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): June 30, 2026

Stoke Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38938**	**47-1144582**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS 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 7.01 Regulation FD.

On June 30, 2026, Stoke Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing the completion of enrollment of 162 patients into the Phase 3 EMPEROR study of zorevunersen, a potential disease-modifying treatment for Dravet syndrome. The Company is furnishing a copy of the Press Release, which is attached hereto as Exhibit 99.1.

The information furnished with this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As noted in the Press Release, enrollment of 162 patients into the EMPEROR study has now completed in the planned primary analysis population across the U.S., U.K., and Japan. A Phase 3 data readout from these patients is anticipated in the third quarter of 2027. Approximately 50 of these patients are through 28 weeks of treatment, the time point at which the primary endpoint of change in major motor seizure frequency is measured. The Company plans to initiate a rolling New Drug Application ("NDA") submission to the U.S. Food and Drug Administration in the first quarter of 2027 and expects completion of the NDA submission in the second half of 2027.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated June 30, 2026
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

SIGNATURES

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: June 30, 2026

By: /s/ Thomas E. Leggett

Thomas E. Leggett
Chief Financial Officer

Exhibit 99.1

Stoke Therapeutics Announces Completion of Enrollment of 162 Patients into the Phase 3 EMPEROR Study of Zorevunersen, an Investigational Medicine for the Treatment of Dravet Syndrome

—Company plans to initiate a rolling U.S. NDA submission to the FDA in the first quarter of 2027—

—Phase 3 data readout anticipated in the third quarter of 2027 to complete the rolling U.S. NDA submission in the second half of 2027—

BEDFORD, Mass.—June 30, 2026—Stoke Therapeutics, Inc. (Nasdaq: STOK) is a biotechnology company dedicated to restoring protein expression by harnessing the body's potential with RNA medicine and has a lead investigational medicine, zorevunersen, in development as a first-in-class potential disease-modifying treatment for Dravet syndrome. The Company today announced the completion of enrollment of 162 patients into the Phase 3 EMPEROR study of zorevunersen. Stoke plans to initiate a rolling New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) in the first quarter of 2027. A Phase 3 data readout is anticipated in the third quarter of 2027 to complete the rolling U.S. NDA submission in the second half of 2027.

The EMPEROR study is progressing, and approximately 50 out of the 162 patients in the U.S., UK and Japan are through 28 weeks of treatment, the time point at which the primary endpoint of change in major motor seizure frequency is measured. An additional cohort of approximately 30 patients in Europe is currently enrolling, and the last patient is expected to enroll in August. No patients have discontinued treatment in the study.

"The rapid enrollment of the Phase 3 EMPEROR study reflects the severity of Dravet syndrome and the potential of zorevunersen to address the underlying genetic cause of the disease, resulting in reduced seizure burden and the opportunity for more neurotypical development," said Ian F. Smith, Chief Executive Officer and Director of Stoke Therapeutics. "With five years of clinical data for zorevunersen and strong awareness among patients, families and investigators, we completed enrollment in just 10 months and are on track for a Phase 3 data readout in the third quarter of 2027. We expect to complete our rolling NDA submission shortly thereafter based on these data, and we continue to build our organization and capabilities to deliver zorevunersen to all patients in the U.S. who may benefit following a potential FDA approval and U.S. launch by early 2028."

“The Dravet Syndrome Foundation was founded to advance understanding of this devastating disease and fight for better treatments. We are deeply gratified to have played a role in designing and delivering clinical studies to create potential new medicines, from early natural history studies of Dravet syndrome through to the successful enrollment of this first-of-its-kind Phase 3 study,” said Mary Anne Meskis, Chief Executive Officer of the Dravet Syndrome Foundation. “This progress reflects our shared commitment to improving outcomes for patients, and we look forward to continuing to advance zorevunersen with the goal of building a very different future for people living with Dravet syndrome and their families.”

Pivotal Phase 3 EMPEROR study progress

The Phase 3 EMPEROR Study (NCT06872125) is a global, double-blind, sham-controlled study. The primary endpoint is change in major motor seizure frequency measured at Week 28, although the study will remain blinded and all data will be analyzed at the end of the 52-week treatment period given that secondary endpoints measuring cognition and behavior will be assessed at Week 52. Enrollment has completed in the planned primary analysis population, which will evaluate zorevunersen compared to sham administered via lumbar puncture (LP) in 162 patients enrolled in the U.S., U.K. and Japan. The data from these patients are anticipated to be the final data required for completion of the planned rolling U.S. NDA submission. An additional cohort of approximately 30 patients is currently being enrolled in Europe (Germany, France, Spain and Italy), where the sham control is administered via a needle prick (NP). The last patient in this cohort is expected to be enrolled in August. Site activation is also underway in China, where zorevunersen was recently granted Breakthrough Therapy Status. Data from the additional patients in Europe and China are not planned for inclusion in the U.S. NDA submission to the FDA.

About Dravet Syndrome

Dravet syndrome is a severe developmental and epileptic encephalopathy (DEE) characterized by recurrent seizures as well as significant cognitive and behavioral impairments. Most cases of Dravet are caused by mutations in one copy of the *SCN1A* gene, leading to insufficient levels of NaV1.1 protein in neuronal cells in the brain. Even when treated with the best available anti-seizure medicines (ASMs), up to 57% of patients with Dravet syndrome do not achieve ≥50% reduction in seizure frequency. Complications of the disease often contribute to a poor quality of life for patients and their caregivers. Developmental and cognitive impairments often include intellectual disability, developmental delays, movement and balance issues, language and speech disturbances, growth defects, sleep abnormalities, disruptions of the autonomic nervous system and mood disorders. Compared with the general epilepsy population, people living with Dravet syndrome have a higher risk of sudden unexpected death in epilepsy, or SUDEP; up to 20% of children and adolescents with Dravet syndrome die before adulthood due to SUDEP, prolonged seizures, seizure-related accidents or infections [1]. Dravet syndrome occurs globally and is not concentrated in a particular geographic area or ethnic group. Currently, it is estimated that up to 38,000 people are living with Dravet syndrome in the U.S. (~16,000), UK, EU-4 and Japan [2]. There are no approved disease-modifying therapies for people living with Dravet syndrome.

