**Q2 Report 2019** Webcast August 15<sup>th</sup>, 2019 Presenters: Renée Aguiar-Lucander, CEO Fredrik Johansson, CFO

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# Summary of key events Q2 2019

Validating out-licensing deal for Nefecon completed for Greater China

- \$121m (SEK 1,1bn) deal value, largest deal between Europe and China for clinical stage asset at announcement
- \$15m (SEK 138m) upfront payment received
  - Access to substantial market near term for Nefecon potential to include China in global Phase 3 trial
  - Potential to facilitate and accelerate full recruitment of trial (450 patients)
  - Cost for clinical development in China borne by partner
- Market opportunity is substantial estimated to be similar in size to the US
- Phase 3 study on plan
  - Sites fully recruited and open, increase in number of screened patients seen in Q2
  - Recruitment of 200 patients before year end on plan
  - Investigator meeting at ERA EDTA in June strong interest in, and support for, the study amongst investigators

### **Post quarter events**

- Additional funds raised, attracting specialist US investor
  - Successful US roadshows resulting in SEK 210m directed share issue which closed on July 3rd
  - BVF Capital Partners L.P. took a significant position
  - Incremental funds enable additional study to be initiated with Nefecon
- In-licensing from Dr. Falk Pharma for US market
  - Euro 1.5m upfront payment, total deal value of Euro 40m
  - Maximizes opportunity to accelerate time to approval and US market access in AIH
  - Creates optionality and flexibility for product portfolio in the US
  - Orphan indication with market exclusivity and reimbursement
- Plans to initiate additional study with Nefecon
  - Open, chronic dosing study
  - Global study with 100-125 patients
  - Leveraging existing PI and site relationships
  - Endpoint stabilization of eGFR and safety
  - Different inclusion criteria to Nefigard, support for treatment paradigm and disease modifying action

### **Everest Medicines - A brief Overview**

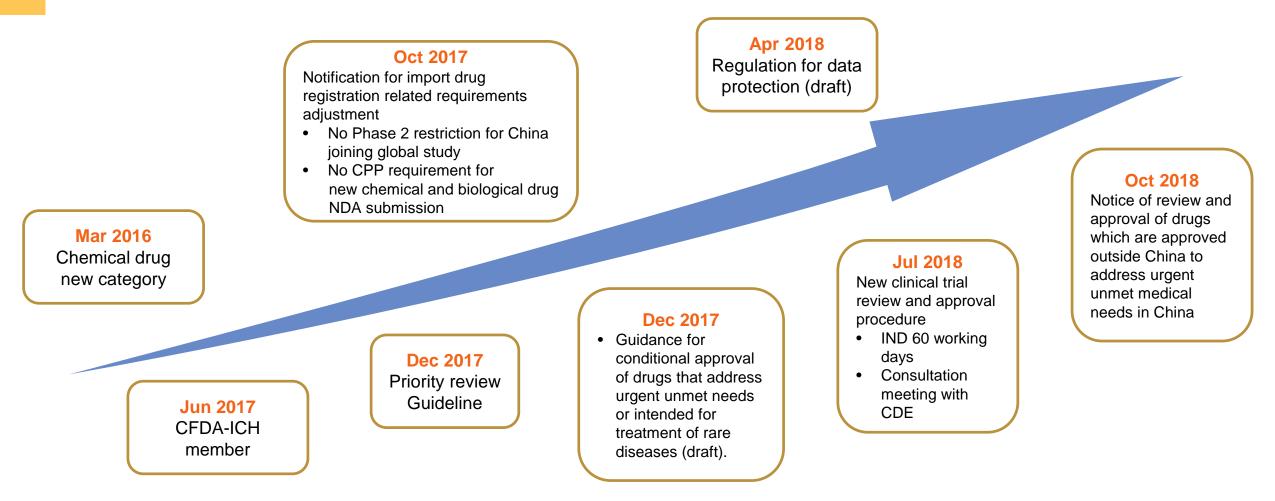
#### Company Founded in 2017

- Backed initially by CBC Group a healthcare focused private equity firm
- Strategic focus: to in-license, develop, and commercialize globally innovative pharmaceutical products for Greater China and other Asian territories
- Focus on 4 therapeutic areas: Oncology, Infectious disease, Cardio-Renal and Immunology
- 80+ employees today, offices in the US and China
- Management team with expertise from local and international large pharmaceutical & financial institutions
- Clinical teams with significant experience predominantly from large pharma
- Successfully in-licensed 9 assets to date from Europe and the US

## **Everest Medicines – In-licensing history**

- July 2017 Everest Medicines Inception
- Nov 2017 MOR202 in-licensed from from MorphoSys, in collaboration with I-MAB
- Dec 2017 Ralinepag and Etrasimod in-licensed from Arena
- Feb 2018 Eravacycline in-licensed from Tetraphase
- June 2018 FGF401 in-licensed from Novartis
- Sept 2018 VNRX-5133 in-licensed from VenatoRx
- Jan 2019 SPR-206 in-licensed from Spero Therapeutics
- April 2019 Sacituzumab Govitecan in-licensed from Immunomedics
- June 2019 Nefecon in-licensed from Calliditas Therapeutics

