

Item 7.01 Regulation FD Disclosure.

On June 22, 2026, Definium Therapeutics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing positive topline data from the Company’s Phase 3 Emerge study of DT120 ODT for the treatment of major depressive disorder. A copy of the Press Release is furnished 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 June 22, 2026, the Company posted a presentation discussing the Emerge topline data (the “Presentation”) on its website. A copy of the Presentation is filed as Exhibit 99.2 hereto, and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 22, 2026
99.2	Emerge Topline Data Presentation, dated June 22, 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: June 22, 2026

By: /s/ Robert Barrow

Name: Robert Barrow

Title: Chief Executive Officer



Definium Therapeutics Announces Positive Topline Results from Phase 3 Emerge Study of DT120 Orally Disintegrating Tablet (ODT) in Major Depressive Disorder

Study met primary and all key secondary efficacy endpoints

8.1 point Montgomery-Åsberg Depression Rating Scale (MADRS) placebo-adjusted change from baseline at Week 6 for the primary endpoint ($p < 0.0001$)

7.3 point MADRS placebo-adjusted change from baseline at Week 12, a secondary endpoint ($p < 0.0001$)

DT120 ODT was generally well tolerated with no serious adverse events or suicidality signal

Company to host webcast today at 8:00 a.m. EDT

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 positive topline results from Emerge, its first randomized, double-blind, placebo-controlled Phase 3 study evaluating a single dose of DT120 (lysergide) ODT 100 µg in adults with major depressive disorder (MDD).

Emerge met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement from baseline compared with placebo, as measured by the change in MADRS total score at week 6. The Least Squares (LS) mean change from baseline in MADRS total score at Week 6 in participants who received DT120 ODT 100 µg was -13.3 compared with -5.2 for patients who received placebo, a LS mean difference of -8.1 points ($p < 0.0001$). Beyond the primary endpoint, the effect was rapid with a placebo-adjusted LS mean reduction in MADRS total score at Week 1 of -14.2 ($p < 0.0001$) and durable with a placebo-adjusted LS mean reduction in MADRS total score of -7.3 at Week 12 ($p < 0.0001$).

"The Emerge topline results represent unprecedented and highly differentiated efficacy, demonstrating that a single dose of DT120 ODT can deliver rapid, robust, and durable relief in MDD," said Rob Barrow, Chief Executive Officer of Definium Therapeutics. "As the first of our Phase 3 studies to report results, Emerge marks a major milestone in our development program and strengthens our confidence in DT120 as a potential best-in-class treatment for mental health disorders. These findings could support a fundamentally new approach to treating MDD for patients and providers who continue to face the limitations of existing treatment options. We are deeply grateful to the patients and investigators who participated in this trial. Grounded in decades of scientific research, these results bring us one step closer to potentially delivering a transformative new treatment option as we advance toward FDA submission."

DT120 ODT was generally well tolerated with 99% of treatment-emergent adverse events mild to moderate in severity, transient, and predominantly occurring on the day of dosing. No new safety signals were identified, including no increase in suicidal ideation or behavior, and discontinuation rates were low and comparable between treatment groups. On the day of dosing, participants were assessed hourly from hours 5 to 8 on a structured end of session checklist (EoSC). The average time to meeting EoSC criteria was 5.8 hours for participants receiving DT120 ODT in Part A, with a median of 5.1 hours and 100% of participants meeting the EoSC criteria by hour 8.

“Many patients with MDD aren’t helped by existing treatments, often experiencing partial responses, frequent medication changes, and long-term side effects,” said John Sonnenberg, Ph.D., Emerge principal investigator, clinical psychologist, founder of Uptown Research Institute, and faculty member at Northwestern University Feinberg School of Medicine. “The Emerge topline results demonstrate that a single dose of DT120 ODT can produce a meaningful and durable benefit for people with depression. Importantly, these results stand apart from existing treatments, representing a potentially new paradigm for the management of major depression.”

Highlights from Emerge Topline Results

The mean baseline MADRS score at study entry was 35.0 in the DT120 ODT treatment group (n=75) and 34.0 in the placebo ODT group (n=74).

Endpoint	DT120 ODT 100 µg	Placebo ODT	Placebo-Adjusted Difference
MADRS: LS mean change at Week 6*	-13.3	-5.2	-8.1 (p<0.0001)
MADRS: LS mean change at Week 12**	-11.0	-3.6	-7.3 (p<0.0001)
MADRS: LS mean change at Week 1**	-17.6	-3.4	-14.2 (p<0.0001)
CGI-S: LS mean change at Week 6**	-1.2	-0.3	-0.9 (p<0.0001)
CGI-S: LS mean change at Week 12**	-1.0	-0.3	-0.7 (p<0.0001)
CGI-S: LS mean change at Day 2**	-1.0	-0.1	-0.9 (p<0.0001)
MADRS: response rate (≥50%) at Week 6***	35%	7%	28% (p<0.001)
MADRS: remission rate (≤12) at Week 6***	24%	3%	21% (p<0.01)

*Pre-specified primary endpoint

**Pre-specified key secondary endpoint

*** Pre-specified secondary endpoint

CGI-S = Clinical Global Impressions – Severity Scale; LS = least squares; LS mean difference = difference in LS means of change from baseline between DT120 and placebo groups

Webcast Details

Definium Therapeutics management will host a webcast at 8:00 a.m. EDT today to review the Phase 3 Emerge study 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 on participating are advised to join 15 minutes prior to the start time.

