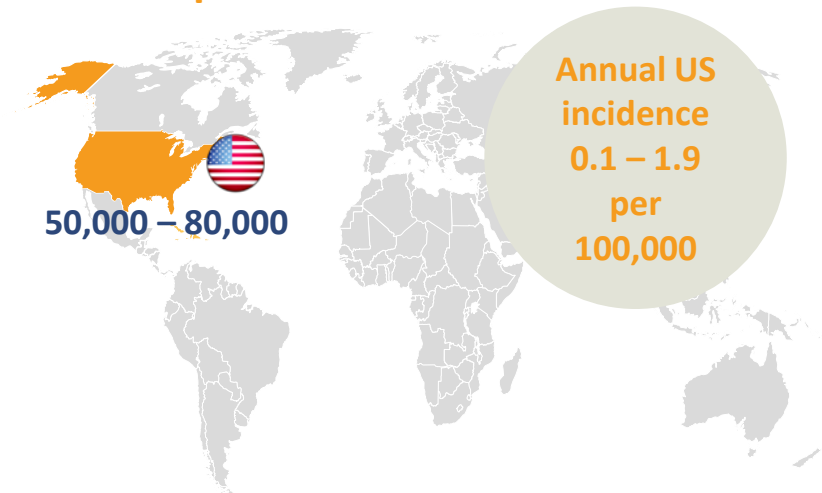
The disease¹

- A rare, orphan, chronic inflammation of the liver
- The cause is unknown
- Leads at variable rates to cirrhosis with complications like portal hypertension, liver failure and liver cancer
- Sparse epidemiology data from US: estimated prevalence of 50,000 – 80,000.

Standard of care³

- Currently no products approved in the US
- Care treatment includes immunosuppression with systemic steroids (prednisone) alone or in combination with azathioprine
- Up to 80% of treated patients report steroid related side effects after 2 years and 15% discontinue due to drug related adverse events
- Calliditas estimates the intolerance and relapse segments together comprise 35-40% of the total population, or approximately 25,000 patients in the US

Estimated prevalence²



Autoimmune Hepatitis (AIH) (cont'd.)

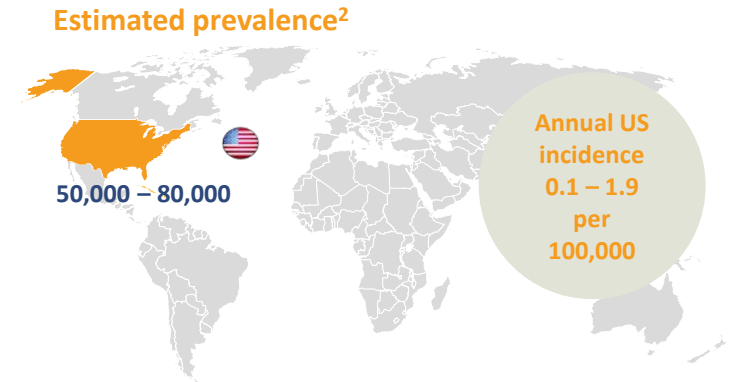
Nefecon as a treatment for Autoimmune Hepatitis

