

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 14, 2026

Definium Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

British Columbia
(State or Other Jurisdiction
of Incorporation)

001-40360
(Commission File Number)

98-1582438
(IRS Employer
Identification No.)

One World Trade Center
Suite 8500
New York, New York
(Address of Principal Executive Offices)

10007
(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 7.01 Regulation FD Disclosure.

On September 14, 2026, Definium Therapeutics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing positive topline data from the Company’s Phase 3 Panorama study of DT120 ODT for the treatment of generalized anxiety disorder. A copy of the Press Release is attached as Exhibit 99.1 hereto, and is incorporated by reference into this Item 7.01.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed to be “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 to be incorporated by reference into any of the Company’s filings with the SEC under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On September 14, 2026, the Company posted a presentation discussing the Panorama topline data (the “Presentation”) to its website. A copy of the Presentation is attached as Exhibit 99.2 hereto, and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated September 14, 2026
99.2	Panorama Topline Data Presentation, dated September 14, 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 14, 2026

By: /s/ Robert Barrow

Name: Robert Barrow

Title: Chief Executive Officer



**Definium Therapeutics Announces Positive Topline Results from Phase 3
Panorama Study of DT120 ODT in Generalized Anxiety Disorder**

Study met primary and all key secondary efficacy endpoints; Panorama is the second positive Phase 3 trial for DT120 ODT in GAD and the third positive Phase 3 trial for DT120 ODT

Participants receiving DT120 ODT 100 µg achieved a statistically significant reduction in Hamilton Anxiety Rating Scale (HAM-A) score, with a placebo-adjusted change of 5.1 points from baseline at Week 12 ($p < 0.0001$, Cohen's $d = 0.64$)

DT120 ODT 100 µg was generally well tolerated, with a safety profile consistent with prior clinical experience

Pre-NDA meeting scheduled in 4Q 2026; NDA filing anticipated in 1H 2027

Company to host webcast today at 8 am EDT

NEW YORK, September 14, 2026 -- Definium Therapeutics, Inc. (Nasdaq: DFTX) ("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 positive topline results from Panorama, the Company's second Phase 3 study of DT120 (lysergide) Orally Disintegrating Tablet (ODT) in adults with generalized anxiety disorder (GAD). This is the Company's third positive Phase 3 readout for DT120 ODT, following the positive Emerge results in major depressive disorder (MDD) announced in June and the positive Voyage results in GAD announced in August.

Panorama met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement from baseline compared with placebo, as measured by the change in Hamilton Anxiety Rating Scale (HAM-A) total score at Week 12. The Least Squares (LS) mean change from baseline in HAM-A total score at Week 12 in participants who received DT120 ODT 100 µg was -9.8 compared with -4.7 for participants who received placebo, an LS mean difference of -5.1 points ($p < 0.0001$), corresponding to a standardized effect size of $d = 0.64$. Efficacy was rapid, with changes seen as early as Day 2 and sustained at all post-baseline timepoints in Part A.

"The Panorama results again met our high expectations and confirmed the unprecedented efficacy of DT120 in GAD," said Rob Barrow, Chief Executive Officer of Definium Therapeutics. "With strong positive results across four complementary studies, we have built a compelling body of evidence that increases our confidence in the potential best-in-class profile of DT120. Building on this momentum, we are advancing toward an NDA submission and look forward to aligning with the FDA at our upcoming pre-NDA meeting. We are deeply grateful to the participants, investigators, site personnel, and our team whose commitment and hard work made this progress possible."

Participants were monitored for a minimum of 8 hours on dosing day and were assessed hourly beginning 5 hours after dosing on a structured end-of-session checklist (EoSC). The average time to meet EoSC criteria was 6.2 hours for participants receiving DT120 ODT 100 µg, with a median of 6.0 hours and 94% of participants meeting EoSC criteria by hour 8. Across over 1,000 treatment sessions in the Phase 3 program through September 10, 2026, 97% of participants met EoSC criteria by hour 8.

"Patients with generalized anxiety disorder often work through two or three medications before finding one they can tolerate, and even then, daily dosing brings its own burden, sedation, weight change, sexual side effects, and for some classes of medications, real dependence risk," said Scott Aaronson, MD, Chief Science Officer, Institute for Advanced Diagnostics and Therapeutics at Sheppard Pratt, and a Panorama investigator. "What stands out about DT120 ODT is that a single dose has the potential to hold a response for months without the patient managing a pill every day. For a condition this chronic and this undertreated, a treatment that removes daily adherence with a novel mechanism of action and a unique effect on cognitive processes underlying anxiety could change how we think about long-term management, not just acute relief."

Highlights from Panorama Topline Results

The mean baseline HAM-A score at study entry was 28.3 in the DT120 ODT 100 µg treatment group (n=96) and 28.0 in the placebo group (n=97).

Primary Endpoint	DT120 ODT 100 µg	Placebo ODT	Placebo-Adjusted Difference
HAM-A: LS mean change at Week 12	-9.8	-4.7	-5.1 (p<0.0001)
Key Secondary Endpoints			
CGI-S: LS mean change at Week 12	-1.0	-0.5	-0.6 (p<0.0001)
HAM-A: LS mean change at Week 1	-9.8	-4.5	-5.3 (p<0.0001)
CGI-S: LS mean change at Day 2	-1.1	-0.3	-0.8 (p<0.0001)
Other Secondary Endpoints			
HAM-A: response rate (≥50%) at Week 12	32%	14%	18% (p<0.05)
HAM-A: remission rate (≤7) at Week 12	15%	4%	12% (p<0.05)
HAM-A: mild or better (<16) at Week 12	35%	17%	19% (p<0.01)

HAM-A = Hamilton Anxiety Rating Scale; CGI-S = Clinical Global Impression-Severity Scale; LS = least squares; LS mean difference = difference in LS means of change from baseline between DT120 and placebo groups; Calculated differences may not equal the arithmetic differences between displayed values due to rounding.

Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons. Consistent with the dose-response profile demonstrated in our Phase 2b trial, DT120 ODT 50 µg demonstrated a placebo-adjusted change of -3.5 and -3.6 at Weeks 4 and 12, approximately 50% and 29% lower than was observed for DT120 ODT 100 µg.

DT120 ODT 100 µg was generally well tolerated, with most treatment-emergent adverse events (TEAEs) mild to moderate in severity, transient, and predominantly occurring on the day of dosing. No new safety signals were identified, including no suicidality signal or suicidal behavior. There were no drug-related serious adverse events. Overall discontinuation rates were similar between DT120 ODT 100 µg, DT120 50 µg, and placebo groups (10.4%, 11.5%, and 10.3%). The overall TEAE rate for DT120 ODT 100 µg, DT120 50 µg, and placebo was 94.8%, 96.1%, and 62.9%. The most common TEAEs (>10%) in the DT120 ODT 100 µg and 50 µg arms on dosing day were illusion (68%, 61%), nausea (37%, 26%), and headache (24%, 28%). Adverse events were collected in accordance with the FDA Guidance for Psychedelic Drug Development, which includes expected effects of the drug that can be characterized as positive or neutral.

Webcast Details

Definium Therapeutics management will host a webcast at 8:00 a.m. EDT to review the Panorama topline results. 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 to participate are advised to join 15 minutes before the start time.

About Panorama

Panorama (MM120-301) is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of DT120 Orally Disintegrating Tablet (ODT) in adults with generalized anxiety disorder (GAD). The study enrolled participants 18 to 74 years of age with a DSM-5-confirmed primary diagnosis of GAD and a minimum Hamilton Anxiety Rating Scale (HAM-A) total score of 20 at screening and baseline. Eligible participants were randomized 2:1:2 to receive a single dose of DT120 ODT 100 µg, DT120 ODT 50 µg, or matching placebo, with the 50 µg arm included to help mitigate functional unblinding. The study consists of a 12-week double-blind treatment period (Part A) followed by a 40-week open-label extension (Part B), during which participants may be eligible to receive up to four additional doses of DT120 ODT 100 µg based on symptom severity, for a total study duration of approximately 56 weeks. The primary endpoint is change from baseline in HAM-A total score at Week 12. Key secondary multiplicity-controlled endpoints are change from baseline in Clinical Global Impression-Severity (CGI-S) scale score at Week 12, change from baseline in HAM-A total score at Week 1, and change from baseline in CGI-S score at Day 2. Panorama enrolled 245 participants across approximately 32 study centers.

About Generalized Anxiety Disorder (GAD)

GAD is one of the most common psychiatric disorders, affecting approximately 26 million U.S. adults.^{1,2} People with GAD experience constant, overwhelming worry that is hard to control. Common symptoms include fatigue, muscle tension, trouble concentrating, and difficulty sleeping.³ GAD is associated with the development of other chronic physical illnesses, as well as depression, other anxiety disorders, and trauma-related conditions. Together, these issues can seriously impact a person's daily life, including substantial functional, economic, and quality-of-life burdens, and are associated with increased healthcare utilization and costs.^{4,5,6} Despite the significant personal and societal burden of GAD, there has been little innovation in the treatment of GAD in the past several decades, with the last new drug approval occurring in 2007.⁷

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-HT_{2A}) 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 Lysergide (LSD)

Lysergide (LSD) is one of the most extensively studied psychopharmaceuticals in history, with over 1,000 published reports.⁸ 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.⁸ LSD, a definitional classic psychedelic, temporarily alters perception, cognition, and emotion, is physiologically safe and non-addictive, and is not associated with withdrawal.⁸ 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-HT_{2A}) receptor, and mechanistic hypotheses suggest that it causes sustained increases in neuroplasticity in a variety of brain regions.^{9,10}

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 planned pre-NDA meeting in 4Q 2026; the Company's anticipated NDA filing in 1H 2027; the potential best in class profile of DT120 ODT; the potential for DT120 ODT to hold a response for months without the patient managing a pill every day; DT120 ODT's potential to change how we think about long-term management; and potential applications for DT120 ODT in other serious brain health disorders. 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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Phase 3 Panorama Study Topline Data Readout



Disclaimer

This presentation (the "Presentation") has been prepared by Definium Therapeutics, Inc. ("Definium", the "Company", "we", "our" or "us") solely for informational purposes. This Presentation does not constitute an offering of, or a solicitation of an offer to purchase, securities of Definium and under no circumstances is it to be construed as a prospectus or advertisement or public offering of securities. Any trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of the products or services of Definium. Any amounts are in USD unless otherwise noted. Definium's securities have not been approved or disapproved by the U.S. Securities and Exchange Commission (the "SEC") or by any state, provincial or other securities regulatory authority, nor has the SEC or any state, provincial or other securities regulatory authority passed on the accuracy or adequacy of this Presentation. Any representation to the contrary is a criminal offense.

