February 26, 2026

Definium Therapeutics Reports Full-Year 2025 Financial Results and Business Updates

Emerge (Phase 3 MDD) enrollment complete; topline data anticipated in late 2Q 2026

Voyage (Phase 3 GAD) approximately 80% enrolled; no change in sample size required; topline readout anticipated in early 3Q 2026

Panorama (Phase 3 GAD) enrollment on track; topline readout expected in 2H 2026

$411.6 million in cash, cash equivalents and investments as of December 31, 2025 expected to fund operations into 2028

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

NEW YORK--(BUSINESS WIRE)-- 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 reported its full-year 2025 financial results and provided business updates.

“We are proud of the strong execution and momentum across our organization, following a year of significant progress in our comprehensive development programs for DT120 ODT,” said Rob Barrow, Chief Executive Officer of Definium Therapeutics. “With our first Phase 3 MDD trial, Emerge, now fully enrolled and advancing toward topline data sooner than anticipated, and our Phase 3 GAD studies, Voyage and Panorama, rapidly progressing toward enrollment completion, 2026 represents a monumental year for Definium. Each of these pivotal readouts represents an important catalyst opportunity to move DT120 ODT one step closer to delivering on its best-in-class potential in both MDD and GAD. We remain committed to precise science and our ambitious view of the potential to deliver meaningful improvements for patients, reinforce our leadership in mental health innovation, and drive long-term shareholder value.”

Business Updates

- Completed equity financing in 4Q 2025 totaling approximately $259 million in gross proceeds, before deducting underwriting discounts and commissions and offering expenses payable by the Company, bringing in multiple new institutional investors, and extending the Company’s cash runway into 2028.
- Published full study results in the *Journal of the American Medical Association* from the Company’s randomized, placebo-controlled Phase 2b trial evaluating a single dose of DT120 across four dose levels in patients with moderate to severe generalized anxiety disorder (GAD). DT120 has received FDA Breakthrough Designation for GAD.
- Further strengthened the leadership team with the appointments of Brandi L. Roberts as Chief Financial Officer and Matt Wiley as Chief Commercial Officer.

- Expanded Board of Directors with appointment of Roger Adsett in January 2026. Mr. Adsett is a highly accomplished biopharmaceutical executive with more than two decades of experience leading landmark drug launches, scaling global commercial organizations, and helping companies establish leadership positions within their therapeutic areas, including specialty, rare disease, and primary care markets. He currently serves as Chief Operating Officer of Insmed.
- Company to host Investor and Analyst Day on April 22, 2026, to discuss program updates and the commercial opportunity for DT120 orally disintegrating tablet (ODT) (lysergide tartrate).

Program Updates and Anticipated Milestones

The program for DT120 ODT (lysergide tartrate) consists of four pivotal Phase 3 studies, two in GAD and two in major depressive disorder (MDD). Each study is comprised of two parts: Part A, a 12-week, randomized, double-blind, placebo-controlled, parallel group assessing the efficacy and safety of DT120 ODT versus placebo, and Part B, a 40-week open-label extension period. The primary endpoint in the GAD studies is the change from baseline in Hamilton Anxiety Scale (HAM-A) score at Week 12 between DT120 ODT 100 µg and placebo; and in the MDD studies the change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) score at Week 6 between DT120 ODT 100 µg and placebo.

DT120 ODT (lysergide tartrate) for MDD

- **Emerge**: study is fully enrolled with 149 patients randomized 1:1 to receive DT120 ODT 100 µg or placebo. Topline data are anticipated in late 2Q 2026.
- **Ascend**: initial sites have been activated, and study initiation has been accelerated with first patient dosing anticipated by early 2Q 2026. The trial is expected to enroll approximately 175 participants randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo.

DT120 ODT (lysergide tartrate) for GAD

- **Voyage**: study enrollment is approximately 80% complete and is expected to conclude in the coming weeks. Topline data are anticipated in early 3Q 2026. The protocol-specified blinded sample size re-estimation is complete, requiring no increase in enrollment. Voyage is expected to enroll approximately 200 participants in the U.S. randomized 1:1 to receive DT120 ODT 100 µg or placebo.
- **Panorama**: study enrollment on track with topline data anticipated in 2H 2026. Panorama is expected to enroll approximately 250 participants, in the U.S. and Europe, randomized 2:1:2 to receive DT120 ODT 100 µg, DT120 ODT 50 µg control, or placebo. Further enrollment updates and the outcome of the protocol-specified, blinded sample size re-estimation is planned to be provided at Investor and Analyst Day on April 22, 2026.

DT402 (R(-)-MDMA) for Autism Spectrum Disorder (ASD)

- Following the completion of its single-ascending dose Phase 1 study of DT402 in adult healthy volunteers, the Company initiated a Phase 2a study in 4Q 2025. The study is a single-dose, open-label study assessing early signals of efficacy of DT402 in treating core socialization and communication symptoms of ASD in up to 20 adult participants. The objectives and endpoints of the study are designed to characterize the

pharmacodynamics and clinical effects of DT402 in adults with ASD, including on multiple functional biomarkers. Initial data from the Phase 2a study is anticipated in 2026.

