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): November 09, 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 November 9, 2026, Definium Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its fiscal quarter ended September 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 November 9, 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: November 9, 2026

By: /s/ Robert Barrow

Name: Robert Barrow
Title: Chief Executive Officer

Exhibit 99.1

Definium Therapeutics Reports Third Quarter 2026 Financial Results and Recent Highlights

Reported positive topline Phase 3 results from two Phase 3 studies of DT120 ODT in generalized anxiety disorder (GAD)

Received FDA Breakthrough Therapy Designation for DT120 ODT in major depressive disorder (MDD)

On track for DT120 ODT NDA filing in first half of 2027

DT402 demonstrated positive initial results in a Phase 2a trial in adults with autism spectrum disorder (ASD); clinical study evaluating multiple dosing paradigms planned for 2027

Approximately $1.05 billion in cash, cash equivalents, and investments as of September 30, 2026

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

NEW YORK, November 9, 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 September 30, 2026, and recent highlights. The Company also reported positive initial results from its Phase 2a trial of DT402 in adults with ASD, with improvements observed across several measures of socialization, communication and other functional outcomes.

"Our positive Phase 3 topline results from Voyage and Panorama this quarter further strengthened the evidence supporting DT120 ODT. Together with our previously reported results, these findings demonstrate consistent, clinically meaningful results across three Phase 3 studies in GAD and MDD, reinforcing our confidence in DT120 ODT's potential to address significant unmet needs across both conditions," said Rob Barrow, Chief Executive Officer. "With Breakthrough Therapy designation in MDD and Ascend progressing, we continue to advance our late-stage program while building the capabilities needed to prepare for potential approval and commercialization. Beyond DT120, we believe DT402 represents an exciting opportunity and its initial results support continued development as we work to deliver differentiated therapies for patients with significant unmet needs."

Third Quarter and Recent Highlights

- **DT120 ODT in GAD:** Reported positive topline results from Phase 3 Voyage study in GAD with 214 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 5.4 points in Hamilton Anxiety Rating Scale (HAM-A) total score from baseline at Week 12 ($p<0.0001$, Cohen's $d=0.81$), the study's primary endpoint.
  - DT120 ODT was generally well tolerated, with no drug-related serious adverse events and no suicidality signal observed in Part A.
- **DT120 ODT in GAD:** Reported positive topline results from Phase 3 Panorama study in GAD with 245 participants randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, 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 5.1 points in HAM-A total score from baseline at Week 12 ($p<0.0001$, Cohen's $d=0.64$), the study's primary endpoint.
- DT120 ODT was generally well tolerated, with no drug-related serious adverse events and no suicidality signal observed in Part A.

- **DT120 ODT in MDD:**
  - Received Breakthrough Therapy designation for DT120 ODT in MDD following positive topline results from Phase 3 Emerge study, which met the primary endpoint and all key secondary efficacy endpoints with a high degree of statistical significance.
  - Continuing enrollment for the Phase 3 Ascend study in 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 is expected in 2027.
- **DT120 ODT in PTSD:** Planning to initiate the Phase 3 Haven study in PTSD in 2027 with approximately 200 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. The planned primary endpoint in the study is the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at Week 8.
- **DT402 in ASD:** The Company's Phase 2a trial of DT402 in five adults with ASD demonstrated positive initial results. The 200 mg single-dose, single arm, open-label study was designed to characterize the pharmacodynamic and clinical effects of DT402 and explore changes across measures of socialization, communication and other functional outcomes. The study endpoints were considered exploratory and were not powered to draw statistical conclusions. Following treatment, improvements were observed across several measures, including reduced rigidity and fixation and increased engagement in social settings, as well as increases in empathy and closeness to others and reductions in anxiety and irritability. DT402 was well tolerated, with the most common adverse events being euphoria, fatigue and enhanced relaxation. Based on these initial findings, the Company plans to further evaluate DT402 in a study that will investigate the safety and clinical activity of multiple dosing paradigms expected to begin in 2027.
- **Scientific engagement:** Presented clinical and scientific data at several major medical meetings, including Psych Congress 2026, the 39th ECNP Congress and the 2026 NEI Fall Congress. Presentations included topline results from the Phase 3 Emerge, Voyage and Panorama studies of DT120 ODT, an overview of the DT120 ODT Phase 3 safety data, and the DT120 ODT Phase 3 development program. At Psych Congress, the Emerge and Voyage posters were named finalists, with Voyage receiving the Top Poster award and Emerge selected for a podium presentation during the *Latest Discoveries & Emerging Trends in MDD* session.
- **Commercial readiness and organizational growth:** Advancing commercial readiness activities and expanding organizational capabilities to support the Company's transition toward commercialization. The Company is also planning its first Commercial Day in the first half of 2027 to highlight the market opportunity for DT120 ODT and provide greater detail on its commercialization strategy and launch preparations.

Third Quarter 2026 Financial Results

Cash, Cash Equivalents and Investments. As of September 30, 2026, the Company had cash, cash equivalents and investments of approximately $1.05 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 September 30, 2026 will be sufficient to fund the Company's operations into 2030.

Research and Development (R&D). R&D expenses were $46.1 million for the three months ended September 30, 2026 compared to $31.0 million for the three months ended September 30, 2025, an increase of $15.1 million. The increase was primarily attributable to an $8.8 million increase in personnel-related costs associated with the expansion of the Company's research and development organization, a $5.9 million increase in expenses related to the DT120 development program, and a $0.6 million increase in preclinical and other program expenses, partially offset by a $0.2 million decrease in DT402 program expenses.

