



DIVISION OF  
CORPORATION FINANCE

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

April 17, 2019

Edward Kaye  
Chief Executive Officer  
Stoke Therapeutics, Inc.  
45 Wiggins Avenue  
Bedford, MA 01730

**Re: Stoke Therapeutics, Inc.**  
**Draft Registration Statement on Form S-1**  
**Submitted March 26, 2019**  
**CIK No. 0001623526**

Dear Dr. Kaye:

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 S-1

Market and industry data, page ii

1. We note your disclosure that you commissioned a report by Health Advances LLC. Please file a consent by Health Advances LLC as an exhibit to your registration statement pursuant to Rule 436 of the Securities Act.

Prospectus summary

Company overview, page 1

2. You state that current treatments for Dravet syndrome provided by your competitors perform "very poorly." Please provide us with your basis for this characterization of their performance or revise your disclosure.

Advantages of TANGO, page 2

3. Please revise this section and throughout to remove comparisons of your ASOs to other product candidates, products and treatments if you have not conducted head-to-head clinical trials. For example, we note your statement on page 2 that TANGO may have several key advantages over existing and emerging therapeutic modalities, your disclosure on page 88 that your product candidate "has the potential to result in significantly improved outcomes compared to existing antiepileptic drugs," and your disclosure on page 102 that "[b]y comparison to the approved drug SPINRAZA, STK-001 possesses less predicted off-target activities."

Our precision medicine platform

Treatment of autosomal dominant haploinsufficiency diseases with TANGO, page 2

4. Your statement on page 3 that ASO delivery to the CNS is particularly well-precedented with one FDA-approved drug creates the implication that your drug candidate will also be approved by the FDA. In addition, your statement on page 2 that your technology can provide a single-drug approach for diseases that are caused by many loss-of-function mutations in a single gene, the inclusion of your "TANGO Technology" as a current or emerging medicine in your chart on page 90 and your statement on page 100 that your precision medicine approach may have a profound impact on individuals and families imply that your current and future product candidates will be approved by the FDA. Such statements are inappropriate given the stage of development of your product candidates. Revise these statements and all other similar statements to eliminate such implication.

Our Programs

Dravet syndrome--STK-001, page 3

5. We note your disclosure on page 3 that you plan to apply for Orphan Drug Designation from the FDA and that you plan to discuss expedited regulatory pathways with regulatory authorities such as Fast Track Designation and Breakthrough Therapy Designation. Please disclose here and throughout, if true, that the FDA has not given any indication as to whether your product candidate will receive an orphan drug designation or be permitted to use expedited regulatory pathways.

Implications of being an emerging growth company and smaller reporting company, page 5

6. 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.

Risk factors

Risks related to our intellectual property

Our owned and in-licensed patents and patent applications, page 36

7. Please clarify what you mean by your disclosure that your in-licensed patent and patent applications generally cover the use of STK-001 but do not specifically cover STK-001 or its use.

Risks related to our common stock and this offering

Anti-takeover provision in our charter documents, page 57

8. We note your disclosure here and on page 147 that your restated certificate of incorporation will contain an exclusive forum provision. Please disclose whether these provisions apply to actions arising under the Securities Act or Exchange Act. If these provisions do not apply to actions arising under the Securities Act or Exchange Act, please also ensure that the exclusive forum provisions in the certificate of incorporation state this clearly. Please also file a copy of your amended and restated certificate of incorporation with your next amendment or tell us when you plan to do so. Note that we may have further comment after review of this document and your revised disclosure.

Use of Proceeds, page 61

9. Please clarify what you mean by "demonstrate clinical proof of concept" by clarifying whether you are referring to preclinical studies or clinical trials.

Management's discussion and analysis of financial condition and results of operations

Critical accounting policies and significant judgments and estimates

Determination of the fair value of common stock, page 81

10. Once you have an estimated offering price or range, please explain to us the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation and beneficial conversion features.

Business, page 86

11. Please revise to disclose the material terms of your sponsored research agreement with the University of Michigan, and file the agreement as an exhibit to your registration statement, if required.

Our precision medicine platform

Tango mechanisms of action, page 93

12. Please balance the disclosure in this section by stating that you have only one product

candidate and that this product candidate is still in preclinical studies.

Dravet syndrome disease overview

STK-001: Preclinical data, page 100

13. Please revise your disclosure of your preclinical studies by identifying the number of mice in each group, as opposed to a range, and the number of groups tested as well as the range of results observed. In addition, please identify the range of increases in the Nav1.1 protein that was observed in your study with monkeys and the number of monkeys sacrificed at 3 days and at 29 days after dosing.
14. Please clarify what you mean by "non-Good Laboratory Practice" on page 103, and disclose whether you will be able to use the results of this test as part of your IND submission to the FDA .

Additional product opportunities, page 104

15. Please revise your disclosure on page 104 and similar statements throughout that refer to your "broader pipeline of first-in-class medicines" as this statement and other similar statements throughout are inappropriate given the stage of development of your product candidate. In this regard, we note that you have identified only one product candidate, which is still in the preclinical stage.

Intellectual property

License agreements

Cold Spring Harbor Laboratory, page 109

16. Please quantify your royalty obligations under the CSHL and Southampton Agreements and the and the percentage of the sublicense revenue if you sublicense rights under the CSHL Agreement.

Notes to Consolidated Financial Statements

8. Convertible preferred stock

Liquidation , page F-18

17. Considering that the company may be subject to an involuntary event, which may trigger payment to the preferred stockholders, please provide us your analysis under ASR 268 supporting your classification of convertible preferred stock within permanent equity.

General

18. Please provide us mockups of any pages that include any additional pictures or graphics to be presented, including any accompanying captions. Please keep in mind, in scheduling your printing and distribution of the preliminary prospectus, that we may have comments after our review of these materials.

Edward Kaye  
Stoke Therapeutics, Inc.  
April 17, 2019  
Page 5

You may contact Rolf Sundwall at 202-551-3105 or Jim Rosenberg at 202-551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Sonia Bednarowski at 202-551-3666 or Justin Dobbie at 202-551-3469 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Healthcare & Insurance