Cautionary Note Regarding Forward-Looking Statements

This Presentation contains, and our officers and representatives may from time to time make, "forward-looking statements" within the meaning of applicable securities laws and are prospective in nature. Forward-looking statements are 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", "continue", "budget", "scheduled", "forecasts", "intends", "anticipates", "projects" or the negative thereof or similar variations. Forward-looking statements in this Presentation include, but are not limited to, statements regarding the anticipated design, timing, progress and results of our investigational programs for DT120 oral disintegrating tablet ("ODT"), a proprietary, pharmaceutically optimized form of lysergide tartrate for the treatment of generalized anxiety disorder, major depressive disorder and posttraumatic stress disorder (including the anticipated topline readout for the Ascend study); the timing of our pre-NDA meeting scheduled for the fourth quarter of 2026; our anticipated NDA filing in the first half of 2027; the success and timing of our development activities; our ability to meet the milestones set forth herein; the likelihood of success of any clinical trials or of obtaining U.S. Food and Drug Administration ("FDA") or other regulatory approvals; our beliefs regarding potential benefits and side effects (or lack thereof) of DT120 ODT; our belief that DT120 ODT represents a best-in-class profile; the potential commercial opportunity for DT120 ODT, if approved, including total addressable market and revenue opportunity; our plans to continue to advance commercial readiness activities, including patient education, access and support, and site of care readiness; our cash runway; our ability to successfully execute on our planned clinical, regulatory and commercial preparation activities; and the potential for psychedelics as a class of treatment options in psychiatry.

There are numerous risks and uncertainties that could cause actual results, plans and objectives to differ materially from those expressed in forward-looking statements, including history of negative cash flows, limited operating history, incurrence of future losses, availability of additional capital, compliance with laws and regulations, difficulty associated with research and development, risks associated with clinical trials or studies, heightened regulatory scrutiny, early stage product development, clinical trial risks, regulatory approval processes, novelty of the psychedelic inspired medicines industry, our ability to maintain effective patent rights and other intellectual property protection for our product candidates, our expectations regarding the size of the eligible patient populations for our lead product candidates, if approved and commercialized; our ability to identify third-party treatment sites to conduct our trials and our ability to identify and train appropriate qualified healthcare practitioners to administer our treatments; the pricing, coverage and reimbursement of our lead product candidates, if approved and commercialized; the rate and degree of market acceptance and clinical utility of our lead product candidates, in particular, and controlled substances, in general; as well as those risk factors described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025, the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2026, and the Company's Quarterly Report on Form 10-Q for the quarterly period ended 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 SEC on EDGAR at www.sec.gov.

Any forward-looking statement made by Definium in this Presentation is based only on information currently available to the Company and speaks only as of the date on which it is made. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this Presentation as a result of new information, future events, changes in expectations or otherwise.

Cautionary Note Regarding Regulatory Matters

The United States federal government regulates drugs through the Controlled Substances Act. DT120 ODT is a proprietary, pharmaceutically optimized form of lysergide D-tartrate and DT402, or R(-)-MDMA, is our proprietary form of the R-enantiomer of MDMA (3,4-methylenedioxymethamphetamine). Lysergide and MDMA are Schedule I substances under the Controlled Substances Act. While the Company is focused on programs using psychedelic or hallucinogenic compounds and non-hallucinogenic derivatives of these compounds, including in DT120 ODT, DT402 and its other product candidates, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates. The Company is a neuro-pharmaceutical drug development company and does not deal with psychedelic or hallucinogenic substances except within laboratory and clinical trial settings conducted within approved regulatory framework. The Company's products will not be commercialized prior to applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended uses is successfully developed.

Market and Industry Data

This Presentation includes market and industry data that has been obtained from third party sources, including industry publications. Definium believes that the industry data is accurate and that the estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although the data is believed to be reliable, Definium has not independently verified any of the data from third party sources referred to in this Presentation or ascertained the underlying economic assumptions relied upon by such sources. References in this Presentation to research reports or to articles and publications should not be construed as depicting the complete findings of the entire referenced report or article. Definium does not make any representation as to the accuracy of such information.



Opening Remarks

Rob Barrow
Chief Executive Officer



Thank you to our
study participants,
investigators and
partners who
made Panorama
possible



Significant need for innovation in the treatment of GAD

Significant disease burden, with impairment in daily functioning, work productivity and quality of life

Population prevalence increased from **3% to 10%** over last 20 years¹

No new drugs approved for GAD **since 2007**

¹ Generalized Anxiety Disorder, <https://www.nimh.nih.gov/health/statistics/generalized-anxiety-disorder>; Mental and Substance Use Disorders Prevalence Study, <https://www.rti.org/publication/mental-substance-use-disorders-prevalence-study-findings-report>

GAD: generalized anxiety disorder

Third Positive Pivotal Readout for DT120 ODT 100 µg

Generalized Anxiety Disorder (GAD)



Voyage

n=214
1:1 randomization

DT120 ODT
vs. Placebo

- Part A: 12-week DB, RCT
- Part B: 40-week Extension with OL Treatment

Met All Primary & Key Secondaries²



Panorama

n=245
2:1:2 randomization

DT120 ODT
vs. Placebo
including 50 µg control

- Part A: 12-week DB, RCT
- Part B: 40-week Extension with OL Treatment

Met All Primary & Key Secondaries²

Major Depressive Disorder (MDD)



Emerge

n=149
1:1 randomization

DT120 ODT
vs. Placebo

- Part A: 12-week DB, RCT
- Part B: 40-week Extension with OL Treatment

Met All Primary & Key Secondaries²



Ascend

Target n=165¹
2:1:2 randomization

DT120 ODT
vs. Placebo
including 50 µg control

- Part A: 12-week DB, RCT
- Part B: 40-week Extension with OL Treatment

Enrolling

Posttraumatic Stress Disorder (PTSD)



Haven

Target n=200¹
1:1 randomization

DT120 ODT
vs. Placebo

- Part A: 12-week DB, RCT
- Part B: 40-week Extension with OL Treatment

Planning

Study met all primary and key secondary endpoints & consistent with dose response demonstrated in Phase 2

¹ Clinical study designs subject to change based on ongoing regulatory discussion and review, including of Phase 3 clinical trial protocols
² Includes the primary endpoint and all hierarchically controlled key secondary endpoints.

DB: double blind; ODT: orally disintegrating tablet; OL: open-label; RCT: randomized controlled trial

Panorama Results Demonstrate Potential Best-in-Class Efficacy in Generalized Anxiety Disorder¹

Rapid, robust and durable efficacy after single dose

- All primary and key secondary endpoints highly statistically significant
- 5.1 point HAM-A improvement over placebo at week 12 primary endpoint ($p < 0.0001$)
- 5.3 point HAM-A improvement over placebo at week 1 ($p < 0.0001$)
- 0.8 point CGI-S improvement over placebo at day 2 ($p < 0.0001$)
- Results consistent with Phase 2 dose-response data

Limited side effect burden

- DT120 ODT 100 µg was generally well tolerated with no new safety signals identified
- No suicidality signal or suicidal behavior

Efficient session dynamics

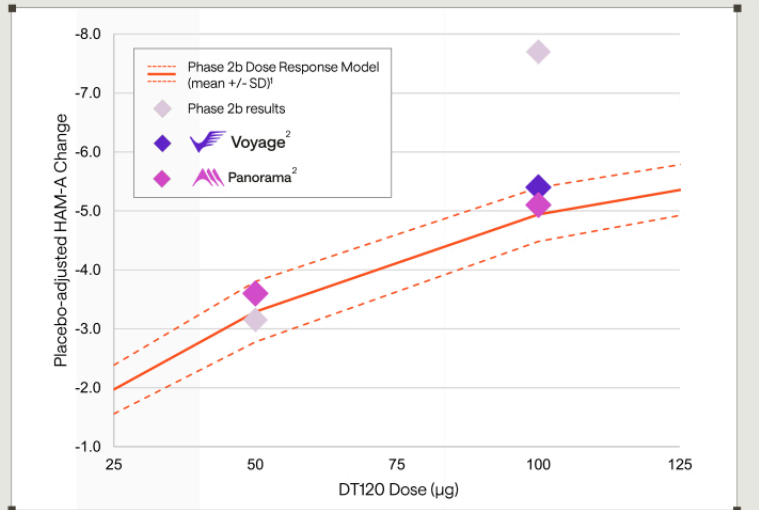
- 6.2 hour average time to clear End of Session Checklist (EoSC)
- 94% participants cleared EoSC by 8 hours

1. Source: Panorama study documents. Safety population in study part A (through week 12)

CGI-S: Clinical Global Impression-Severity Scale; HAM-A: Hamilton Anxiety Scale; ODT: orally disintegrating tablet

Phase 3 Results Align with DT120 Dose-Response Model

DT120 Dose Response Relationship



Highlights

Largest separation from placebo observed at 100 µg

- Week 4: 50% less separation at 50 µg³
- Week 12: 29% less separation at 50 µg

Dose response observed despite 'functional unblinding' at all doses

- 91% and 95% of participants at 50 and 100 µg correctly guessed assignment to drug

Phase 3 results align with dose-response model established in Phase 2b

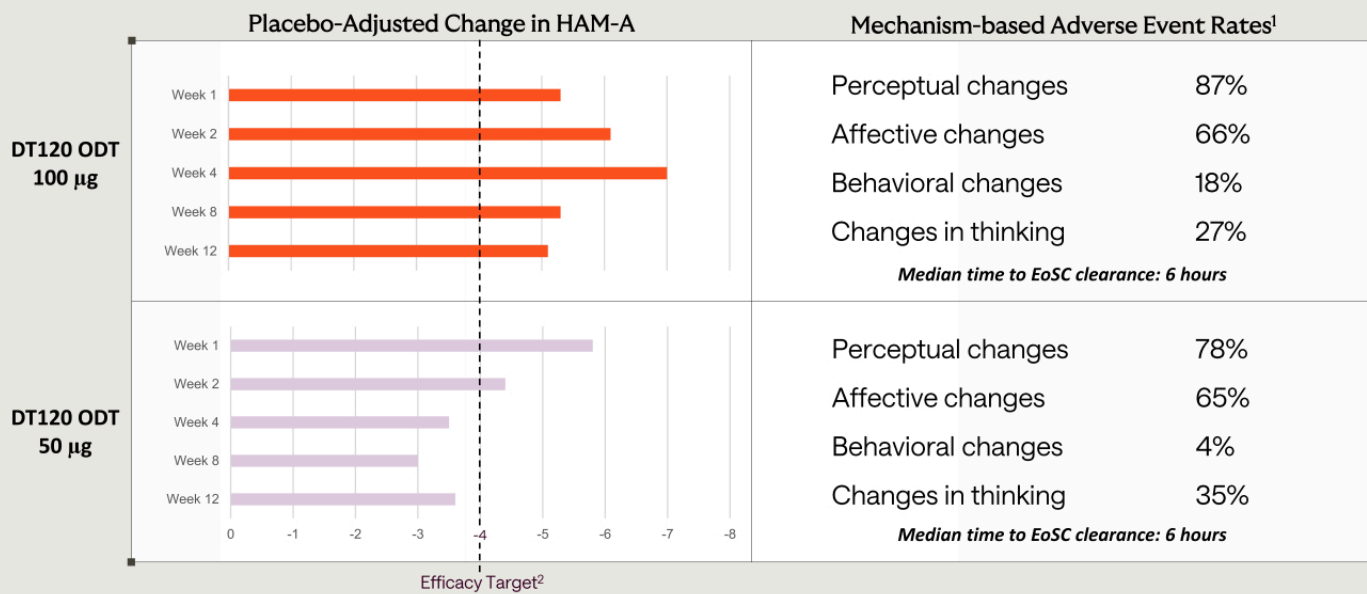
Results support the conclusion that DT120 dose response is not attributable to functional unblinding

1. Based on Phase 2b best-fit prespecified dose response model (Emax) at week 4, per protocol population.
2. ITT population. Placebo-adjusted HAM-A at week 12 using a Mixed-Effects Model Repeated Measures (MMRM) statistical analysis with reference-based imputation.
3. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.