General and Administrative (G&A). G&A expenses were $26.1 million for the three months ended September 30, 2026, compared to $14.7 million for the three months ended September 30, 2025, an increase of $11.4 million. The increase was primarily due to a $3.5 million increase in corporate and government affairs expenses, a $3.4 million increase in commercial-preparedness related expenses, a $3.3 million increase in personnel-related expenses as the Company expanded its organizational capabilities, a $0.7 million increase in legal and patent expenses, a $0.4 million increase in other miscellaneous administrative expenses, and a $0.1 million increase in stock-based compensation expenses.

Net loss. Net loss for the three months ended September 30, 2026 was $51.0 million, compared to $67.3 million for the three months ended September 30, 2025. The decrease in net loss was primarily attributable to a gain from the change in fair value of the Company's 2022 USD financing warrants and higher interest income, partially offset by increased operating expenses.

Conference Call and Webcast Reminder

Definium Therapeutics management will host a webcast at 4:30 p.m. EST today to provide a corporate update and review the Company's third 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 is an ergoline derivative belonging to the group of classic serotonergic psychedelics, which acts as a partial agonist at 5-hydroxytryptamine serotonin-2A (5-HT2A) receptors. DT120 ODT is Definium's proprietary and pharmaceutically optimized formulation of Lysergide (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 onset of transient cognitive, perceptual, and affective changes, improved bioavailability, and a lower incidence of gastrointestinal side effects. Definium is developing DT120 ODT, the tartrate salt form of lysergide, for generalized anxiety disorder (GAD), major depressive disorder (MDD), and posttraumatic stress disorder (PTSD), and is exploring its potential applications in other serious brain health disorders. DT120 has received Breakthrough Therapy designation from the FDA for GAD and MDD. 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 DT402
DT402 is the Company’s proprietary form of R(-)-MDMA (rectus-3,4 methylenedioxymethamphetamine), being developed for the treatment of core symptoms of autism spectrum disorder (ASD). MDMA is a synthetic molecule that is often referred to as an empathogen because it is reported to increase feelings of connectedness and compassion. Preclinical and early-stage clinical studies of R(-)-MDMA demonstrate its acute pro-social and empathogenic effects, while its diminished dopaminergic activity suggest that it has the potential to exhibit less stimulant activity, neurotoxicity, hyperthermia and abuse liability compared to racemic MDMA or the S(+)-enantiomer.

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 https://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 address significant unmet needs across GAD and MDD; the Company’s anticipated NDA filing in the first half of 2027; 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 expectations to further evaluate DT402 in a study that will investigate the safety and clinical activity of multiple dosing paradigms beginning in 2027; the Company’s expectation to hold a Commercial Day in the first half of 2027; 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 the Company's 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 for the Company's product candidates; the Company's expectations regarding the size of the eligible patient populations for its lead product candidates, if approved and commercialized; the Company's ability to identify third-party treatment sites to conduct its trials and its ability to identify and train appropriate qualified healthcare practitioners to administer its treatments; the pricing, coverage and reimbursement of the Company's lead product candidates, if approved and commercialized; the rate and degree of market acceptance and clinical utility of the Company's lead product candidates, in particular, and controlled substances, in general; 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, June 30, 2026 and September 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:
ir@definiumtx.com

Media:
media@definiumtx.com

Definium Therapeutics, Inc.
Consolidated Balance Sheets

(in thousands, except share amounts)	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 241,150	$ 257,837
Short-term investments	805,698	153,756
Prepaid and other current assets	4,911	7,727
Total current assets	1,051,759	419,320
Goodwill	19,918	19,918
Other non-current assets	2,606	862
Total assets	$ 1,074,283	$ 440,100
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 9,277	$ 5,347
Accrued expenses	37,125	20,446
2022 USD Financing Warrants	21,328	40,905
Total current liabilities	67,730	66,698
Credit facility, long-term	36,661	40,579
Other non-current liabilities	1,858	496
Total liabilities	106,249	107,773
Commitments and contingencies		
Shareholders' equity:		
Common shares, no par value, unlimited authorized as of September 30, 2026 and December 31, 2025; 136,887,557 and 98,776,265 issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	1,838,580	913,914
Accumulated other comprehensive (loss) income	(829)	1,085
Accumulated deficit	(869,717)	(582,672)
Total shareholders' equity	968,034	332,327
Total liabilities and shareholders' equity	$ 1,074,283	$ 440,100

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

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 46,141	$ 30,978	$ 136,290	$ 84,144
General and administrative	26,138	14,691	70,286	34,587
Total operating expenses	72,279	45,669	206,576	118,731
Loss from operations	(72,279)	(45,669)	(206,576)	(118,731)
Other income/(expense):				
Interest income	10,139	2,262	17,183	7,469
Interest expense	(1,150)	(1,274)	(3,628)	(4,214)
Foreign exchange loss, net	(21)	(39)	(97)	(107)
Change in fair value of 2022 USD Financing Warrants	12,350	(22,545)	(93,927)	(17,774)
Total other income/(expense)	21,318	(21,596)	(80,469)	(14,626)
Net loss	(50,961)	(67,265)	(287,045)	(133,357)
Other comprehensive loss				
Unrealized gain/(loss) on investments	(1,245)	196	(1,913)	242
Loss on foreign currency translation	(1)	(2)	(1)	(60)
Comprehensive loss	$ (52,207)	$ (67,071)	$ (288,959)	$ (133,175)
Net loss per common share, basic	$ (0.37)	$ (0.78)	$ (2.42)	$ (1.56)
Net loss per common share, diluted	$ (0.46)	$ (0.78)	$ (2.42)	$ (1.56)
Weighted-average common shares, basic	135,941,973	85,885,516	118,571,999	85,436,678
Weighted-average common shares, diluted	137,346,685	85,885,516	118,571,999	85,436,678