### Multiple policies in place to expedite innovative drug development in China



China FDA reform encourages innovation in drug development by:

- Optimizing and expediting the review and approval process
- Encouraging simultaneous development by allowing China joining global development programs

# **China Market Opportunity**

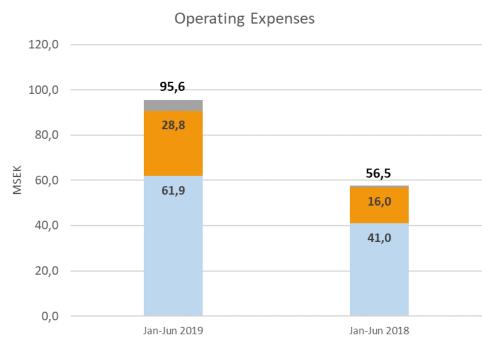
#### Renal biopsies & IgAN

- Renal biopsies have grown dramatically in China since they were first performed in the 1980s
- No national registry data, so data comes mainly from retrospective single center / regional studies to date
- Approximately 1,000 to 1,250 hospitals (mainly located in larger cities) carry out renal biopsies today in China, performing an estimated 300 biopsies per year resulting in a total of 300,000 – 370,000 biopsies being carried out per year in total
- This is also supported by certain single center studies showing a high biopsy rate, around 280pmppy (per million persons per year), resulting in an even higher annual biopsy numbers
- In large retrospective studies, 70 75% of renal biopsies relate to Primary Glomerular Nephritis (PGN) with IgAN being the largest subgroup, ranging from 25 50% depending on the study, region, time period etc

#### Market opportunity

- Greater China has a population of approximately 1.4bn people, which implies that the total IgAN population is very sizeable
- Assuming that biopsies have been carried out fairly regularly for at least the last 10 years it would indicate as per above that the actual diagnosed population today is around 600,000 – 800,000 people
- As biopsies are still limited to large hospitals, the actual patient population today should be significantly larger, likely at least 2x and prevalence in turn significantly higher again

# **Financial overview of the period Jan-Jun 2019**



Research and development expenses
 Sales and administration expenses
 Other operating expenses

- Revenues of SEK 138.2 M (-) from the upfront payment of the China out-licensing deal (USD 15m)
- Operating profit of SEK 42.7 M (-56.4)
  - Research and development expenses increased to SEK 61.9 M (41.0), representing 65% of total operating expenses
  - Sales and administrative expenses increased to SEK 28.8 M (16.0), due to pre-commercial activities in the US and China deal related transaction cost.
- Cash flow from operating activities of SEK -108.7 M (-70.5). The USD 15 M payment from the China out-licencing deal was received post close of the reporting period.
- The cash position per end of June 2019, was SEK 534.9 M (17.0)
- In total, approximately SEK 340 M has been received in Q3 from the direct share issue and the Everest payment

# **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
• IPO raising \$82m on Nasdaq OMX	<ul> <li>NEFIGARD first patient in</li> <li>Application for ODD for second indication submitted</li> <li>Application for ODD for third indication submitted</li> </ul>	<ul> <li>Filing of Pediatric Investigational Plan submitted to EMA</li> <li>Approval of ODD designation for second indication</li> <li>Approval of ODD designation for third indication</li> </ul>	<ul> <li>EMA meeting to discuss surrogate marker</li> <li>FDA meeting regarding regulatory pathway for second indication</li> <li>200 patients recruited</li> </ul>	<ul> <li>Clinical trial initiation of chronic dosing study with Nefecon subject to regulatory approval</li> <li>EMA decision regarding pediatric pathway</li> <li>FDA meeting regarding regulatory pathway for third indication</li> </ul>	<ul> <li>Top line read out for 200 patients</li> <li>Study fully recruited</li> </ul>	<ul> <li>Filing with regulatory agencies for market approval</li> <li>Enrolment first patient in treatment modality trials / label expansion</li> </ul>	<ul> <li>Interim analysis based on 450 patients for validation of surrogate marker</li> <li>Commercial launch of Nefecon</li> </ul>

### **Investment Overview**

Novel treatment of IgA nephropathy (IgAN) with potential **disease modifying** effect

- 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

- **Only successful** placebo controlled, randomized Ph2b study in IgA nephropathy (150 patients)
- 5
- Design of ongoing clinical Phase 3 study NEFIGARD replicates Phase 2b



Additional potential for **pipeline** development, in-licensing targeting orphan disease



Significant **unmet medical need** with USD 1bn market opportunity in USA alone, no approved drugs in Europe or the US