About Emerge

Emerge is a Phase 3, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of a single 100 µg dose of DT120 ODT versus placebo in participants with major depressive disorder (MDD).

The study consists of a 12-week double-blind phase (Part A) followed by a 40-week open-label extension phase (Part B) during which participants may be eligible to receive DT120 ODT based on symptom severity. The study enrolled 149 participants aged 18 to 74 years across 20 sites with a DSM-5-confirmed diagnosis of MDD, a Montgomery-Åsberg Depression Rating Scale (MADRS) total score of at least 26, and a Clinical Global Impression–Severity (CGI-S) score of at least 4 at screening and baseline.

The primary endpoint is change from baseline in the MADRS total score at Week 6. Key secondary endpoints are change from baseline in CGI-S score at Week 6, Week 12 and Day 2 and change from baseline in MADRS total score at Week 12 and Week 1.

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

About Major Depressive Disorder (MDD)

Major Depressive Disorder (MDD) is the second-most common mental health disorder in the U.S., with over 21 million adults experiencing a major depressive episode (MDE) each year.^{1,2} This disorder, a leading cause of disability worldwide,³ brings persistent feelings of worthlessness, fatigue, and recurrent thoughts of death⁴ while increasing long-term mortality risk by 40%.⁵ MDD also carries a \$326 billion annual economic burden in the U.S., driven by healthcare costs and lost productivity.⁶ The MDD treatment paradigm is characterized by critical unmet needs, including fewer than one-third of patients reaching remission with first-line treatments,⁷ 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 DT120 (lysergide) 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-HT_{2A}) 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. DT120 has received Breakthrough Therapy designation from the FDA for GAD. 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.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 isn't 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-HT_{2A}) 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 anticipated design, timing, progress and results of the Company’s investigational programs for DT120 ODT for the treatment of generalized anxiety disorder, major depressive disorder and posttraumatic stress disorder (including the anticipated topline readouts for the Voyage, Panorama, and Ascend studies), the success and timing of the Company’s development activities; the likelihood of success of any clinical trials or of obtaining U.S. Food and Drug Administration (“FDA”) or other regulatory approvals; the Company’s beliefs regarding potential benefits of its product candidates; the Company’s belief that DT 120 ODT can deliver rapid, robust, and durable relief for people living with MDD; the Company’s belief that DT120 ODT could be a best-in-class treatment for mental health disorders; the Company’s belief that the results from its Phase 3 Emerge Study of DT120 ODT could support a fundamentally new approach to treating MDD and a transformative new treatment option; the ability of DT120 ODT to be a potentially new paradigm for the management of major depression; and the potential for psychedelics as a class of treatment options in psychiatry. 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 Report on Form 10-Q for the fiscal quarter ended March 31, 2026, under headings such as “Special Note Regarding Forward-Looking Statements,” and “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other filings and furnishings made by the Company with the securities regulatory authorities in all provinces and territories of Canada which are available under the Company’s profile on SEDAR+ at www.sedarplus.ca and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events, changes in expectations or otherwise.

References:

1. National Institute of Mental Health (NIMH). “Major Depression: Prevalence of Major Depressive Episode Among Adults.” Updated 2024.
2. Substance Abuse and Mental Health Services Administration (SAMHSA). “2023 National Survey on Drug Use and Health (NSDUH).”
3. World Health Organization (WHO). “Depression Fact Sheet.” Updated 2023.
4. American Psychiatric Association. “Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5).” 2013.
5. Cuijpers, P., et al. “Long-Term Mortality Risk in Depression: A 20-Year Follow-Up Study.” JAMA Psychiatry, 2023.
6. Greenberg, P. E., et al. “The Economic Burden of Adults with Major Depressive Disorder in the United States (2020).” Journal of Clinical Psychiatry, 2024.
7. Rush, A. J., et al. “Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR*D Report.” American Journal of Psychiatry, 2006.
8. APA. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. Published 2010.

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11. Braund TA, Tillman G, et al. Antidepressant Side Effects and Their Impact on Treatment Outcome in People with Major Depressive Disorder: An Ispot-D Report. *Transl Psychiatry*. 2021;11(1):417.
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14. Passie, T, Halpern, JH, Stichtenoth, DO, et al. "The Pharmacology of Lysergic Acid Diethylamide: A Review." *CNS Neuroscience & Therapeutics*. 2008;14:295–314.
15. Liechti, ME. "Modern clinical research on LSD." *Neuropsychopharmacology*. 2017;42: 2114–2127.

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Phase 3 Emerge 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 are 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 readouts for the Voyage, Panorama and Ascend studies), DT402, also referred to as R(-)-MDMA, and any other product candidates; potential expansion of our current pipeline; 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 & Drug Administration ("FDA") or other regulatory approvals; our beliefs regarding potential benefits of our product candidates; our belief that DT120 ODT represents a best-in-class profile; the potential commercial opportunity for DT120 ODT, if approved, including total addressable market; our plans to continue to advance commercial readiness activities, including market access and provider education; our cash position; 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 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, and the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2026, under headings such as "Special Note Regarding Forward-Looking Statements," and "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other filings and furnishings made by the Company with the securities regulatory authorities in all provinces and territories of Canada which are available under the Company's profile on SEDAR+ at www.sedarplus.ca and with the SEC on EDGAR at www.sec.gov.