GAD: generalized anxiety disorder

Benefit-Risk Highlights Differentiation of DT120 ODT 100 µg

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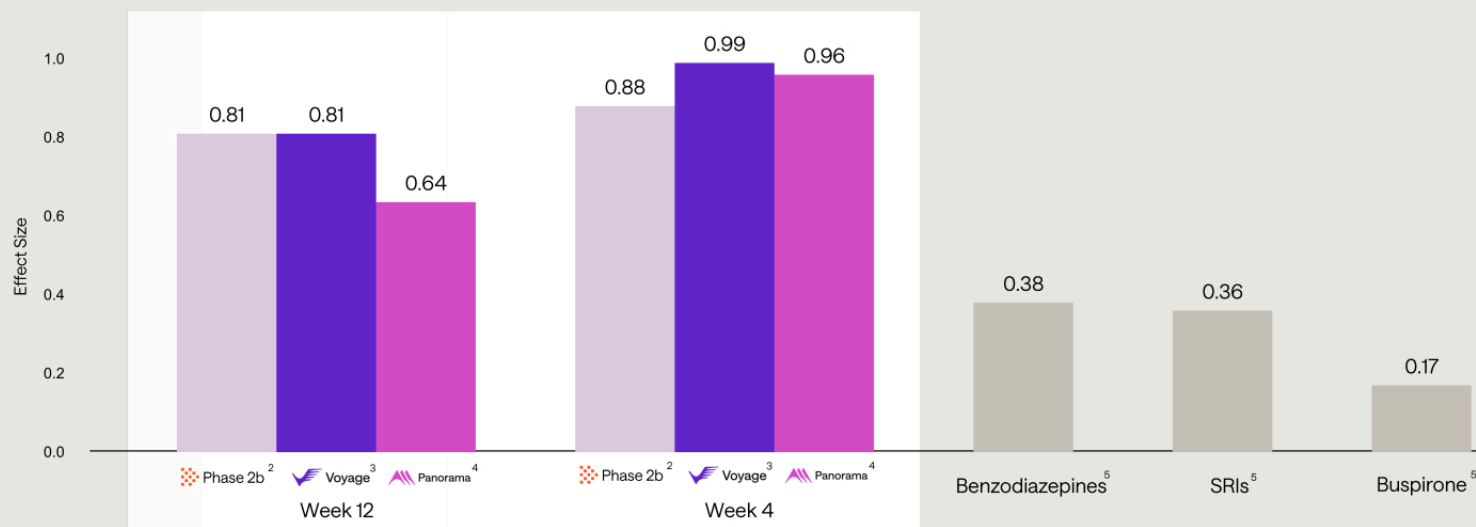


Efficacy target only achieved at 100 µg with similar adverse event profile across doses

1. Mechanism-based adverse event rates based on number of participants experiencing in Part A; safety population. Adverse event categories are a summary of MedDRA preferred terms that represent distinct domains of anticipated lysergide effects.
2. Dashed line represents target product profile: durable efficacy of 4 points or greater which represents a potential best-in-class profile.

EoSC: end of session checklist; HAM-A: Hamilton Anxiety Rating Scale; MedDRA: Medical Dictionary for Regulatory Activities

DT120 100 µg Efficacy Stands Out Against Approved GAD Treatments¹



DT120 observed effect size consistently larger than GAD standard of care

¹ The information presented in this slide is derived from multiple clinical trials, each conducted under distinct protocols and settings. As such, these data may not be directly comparable due to the lack of a head-to-head comparison. Differences in trial design, patient demographics, and other variables may account for variations in the observed outcomes. Study results for each drug are intended to be representative, however, multiple trials of the approved treatments have been conducted with varying results, including results that may have demonstrated a larger or smaller treatment effect than those presented. Buspirone and benzodiazepines are approved for anxiety disorders which include GAD; ² R Robison, JAMA. 2025 Sep 4; e2513481. doi:10.1001/jama.2025.13481; ³ Source: Voyage study documents; ⁴ Source: Panorama study documents; ⁵ RB Hidalgo, J Psychopharmacol. 2007 Nov;21(8):864-72

GAD: generalized anxiety disorder, SRI: serotonin reuptake inhibitors

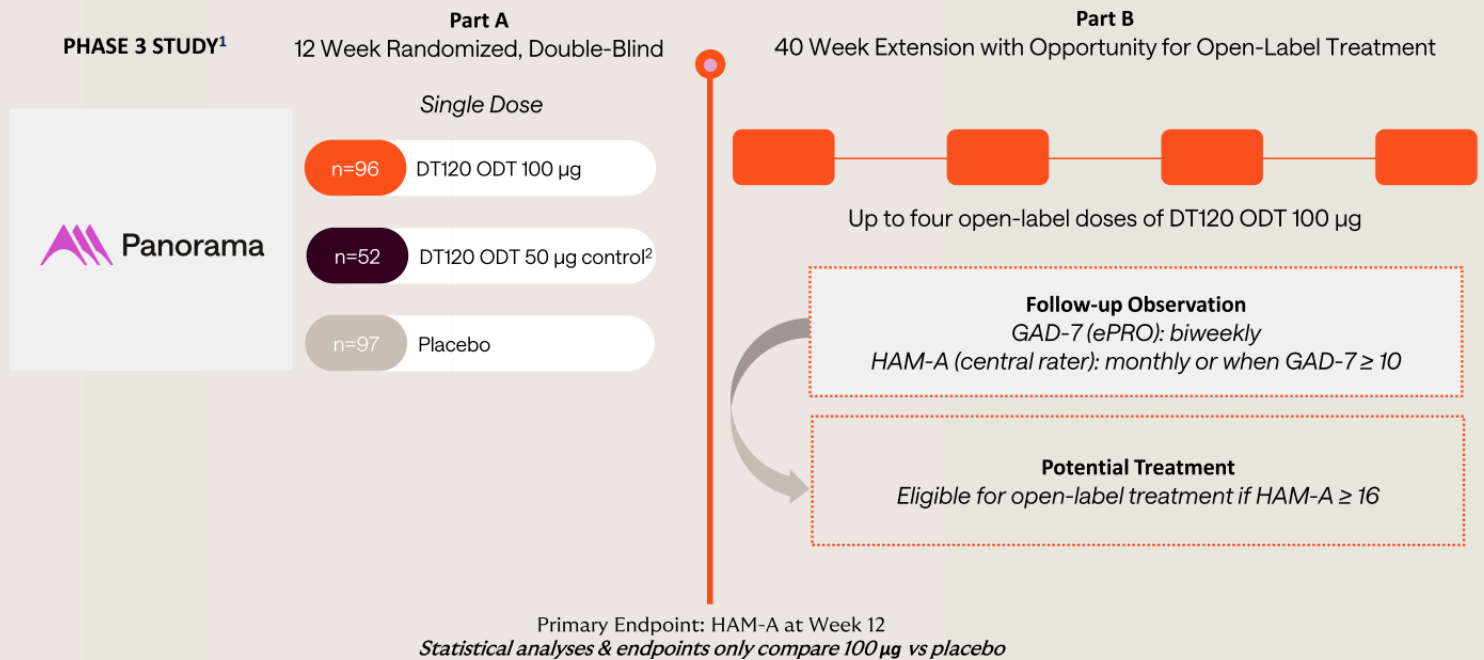


Phase 3 Panorama Study Results

Part A – Topline Results

Dan Karlin, MD
Chief Medical Officer

Panorama Trial Design

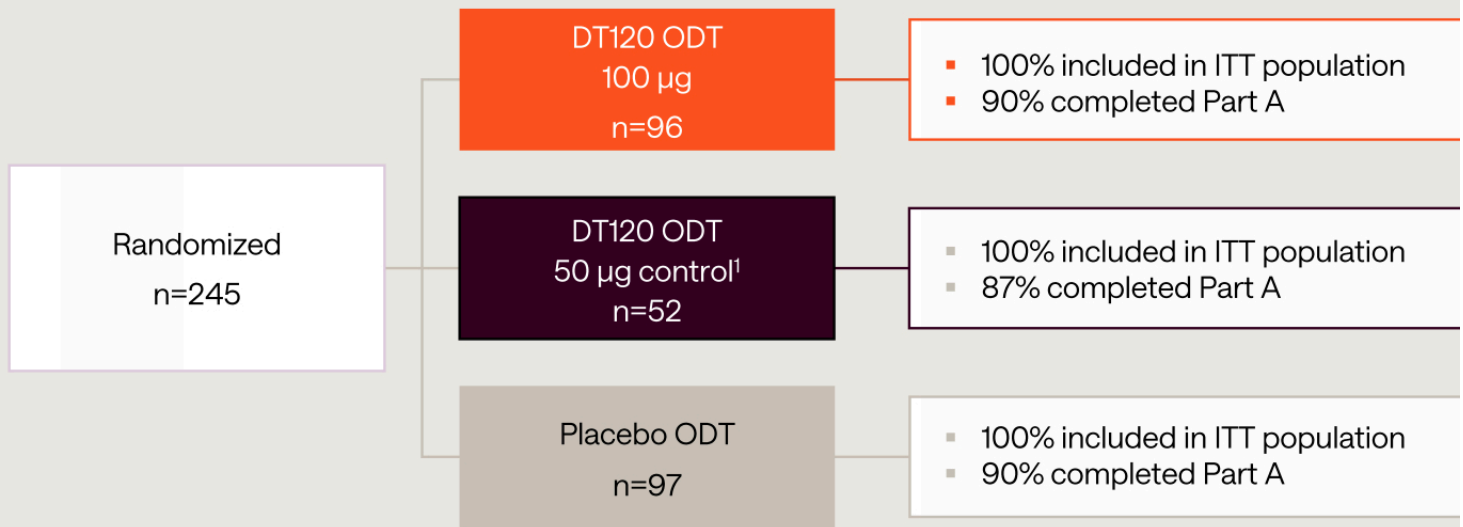


1. Source: Definium internal study documents.

2. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.

