

## Interim Report Q3, 2019

### Positive Regulatory Outcome - Enhanced study design

“This third quarter of 2019 saw us move steadily towards full recruitment of the NeflgArd study, despite a somewhat slower pace during the summer months. We can now see the finish line and we hope that the next couple of months develop as planned so that we can achieve our ambitious goal. Due to our interactions with the FDA during the year, we have been able to achieve acceptance by the FDA of a revised design of the confirmatory part of our study, using a more sensitive endpoint, which reduces the number of patients and shortens the confirmatory part of the trial substantially. We also received positive advice from EMA related to our revised study design as well as a confirmed path forward towards conditional approval in Europe.”

*Renée Aguiar-Lucander, CEO*

### Summary of Q3 2019

July 1 - September 30, 2019

- Net sales for the period amounted to 0.0 (0.0) million.
- Net income (loss) for the period was SEK -50.1 (-31.4) million.
- Earnings before and after dilution per share totaled SEK -1.30 (-0.91).
- At September 30, 2019, cash and cash equivalents amounted to SEK 805.1 (685.9) million.

### Significant events during Q3 2019, in summary

- In July, Calliditas completed a directed new share issue of 3.5 million shares, raising approximately SEK 210 million with the aim of expanding ongoing research programs and accelerating activities related to the pipeline.
- In August, Calliditas entered into an exclusive in-licensing agreement of Budenofalk 3mg oral capsule for the US market with Dr Falk Pharma. This enables Calliditas to potentially accelerate its development of the pipeline indication related to the orphan liver disease Autoimmune hepatitis (AIH).
- In September, Calliditas obtained positive feedback from the US Food and Drug Administration (FDA) that has a significant impact on the confirmatory part of the ongoing pivotal Phase 3 study NeflgArd. The FDA accepted a two-year eGFR based end point for the Part B of the study resulting in a reduction from 450 to 360 patients, with significant positive impact on overall costs and recruitment time.

### Significant events after the end of reporting period, in summary

- In October, Calliditas obtained positive advice from the European Medicines Agency (EMA) in which the agency expressed support for conditional marketing authorization (CMA) of the company's lead compound Nefecon, subject as usual to sufficient quality of the full data set at time of filing.

**Investor presentation November 14, 15:00 CET**

Audio cast with teleconference, Q3 2019, November 14, 2019, 15:00 (Europe/Stockholm)

Webcast: <https://tv.streamfabriken.com/calliditas-therapeutics-q3-2019>

Teleconference: Dial-in number SE +46850558368 UK: +443333009266 US: +18335268395

**Financial calendar**

Year-end report for the period January 1 – December 31, 2019	February 14, 2020
Interim report for the period January 1 – March 31, 2020	May 14, 2020
Interim report for the period January 1 – June 30, 2020	August 13, 2020
Interim report for the period January 1 – September 30, 2020	November 12, 2020

**For further information, please contact:**

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**About Calliditas Therapeutics**

Calliditas Therapeutics is a specialty pharmaceutical company based in Stockholm, Sweden. It is focused on developing high quality pharmaceutical products for patients with a significant unmet medical need in niche indications, in which the Company can partially or completely participate in the commercialization efforts. The Company is focused on the development and commercialization of the product candidate Nefecon, a unique formulation optimized to combine a time lag effect with a concentrated release of the active substance budesonide, within a designated target area. This patented, locally acting formulation is intended for treatment of patients with the inflammatory renal disease IgA nephropathy (IgAN). Calliditas Therapeutics is running a global Phase 3 study within IgAN and aims to commercialize Nefecon in the US. The company is listed on Nasdaq Stockholm (ticker: CALTX). Visit [www.calliditas.com](http://www.calliditas.com) for further information.