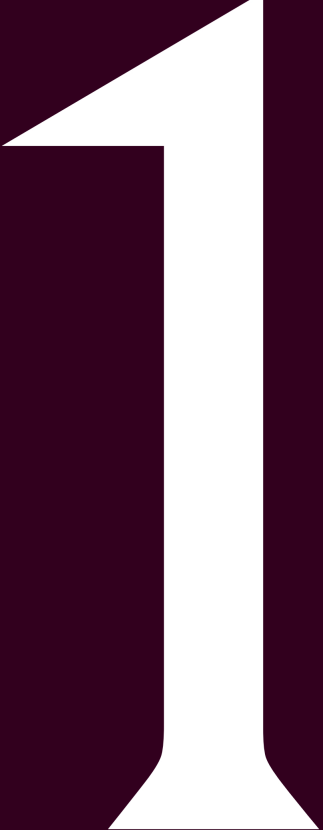
Any forward-looking statement made by Definium in this Presentation is based only on information currently available to the Company and speaks only as of the date on which it is made. Except as required by law, the Company undertakes no duty or obligation to update any forward-looking statements contained 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 frameworks. 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 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 Emerge
possible



Target Product Profile to Address Significant Unmet Need

Definium
THERAPEUTICS

1

Dose¹

5-8

Hours in
the Clinic²

12+

Weeks of
Durability¹

50M

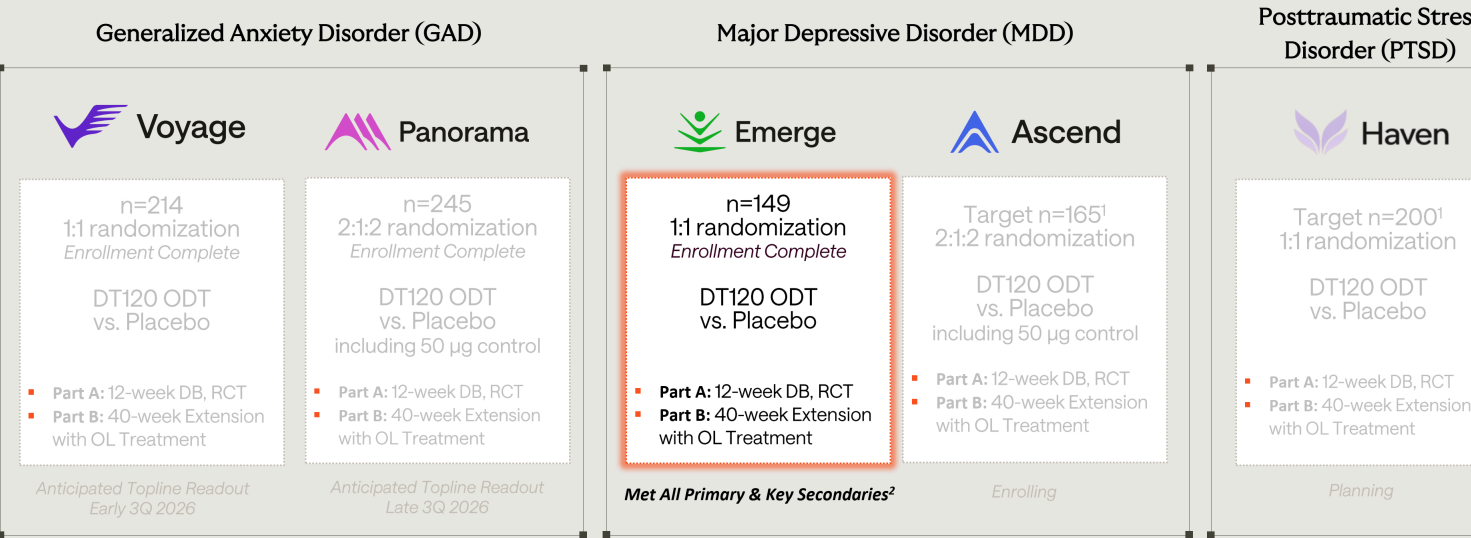
US Adults with
GAD & MDD³

1. Single dose regimen is being studied in pivotal clinical trials with primary and secondary outcome measures through 12 weeks after administration. Phase 3 studies include 40 week extension phase to characterize durability of response beyond 12 weeks in participants up until the time of discontinuation or the administration of open-label DT120.
2. Required monitoring period for all participants in pivotal studies is 8 hours and requires that participants clear the End of Session Checklist.
3. 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.

