

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): March 25, 2024

Stoke Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38938
(Commission File Number)

47-1144582
(IRS Employer
Identification No.)

45 Wiggins Ave
Bedford, Massachusetts
(Address of Principal Executive Offices)

01730
(Zip Code)

Registrant's Telephone Number, Including Area Code: (781) 430-8200

(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 2.02 Results of Operations and Financial Condition.

On March 25, 2024, Stoke Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2023. A copy of the press release is attached as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Stoke Therapeutics, Inc. regarding its full year 2023 financial results, dated March 25, 2024
104	Cover Page Interactive Data File (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: March 25, 2024

By: /s/ Stephen J. Tulipano

Stephen J. Tulipano
Chief Financial Officer

Stoke Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results

– As of December 31, 2023, Company had \$201.4 million in cash, cash equivalents, and marketable securities, anticipated to fund operations to the end of 2025 –

BEDFORD, Mass., March 25, 2024 – Stoke Therapeutics, Inc. (Nasdaq: STOK), a biotechnology company dedicated to addressing the underlying cause of severe diseases by upregulating protein expression with RNA-based medicines, today reported financial results for the full year ended December 31, 2023.

Year End 2023 Financial Results

- As of December 31, 2023, Stoke had \$201.4 million in cash, cash equivalents, and marketable securities, which is anticipated to fund operations to the end of 2025.
- Revenue recognized for upfront license fees and services provided from a License and Collaboration Agreement with Acadia Pharmaceuticals for the year ended December 31, 2023 was \$8.8 million, compared to \$12.4 million, for the year ended December 31, 2022.
- Net loss for the year ended December 31, 2023 was \$104.7 million, or \$2.38 per share compared to \$101.1 million, or \$2.60 per share for 2022.
- Research and development expenses for the year ended December 31, 2023 were \$82.2 million, compared to \$77.8 million for 2022.
- General and administrative expenses for the year ended December 31, 2023 were \$41.3 million, compared to \$38.9 million for 2022.
- The increase in expenses for the year ended December 31, 2023 as compared to the same period in 2022 primarily relate to increases in costs associated with personnel, third party contracts, consulting, facilities and other costs associated with development activities for STK-001 and STK-002, research on additional therapeutics and growing a public corporation.

Fourth Quarter 2023 Financial Results

- Revenue recognized for upfront license fees and services provided from a License and Collaboration Agreement with Acadia Pharmaceuticals for the three months ended December 31, 2023 was \$2.8 million, compared to \$3.3 million, for the same period in 2022.
 - Net loss for the three months ended December 31, 2023 was \$27.0 million, or \$0.60 per share, compared to \$25.7 million, or \$0.65 per share, for the same period in 2022.
 - Research and development expenses for the three months ended December 31, 2023 were \$21.8 million, compared to \$21.1 million for the same period in 2022.
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- General and administrative expenses for the three months ended December 31, 2023 were \$10.6 million, compared to \$9.4 million for the same period in 2022.
- The increase in expenses for the three months ended December 31, 2023 as compared to the same period in 2022 primarily relate to increases in costs associated with personnel, third party contracts, consulting, facilities and other costs associated with development activities for STK-001 and STK-002, research on additional therapeutics and growing a public corporation.

About Stoke Therapeutics

Stoke Therapeutics (Nasdaq: STOK), is a biotechnology company dedicated to addressing the underlying cause of severe diseases by upregulating protein expression with RNA-based medicines. Using Stoke's proprietary TANGO (Targeted Augmentation of Nuclear Gene Output) approach, Stoke is developing antisense oligonucleotides (ASOs) to selectively restore protein levels. Stoke's first compound, STK-001, is in clinical testing for the treatment of Dravet syndrome, a severe and progressive genetic epilepsy. Dravet syndrome is one of many diseases caused by a haploinsufficiency, in which a loss of ~50% of normal protein levels leads to disease. Stoke is pursuing the development of STK-002 for the treatment of autosomal dominant optic atrophy (ADOA), the most common inherited optic nerve disorder. Stoke's initial focus is haploinsufficiencies and diseases of the central nervous system and the eye, although proof of concept has been demonstrated in other organs, tissues, and systems, supporting its belief in the broad potential for its proprietary approach. Stoke is headquartered in Bedford, Massachusetts with offices in Cambridge, Massachusetts. For more information, visit <https://www.stoketherapeutics.com/>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provision of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the Company's cash runway. Statements including words such as "anticipate," "plan," "will," "continue," "expect," or "ongoing" 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 our results to differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, risk and uncertainties related to: the Company's ability to advance, obtain regulatory approval of, and ultimately commercialize its product candidates; the timing of data readouts and interim and final results of preclinical and clinical trials; 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; preliminary interim data readouts of ongoing trials may show results that change when such trials are completed; the Company's ability to fund development activities and achieve development goals into 2025; the Company's ability to protect its intellectual property; the direct or indirect impact of global business, political and macroeconomic conditions, including inflation, interest rate volatility, cybersecurity events, uncertainty with respect to the federal budget, instability in the global banking system and