ePRO: electronic Patient-Reported Outcome; GAD: generalized anxiety disorder; GAD-7: a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of anxiety; HAM-A: Hamilton Anxiety Rating Scale; ODT: orally disintegrating tablet; µg: microgram

Participant Disposition



1. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.
ITT: intent to treat; ODT: orally disintegrating tablet

Demographic	DT120 ODT 100 µg n=96	DT120 ODT 50 µg control ² n=52	Placebo ODT n=97	Overall n=245
Mean age (years)	39.8	40.4	42.3	40.9
Sex (% female)	62%	56%	62%	60%
Race (% white)	82%	85%	84%	83%
Baseline HAM-A score ^{3,4}	28.3 (5.5)	27.7 (4.8)	28.0 (5.6)	28.0 (5.4)
Baseline CGI-S score ^{3,5}	4.7 (0.5)	4.7 (0.6)	4.7 (0.6)	4.7 (0.6)
Past Psychedelic Use, n (%)				
Any psychedelic ⁶	11 (12%)	8 (15%)	16 (17%)	35 (14%)
LSD	4 (4%)	4 (8%)	8 (8%)	16 (7%)

1. Based on ITT population.

2. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.

3. Mean (SD).

4. The HAM-A is a 14-item clinician-rated outcome measure assessing various domains of anxiety with a range of 0-56. In Panorama, HAM-A ratings were assessed by central raters blinded to both treatment assignment and visit number.

5. The CGI-S is a clinician-rated outcome measure assessing overall severity of illness with a range of 1 to 7.

6. Psychedelics include LSD, psilocybin, dimethyltryptamine and other classic serotonergic psychedelics.

CGI-S: Clinical Global Impressions - Severity Scale; HAM-A: Hamilton Anxiety Rating Scale; ITT: intent to treat; LSD: lysergic acid diethylamide; ODT: orally disintegrating tablet

Baseline Characteristics | Representative of GAD Patients with High Burden of Disease¹

Diagnostic Trait	DT120 ODT 100 µg n=96	DT120 ODT 50 ug control ² n=52	Placebo ODT n=97	Overall n=245
HAM-A score ²	28.3 (5.5)	27.7 (4.8)	28.0 (5.6)	28.0 (5.4)
HAM-A severity, n (%)				
Moderate (<24) ⁴	20 (21%)	9 (17%)	27 (28%)	56 (23%)
Severe (≥24)	76 (79%)	43 (83%)	70 (72%)	189 (77%)
Number of past GAD treatments, n (%)				
0	29 (30%)	14 (27%)	17 (18%)	60 (25%)
1	20 (21%)	15 (29%)	22 (23%)	57 (23%)
2+	47 (49%)	23 (44%)	58 (60%)	128 (52%)
Comorbid MDD ⁵ , n (%)	28 (29%)	17 (33%)	25 (26%)	70 (29%)
MADRS score ³	13.3 (4.4)	13.4 (4.5)	13.5 (3.9)	13.4 (4.2)
Years since Diagnosis of GAD ³	6.9 (7.6)	9.4 (11.4)	9.9 (8.8)	8.6 (9.0)
Years since Onset of GAD Symptoms ³	16.4 (12.6)	18.2 (15.5)	19.1 (13.4)	17.8 (13.6)

1. Based on ITT population

2. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.

3. Mean (SD)

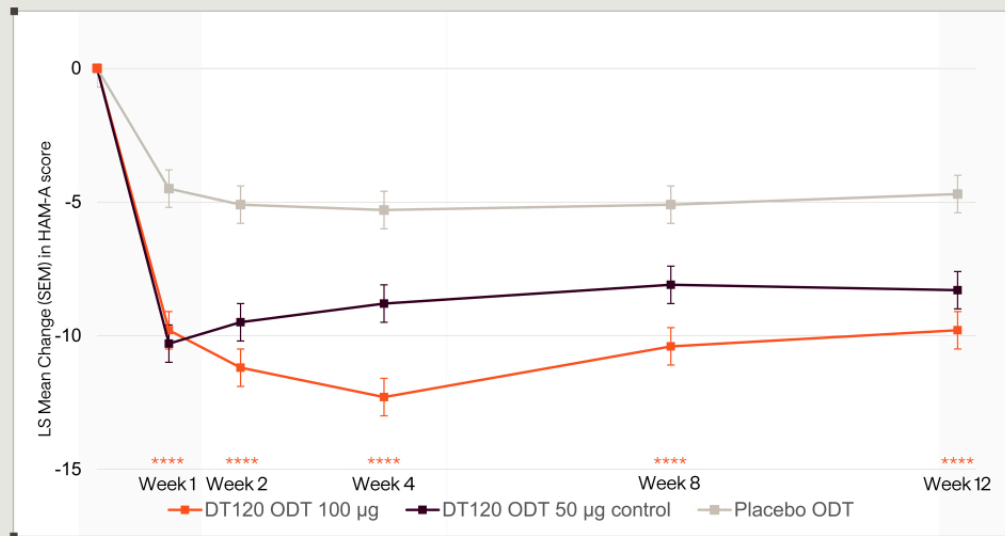
4. Eligibility criteria required a baseline HAM-A score of 20 or greater; Moderate symptoms are defined as a HAM-A score of 16 – 23.

5. Eligibility criteria excluded participants currently in a major depressive episode.

GAD: generalized anxiety disorder; HAM-A: Hamilton Anxiety Rating Scale; ITT: intent to treat; MADRS: Montgomery-Åsberg Depression Rating Scale; MDD: major depressive disorder; ODT: orally disintegrating tablet; SD: standard deviation

DT120 ODT 100 µg Showed Statistically & Clinically Significant HAM-A Improvements at All Timepoints^{1,2}

Primary Endpoint: HAM-A Change from Baseline to Week 12



Highlights

Change from Baseline²

	100 µg	50 µg
Week 1:	-9.8	-10.3
Week 4:	-12.3	-8.8
Week 8:	-10.4	-8.1
Week 12:	-9.8	-8.3

Improvement over Placebo²

	100 µg	50 µg
Week 1:	-5.3	-5.8
Week 4:	-7.0	-3.5
Week 8:	-5.3	-3.0
Week 12:	-5.1	-3.6

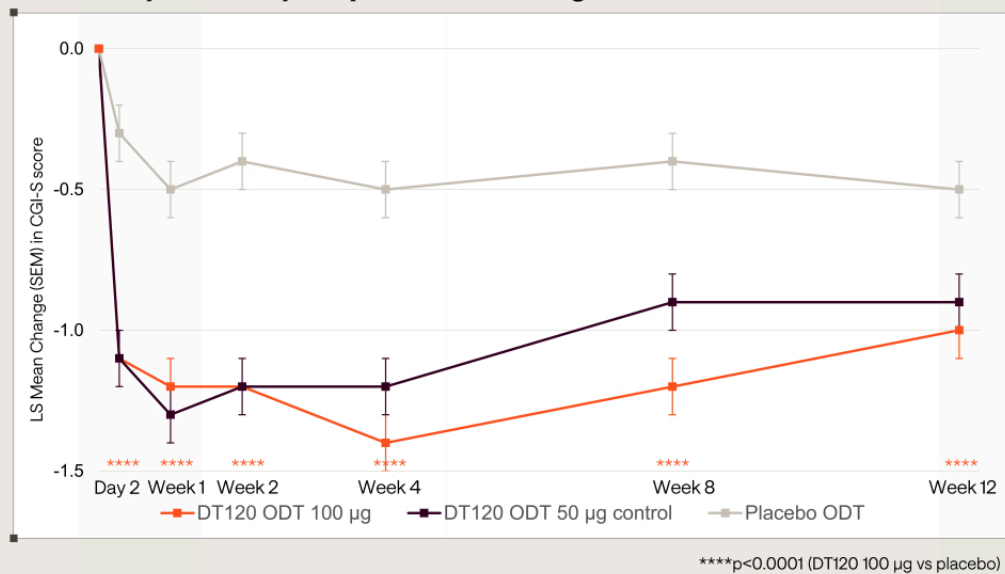
1. Source: Panorama study documents. ITT population. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.
2. Primary endpoint of the study was change in HAM-A at week 12 between 100 µg and placebo using a Mixed-Effects Model Repeated Measures (MMRM) statistical analysis with reference-based imputation.

HAM-A: Hamilton Anxiety Rating Scale; LS Mean: least squares mean; ODT: orally disintegrating tablet; SEM: standard error of the mean

DT120 ODT 100 µg Showed Statistically & Clinically Significant CGI-S Improvements at All Timepoints^{1,2}

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Key Secondary Endpoint: CGI-S Change from Baseline to Week 12



Highlights

Change from Baseline²

	100 µg	50 µg
Day 2:	-1.1	-1.1
Week 1:	-1.2	-1.3
Week 4:	-1.4	-1.2
Week 12:	-1.1	-0.9

Improvement over Placebo²

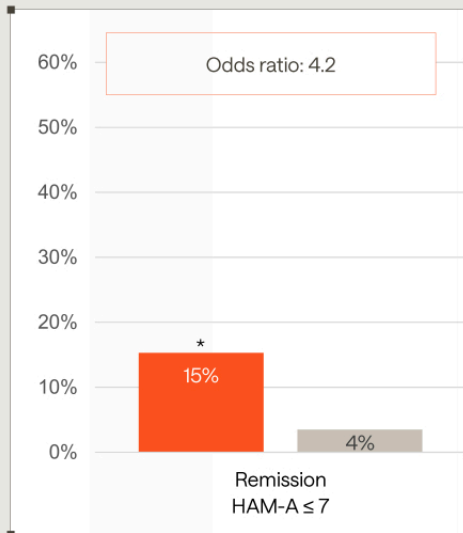
	100 µg	50 µg
Day 2:	-0.8	-0.8
Week 1:	-0.7	-0.8
Week 4:	-1.0	-0.7
Week 12:	-0.6	-0.4

1. Source: Panorama study documents. ITT population. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.
 2. Key secondary endpoints of the study was change in CGI-S at day 2 and week 12 between 100 µg and placebo using a Mixed-Effects Model Repeated Measures (MMRM) statistical analysis with reference-based imputation.
 CGI-S: Clinical Global Impressions - Severity scale; LS Mean: least squares mean; ODT: orally disintegrating tablet; SEM: standard error of the mean

