
**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): May 07, 2026

Definium Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

British Columbia
(State or Other Jurisdiction
of Incorporation)

001-40360
(Commission File Number)

98-1582438
(IRS Employer
Identification No.)

One World Trade Center
Suite 8500
New York, New York
(Address of Principal Executive Offices)

10007
(Zip Code)

Registrant's Telephone Number, Including Area Code: (212) 220-6633

(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 Shares	DFTX	The Nasdaq Stock Market LLC

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 May 7, 2026, Definium Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter ended March 31, 2026, as well as information regarding a conference call to discuss these financial results and the Company's recent corporate highlights. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

The information contained in this Item 2.02 of this Current Report (including Exhibit 99.1) is being furnished and 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 in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 7, 2026
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.

DEFINIUM THERAPEUTICS, INC.

Date: May 7, 2026

By: /s/ Robert Barrow

Name: Robert Barrow

Title: Chief Executive Officer

Definium Therapeutics Reports First Quarter 2026 Financial Results and Recent Highlights

Three Phase 3 topline data readouts for DT120 ODT expected in the coming months

DT120 ODT program expanded into PTSD with Phase 3 Haven study expected to initiate in 2027

\$373.4 million in cash, cash equivalents, and investments as of March 31, 2026, expected to fund operations into 2028

Conference call scheduled today at 4:30 p.m. EDT

NEW YORK, May 7, 2026 -- Definium Therapeutics, Inc. (“Definium” or the “Company”) (NASDAQ: DFTX), a late-stage clinical biopharmaceutical company developing a new generation of therapeutics intended to address underlying causes of psychiatric and neurological disorders, today reported financial results for the quarter ended March 31, 2026, and recent highlights.

“After an exceptionally productive start to 2026, we are thrilled to enter an exciting and transformative period for Definium, marked by three pivotal data readouts for DT120 ODT anticipated within the next five months and an expanded development program in PTSD,” said Rob Barrow, Chief Executive Officer of Definium Therapeutics. “With enrollment complete in our Emerge and Voyage studies, Panorama enrolling its final participants, and Ascend now underway, our momentum has never been stronger. We are energized by the prospect of reaching multiple critical milestones that will shape our path forward and propel our regulatory strategy for DT120 ODT. Our team remains laser-focused on executing with discipline and scientific rigor to deliver robust, high-quality studies across our pivotal pipeline. We are driven by the urgent need to bring new hope and effective solutions to the millions of individuals battling depression, anxiety, and PTSD.”

First Quarter 2026 and Other Recent Highlights

- Completed enrollment in Emerge (MDD) with 149 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. Topline data expected in late 2Q 2026.
- Completed enrollment in Voyage (GAD) with 214 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. Topline data expected in early 3Q 2026.
- Completed the blinded sample size re-estimation for Panorama (GAD) with total target enrollment updated to 200 participants. Current enrollment is over 200 participants, and screening has been closed. Participants are randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo. Topline data expected in late 3Q 2026 (updated from 2H 2026).
- Continued to activate sites for Ascend, with first patient dosing anticipated in 2Q 2026. The trial is expected to enroll approximately 175 participants randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo.
- Expanded DT120 ODT clinical development program into PTSD with plans to initiate Haven, a Phase 3 study in PTSD. Haven is expected to enroll approximately 200 participants randomized 1:1 to receive DT120 ODT or placebo. The primary endpoint in the study is the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at Week 8. Study initiation expected in 2027.

- Hosted an Investor and Analyst Day in New York on April 22, 2026. The event featured Definium’s executive leadership team alongside distinguished expert clinicians, who discussed the evolving treatment landscape in psychiatry, significant unmet need, emerging opportunities to improve outcomes for patients, and the Company’s clinical and commercial progress for DT120 ODT.

First Quarter 2026 Financial Results

Cash, Cash Equivalents and Investments. As of March 31, 2026, Definium Therapeutics had cash, cash equivalents and investments of \$373.4 million compared to \$411.6 million as of December 31, 2025. Based on the Company’s current operating plan and anticipated milestones, the Company believes that its cash, cash equivalents and investments as of March 31, 2026 will be sufficient to fund the Company’s operations into 2028.