volatile market conditions, and global events, including public health crises, and ongoing geopolitical conflicts, such as the conflicts in Ukraine and the Middle East; and other risks and uncertainties described under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, its quarterly reports on Form 10-Q, and the other documents the Company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Financial Tables Follow

Stoke Therapeutics, Inc. and subsidiary
Consolidated balance sheets
(in thousands, except share and per share amounts)

	As of December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 191,442	\$ 113,556
Marketable securities	9,952	116,039
Prepaid expenses	11,320	10,932
Other current assets	2,561	2,955
Interest receivable	64	588
Total current assets	\$ 215,339	\$ 244,070
Restricted cash	569	569
Operating lease right-of-use assets	6,611	4,753
Property and equipment, net	5,823	6,675
Total assets	\$ 228,342	\$ 256,067
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,695	\$ 766
Accrued and other current liabilities	13,815	15,748
Deferred revenue - current portion	15,309	14,880
Total current liabilities	\$ 30,819	\$ 31,394
Deferred revenue - net of current portion	33,074	36,856
Other long term liabilities	4,884	2,968
Total long term liabilities	\$ 37,958	\$ 39,824
Total liabilities	\$ 68,777	\$ 71,218
Stockholders' equity		
Common stock, par value of \$0.0001 per share; 300,000,000 shares authorized, 45,918,233 and 39,439,575 shares issued and outstanding as of December 31, 2023 and 2022, respectively	5	4
Additional paid-in capital	561,433	483,170
Accumulated other comprehensive loss	(24)	(1,175)
Accumulated deficit	(401,849)	(297,150)
Total stockholders' equity	\$ 159,565	\$ 184,849
Total liabilities and stockholders' equity	\$ 228,342	\$ 256,067

Stoke Therapeutics, Inc. and subsidiary
Consolidated statements of operations and comprehensive loss
(in thousands, except share and per share amounts)

	Three months ended December 31, (unaudited)		Year Ended December 31,	
	2023	2022	2023	2022
Revenue	\$ 2,801	\$ 3,269	\$ 8,780	\$ 12,405
Operating expenses:				
Research and development	21,778	21,061	82,231	77,837
General and administrative	10,610	9,383	41,322	38,924
Total operating expenses	32,388	30,444	123,553	116,761
Loss from operations	(29,587)	(27,175)	(114,773)	(104,356)
Other income (expense):				
Interest income (expense), net	2,587	1,479	9,908	3,122
Other income (expense), net	42	41	166	167
Total other income (expense)	2,629	1,520	10,074	3,289
Net loss	\$ (26,958)	\$ (25,655)	\$ (104,699)	\$ (101,067)
Net loss per share—basic and diluted	\$ (0.60)	\$ (0.65)	\$ (2.38)	\$ (2.60)
Weighted average common shares outstanding—basic and diluted	44,958,894	39,434,027	43,994,862	38,897,442
Comprehensive loss:				
Net loss	\$ (26,958)	\$ (25,655)	\$ (104,699)	\$ (101,067)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	122	528	1,151	(1,007)
Total other comprehensive gain (loss)	\$ 122	\$ 528	\$ 1,151	\$ (1,007)
Comprehensive loss	\$ (26,836)	\$ (25,127)	\$ (103,548)	\$ (102,074)

Stoke Media & Investor Contacts:

Dawn Kalmar
Chief Communications Officer
dkalmar@stoketherapeutics.com
781-303-8302

Eric Rojas
Vice President, Investor Relations
IR@stoketherapeutics.com
617-312-2754