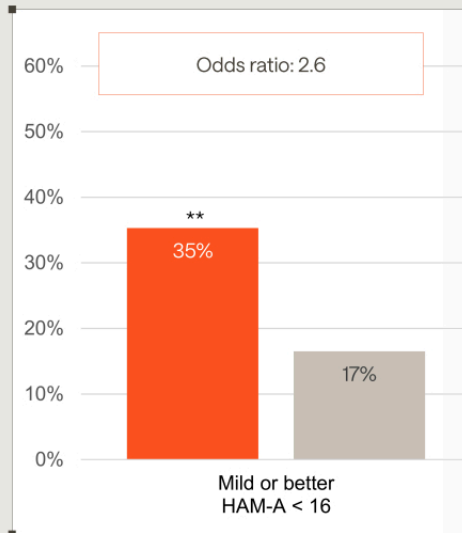
DT120 ODT 100 µg Effects Supported by Robust, Clinically Significant Response and Remission Rates¹

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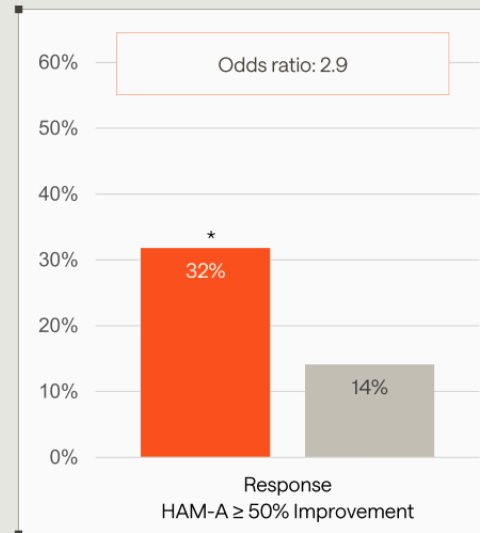
Remission Rate at Week 12



Mild or Better at Week 12



Response Rate at Week 12



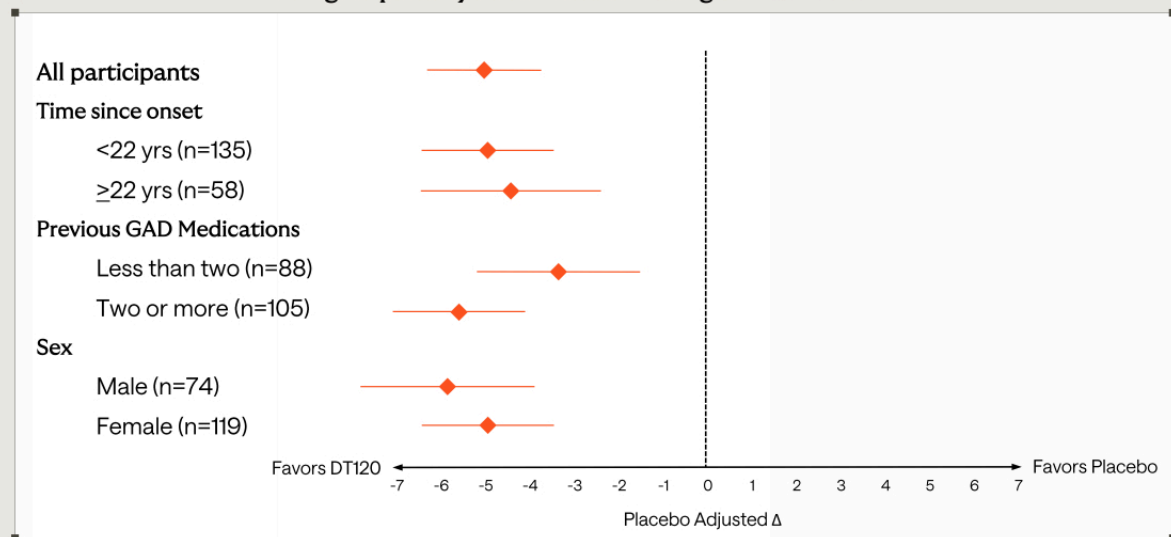
DT120 ODT 100 µg Placebo ODT

** p<0.01; *p<0.05

¹ Source: Panorama study documents. ITT population. Pre-planned secondary endpoints.
HAM-A: Hamilton Anxiety Rating Scale; ODT: orally disintegrating tablet

Treatment Effect Maintained Across Key Subgroups – Including Those Failed by 2+ Prior Treatments¹

Subgroup Analysis of HAM-A Change at Week 12^{2, 3}



1. Source: Panorama study documents. Subgroup analysis of ITT population; 100 µg and placebo groups only.

2. Data presented as Least Squares mean ± standard error.

3. For each subgroup, the change from baseline in HAM-A total score is analyzed using the same MMRM model as the primary efficacy analysis. If the number of patients is small for a subgroup, the treatment difference will not be stable as it would be highly sensitive to outliers.

Δ: change; GAD: generalized anxiety disorder; HAM-A: Hamilton Anxiety Rating Scale; MMRM: Mixed-Effects Model Repeated Measures

DT120 ODT 100 µg was Generally Well-Tolerated and Consistent with Prior Clinical Experience¹

Favorable tolerability profile

- AE profile consistent with prior studies of DT120
- Most adverse events (AEs) were mild-to-moderate in severity
- Most treatment emergent AEs (TEAEs) occurred and resolved on dosing day
- No drug related serious adverse events (SAEs)

No suicidal behavior or suicidality signal²

- No suicidal or self-injurious behavior
- No indication of increased suicide-related risk

1. Source: Panorama study documents. Safety population in study part A (through week 12).
2. Participant suicidality assessment based on changes in C-SSRS.

C-SSRS: Columbia-Suicide Severity Rating Scale; ODT: orally disintegrating tablet

Adverse Events Were Generally Mild-to-Moderate in Severity^{1,2}

Adverse Event	DT120 ODT 100 µg n=96	DT120 ODT 50 µg control ³ n=51	Placebo ODT n=97
Any TEAE	91 (95%)	49 (96%)	61 (63%)
Mild	51 (53%)	29 (57%)	30 (31%)
Moderate	39 (41%)	19 (37%)	29 (30%)
Severe	1 (1%)	1 (2%)	2 (2%)
Any Study Drug-Related TEAE	90 (94%)	47 (92%)	34 (35%)
Any Adverse Event of Special Interest (AESI)	84 (88%)	43 (84%)	31 (32%)
Any SAE ⁴	2 (2%)	1 (2%)	1 (1%)
Any Treatment Related SAE	0	0	0
Any TEAE Leading to Discontinuation	0	0	0
Any TEAE Leading to Death	0	0	0

- Source: Panorama study documents. Safety population in study part A.
- Adverse events were collected in accordance with FDA Final Guidance for Psychedelic Drug Development, which includes expected effects characterized as positive, favorable, or neutral.
- Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.
- All SAEs were deemed unrelated to the study drug.

AESI: adverse event of special interest; ODT: orally disintegrating tablet; SAE: serious adverse event; TEAE: treatment-emergent adverse event

Most Common TEAEs Demonstrated Favorable Tolerability Profile of DT120 ODT 100 µg^{1,2,3}

TEAEs with Incidence ≥10%	Dosing Day			After Dosing Day		
	DT120 ODT 100 µg (n=96)	DT120 ODT 50 µg control ⁴ (n=51)	Placebo ODT (n=97)	DT120 ODT 100 µg (n=96)	DT120 ODT 50 µg control ⁴ (n=51)	Placebo ODT (n=97)
Illusion	65 (68%)	31 (61%)	12 (12%)	3 (3%)	0	0
Nausea	35 (37%)	13 (26%)	4 (4%)	2 (2%)	4 (8%)	1 (1%)
Headache	23 (24%)	14 (28%)	13 (13%)	13 (14%)	6 (12%)	10 (10%)
Euphoric Mood	30 (31%)	16 (31%)	5 (5%)	1 (1%)	0	0
Fatigue	22 (23%)	5 (10%)	6 (6%)	7 (7%)	1 (2%)	4 (4%)
Dizziness	22 (23%)	10 (20%)	3 (3%)	1 (1%)	1 (2%)	0
Anxiety	16 (17%)	7 (14%)	7 (7%)	6 (6%)	3 (6%)	5 (5%)
Crying	20 (21%)	6 (12%)	0	0	1 (2%)	0
Feeling cold	14 (15%)	2 (4%)	6 (6%)	0	0	1 (1%)
Paraesthesia	13 (14%)	4 (8%)	3 (3%)	0	1 (2%)	1 (1%)
Time Perception Altered	13 (14%)	4 (8%)	1 (1%)	0	0	0
Feeling of Relaxation	12 (13%)	8 (16%)	11 (11%)	1 (1%)	0	0
Inappropriate Affect	12 (13%)	4 (8%)	0	0	0	0
Feeling Hot	11 (12%)	4 (8%)	4 (4%)	0	0	0
Emotional Disorder	8 (8%)	3 (6%)	3 (3%)	3 (3%)	0	0
Feeling Abnormal	10 (10%)	7 (14%)	4 (4%)	0	0	1 (1%)
Restlessness	10 (10%)	1 (2%)	3 (3%)	1 (1%)	0	1 (1%)
Tremor	10 (10%)	4 (8%)	1 (1%)	1 (1%)	0	0

1. Source: Panorama study documents. Safety population in study part A (through week 12).

2. Adverse events were collected in accordance with FDA Guidance for Psychedelic Drug Development, which includes expected effects characterized as positive, favorable, or neutral.

3. AEs over 10% in the 100 µg arm are shown above.

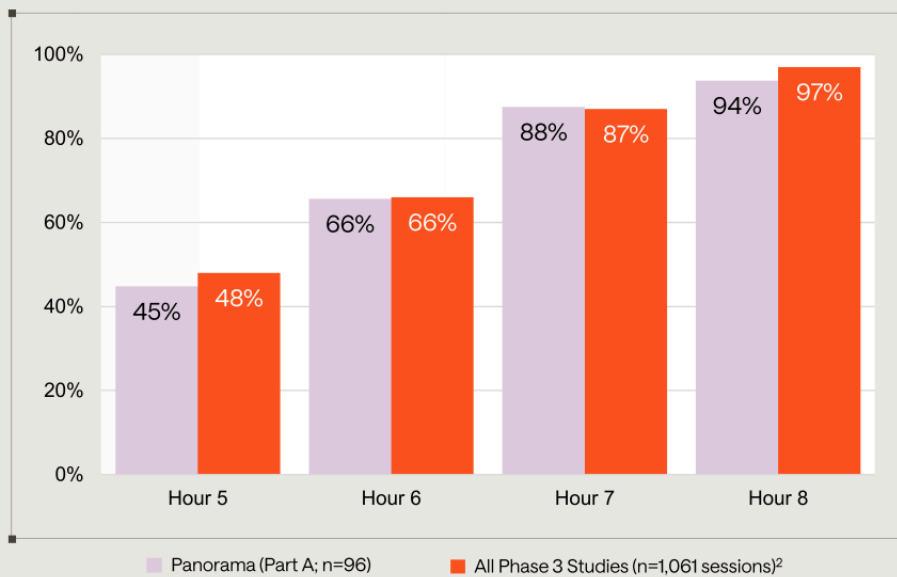
4. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.

