



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

January 10, 2020

Renée Aguiar-Lucander  
Chief Executive Officer  
Calliditas Therapeutics AB  
Kungsbron 1, C8  
SE-111 22  
Stockholm, Sweden

**Re: Calliditas Therapeutics AB**  
**Draft Registration Statement on Form F-1**  
**Submitted December 13, 2019**  
**CIK No. 0001795579**

Dear Ms. Aguiar-Lucander:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form F-1

Cover Page

1. We note your disclosure of the closing price of your common shares on Nasdaq Stockholm in SEK, which will be equal to the disclosed price per ADS in U.S. dollars based on the SEK/U.S. dollar exchange rate as of the most recent date. Additionally, we note your disclosure on page 161 indicating that the price will be determined by negotiations with the underwriters considering results of operations, current financial condition, future prospects, markets, economic conditions in and future prospects for your industry, management, and currently prevailing general conditions in the equity security markets, including current market conditions of comparable companies. You may use the

most recent home market trading price, converted to U.S. dollars at the most recent exchange rate in lieu of a price range, assuming the U.S. IPO price will be substantially similar to the home market trading price and you provide clarification of this intention. If you expect that the U.S. IPO price will not be substantially similar to the home market trading price, please disclose on the prospectus cover page a bona fide price range of the offered securities. If you intend to price the securities based on the Nasdaq Stockholm market price, you may disclose a percentage range based on that price (for example, 10% of the home market price) within which you intend to price the securities. See, for example, Item 501(b)(3) of Regulation S-K.

Prospectus Summary, page 1

2. It appears from your disclosure in the first risk factor on page 14 that the FDA, EMA and comparable regulatory authorities have not determined the required level of reduction of proteinuria that you would need to demonstrate in order to obtain marketing approvals based on that surrogate biomarker. Please clarify your statement that Nefecon was associated with a statistically significant and clinically meaningful reduction in proteinuria to clarify that the FDA and EMA have not determined the required reduction for purposes of your trials and that the reduction you have observed in your trials might not be a sufficiently significant reduction to satisfy the FDA and EMA.
3. Please clarify in the summary that the FDA's accelerated approval pathway may not lead to a faster development process or regulatory review and does not increase the likelihood that a product candidate will receive approval.

Our Pipeline, page 4

4. Please remove the 2021 anticipated milestone related to filing an NDA. This appears to be a prediction that the Phase 3 trial will be successful.

Implications of Being an Emerging Growth Company, page 6

5. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Our product candidates may have serious adverse, undesirable or unacceptable side effects ..., page 18

6. Please identify the two drug-related serious adverse events.

Management's Discussion and Analysis of Financial Condition and Results of Operations  
Critical Accounting Policies and Significant Judgments and Estimates  
Warrants, page 85

7. You disclose in Note 8 on page F-19 that warrants are measured at fair value using the Black-Scholes model. Revise your disclosure to explain why illiquidity rebates are used in the valuation and the impact the illiquidity rebates and negative risk-free rates factors have on your estimates of fair value. Please explain to us your basis for including illiquidity rebates with the typical assumptions used to employ the Black-Scholes model and tell us how you determined the illiquidity rebates of 30% and 15% are reasonable.

Budenofalk for Autoimmune Hepatitis, page 103

8. Please file the in-licensing agreement with Falk Pharama as an exhibit or explain the basis for your determination that it is not required to be filed.

License Agreement with Everest Medicines, page 104

9. Please revise to disclose the tiered royalty ranges within a ten-percent range (e.g., 5% to 15%, single digit to mid-teens or two tiers ranging up to 20%). Provide similar disclosure for the royalty payments that may be required under the license agreements with Archimedes and Dr. Falk Pharma indicated on page 83.

Patents, page 106

10. We note your disclosure that you license a patent family that protects a formulation for the oral delivery of budesonide and the medicinal use thereof. Please identify the co-owner of the patent family, describe the material terms of the license agreement and file this agreement as an exhibit in accordance with Regulation S-K Item 601(b)(10)(ii)(B).
11. Please revise to clarify if your patent protection and related license is limited to the oral drug delivery composition of budesonide or if other budesonide delivery mechanisms are separately licensed to other parties or are protected under different patents. If you could be subject to competition from other delivery methods of budesonide, or other corticosteroids, that would not be protected by your current patents, please include appropriate disclosure, including risk factor disclosure.

Principal Shareholders, page 133

12. Please identify the natural persons who are the beneficial owners of the shares held by the 5% or greater shareholders identified in your table.

Renée Aguiar-Lucander  
Calliditas Therapeutics AB  
January 10, 2020  
Page 4

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm, page F-2

13. We note your disclosures on page F-9 in which you discuss the change in accounting principle. Please have your auditor tell us why it did not include an explanatory paragraph discussing this change in accounting principle in accordance with PCAOB AS 3101.18.c. and AS 2820.

You may contact Sasha Parikh at (202) 551-3627 or Lynn Dicker at (202) 551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Tim Buchmiller at (202) 551-3635 or Suzanne Hayes at (202) 551-3675 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Life Sciences

cc: Michael Rosenberg, Esq.