Q1 Report 2019

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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. 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 1bn market opportunity, no approved drugs

Summary of key events Q1 2019

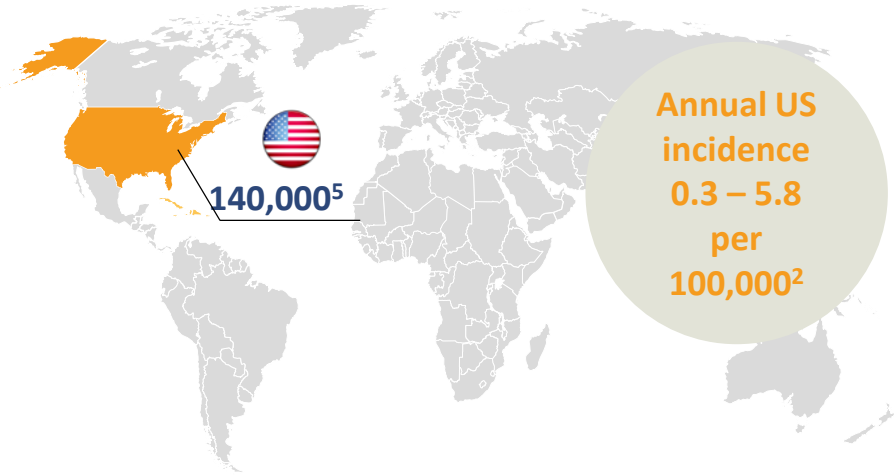
- Phase 3 study on plan
  - Study approved in all 19 countries
  - Patients randomized in all geographic regions
  - Sites capped at 143, 134 sites initiated
  - Screening pipeline building according to plan
- ODD awarded in AIH and PBC
  - AIH – significant unmet medical need – similar issues as IgA nephropathy
  - Some PBC (NASH) trials have disappointed recently, opportunity for safe and efficacious anti-inflammatory compound
- Senior staff added
  - Andrew Udell, VP Commercial North America
  - Dr Frank Bringstrup, VP Regulatory
  - Dr Krassimir Mitchev, VP Medical Affairs

Primary Biliary Cholangitis (PBC)

The disease[1]

- A progressive chronic autoimmune disease of the liver
- The bile ducts are destroyed by inflammatory processes, bile accumulates in the liver causing an increase in the liver volume (cholestasis)
- If untreated, the active liver tissue is destroyed and replaced by fibrous tissue, cirrhosis and liver transplant
- Early symptoms include fatigue, itchy skin and dry eyes/mouth. Later stages - liver stiffness, musculoskeletal pain, edema, jaundice and underactive thyroid

Estimated prevalence



Standard of care

- Ursodeoxycholic acid (UDCA) and obeticholic acid (Ocaliva) are the only FDA-approved medical treatments for PBC[3]
- Approximately 40% of patients do no respond to UDCA, Ocaliva has had issues with side effects (pruritus)
- No targeted anti-inflammatory therapy is registered in the US or Europe
- Previous trials indicates that corticosteroids may alleviate symptoms and improve biochemical and histologic findings[4]

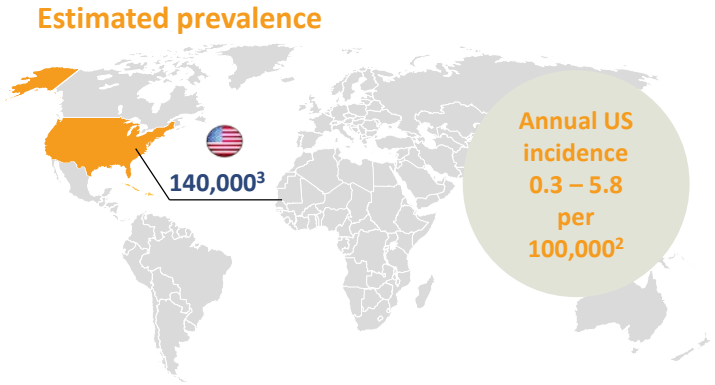
Sources: 1) Lindor et al, Hepatology. 2009 Jul;50(1):291-308,EASL PBC Clinical Practice Gudielines, Journal of Hepatology 2017; 67:145–172. 2) Nguyen et al, Best Pract Res Clin Gastroenterol 2010; 24(5): 647–654. 3) Kim et al, Gastroenterology 2000;119:1631–1636). 4) EASL PBC Clinical Practice Gudielines, Journal of Hepatology 2017; 67:145–172. 5) Company estimate based on prevalence reported by Kim et al Gastroenterology 2000; 119(6):1631-6. 6) Company estimate based on prevalence reported by Kim et al Gastroenterology 2000; 119(6):1631-6 and Nguyen et al, Best Pract Res Clin Gastroenterol 2010; 24(5):647-54.