GAD: generalized anxiety disorder; MDD: major depressive disorder

Emerge Topline Results | June 2026 ♦

First Pivotal Readout for DT120 ODT



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; HAM-A: Hamilton Anxiety Rating Scale; MADRS: Montgomery-Åsberg Depression Rating Scale; ODT: orally disintegrating tablet; OL: open-label; RCT: randomized controlled trial; Δ: placebo-adjusted delta

Emerge Results Demonstrate Potential Best-in-Class Efficacy in Major Depressive Disorder

Rapid, robust and durable efficacy after single dose

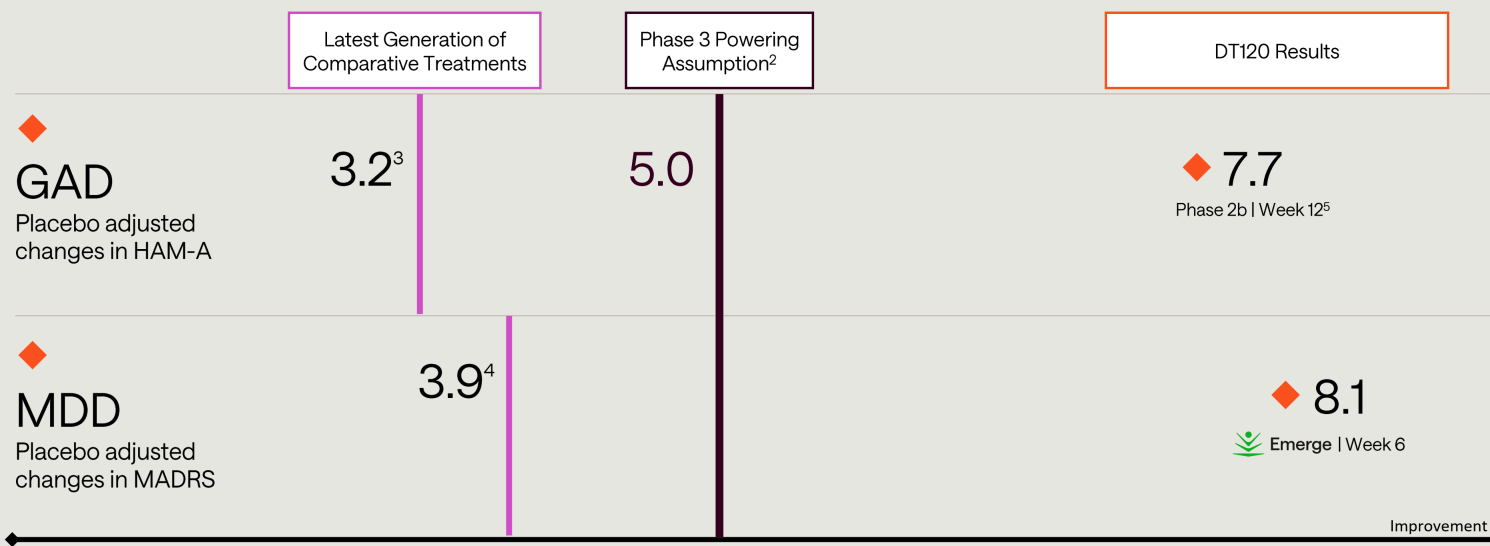
- All primary and key secondary endpoints highly statistically significant
- 8.1 point MADRS improvement over placebo at week 6 primary endpoint ($p < 0.0001$)
- 7.3 point MADRS improvement over placebo at week 12 ($p < 0.0001$)
- 0.9 point CGI-S improvement over placebo at day 2 ($p < 0.0001$)

Limited side effect burden

- DT120 ODT generally well tolerated
- No SAEs or suicidality signal

Efficient session dynamics

- 5.8 hour average time to clear End of Session Checklist (EoSC)
- All participants cleared EoSC by 8 hours



8.1 point placebo-adjusted difference in MDD with extended durability and favorable tolerability represents a potential best-in-class profile

1.

The information presented in this slide on comparative treatments 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.

2.

Median placebo-adjusted change of comparative treatments for GAD. See references on slide 19 of Investor and Analyst Day Presentation filed on Form 8-K, Exhibit 99.2 on April 22, 2026 with the SEC.

3.

Median placebo-adjusted change of comparative treatments for depression symptoms. See references on slide 20 of Investor and Analyst Day Presentation filed on Form 8-K, Exhibit 99.2 on April 22, 2026 with the SEC.

4.

R Robinson, JAMA. 2025 Sep 4; e2513481. doi:10.1001/jama.2025.13481.

5.

MADRS change from Baseline to week 12 was a secondary endpoint in Study MMED008.

