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 12, 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 8.01 Other Events.

On May 12, 2026, Definium Therapeutics, Inc. (the “Company”) issued a press release announcing the first patient dosed in the Company's Phase 3 Ascend study of DT120 Orally Disintegrating Tablet in Major Depressive Disorder. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 12, 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 12, 2026

By: /s/ Robert Barrow

Name: Robert Barrow
Title: Chief Executive Officer

Definium Therapeutics Announces First Patient Dosed in Ascend, the Second Phase 3 Pivotal Study of DT120 ODT in Major Depressive Disorder

The primary endpoint will measure the change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) score at Week 6 between DT120 Orally Disintegrating Tablet (ODT) 100 µg and placebo

Ascend builds on positive Phase 2b study results in generalized anxiety disorder, which showed the potential antidepressant effects of DT120

Topline data from the 12-week double-blind period is anticipated in 2027

NEW YORK -- Definium Therapeutics, Inc. (Nasdaq: DFTX) ("Definium" or the "Company"), a late-stage clinical biopharmaceutical company developing a new generation of therapeutics intended to address the underlying causes of psychiatric and neurological disorders, today announced that the first patient has been dosed in Ascend, its second Phase 3 study evaluating DT120 ODT (lysergide tartrate) for the treatment of major depressive disorder (MDD). The Ascend study will evaluate the efficacy and safety of DT120 ODT versus placebo and is expected to enroll 175 participants in the United States.

"DT120 ODT represents a potentially transformative treatment for people living with MDD, with our findings from our DT120 Phase 2b study showing strong effects on depression symptoms," said Daniel R. Karlin, M.D. M.A., Chief Medical Officer of Definium. "Too often, existing treatments for MDD fall short, leading many patients to be treated with multiple medications without lasting relief. We expect the Ascend study to continue to build on the clinical evidence that DT120 ODT can deliver a meaningfully differentiated option for one of psychiatry's most significant unmet needs and help alter the course of the growing mental health crisis. As we rapidly approach the anticipated topline readout from our first Phase 3 Study in MDD, Emerge, we believe Definium is entering a pivotal period that could enable meaningful advances in the treatment landscape for patients living with depression and anxiety."

The design of Ascend is aligned with Emerge, as well as the Company's Phase 3 trials of DT120 ODT in generalized anxiety disorder (GAD), and is conducted in two parts: Part A, a 12-week, randomized, double-blind, placebo-controlled, parallel-group period; and Part B, a 40-week extension period during which participants will be eligible for open-label treatment with DT120 ODT based on symptom severity. As with the Company's Panorama study of DT120 ODT in GAD, participants will be randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg, or placebo. The 50 µg arm is intended to confound participants' ability to accurately assess the dose condition to which they have been randomized. This approach continues to build on the Company's Phase 2b study of DT120 in GAD, which the Company believes demonstrated that DT120's clinical activity is not attributable to functional unblinding and aligns with FDA guidance on the use of complementary designs across our DT120 clinical development program. The primary endpoint of Ascend is the change from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS) at Week 6 between DT120 ODT 100 µg and placebo.

About Major Depressive Disorder (MDD)
Major Depressive Disorder (MDD) is the second-most common mental health disorder in the U.S., with over 21 million adults experiencing a major depressive episode (MDE) each year.[1,2] This disorder, a leading cause of disability worldwide,[3] brings persistent feelings of worthlessness, fatigue, and recurrent thoughts of death[4] while increasing long-term mortality risk by 40%.[5] MDD also carries a $326 billion annual economic burden in the U.S., driven by healthcare costs and lost productivity.[6] The MDD treatment paradigm is characterized by critical unmet needs, including fewer than one-third of patients reaching remission with first-line

treatments[8], onset of clinical activity that takes weeks to months[9,10], poor tolerability[11,12], and frequent switching, augmentation, and discontinuation of pharmacotherapy[13].

About DT120 (lysergide tartrate) 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 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 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), 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 Lysergide (LSD)
Lysergide (LSD) is one of the most extensively studied psychopharmaceuticals in history, with over 1,000 published reports.[1] First synthesized in 1938 by Swiss chemist Albert Hofmann in his search for active principles from ergot fungus, its profound psychological effects were discovered in 1943, which transformed psychiatric research.[1] LSD, a definitional classic psychedelic, temporarily alters perception, cognition, and emotion, is physiologically safe, non-addictive, and isn't associated with withdrawal.[1] While its precise mechanism of action in the treatment of psychiatric illness is unknown, its acute perceptual, cognitive, and affective effects are mediated by agonism of the serotonin 5-hydroxytryptamine 2A (5-HT2A) receptor, and mechanistic hypotheses suggest that it causes sustained increases in neuroplasticity in a variety of brain regions.[2,3]

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.

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 Emerge study for DT120 ODT in MDD in late 2Q 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 expectation that Ascend will enroll 175 participants; the Company's belief that the clinical activity of DT120 is not attributable to functional unblinding; the Company's beliefs regarding potential benefits of its product candidates; the Company's belief that DT120 ODT represents a potentially transformative treatment for MDD; and the Company's belief in DT120 ODT's differentiated therapeutic profile. 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 more information, visit https://definiumtx.com/ and follow Definium Therapeutics on Instagram, LinkedIn, and X.

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