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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 7, 2020

Stoke Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38938**	**47-114582**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

45 Wiggins Ave **Bedford, Massachusetts**	**01730**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 430-8200

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**STOK**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 7, 2020, Stoke Therapeutics (the "Company") announced plans to move forward with dosing of STK-001, a proprietary antisense oligonucleotide ("ASO"), in children and adolescents pursuant to the Company's Phase 1/2a MONARCH study for Dravet syndrome. The Company announced that it will add an additional higher dose level to the single ascending dose ("SAD") portion of the ongoing MONARCH study such that a total of three dose levels will now be evaluated in this portion of the study: 10 mg, 20 mg, and 30mg. Dosing above 30mg in this study remains on partial clinical hold by the U.S. Food and Drug Administration (the "FDA").

In addition, subject to review by the FDA, the Company is preparing to add a multiple ascending dose ("MAD") portion to the MONARCH study, replacing Part B. This decision is based on new preclinical repeat-dose toxicology data, which were reviewed by the FDA as part of ongoing discussions with the Company. There were no adverse effects observed in the non-human primate ("NHP") repeat dose study. The Company plans to submit a protocol amendment to the FDA in the coming days reflecting these changes to the SAD and MAD portions of the MONARCH study.

In March 2020, the Company announced the FDA had placed a partial clinical hold on higher doses of STK-001 in the MONARCH study, pending additional preclinical testing to determine the safety profile of doses higher than the current no observed adverse effect level ("NOAEL"). When intrathecal doses above the NOAEL were administered to NHPs, adverse hind limb paresis was observed. This finding is known to occur following intrathecal delivery of ASOs to NHPs and is not known to translate to the human experience. When extremely high dose levels were administered, acute convulsions were observed immediately following STK-001 administration. The dose levels were well above the range of corresponding human doses that would ever be administered in the clinic, and were delivered in a formulation that was at a higher concentration than would be administered in the clinic. There is no apparent correlation of these acute adverse events with the mechanism of action of STK-001.

Enrollment and dosing in the MONARCH study remain ongoing. The Company expects preliminary clinical data relating to the MONARCH study in 2021.

This report contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: our expectations about the Company's proprietary approach to precisely upregulate protein expression using TANGO ASOs and the potential benefits thereof. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "potential," "possible," "will," "would," and other words and terms of similar meaning. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our expectation about the dosing, timing and execution of our Phase 1/2a MONARCH study of STK-001, including our ability to include a multiple ascending dose portion in the study and the partial clinical hold on Part B of the study; risks related to the direct and indirect impact of COVID-19; our ability to develop, obtain regulatory approval for and commercialize current and future product candidates; the timing and results of preclinical studies and clinical trials; the risk that positive results in a clinical trial may not be replicated in subsequent trials or success in early stage clinical trials may not be predictive of results in later stage clinical trials; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials; the risk that regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; risks related to the occurrence of adverse safety events; risks related to failure to protect and enforce our intellectual property, and other proprietary rights; risks related to failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; risks relating to technology failures or breaches; our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential delays, work stoppages, or supply chain disruptions caused by the coronavirus pandemic; risks associated with current and potential future healthcare reforms; risks relating to attracting and retaining key personnel; failure to comply with legal and regulatory requirements; risks relating to access to capital and credit markets; environmental risks; risks relating to the use of social media for our business; and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STOKE THERAPEUTICS, INC.

Date: October 7, 2020

By: /s/ Stephen J. Tulipano

Stephen J. Tulipano
Chief Financial Officer