About Zorevunersen

Zorevunersen is an investigational antisense oligonucleotide that is designed to treat the underlying cause of Dravet syndrome by increasing functional NaV1.1 protein production in brain cells from the unaffected (wild-type) copy of the *SCN1A* gene. This highly differentiated mechanism of action aims to reduce seizure frequency beyond what has been achieved with anti-seizure medicines and to improve neurodevelopment, cognition and behavior. Zorevunersen has demonstrated the potential for disease modification and has been granted orphan drug designation by the FDA and the EMA. The FDA has also granted zorevunersen rare pediatric disease designation and Breakthrough Therapy Designation for the treatment of Dravet syndrome with a confirmed mutation not associated with gain-of-function in the *SCN1A* gene, and China's Center for Drug Evaluation has granted zorevunersen Breakthrough Therapy Designation. Stoke has a strategic collaboration with Biogen (Nasdaq: BIIB) to develop and commercialize zorevunersen for Dravet syndrome. Under the collaboration, Stoke retains exclusive rights for zorevunersen in the United States, Canada, and Mexico; Biogen receives exclusive rest of world commercialization rights. Zorevunersen is currently in clinical development, and its safety and efficacy have not been evaluated by any regulatory authority.

About the Phase 3 EMPEROR Study

The Phase 3 EMPEROR Study (NCT06872125) is a global, double-blind, sham-controlled study evaluating the efficacy, safety and tolerability of zorevunersen in children ages 2 to <18 with Dravet syndrome with a confirmed variant in the *SCN1A* gene not associated with gain-of-function. Participants are randomized 1:1 to receive either zorevunersen via intrathecal administration or a sham comparator for a 52-week treatment period following an 8-week baseline period. Following the completion of the study treatment period, eligible participants will be offered ongoing treatment with zorevunersen as part of an open-label period of the study. The primary endpoint of the study is percent change from baseline in major motor seizure frequency at week 28 in patients receiving zorevunersen as compared to sham. The key secondary endpoints are the durability of effect on major motor seizure frequency and improvements in behavior and cognition as measured by Vineland-3 subdomains, including expressive communication, receptive communication, interpersonal relationships, coping skills and personal skills. Additional endpoints include safety, Clinician Global Impression of Change (CGI-C), Caregiver Global Impression of Change (CaGI-C) and the Bayley Scales of Infant Development (BSID-IV). For more information, visit https://clinicaltrials.gov/study/NCT06872125.

About Stoke Therapeutics

Stoke Therapeutics (Nasdaq: STOK), is a biotechnology company dedicated to restoring protein expression by harnessing the body's potential with RNA medicine. Using Stoke's proprietary TANGO (Targeted Augmentation of Nuclear Gene Output) approach, Stoke is developing antisense oligonucleotides (ASOs) to selectively restore naturally-occurring protein levels. Stoke's first medicine in development, zorevunersen, has demonstrated the potential for disease modification in patients with Dravet syndrome and is currently being evaluated in a Phase 3 study. Stoke's initial focus are diseases of the central nervous system and the eye that are caused by a loss of ~50% of normal protein levels (haploinsufficiency). Proof of concept has been demonstrated in other organs, tissues, and systems, supporting broad potential for Stoke's proprietary approach. Stoke is headquartered in Bedford, Massachusetts. For more information, visit https://www.stoketherapeutics.com/ and follow us on LinkedIn.

Stoke Therapeutics Cautionary Note Regarding Forward-Looking Statements

This press release 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: the ability of zorevunersen to treat the underlying causes of Dravet syndrome and reduce seizures or show improvements in behavior and cognition at the indicated dosing levels or at all; the potential benefits, safety and efficacy of zorevunersen; the timing and expected progress of clinical trials, data readouts, regulatory meetings, regulatory decisions and other presentations; the characterization of Stoke's meeting and discussions with the FDA; and Stoke's ability to achieve an NDA submission or approval on the expedited timeframe disclosed or at all. Statements including words such as "plan," "potential," "will," "continue," "expect," or similar words and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they prove incorrect or do not fully materialize, could cause Stoke's results to differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, risks and uncertainties related to: Stoke's ability to advance, obtain regulatory approval and ultimately commercialize its product candidates; that if collaborators were to breach or terminate their agreements, Stoke would not obtain the anticipated financial or other benefits; the possibility that Stoke and Biogen may not be successful in their development of zorevunersen and that, even if successful, they may be unable to successfully commercialize zorevunersen; the potential that positive results in a clinical trial may not be replicated in subsequent trials or successes in early stage clinical trials may not be predictive of results in later stage trials; Stoke's ability to protect its intellectual property; Stoke's ability to fund development activities and achieve development goals into 2028; and the other risks and uncertainties described under the heading "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2025, its quarterly reports on Form 10-Q, and the other documents it files with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Stoke undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

References:

1. Symonds, J. et al. Early childhood epilepsies: epidemiology, classification, aetiology, and socio-economic determinants. *Brain.* 2021;144(9):2879-2891.
2. Based on Stoke Therapeutics' preliminary estimates, which scaled annual incidence to prevalence using country-specific live birth rates over the past 85 years and adjusted for Dravet-specific mortality. The estimate is based on incidence rates published by Wu et al., Pediatrics, 2015.

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