April 22, 2026

Definium Therapeutics Highlights DT120 ODT (Lysergide Tartrate) Clinical Advancements and Commercial Strategy at Investor and Analyst Day

MDD: Emerge topline data readout on track for late 2Q 2026; Ascend sites activated with first patient dosing anticipated in 2Q 2026

GAD: Voyage enrollment complete with 214 patients with topline data readout on track for early 3Q 2026; Panorama sample size re-estimation complete and target sample size updated to 200; screening closed with topline readout now expected in late 3Q 2026

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

NEW YORK--(BUSINESS WIRE)-- 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 highlighted the advancement of its DT120 ODT (lysergide tartrate) clinical program and commercial strategy in major depressive disorder (MDD) and generalized anxiety disorder (GAD), with three anticipated topline readouts in the next six months serving as important near-term catalysts. The Company also announced an expansion of the DT120 ODT program with the planned initiation of the Phase 3 Haven study in posttraumatic stress disorder (PTSD).

"We are building Definium to be a leader in psychiatry, focused on delivering a differentiated, scalable franchise for patients with depression, anxiety, and trauma, anchored by DT120 ODT, which we believe could be a best-in-class therapy," said Rob Barrow, Chief Executive Officer of Definium Therapeutics. "With three pivotal readouts expected over the next six months, we are rapidly establishing comprehensive clinical evidence for DT120 ODT. Together, these trial outcomes will inform our regulatory approach, including an expeditious path to a potential NDA submission. We continue to execute with focus and urgency to deliver transformative treatments for patients and sustained value for shareholders."

The Company is preparing for its next phase of growth with the same rigor and discipline that have underpinned the clinical development of DT120 ODT, which represents a potential multi-billion-dollar commercial opportunity supported by a differentiated therapeutic profile and broad applicability across care settings. Definium is advancing a focused, patient-centric commercial strategy, including a scalable delivery model designed to support efficient adoption and long-term utilization. In parallel, the Company is proactively positioning for access and reimbursement with plans to leverage established and emerging practice patterns and existing administrative pathways to enable timely market uptake.

Clinical Advancements

DT120 ODT (lysergide tartrate) for MDD

- **Emerge**: Fully enrolled with 149 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. Topline data on track for late 2Q 2026.
- **Ascend**: Sites activated with first dosing anticipated in 2Q 2026. Study plans to enroll 175 participants randomized 2:1:2 to DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo.

DT120 ODT (lysergide tartrate) for GAD

- **Voyage**: Fully enrolled with 214 participants randomized 1:1 to receive DT120 ODT 100 µg or placebo. Topline data on track for early 3Q 2026.
- **Panorama**: Blinded sample size re-estimation complete with total target enrollment updated to 200 participants. Current enrollment over 200 participants and screening now closed. Participants randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo. Topline data now anticipated in late 3Q 2026 (updated from 2H 2026).

DT120 ODT (lysergide tartrate) for PTSD

- **Haven:** Phase 3 study in PTSD expected to enroll approximately 200 participants randomized 1:1 to receive DT120 ODT or placebo. Primary endpoint in the study is the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at Week 8. Study initiation expected in 2027.

Today's Investor and Analyst Day featured Definium's executive leadership team alongside distinguished expert clinicians, who discussed the evolving treatment landscape in psychiatry, persistent unmet need, and emerging opportunities to improve outcomes for patients, as well as the Company's clinical progress and commercial strategy. Presentation materials from today's event are available here.

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 for the Phase 3 Voyage study of DT120 ODT in GAD in early 3Q 2026; the Company's anticipated topline readout for the Phase 3 Panorama study for DT120 ODT in GAD in late 3Q 2026; the Company's anticipated topline readout 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 the enrollment for each of the Panorama and Ascend studies; the Company's expectation to initiate the Haven study of DT120 ODT in PTSD in 2027; the Company's expectations regarding enrollment and trial design for the Haven study; the Company's beliefs regarding potential benefits of its product candidates; the Company's belief that DT120 ODT could be a best-in-class therapy; the Company's regulatory plans, including the timing of any potential NDA submissions; the Company's belief in DT120 ODT's differentiated therapeutic profile and broad applicability across care settings; the potential market opportunity for DT120 ODT; the Company's commercial strategy; and patient access to and reimbursement of 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 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.

References:

1. Nichols, D. E. (2016). Psychedelics. Pharmacological Reviews, 68(2), 264–355. https://doi.org/10.1124/pr.115.011478
2. Passie, T., Halpern, J. H., Stichtenoth, D. O., Emrich, H. M., & Hintzen, A. (2008). The pharmacology of lysergic acid diethylamide: A review. CNS Neuroscience & Therapeutics, 14, 295–314. https://doi.org/10.1111/j.1755-5949.2008.00059.x
3. Liechti, M. E. (2017). Modern clinical research on LSD. Neuropsychopharmacology, 42, 2114–2127. https://doi.org/10.1038/npp.2017.86

View source version on businesswire.com:
https://www.businesswire.com/news/home/20260422742468/en/

Investors:
Gitanjali Jain
VP, Head of Investor Relations ir@definiumtx.com

Media:
media@definiumtx.com

Source: Definium Therapeutics, Inc.