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): August 06, 2026

Definium Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

British Columbia	**001-40360**	**98-1582438**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
One World Trade Center Suite 8500 New York, New York		**10007**
(Address of Principal Executive Offices)		**(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 August 6, 2026, Definium Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter ended June 30, 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.

Exhibit No.	Description
99.1	Press Release, dated August 6, 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: August 6, 2026

By: /s/ Robert Barrow

Name: Robert Barrow
Title: Chief Executive Officer

Exhibit 99.1

Definium Therapeutics Reports Second Quarter 2026 Financial Results and Recent Highlights

Announced positive topline results from Phase 3 Emerge study of DT120 ODT in major depressive disorder (MDD), demonstrating rapid, robust, and durable efficacy

Topline results from Phase 3 GAD studies of DT120 ODT in generalized anxiety disorder (GAD) on track: Voyage results anticipated week of August 10; Panorama results anticipated September 2026

Approximately $1.1 billion in cash, cash equivalents, and investments as of June 30, 2026

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

NEW YORK, August 6, 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 June 30, 2026, and recent highlights.

"The second quarter marked a meaningful inflection point for Definium as we further established our leadership position in psychedelic medicine," said Rob Barrow, Chief Executive Officer of Definium Therapeutics. "The unprecedented Phase 3 Emerge results validated the highly differentiated profile of DT120 ODT and reinforced its potential to become a best-in-class treatment across multiple psychiatric disorders. We also continued to execute across our pipeline, completing enrollment in Voyage and Panorama and initiating enrollment in Ascend. Our public offering generated approximately $805 million in gross proceeds and provides the capital to advance our clinical and commercial strategy from a position of strength. We believe Definium is uniquely positioned to advance a potential new treatment paradigm across some of the field's largest and most underserved indications."

Business Updates

- Completed an underwritten public offering of 23,676,471 common shares of the Company for gross proceeds of $805 million. Net proceeds from the offering were approximately $757.9 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company.
- Launched *Wired for Worry,* a new healthcare provider disease education platform designed to deepen understanding of GAD, reinforce the importance of ongoing assessment, and help healthcare professionals better understand the neurobiological mechanisms that may contribute to the disorder.

Program Status and Anticipated Milestones

- Announced positive topline results from Phase 3 Emerge study (MDD) with 149 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. Key findings included:
    - Met the primary endpoint and all key secondary efficacy endpoints with a high degree of statistical significance.
    - Demonstrated a statistically significant and clinically meaningful placebo-adjusted improvement of 8.1 points in Montgomery-Åsberg Depression Rating Scale (MADRS) total score from baseline at Week 6 (Cohen's d = 0.83; p<0.0001), the study's primary endpoint.
    - Demonstrated a statistically significant placebo-adjusted improvement of 7.3 points in MADRS total score from baseline at Week 12 (p<0.0001), the study's key secondary endpoint.
    - DT120 ODT was generally well tolerated, with no serious adverse events and no suicidality signal observed.
- Completed enrollment of Phase 3 Voyage study (GAD) with 214 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. Topline data anticipated the week of August 10, 2026.
- Completed enrollment of Phase 3 Panorama study (GAD) with 245 participants randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo. Topline data anticipated in September 2026.
- Initiated enrollment of Phase 3 Ascend study (MDD). The trial is expected to enroll approximately 165 participants randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo. Topline data expected in 2027.
- Phase 3 Haven study in posttraumatic stress disorder (PTSD) is expected to initiate in 2027 and enroll approximately 200 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. The primary endpoint in the study is expected to be the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at Week 8.

Second Quarter 2026 Financial Results

Cash, Cash Equivalents and Investments. As of June 30, 2026, Definium Therapeutics had cash, cash equivalents and investments of approximately $1.1 billion 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 June 30, 2026 will be sufficient to fund the Company's operations into 2030.

Research and Development (R&D). R&D expenses were $48.7 million for the three months ended June 30, 2026 compared to $29.8 million for the three months ended June 30, 2025, an increase of $18.9 million. The increase was primarily due to an increase of $12.9 million in expenses related to our DT120 program, an increase of $5.7 million in internal personnel costs as a result of increasing research and development capabilities, and an increase of $0.6 million in preclinical and other program expenses, partially offset by a decrease of $0.3 million in DT402 program expenses.