2025 Financial Results

Cash, Cash Equivalents and Investments. As of December 31, 2025, Definium Therapeutics had cash, cash equivalents and investments of $411.6 million compared to $273.7 million as of December 31, 2024. Based on the Company's current operating plan and anticipated milestones, the Company believes that its cash, cash equivalents and investments as of December 31, 2025 will be sufficient to fund the Company's operations into 2028.

Research and Development (R&D). R&D expenses were $117.7 million for the year ended December 31, 2025, compared to $65.3 million for the year ended December 31, 2024, an increase of $52.4 million. The increase was primarily due to increases of $44.7 million in DT120 program expenses, $9.3 million in internal personnel costs reflecting expanded research and development capabilities, and $0.4 million in preclinical and other program expenses, partially offset by a $2.0 million reduction in DT402 program expenses.

General and Administrative (G&A). G&A expenses were $48.6 million for the year ended December 31, 2025, compared to $38.6 million for the year ended December 30, 2024, an increase of $10.0 million. The increase was primarily due to increases of $6.0 million in professional services and pre-commercialization activities, $3.6 million in personnel-related expenses, $0.7 million in directors' deferred share unit expenses and $0.5 million in other miscellaneous administrative expenses, offset by a reduction of $0.8 million in legal and patent-related 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 full-year 2025 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 (lysergide tartrate) is an ergoline derivative belonging to the group of classic serotonergic psychedelics which acts as a partial agonist at specific serotonin receptors (human 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, which is designed to deliver several unique advantages, such as 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), and is exploring its potential applications in other serious brain health disorders.

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 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 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 anticipated topline readout (Part A results) for the Phase 3 Voyage study of DT120 ODT in GAD in early 3Q 2026; the Company's anticipated topline readout (Part A results) for the Phase 3 Panorama study for DT120 ODT in GAD in the second half of 2026; 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 plans to dose the first patient the Phase 3 Ascend study of DT120 ODT in MDD by early 2Q; the Company's expectations regarding the enrollment for each of the Voyage, Panorama and Ascend studies, including the Company's belief that Voyage will complete enrollment in the coming weeks; the Company's beliefs regarding potential benefits of its product candidates; the Company's expectations regarding enrollment in its Phase 2a study of DT402 for the treatment of ASD; the Company's anticipated initial data readout for its Phase 2a study of DT 402 for the treatment of ASD in 2026; the Company's expectation that its cash, cash equivalents and investments will fund operations into 2028; and potential additional indications for DT120 ODT and DT402. 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.

Definium Therapeutics, Inc.
Consolidated Balance Sheets

(in thousands, except share amounts)	December 31, 2025	2024
Assets		
Current assets:		
Cash and cash equivalents	$ 257,837	$ 273,741
Short-term investments	153,756	—
Prepaid and other current assets	7,727	7,879
Total current assets	419,320	281,620
Goodwill	19,918	19,918
Other non-current assets	862	613
Total assets	$ 440,100	$ 302,151
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 5,347	$ 2,010
Accrued expenses	20,446	12,829
2022 USD Financing Warrants	40,905	24,010
Total current liabilities	66,698	38,849
Credit facility, long-term	40,579	21,854
Other non-current liabilities	496	—
Total liabilities	107,773	60,703
Commitments and contingencies		
Shareholders' equity:		
Common shares, no par value, unlimited authorized as of December 31, 2025 and 2024, respectively; 98,776,265 and 75,100,763 issued and outstanding as of December 31, 2025 and 2024, respectively	—	—
Additional paid-in capital	913,914	639,508
Accumulated other comprehensive income	1,085	819
Accumulated deficit	(582,672)	(398,879)
Total shareholders' equity	332,327	241,448
Total liabilities and shareholders' equity	$ 440,100	$ 302,151

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

(in thousands, except share and per share amounts)	Year Ended December 31, 2025	2024
Operating expenses:		
Research and development	$ 117,665	$ 65,297
General and administrative	48,644	38,619
Total operating expenses	166,309	103,916
Loss from operations	(166,309)	(103,916)
Other income/(expense):		
Interest income	10,960	11,558
Interest expense	(5,482)	(2,283)
Foreign exchange loss, net	(131)	(638)
Change in fair value of 2022 USD Financing Warrants	(22,831)	(15,941)
Gain on extinguishment of contribution payable	—	2,541
Total other expense, net	(17,484)	(4,763)
Net loss	(183,793)	(108,679)
Other comprehensive loss		
Unrealized gain on investments	330	—
Gain/(loss) on foreign currency translation	(64)	476
Comprehensive loss	$ (183,527)	$ (108,203)
Net loss per common share, basic and diluted	$ (2.06)	$ (1.54)
Weighted-average common shares, basic and diluted	89,327,608	70,461,067

View source version on businesswire.com:
https://www.businesswire.com/news/home/20260226343522/en/

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

Media:
media@definiumtx.com

Source: Definium Therapeutics, Inc.