Panorama Topline Results | September 2026 ♦

AE: adverse event; ODT: orally disintegrating tablet; TEAE: treatment-emergent adverse event

1,000+ DT120 ODT 100 µg Dosing Sessions Demonstrated a Scalable Path to Clinical Practice¹

Time to End of Session Checklist (EoSC) Clearance



Highlights

- Average time to clearance of EoSC is 6.2 hours in Panorama¹
- Two thirds of participants clear EoSC at hour 6¹
- 95+% of participants clear EoSC by hour 8²
- Emerging evidence of predictable 5 to 8 hour sessions

1. Source: Panorama study documents. Safety population in study part A (100 µg). Time at which participant first meets End of Session Checklist criteria.
2. Based on Interim analysis of EoSC as of September 10, 2026 from all dosing sessions in Emerge, Voyage and Panorama.

ODT: orally disintegrating tablet; EoSC: End of Session Checklist



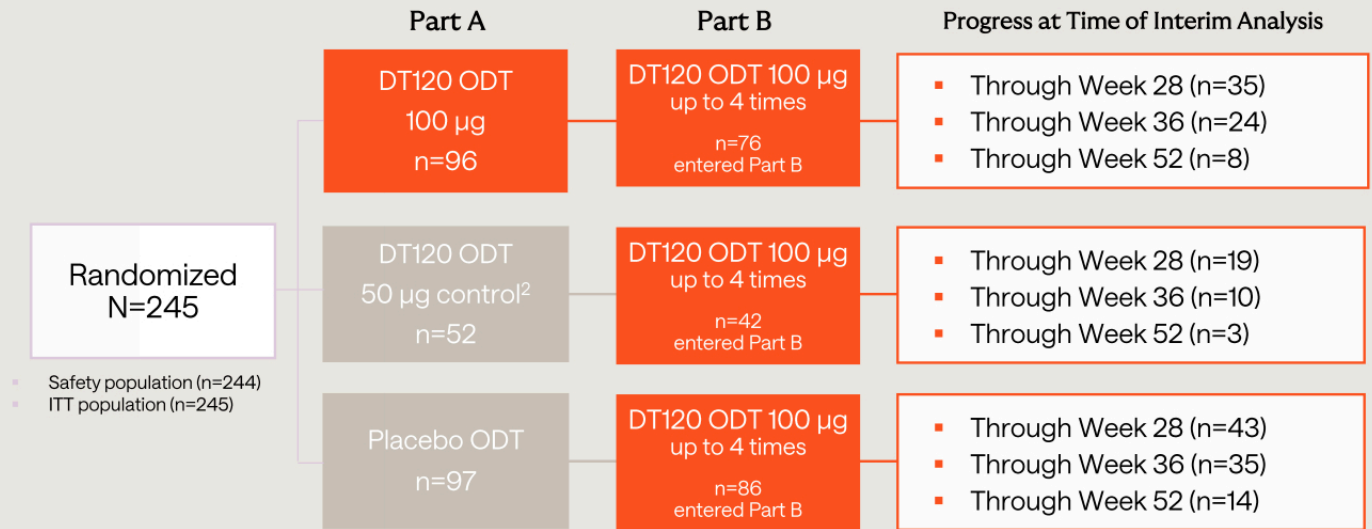
Phase 3 Panorama Topline Results

Part B – Interim Analysis

Dan Karlin, MD

Chief Medical Officer

Part B Disposition¹



1. Based on interim analysis as of August 11, 2026. Interim analysis based on partial data and subject to change.
2. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.
ITT: intent-to-treat; ODT: orally disintegrating tablet

Part B Enrollment & Baseline Characteristics¹

Demographic (Part B) ²	DT120 ODT 100 µg n=62	DT120 ODT 50 µg control ³ n=33	Placebo ODT n=68	Total n=163
Mean age (years)	39.5	42.3	42.8	41.4
Sex, female (%)	62.9%	51.5%	58.8%	58.9%
Race (% white)	82.3%	87.9%	83.8%	84.0%
HAM-A score at Part B Entry	18.3	21.6	23.3	21.1
CGI-S score at Part B Entry	3.7	4.0	4.2	4.0

1. Based on interim analysis as of August 11, 2026. Extension population. Interim analysis based on partial data and subject to change.

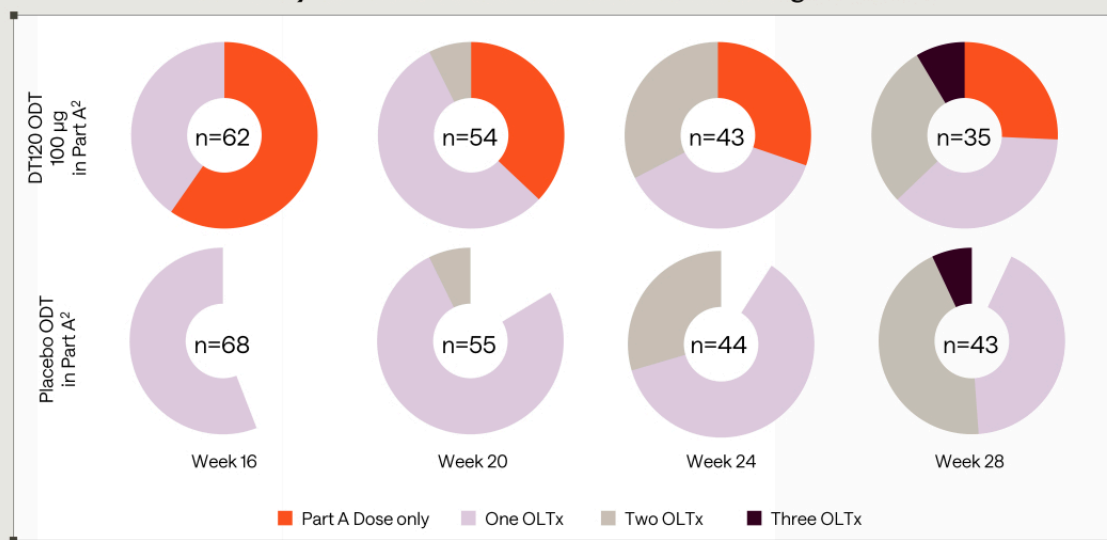
2. ITT population who entered Part B. Data based on Week 12 in Part A.

3. Panorama included a DT120 ODT 50 µg control arm (n=52) that was not designed or powered for statistical comparisons.

CGI-S: Clinical Global Impressions - Severity Scale; HAM-A: Hamilton Anxiety Rating Scale; ITT: intent-to-treat; ODT: orally disintegrating tablet

Treatment Patterns in Part B Provide Early Insights into Paradigm beyond 12 Weeks¹

Summary of Cumulative DT120 ODT Doses through Week 28

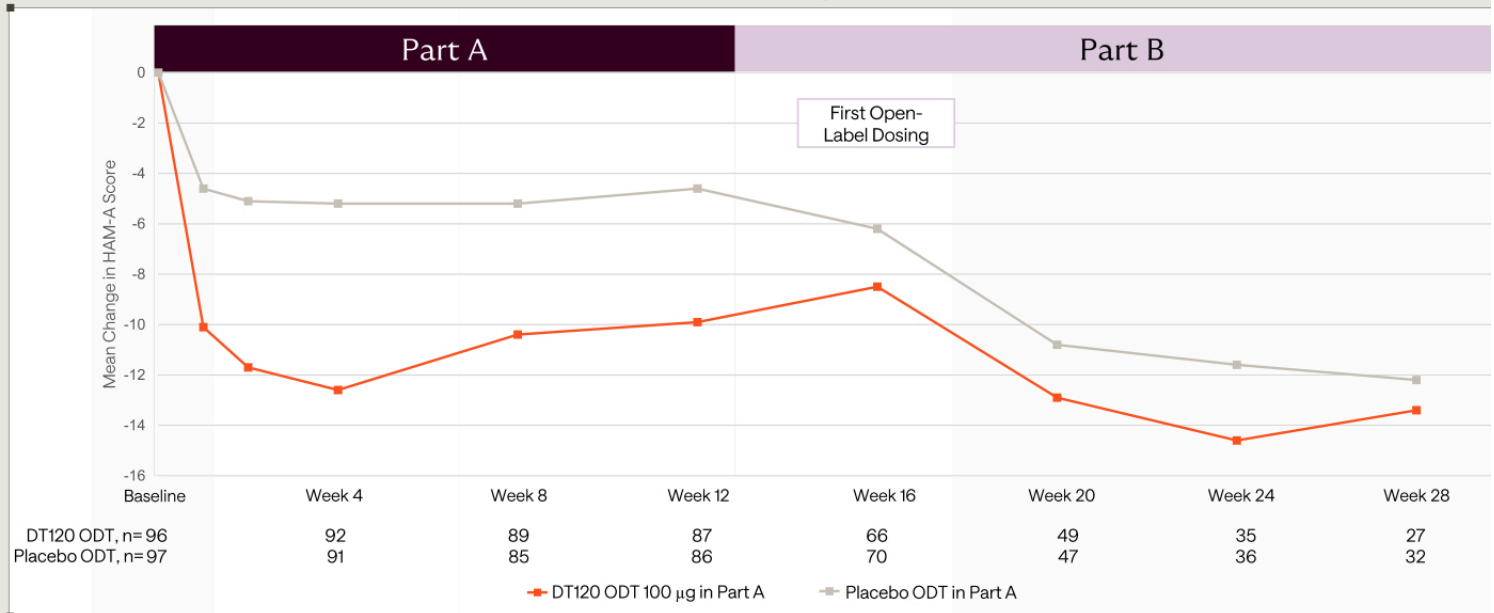


1. Based on interim analysis as of August 11, 2026. Extension population. Interim analysis based on partial data and subject to change. 50 µg cohort not included due to small n.
2. n is the number of participants in the Extension population who had the specified number of doses up to the corresponding visit.