Emerge Topline Results | June 2026 ◆

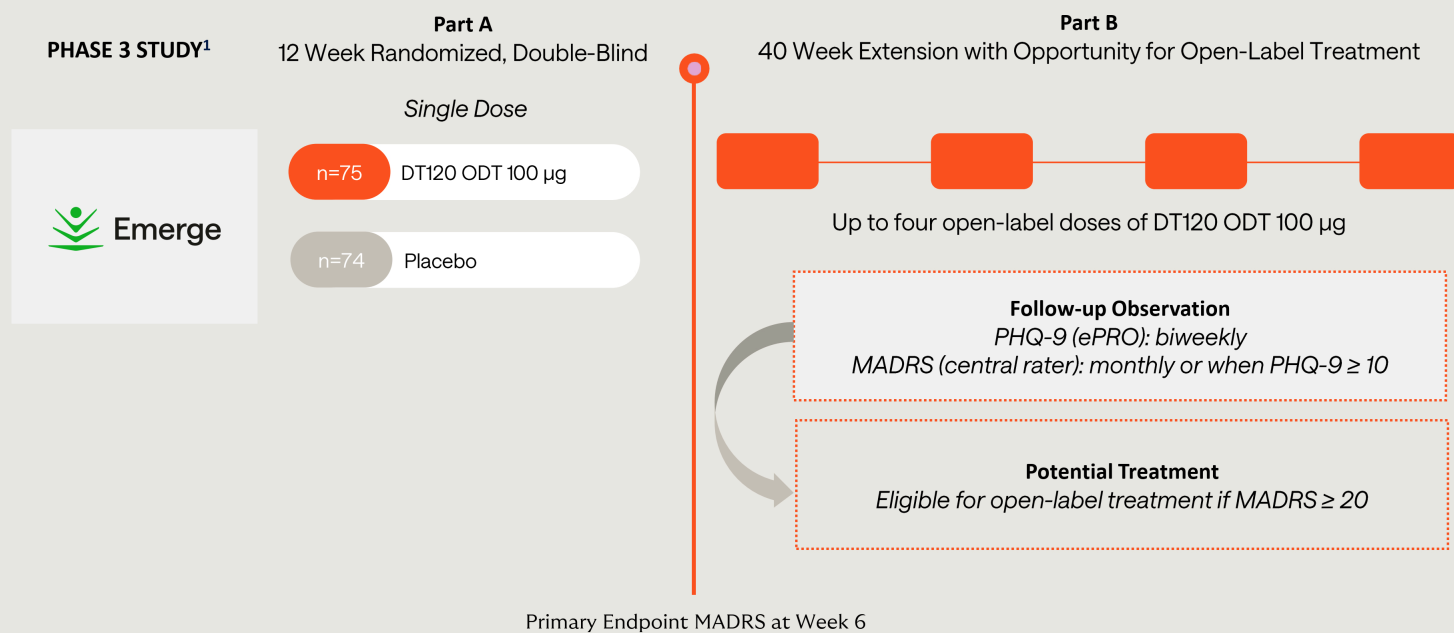


Phase 3 Emerge Study Results

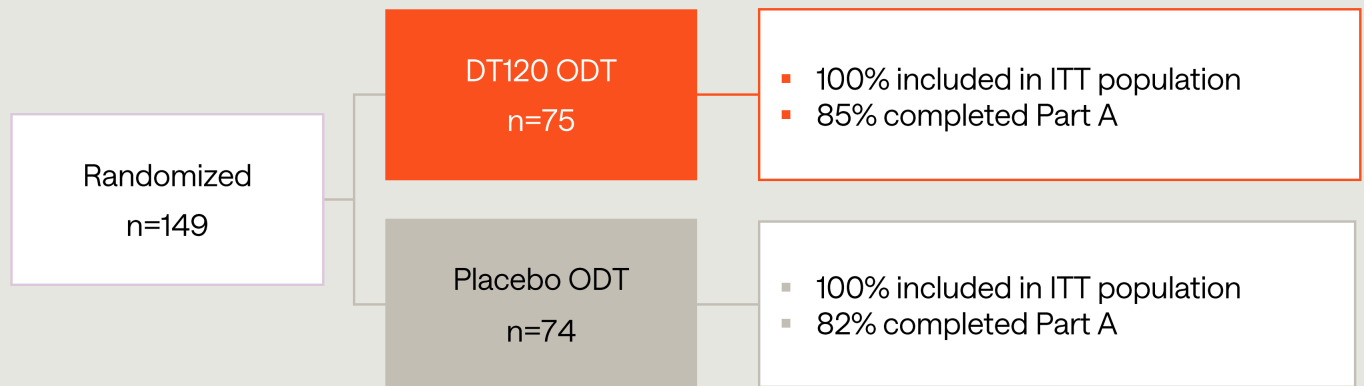
Part A – Topline Results

Dan Karlin, MD
Chief Medical Officer

Emerge Trial Design



Participant Disposition



Demographic	DT120 ODT n=75	Placebo ODT n=74	Overall n=149
Mean age (years)	44.9	42.2	43.6
Sex (% female)	49%	42%	46%
Race (% white)	64%	69%	66%
Baseline MADRS score ^{2,3}	35.0 (5.0)	34.0 (3.7)	34.5 (4.4)
Baseline CGI-S score ^{2,4}	4.7 (0.6)	4.8 (0.6)	4.8 (0.6)
Past Psychedelic Use, n (%)			
Any psychedelic ⁵	13 (17%)	10 (14%)	23 (15%)
LSD	3 (4%)	3 (4%)	6 (4%)

1. Based on ITT population.
2. Mean (SD).
3. The MADRS is a 10-item clinician-rated outcome measure assessing various domains of depression with a range of 0-60. In Emerge, MADRS ratings were assessed by central raters blinded to both treatment assignment and visit number.
4. The CGI-S is a clinician-rated outcome measure assessing overall severity of illness with a range of 1 to 7.
5. Psychedelics include LSD, psilocybin, dimethyltryptamine and other classic serotonergic psychedelics.