Regulatory pathway to product registration

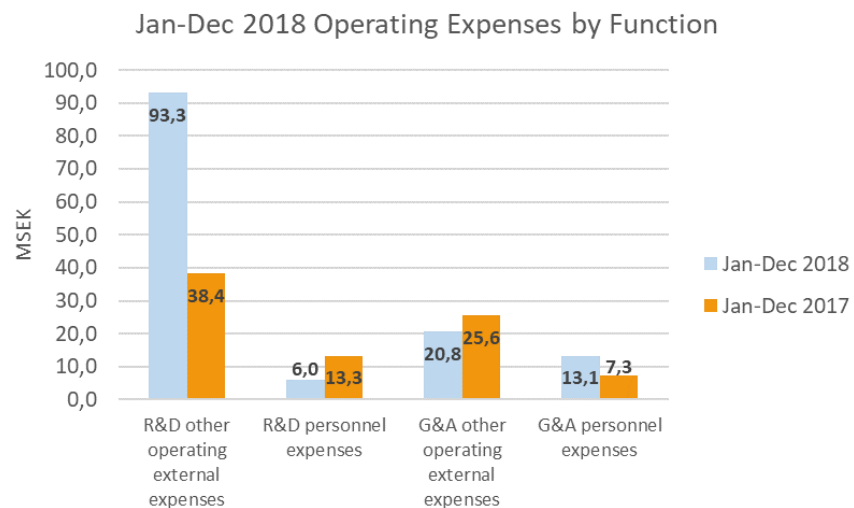
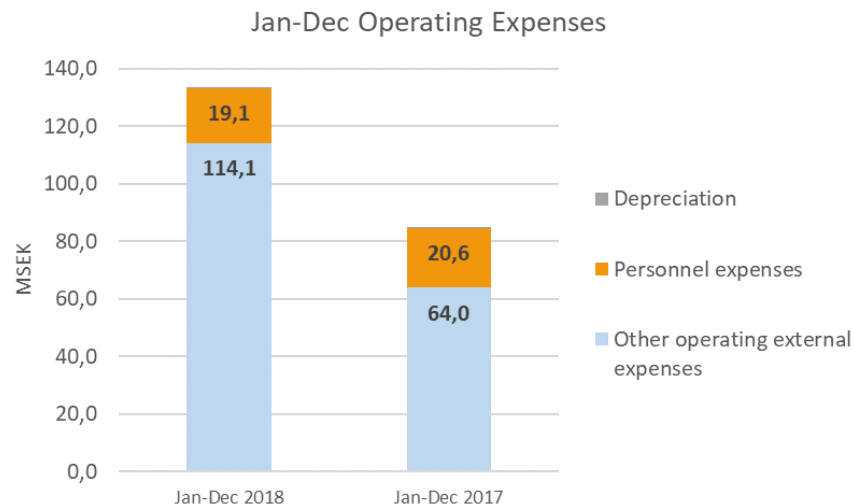
- Calliditas anticipates that the regulatory pathway to registration for AIH would be similar to that of Nefecon for IgA nephropathy
- The Company anticipates biochemical markers of liver disease would be acceptable as surrogate endpoints in an accelerated approval procedure where the clinical outcome would be prolongation of time to cirrhosis and/or prevention of progression of cirrhosis

Environment

- Would provide a familiar treatment option built on immune suppression in an autoimmune disease to provide an at least equal efficacy combined with a significantly safer option to systemic steroids
- There are a small number of therapies in clinical development for AIH, which include compounds from Conatus Pharmaceuticals, TaiwanJ Pharmaceuticals and BioIncept¹








Financial overview of the period Jan-Dec 2018



- Operating loss of SEK -132.5 M (loss: -84.5)
 - Personnel expenses decreased to SEK 19.1 M (20.6). Credit received in Q1 of SEK 1.5 M on payroll tax attributable to R&D.
 - Other operating expenses increased to SEK 114.1 M (64.0), due to the start of the NeflgArd study.
- Cash flow from operating activities of SEK -128.2 M (- 68.0).
- Net cash from IPO of SEK 684.2 M received in July.
- Net cash flow for 2018 was SEK 588.4 M (33.2).
- The cash position per end of Dec 2018, was SEK 646.2 M (57.4).

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	H1 2022
<ul style="list-style-type: none"> Filing of new patent application related to Nefecon  	<ul style="list-style-type: none"> NeflgArd first patient in  Application for ODD for second indication submitted  Application for ODD for third indication submitted  	<ul style="list-style-type: none"> Filing of Pediatric Investigational Plan submitted to EMA Approval of ODD designation for second indication  Approval of ODD designation for third indication 	<ul style="list-style-type: none"> EMA decision regarding pediatric pathway FDA / EMA meetings regarding regulatory pathway for second indication Publication of new data from exploratory studies from Phase 2b in a major scientific journal 	<ul style="list-style-type: none"> NeflgArd Part A fully recruited 	<ul style="list-style-type: none"> Top line data NeflgArd 200 patients NeflgArd study fully recruited 	<ul style="list-style-type: none"> Enrolment first patient in treatment modality trials / label expansion Filing with regulatory agencies 	<ul style="list-style-type: none"> Interim analysis based on 450 patients

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Questions