ITT: intent-to-treat; ODT: orally disintegrating tablet; OLTx: open-label treatment

HAM-A Scores Improved Further with Additional Treatments in Part B

HAM-A Scores through Week 28^{1,2}

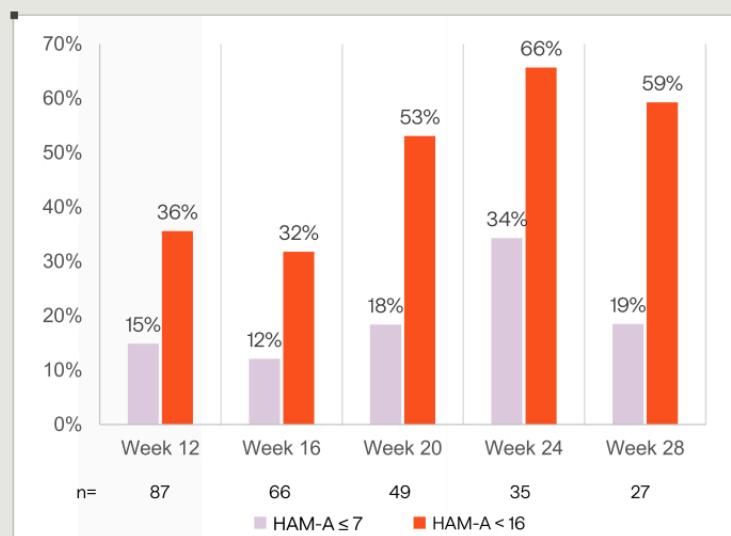


1. Based on interim analysis as of August 11, 2026. ITT Part A+B population with treatment policy strategy. Interim analysis based on partial data and subject to change. 50 µg cohort not included due to small n.
2. n is the number of participants in the ITT Part A+B population with non-missing HAM-A score at Baseline and the respective visit.

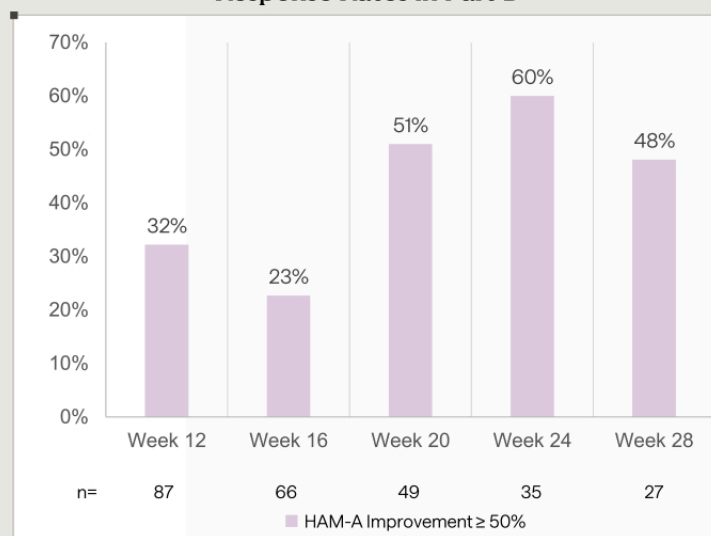
HAM-A: Hamilton Anxiety Rating Scale; LS Mean: least squares mean; ODT: orally disintegrating tablet

Subsequent Treatments Further Improved Response and Remission Rates through Week 28^{1,2}

Mild and Remission Rates in Part B



Response Rates in Part B



1. Source: Panorama study documents. Based on interim analysis as of August 11, 2026. ITT Part A+B population. Interim analysis based on partial data and subject to change.

2. Only includes participants who received DT120 ODT in Part A.

HAM-A: Hamilton Anxiety Rating Scale, ITT: intent-to-treat

4

Next Steps

Rob Barrow
Chief Executive Officer

Compelling Evidence Across Four Late-Stage Trials with Complementary Designs¹

Generalized Anxiety Disorder (GAD)

Major Depressive Disorder (MDD)

	 Phase 2b Study MMED008	 Voyage	 Panorama	 Emerge
Design	5 arms	2 arms	3 arms	2 arms
Baseline HAM-A	30.2	27.9	28.0	17.1
Baseline MADRS	27.2	13.5	13.4	34.5
Pooled endpoint SD	11.1	7.2	8.4	10.4
Primary endpoint ² DT120 vs. placebo	-7.7 p<0.01	-5.4 p<0.0001	-5.1 p<0.0001	-8.1 p<0.0001

Robust data package aligned with FDA guidance supports advancement of NDA submission for DT120 ODT³

1. The information presented in this slide is derived from multiple clinical trials, each conducted under distinct protocols and settings. As such, these data may not be directly comparable due to the lack of a head-to-head comparison.
2. Primary endpoint in Voyage and Panorama is the change from baseline in HAM-A total score at Week 12; in Study MMED008 the primary endpoint was change from baseline in HAM-A total score at week 4. Primary endpoint in Emerge was the change from baseline in MADRS score at Week 6.
3. Regulatory strategy for GAD & MDD to be discussed at pre-NDA meeting in 4Q 2026.

HAM-A: Hamilton Anxiety Rating Scale; MADRS: Montgomery-Åsberg Depression Rating Scale; SD: standard deviation

Compelling Development Program Supporting Plans for DT120 ODT New Drug Application

Registrational Program Completion Anticipated by YE 2026¹

4

Four positive Phase 2 & 3 studies with complementary designs across multiple indications and control conditions



Comprehensive clinical pharmacology, nonclinical and CMC programs



NDA-enabling manufacturing at established commercial sites



Breakthrough therapy designations in GAD & MDD with enhanced regulatory engagement

Key Psychedelics Considerations

- ✓ No psychotherapeutic intervention beyond study drug
- ✓ Statistically significant dose-response demonstrated
- ✓ Blinded central raters with assessment of blind integrity
- ✓ Thorough evaluation of blinding & expectancy
- ✓ Structured real world-ready assessment to determine session monitoring duration
- ✓ Robust and consistent adverse event capture supports a well-characterized safety profile

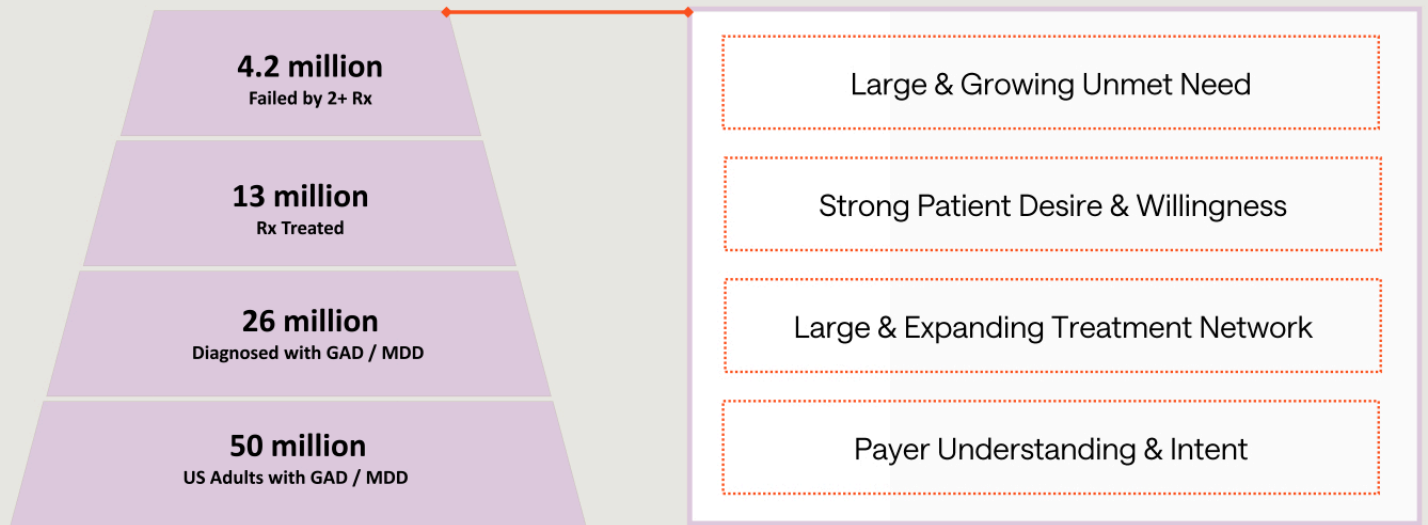
Pre-NDA meeting scheduled for 4Q 2026²; NDA filing anticipated in 1H 2027

1. Registrational program represents studies anticipated to be required at the time of NDA submission; additional studies, including Part B of Phase 3 studies, are ongoing.
2. Regulatory filing strategy for GAD & MDD to be discussed at pre-NDA meeting.

CMC: chemistry, manufacturing and controls; GAD: generalized anxiety disorder; MDD: major depressive disorder; NDA: new drug application; ODT: oral dissolving tablet

Opportunity to Deliver Significant Impact and Value Creation¹

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Addressable market means potential 100,000 patient impact & \$5 billion revenue opportunity per 2.5% penetration

1. Ringelsen, H., et al. (2023). Mental and Substance Use Disorders Prevalence Study (MDPS): Findings Report. Zhou, Y., Et al. (2017). Nature. Comorbid generalized anxiety disorder and its association with quality of life in patients with major depressive disorder. RTI International and current U.S. Census data and internal company estimates. Veeva COMPASS Open Claims Analysis Data on File, 2017 – 2025.
2. Assuming median Spravato® surrogate pricing range; the price of DT120 ODT has not been established.