CGI-S: Clinical Global Impressions - Severity Scale; ITT: intent to treat; LSD: lysergic acid diethylamide; MADRS: Montgomery-Åsberg Depression Rating Scale; ODT: orally disintegrating tablet

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

Diagnostic Trait	DT120 ODT n=75	Placebo ODT n=74	Overall n=149
MADRS score, n (SD)	35.0 (5.0)	34.0 (3.7)	34.5 (4.4)
MADRS severity, n (%)			
Moderate (20 - 30)	15 (20%)	10 (14%)	25 (17%)
Severe (≥ 31)	60 (80%)	64 (87%)	124 (83%)
Number of past antidepressants, n (%)			
0	18 (24%)	23 (31%)	41 (28%)
1	16 (21%)	13 (18%)	29 (20%)
2+	41 (55%)	38 (51%)	79 (53%)

1. Based on ITT population

ITT: intent to treat; MADRS: Montgomery-Åsberg Depression Rating Scale; MDD: major depressive disorder; ODT: orally disintegrating tablet; SD: standard deviation

Baseline Characteristics | Course of Illness Consistent with Representative and High Burden Population¹

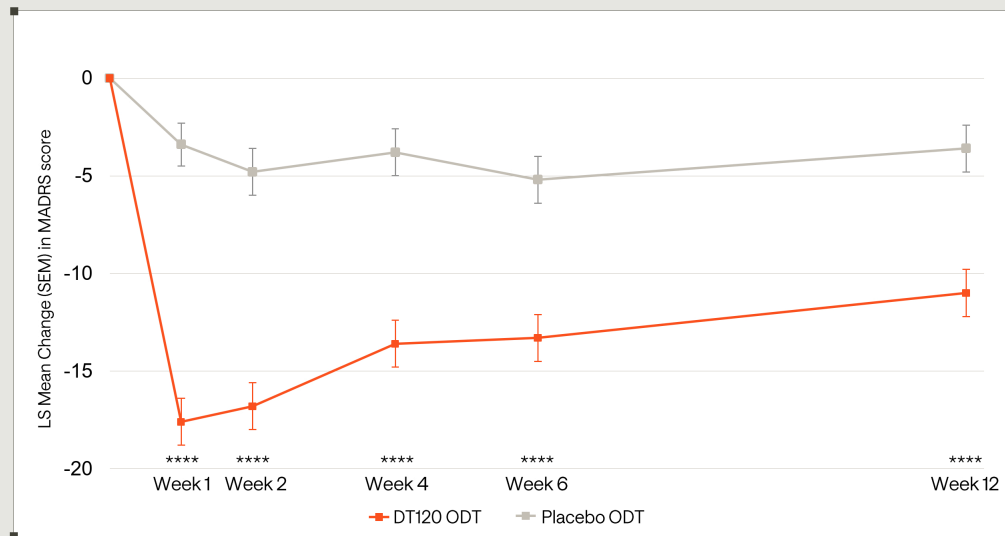
Diagnostic Trait	DT120 ODT n=75	Placebo ODT n=74	Overall N=149
Length of current depressive episodes			
Mean months (SD)	8.8 (5.0)	8.9 (5.8)	8.9 (5.4)
< 1 year	60 (80%)	52 (70%)	112 (75%)
1 - 2 years	15 (20%)	22 (30%)	37 (25%)
> 2 years	0	0	0
Number of lifetime depressive episodes			
Mean (SD)	5.5 (3.5)	6.2 (5.4)	5.8 (4.6)
1 - 2	24 (32%)	25 (34%)	49 (33%)
3 - 4	26 (35%)	21 (28%)	47 (32%)
≥ 5	25 (33%)	28 (38%)	53 (36%)

1. Based on ITT population

ITT: intent to treat; ODT: orally disintegrating tablet; SD: standard deviation

DT120 ODT Showed Statistically & Clinically Significant Improvements on MADRS at All Timepoints^{1,2}

Primary Endpoint: MADRS Change from Baseline to Week 6



****p<0.0001

Highlights

Change from Baseline²

- Week 1: -17.6 points
- Week 4: -13.6 points
- Week 6: -13.3 points
- Week 12: -11.0 points

Improvement over Placebo²

- Week 1: -14.2 points
- Week 4: -9.8 points
- Week 6: -8.1 points
- Week 12: -7.3 points

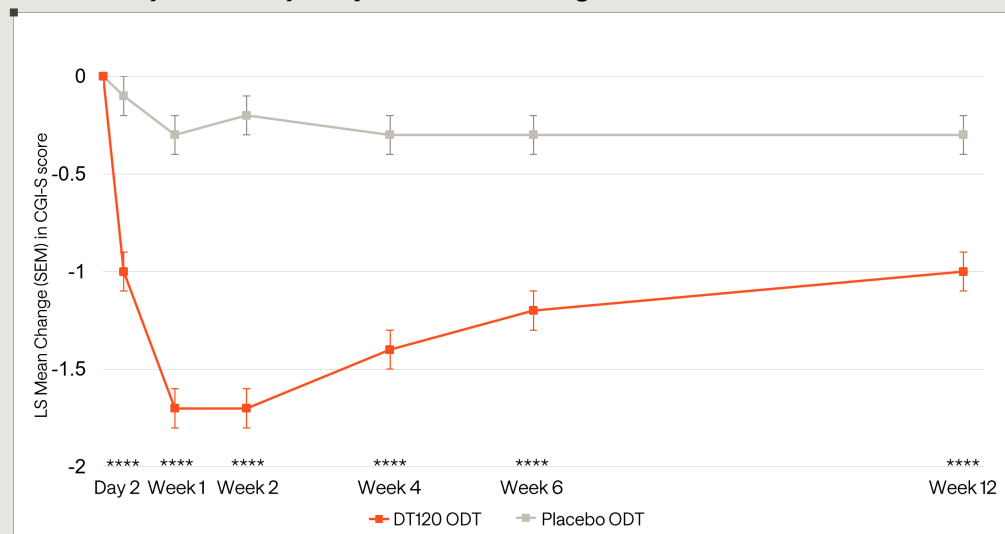
1. Source: Emerge study documents, ITT population.