General and Administrative (G&A). G&A expenses were $26.4 million for the three months ended June 30, 2026, compared to $11.1 million for the three months ended June 30, 2025, an increase of $15.3 million. The increase was primarily due to an increase of $7.6 million in stock-based compensation expenses, an increase of $2.6 million in corporate and government affairs expenses, an increase of $2.0 million in personnel-related expenses, an increase of $1.8 million in commercial-preparedness related expenses, an increase of $0.6 million in legal and patent expenses, and an increase of $0.7 million in other miscellaneous administrative expenses.

Net loss. Net loss for the three months ended June 30, 2026 was significantly impacted by an $86.2 million non-cash increase in the fair value of warrant liabilities associated with the appreciation in the Company's share price during the period. Net loss for the three months ended June 30, 2026 was $159.0 million, compared to $42.7 million for the three months ended June 30, 2025.

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 second quarter 2026 financial results and business highlights. Listeners can register for the webcast via this link. 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-HT2A) 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, designed to deliver several unique advantages, including 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. Definium maintains a strong foundation to protect and extend the long-term value of the DT120 ODT franchise through a multi-layered intellectual property strategy spanning composition, formulation, and methods-of-use patents.

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 belief in DT120 ODT's potential to become a best-in-class treatment across multiple psychiatric disorders; the Company's anticipated topline readout (Part A results) for the Phase 3 Voyage study of DT120 ODT in GAD the week of August 10, 2026; the Company's anticipated topline readout (Part A results) for the Phase 3 Panorama study for DT120 ODT in GAD in September 2026; the Company's anticipated topline readout (Part A results) for the Phase 3 Ascend study for DT120 ODT in MDD in 2027; 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 Ascend and 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 2030; and potential additional indications for DT120 ODT. 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 Reports on Form 10-Q for the fiscal quarters ended March 31, 2026 and June 30, 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 or to be 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:
Gitanjali Jain
VP, Head of Investor Relations
ir@definiumtx.com

Media:
media@definiumtx.com

Definium Therapeutics, Inc.
Consolidated Balance Sheets

(in thousands, except share amounts)	June 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 655,267	$ 257,837
Short-term investments	428,612	153,756
Prepaid and other current assets	8,222	7,727
Total current assets	1,092,101	419,320
Goodwill	19,918	19,918
Other non-current assets	880	862
Total assets	$ 1,112,899	$ 440,100
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 6,965	$ 5,347
Accrued expenses	37,222	20,446
2022 USD Financing Warrants	113,017	40,905
Total current liabilities	157,204	66,698
Credit facility, long-term	36,467	40,579
Other non-current liabilities	549	496
Total liabilities	194,220	107,773
Commitments and contingencies		
Shareholders' equity:		
Common shares, no par value, unlimited authorized as of June 30, 2026 and December 31, 2025; 134,365,950 and 98,776,265 issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	1,737,018	913,914
Accumulated other comprehensive income	417	1,085
Accumulated deficit	(818,756)	(582,672)
Total shareholders' equity	918,679	332,327
Total liabilities and shareholders' equity	$ 1,112,899	$ 440,100

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

(in thousands, except share and per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 48,665	$ 29,809	$ 90,149	$ 53,166
General and administrative	26,412	11,094	44,148	19,896
Total operating expenses	75,077	40,903	134,297	73,062
Loss from operations	(75,077)	(40,903)	(134,297)	(73,062)
Other income/(expense):				
Interest income	3,587	2,774	7,044	5,207
Interest expense	(1,233)	(2,338)	(2,478)	(2,940)
Foreign exchange loss, net	(32)	(49)	(76)	(68)
Change in fair value of 2022 USD Financing Warrants	(86,231)	(2,228)	(106,277)	4,771
Total other income/(expense)	(83,909)	(1,841)	(101,787)	6,970
Net loss	(158,986)	(42,744)	(236,084)	(66,092)
Other comprehensive loss				
Unrealized gain/(loss) on investments	(406)	36	(668)	46
Loss on foreign currency translation	(1)	(31)	—	(58)
Comprehensive loss	$ (159,393)	$ (42,739)	$ (236,752)	$ (66,104)
Net loss per common share, basic	$ (1.44)	$ (0.50)	$ (2.15)	$ (0.78)
Net loss per common share, diluted	$ (1.44)	$ (0.50)	$ (2.15)	$ (0.81)
Weighted-average common shares, basic	110,684,720	85,347,677	109,743,062	85,208,539
Weighted-average common shares, diluted	110,684,720	85,347,677	109,743,062	87,099,006