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): September 08, 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 September 8, 2026, Definium Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing that the U.S. Food and Drug Administration has granted breakthrough designation to the Company's DT120 ODT program for the treatment of major depressive disorder. A copy of the Press Release is attached as Exhibit 99.1 hereto, and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated September 8, 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: September 8, 2026

By: /s/ Robert Barrow

Name: Robert Barrow
Titel: Chief Executive Officer

Definium Therapeutics Receives Breakthrough Therapy Designation for DT120 (lysergide) Orally Disintegrating Tablet (ODT) in Major Depressive Disorder (MDD) Following Positive Phase 3 Results

Second FDA Breakthrough Therapy designation for DT120 reinforces its potential across MDD and generalized anxiety disorder (GAD), two disorders with significant unmet need

NEW YORK -- Definium Therapeutics, Inc. (“Definium” or the “Company”), a late-stage clinical biopharmaceutical company developing a new generation of therapeutics intended to address underlying causes of psychiatric and neurological disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for DT120 (lysergide) ODT. The designation was supported by the significant unmet medical need in MDD and results from the Company's Phase 3 Emerge study, in which a single 100 µg dose of DT120 ODT demonstrated a statistically significant 8.1-point placebo-adjusted improvement in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 6 ($p<0.0001$), with durable efficacy through Week 12.

This milestone marks the second Breakthrough Therapy designation from the FDA for the DT120 development program, following its initial designation for the potential treatment of GAD. The FDA’s Breakthrough Therapy designation is a process designed to expedite the development and review of innovative medicines intended to treat serious conditions where preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over available therapy on one or more clinically significant endpoints.

"Securing our second Breakthrough Therapy designation, closely following the unprecedented results from our Phase 3 Emerge study, underscores the potential of DT120 to meaningfully transform the treatment landscape for people living with serious mental health disorders," said Rob Barrow, Chief Executive Officer of Definium Therapeutics. "This recognition of DT120’s promise, first in GAD and now in MDD, reinforces the urgency to advance and deliver rapid, durable benefit across multiple indications. Our focus remains on developing innovative therapies that have the potential to expand treatment options and improve outcomes for the millions of people who continue to seek meaningful relief."

MDD is characterized by at least five depressive symptoms, lasting two weeks or longer, which may include feelings of worthlessness, fatigue, impaired social functioning, and recurrent thoughts of death.[1] With more than 21 million U.S. adults experiencing a major depressive episode each year, MDD is the second-most common mental health disorder in the U.S. and a leading cause of disability worldwide.[2,3,4] Despite the availability of first-line treatments, fewer than one-third of patients reach remission, underscoring the critical unmet need for more effective treatment options.[5]

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 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), 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 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.[2,3] This disorder, a leading cause of disability worldwide,[3] brings persistent feelings of worthlessness, fatigue, and recurrent thoughts of death[1] while increasing long-term mortality risk by 40%.[6] MDD also carries a $326 billion annual economic burden in the U.S., driven by healthcare costs and lost productivity.[7] The MDD treatment paradigm is characterized by critical unmet needs, including fewer than one-third of patients reaching remission with first-line treatments,[5] onset of clinical activity that takes weeks to months,[8,9] poor tolerability,[10,11] and frequent switching, augmentation, and discontinuation of pharmacotherapy.[12]

About Lysergide (LSD)

Lysergide (LSD) is one of the most extensively studied psychopharmaceuticals in history, with over 1,000 published reports.[13] 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.[13] LSD, a definitional classic psychedelic, temporarily alters perception, cognition, and emotion, is physiologically safe, non-addictive, and is not associated with withdrawal.[13] 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.[14,15]

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 potential of DT120 ODT across MDD and GAD; the potential of DT120 to meaningfully transform the treatment landscape for people living with serious mental health disorders; the potential of DT120 ODT to expand treatment options and improve outcomes; the Company's beliefs regarding potential benefits of its product candidates; and the potential to explore 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 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 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.

References:

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