2. Primary endpoint of the study was change in MADRS at week 6 using a Mixed-Effects Model Repeated Measures (MMRM) statistical analysis with reference-based imputation.

LS Mean: least squares mean; MADRS: Montgomery-Åsberg Depression Rating Scale; ODT: orally disintegrating tablet; SEM: standard error of the mean

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

Key Secondary Endpoint: CGI-S Change from Baseline to Week 6



Highlights

Change from Baseline²

- Day 2: -1.0 points
- Week 1: -1.7 points
- Week 4: -1.4 points
- Week 6: -1.2 points
- Week 12: -1.0 points

Improvement over Placebo²

- Day 2: -0.9 points
- Week 1: -1.4 points
- Week 4: -1.1 points
- Week 6: -0.9 points
- Week 12: -0.7 points

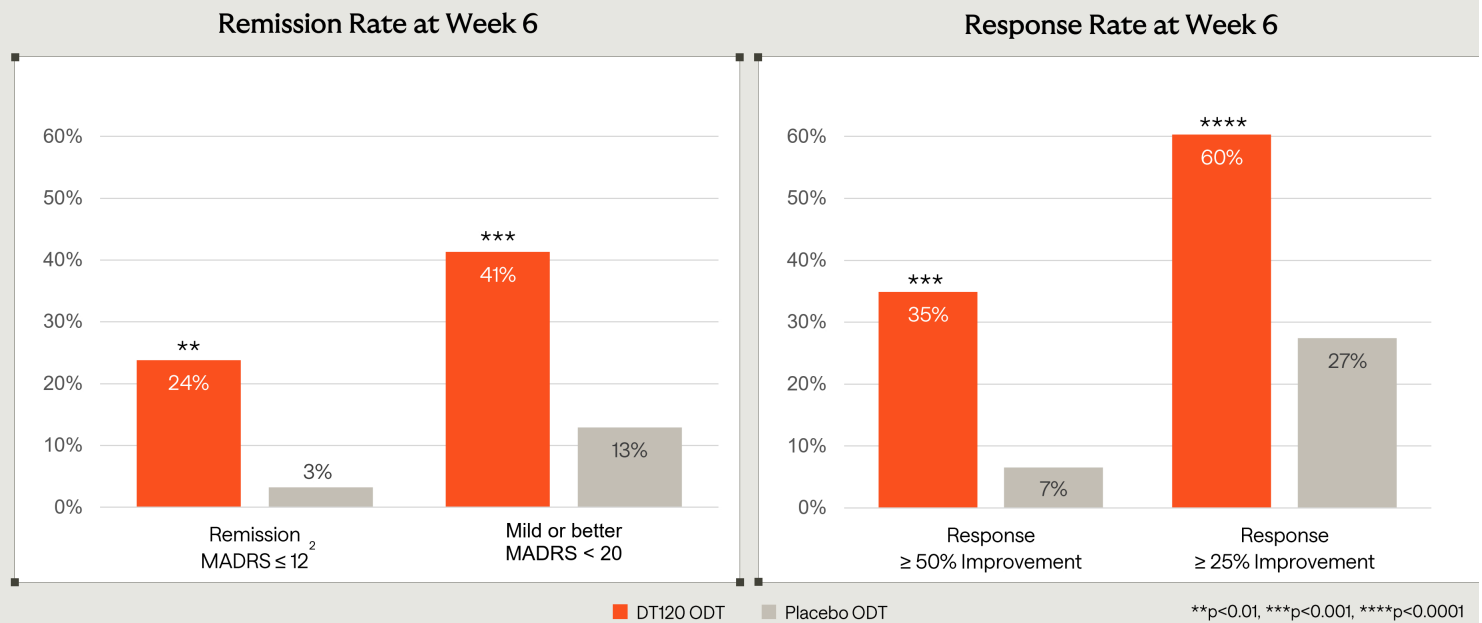
****p<0.0001

1. Source: Emerge study documents, ITT population.

2. Key secondary endpoint of the study was change in CGI-S at week 6 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