Research and Development (R&D). R&D expenses were \$41.5 million for the three months ended March 31, 2026 compared to \$23.4 million for the three months ended March 31, 2025, an increase of \$18.1 million. The increase was primarily due to increases of \$15.2 million in DT120 ODT program expenses, \$3.2 million in internal personnel costs reflecting expanded research and development capabilities, and \$0.3 million in DT402 program expenses, partially offset by a decrease of \$0.6 million in preclinical and other program expenses.

General and Administrative (G&A). G&A expenses were \$17.7 million for the three months ended March 31, 2026, compared to \$8.8 million for the three months ended March 31, 2025, an increase of \$8.9 million. The increase was primarily due to increases of \$3.9 million in stock-based compensation expense, \$1.4 million in personnel-related expenses, \$1.4 million in commercial-preparedness related expenses, \$1.4 million in corporate and government affairs expenses, and \$1.2 million in legal and patent expenses, partially offset by a reduction of \$0.4 million in other miscellaneous administrative expenses.

Conference Call and Webcast Reminder

Definium Therapeutics management will host a webcast at 4:30 p.m. EDT today to provide a corporate update and review the Company’s first quarter 2026 financial results and business highlights. Listeners can register for the webcast via [this link](#). Analysts wishing to participate in the question-and-answer session should use [this link](#). A replay of the webcast will be available via the Investor Relations section of the Definium Therapeutics website, ir.definiumtx.com, and archived for at least 30 days after the webcast. Those who plan on participating are advised to join 15 minutes prior to the start time.

About DT120 Orally Disintegrating Tablet (ODT)

DT120 ODT (lysergide tartrate) is an ergoline derivative belonging to the group of classic serotonergic psychedelics which acts as a partial agonist at serotonin-2A (5-HT_{2A}) receptors. DT120 ODT is Definium’s proprietary and pharmaceutically optimized formulation of LSD. DT120 ODT is an advanced formulation incorporating Catalent’s Zydis® ODT fast-dissolve technology, which is designed to deliver several unique advantages, such as faster absorption and faster onset of transient cognitive, perceptual, and affective changes, improved bioavailability, and lower incidence of gastrointestinal side effects. Definium is developing DT120, the tartrate salt form of lysergide, for generalized anxiety disorder (GAD), major depressive disorder (MDD), posttraumatic stress disorder (PTSD), and is exploring its potential applications in other serious brain health disorders.

About Definium Therapeutics

The mission of Definium Therapeutics is to forge a new era of psychiatry by applying scientific rigor to psychedelics, with the goal of developing accessible treatments that unlock healing at scale. Guided by a recognition that patients deserve more than better, Definium is relentlessly advancing a new generation of therapeutics intended to address underlying causes of psychiatric and neurological disorders. By turning evidence into impact, Definium aims to change the trajectory of today’s mental health care crisis and enable a healthier future. Headquartered in New York, Definium Therapeutics trades on Nasdaq under the symbol DFTX.

For more information, visit www.definiumtx.com and follow Definium Therapeutics on Instagram, LinkedIn and X.