Primary Biliary Cholangitis (PBC) (cont´d.)

Nefecon as a treatment for Primary Biliary Cholangitis

Regulatory pathway to product registration

- Calliditas anticipates that the regulatory pathway to registration for PBC would be similar to that of Nefecon for IgA nephropathy
  - Subpart H
  - ALP as surrogate marker for accelerated approval
- Nefecon has obtained orphan drug designation for PBC

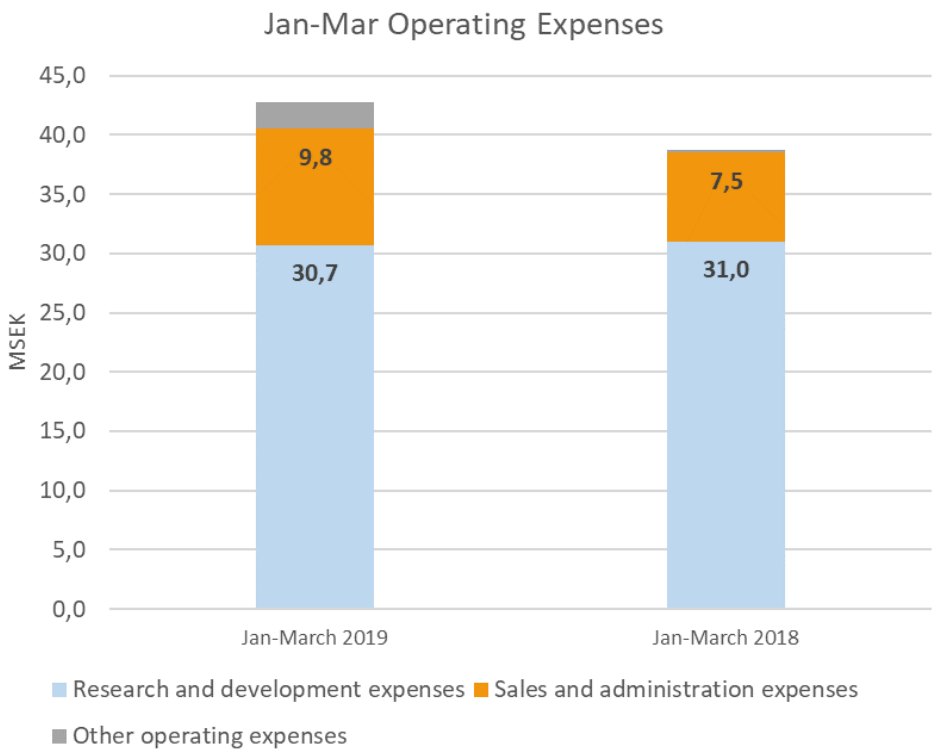


Competition

- Calliditas' assessment of pipeline competition suggests there are in the order of 10 mid to late stage clinical projects in the field of PBC
- Most of these projects either target PPARs or FXRs and none is a targeted immune suppressant based therapy like Nefecon[1]

Source: 1) clinicaltrials.gov, NIH U.S. National Library of Medicine. 2) Nguyen et al, Best Pract Res Clin Gastroenterol. 2010 Oct; 24(5): 647–654). 3) Company estimate based on prevalence reported by Kim et al Gastroenterology 2000; 119(6):1631-6.

Financial overview of the period Jan-Mar 2019



- No revenues reported
- Operating loss of SEK -42.6 M (loss: -38.2)
  - Research and development expenses almost flat of SEK 30.7 M (31.0), representing 72% of total operating expenses
  - Sales and administrative expenses increased to SEK 9.8 M (7.5), due to build-up of pre-commercial activities
- Cash flow from operating activities of SEK -49.4 M (-33.8)
- The cash position per end of Mar 2019, was SEK 596.9 M (53.1)

Going forward: focus on Nefecon program & Pipeline

Ongoing updates regarding commercial strategy and plans

H1 2018	H2 2018	H1 2019	H2 2019	H1 2020	H2 2020	H1 2021	H1 2022
• Filing of new patent application related to Nefecon ✓	• NEFIGARD first patient in ✓ • Application for ODD for second indication submitted ✓ • Application for ODD for third indication submitted ✓	• Filing of Pediatric Investigational Plan submitted to EMA ✓ • Approval of ODD designation for second indication ✓ • Approval of ODD designation for third indication ✓	• EMA meeting to discuss surrogate marker • FDA meeting regarding regulatory pathway for second indication • 200 patients recruited	• Clinical trial for pipe line indication initiated subject to FDA guidance • EMA decision regarding pediatric pathway	• Top line read out for 200 patients • Study fully recruited	• Filing with regulatory agencies for market approval • Enrolment first patient in treatment modality trials / label expansion	• Interim analysis based on 450 patients for validation of surrogate marker • Commercial launch of Nefecon

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Questions