GAD: generalized anxiety disorder; MDD: major depressive disorder; Rx: prescription

Panorama Topline Results | September 2026 ♦

Modest Adoption Yields Significant Opportunity Given Large and Growing Delivery Ecosystem

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2

patients per month

24

patients per year

~4,000

interventional
psychiatry clinics¹

100K

patients treated

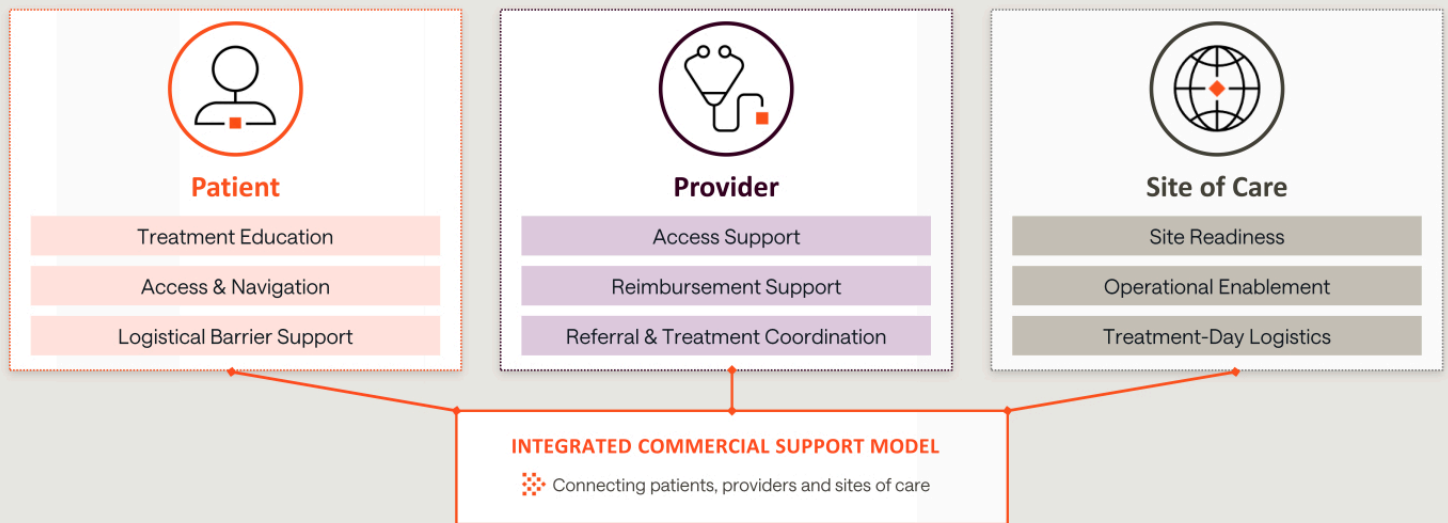
\$5B

Potential Gross
Revenue Opportunity²

Significant revenue potential requires only modest uptake across an established treatment network

1. Represents approximately half of estimated number of sites in the Spravato® REMS program. <https://www.spravatohcp.com/find/treatment-center/>
2. Assumes midpoint of surrogate pricing range for Spravato®. The price of DT120 ODT has not been established.

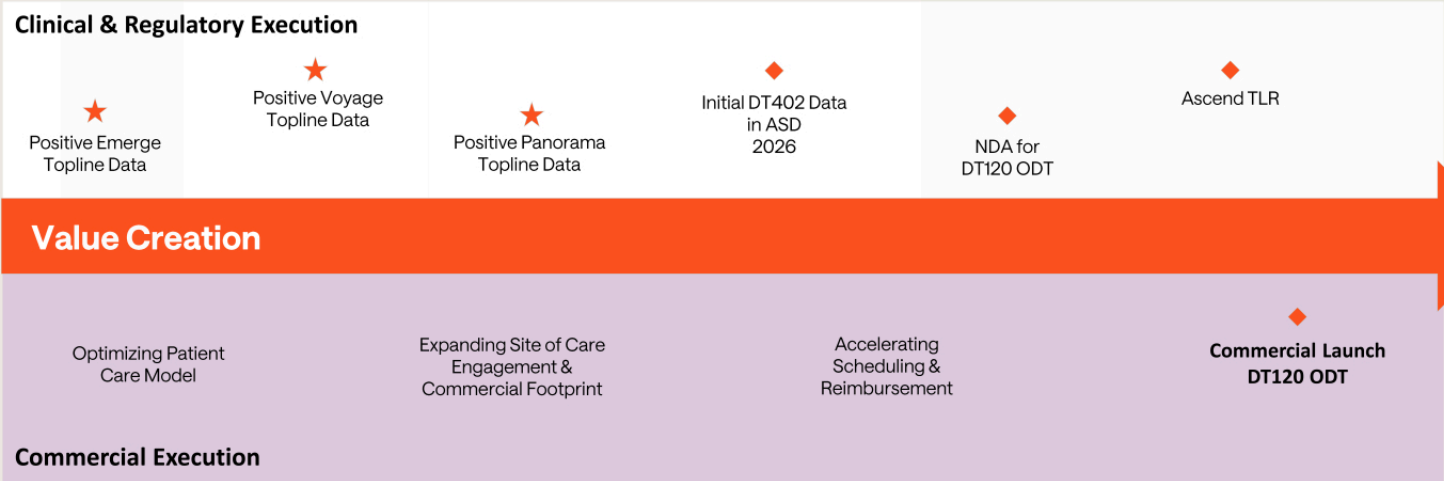
Core Focus to Enable Commercial Impact & Success



We are committed to delivering the best patient and provider experience to maximize impact

Building a Psychiatry Powerhouse with Two Distinct Drivers¹

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1. Timing estimates subject to clinical progress and regulatory interactions.

ASD: autism spectrum disorder; ODT: orally disintegrating tablet; NDA: new drug application; TLR: topline data readout

Panorama Topline Results | September 2026

◆

Maintaining Momentum with Multiple Milestones Ahead

Cash, Cash Equivalents & Investments

~\$1.1 billion

as of June 30, 2026

Cash runway expected to extend into 2030¹

2026 – Recent Completed Milestones



Emerge (MDD)

Positive Topline Data | June 2026



Voyage (GAD)

Topline Readout | August 2026



Panorama (GAD)

Topline Readout | September 2026



MDD

BTB | September 2026

2026 – Anticipated Milestones



DT120 NDA

Pre-NDA Meeting | 4Q 2026



DT402

Initial Data in ASD | 4Q 2026

2027 – Anticipated Milestones



DT120 NDA

Filing | 1H 2027



DT120 Commercial Day

Event | 1H 2027



DT120 Ascend (MDD)

Topline Readout | 2027



DT120 Haven (PTSD)

Study Initiation | 2027

¹ Based on the Company's current operating plan and anticipated milestones.

ASD: autism spectrum disorder; BTB: breakthrough therapy designation; GAD: generalized anxiety disorder; G&A: general & administrative; MDD: major depressive disorder; NDA: new drug application; PTSD: posttraumatic stress disorder



Precise science. Boundless impact.

Q&A Session

Definium 
THERAPEUTICS

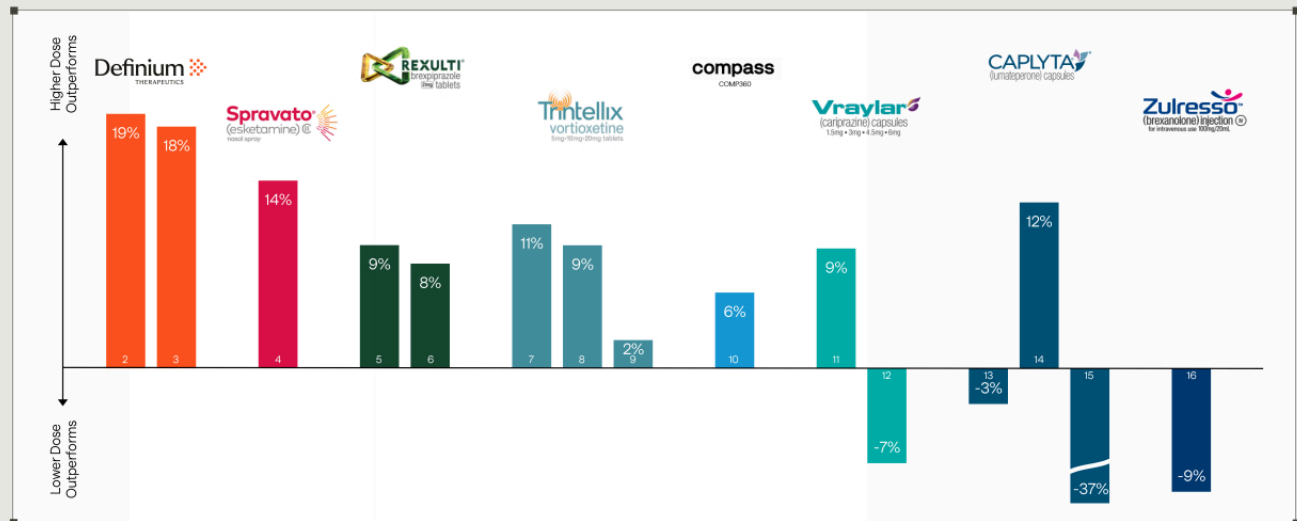


A

Appendix

DT120 Program is a Rare Example of Consistent Dose-Dependent Efficacy in Psychiatry¹

% Improvement of High Dose over Low Dose in Late-Stage Studies²



1. Bar chart shows the percentage change between the high dose and lowest dose of drug studied in each clinical trial. 2. Phase 2b study: 100 µg vs. 25 µg; 3. Panorama: 100 µg vs. 50 µg; 4. Study 3: 84 mg vs 56 mg; 5. Study 2: 3 mg vs 1 mg; 6. Study 3+4: 4 mg vs 2 mg; 7. Study 5: 20 mg vs 10 mg; 8. Study 3+4: 20 mg vs 15 mg; 9. Study 1+2: 10 mg vs 5 mg; 10. Study COMP006: 25 mg vs 10 mg; 11. Study 1f: 2+4.5 mg vs 1-2 mg; 12. Study 10: 3 mg vs 1.5 mg; 13. Study 302: 42 mg vs 14 mg; 14. Study 301: 42 mg vs 28 mg; 15. Study 005: 84 mg vs 42 mg; 16. Study 1: 90 µg vs 60 µg
2. The information presented in this slide is derived from multiple clinical trials, each conducted under distinct protocols and settings. As such, these data may not be directly comparable due to the lack of a head-to-head comparison.

Clinical Outcome Assessments in GAD and MDD

Hamilton Anxiety Scale (HAM-A)¹

Range: 0-56

- | |
|---|
| 1. Anxious mood – worry, fear |
| 2. Tension – restlessness, inability to relax |
| 3. Fears – of dark, strangers, being alone, etc. |
| 4. Insomnia |
| 5. Intellectual – concentration, memory |
| 6. Depressed Mood |
| 7. Somatic (muscular) – aches, twitching |
| 8. Somatic (sensory) – tinnitus, blurred vision |
| 9. Cardiovascular symptoms – palpitations, chest pain |
| 10. Respiratory symptoms – shortness of breath |
| 11. Gastrointestinal symptoms – nausea, cramps |
| 12. Genitourinary symptoms – frequency, libido changes |
| 13. Autonomic symptoms – dry mouth, sweating |
| 14. Behavior during interview – fidgeting, restlessness |

Montgomery-Åsberg Depression Rating Scale (MADRS)²

Range: 0-60

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|----------------------------------|
| 1. Apparent sadness |
| 2. Reported sadness |
| 3. Inner Tension |
| 4. Reduced Sleep |
| 5. Reduced Appetite |
| 6. Concentration Difficulties |
| 7. Lassitude |
| 8. Inability to Feel (Anhedonia) |
| 9. Pessimistic Thoughts |
| 10. Suicidal Thoughts |

Psychological effects

Physical effects

1. Source: Hamilton M. The assessment of anxiety states by rating. Br J Med Psychol 1959; 32:50–55.

2. Source: Montgomery, S. A., & Åsberg, M. (1979). A new depression scale designed to be sensitive to change. British Journal of Psychiatry, 134(4), 382–389.