Forward-Looking Statements

Certain statements in this news release related to the Company constitute "forward-looking information" within the meaning of applicable securities laws and are prospective in nature. Forward-looking information is not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as "will", "may", "should", "could", "intend", "estimate", "plan", "anticipate", "expect", "believe", "potential" or "continue", or the negative thereof or similar variations. Forward-looking information in this news release includes, but is not limited to, statements regarding the Company's anticipated topline readout (Part A results) for the Phase 3 Voyage study of DT120 ODT in GAD in early 3Q 2026; the Company's anticipated topline readout (Part A results) for the Phase 3 Panorama study for DT120 ODT in GAD in late 3Q 2026; the Company's anticipated topline readout (Part A results) for the Phase 3 Emerge study for DT120 ODT in MDD in late 2Q 2026; the Company's plans to dose the first patient in the Phase 3 Ascend study of DT120 ODT in MDD in 2Q 2026; the Company's expectations regarding enrollment for each of the Haven and Ascend studies; the Company's expectations to initiate the Haven study in 2027; the Company's planned trial design for Haven; the Company's beliefs regarding potential benefits of its product candidates; the Company's expectation that its cash, cash equivalents and investments will fund operations into 2028; and potential additional indications for DT120 ODT and DT402. There are numerous risks and uncertainties that could cause actual results and the Company's plans and objectives to differ materially from those expressed in the forward-looking information, including history of negative cash flows; limited operating history; incurrence of future losses; availability of additional capital; compliance with laws and regulations; legislative and regulatory developments, including decisions by the Drug Enforcement Administration and states to reschedule any of our product candidates, if approved, containing Schedule I controlled substances, before they may be legally marketed in the U.S.; difficulty associated with research and development; risks associated with clinical studies or studies; heightened regulatory scrutiny; early stage product development; clinical study risks; regulatory approval processes; novelty of the psychedelic inspired medicines industry; ability to maintain effective patent rights and other intellectual property protection; as well as those risk factors discussed or referred to herein and the risks, uncertainties and other factors described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 and its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2026 under headings such as "Special Note Regarding Forward-Looking Statements," and "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other filings and furnishings made by the Company with the securities regulatory authorities in all provinces and territories of Canada which are available under the Company's profile on SEDAR+ at www.sedarplus.ca and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events, changes in expectations or otherwise.

For further information, please contact:**Investors:**

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Media:

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Definium Therapeutics, Inc.
Consolidated Balance Sheets

(in thousands, except share amounts)	March 31, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 262,518	\$ 257,837
Short-term investments	110,904	153,756
Prepaid and other current assets	7,141	7,727
Total current assets	<u>380,563</u>	<u>419,320</u>
Goodwill	19,918	19,918
Other non-current assets	812	862
Total assets	<u>\$ 401,293</u>	<u>\$ 440,100</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,127	\$ 5,347
Accrued expenses	24,514	20,446
2022 USD Financing Warrants	49,471	40,905
Total current liabilities	<u>81,112</u>	<u>66,698</u>
Credit facility, long-term	40,773	40,579
Other non-current liabilities	559	496
Total liabilities	<u>122,444</u>	<u>107,773</u>
Commitments and contingencies		
Shareholders' equity:		
Common shares, no par value, unlimited authorized as of March 31, 2026 and December 31, 2025, respectively; 104,044,508 and 98,776,265 issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	937,795	913,914
Accumulated other comprehensive income	824	1,085
Accumulated deficit	(659,770)	(582,672)
Total shareholders' equity	<u>278,849</u>	<u>332,327</u>
Total liabilities and shareholders' equity	<u>\$ 401,293</u>	<u>\$ 440,100</u>

Definium Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

(in thousands, except share and per share amounts)	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	\$ 41,484	\$ 23,357
General and administrative	17,736	8,802
Total operating expenses	59,220	32,159
Loss from operations	(59,220)	(32,159)
Other income/(expense):		
Interest income	3,457	2,433
Interest expense	(1,245)	(602)
Foreign exchange loss, net	(44)	(19)
Change in fair value of 2022 USD Financing Warrants	(20,046)	6,999
Total other income/(expense)	(17,878)	8,811
Net loss	(77,098)	(23,348)
Other comprehensive loss		
Unrealized gain/(loss) on investments	(262)	10
Gain/(loss) on foreign currency translation	1	(27)
Comprehensive loss	\$ (77,359)	\$ (23,365)
Net loss per common share, basic	\$ (0.71)	\$ (0.27)
Net loss per common share, diluted	\$ (0.71)	\$ (0.35)
Weighted-average common shares, basic	108,790,941	85,067,855
Weighted-average common shares, diluted	108,790,941	87,091,461