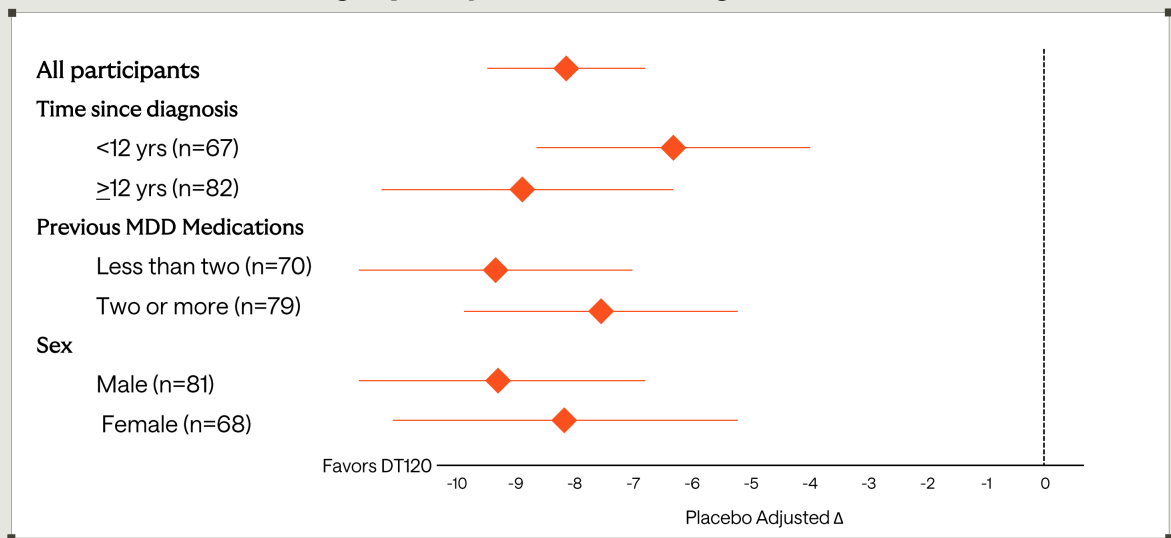
DT120 ODT Effects Supported by Robust, Statistically Significant Response and Remission Rates¹



1. Source: Emerge study documents. ITT population. Pre-planned secondary endpoint.
2. Remission rates using a cutoff of MADRS ≤ 10 was 24% for DT120 ODT compared to 3% for placebo ODT.
ODT: orally disintegrating tablet; MADRS: Montgomery-Åsberg Depression Rating Scale

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

Subgroup Analysis of MADRS Change at Week 6²



1. Source: Emerge study documents. Subgroup analysis of ITT population.
2. Data presented as LSmean ± standard error.
3. For each subgroup, the change from baseline in MADRS 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 ; MADRS: Montgomery-Åsberg Depression Rating Scale

DT120 ODT was Generally Well-Tolerated and Consistent with Known Pharmacology¹

Favorable tolerability profile

- AE profile consistent with prior studies of DT120
- 99% of adverse events (AEs) were mild-to-moderate in severity²
- Most treatment emergent AEs (TEAEs) occurred and resolved on dosing day
- No TEAEs led to study withdrawal

No SAEs³

- No serious adverse events (SAEs)

No suicidal behavior or suicidality signal⁴

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

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

2. The one severe adverse event that occurred was a recurrence of chronic back pain occurring approximately 6 weeks after dosing.

3. No serious adverse events have been observed in the Emerge study at the time of the data analysis. At the time of the analysis, a total of 4 serious adverse events have been recorded across all studies of DT120 ODT, including an SAE deemed treatment-related, resulting in an SAE rate of approximately 0.6% across studies and populations.

4. Suicidality assessment based on changes in C-SSRS.

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

Adverse Events were Mild-to-Moderate in Severity with No TEAEs Leading to Discontinuation¹

Adverse Event	DT120 ODT n=75	Placebo ODT n=74
Any TEAE	74 (99%)	42 (57%)
Mild	45 (61%)	31 (74%)
Moderate	28 (38%)	11 (26%)
Severe	1 (1%) ²	0
Any Study Drug-Related TEAE	74 (99%)	24 (32%)
Any Adverse Event of Special Interest (AESI)	71 (95%)	15 (20%)
Any Treatment-Emergent SAE	0	0
Any TEAE Leading to Discontinuation	0	0
Any TEAE Leading to Death	0	0

1. Source: Emerge study documents. Safety population in study part A.

2. Severe adverse event was a recurrence of chronic back pain occurring approximately 6 weeks after dose.

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

Most Common (≥10%) TEAEs Demonstrate Favorable Tolerability Profile of DT120 ODT¹

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TEAEs with Incidence ≥10%	DT120 ODT (n=75)		Placebo ODT (n=74)	
	Dosing Day	After Dosing Day	Dosing Day	After Dosing Day
Illusion	48 (64%)	0	2 (3%)	0
Euphoric Mood	22 (29%)	0	3 (4%)	0
Nausea	20 (27%)	0	2 (3%)	0
Headache	12 (16%)	9 (12%)	2 (3%)	2 (3%)
Feeling of Relaxation	12 (16%)	0	2 (3%)	0
Anxiety	11 (15%)	2 (3%)	0	0
Feeling Abnormal	11 (15%)	1 (1%)	1 (1%)	0
Thinking Abnormal	10 (13%)	1 (1%)	1 (1%)	0
Crying	9 (12%)	0	1 (1%)	0
Disorientation	9 (12%)	0	0	0
Dizziness	9 (12%)	0	1 (1%)	0
Paraesthesia	9 (12%)	0	1 (1%)	0
Emotional Disorder	8 (11%)	1 (1%)	0	0
Blood Pressure Increase	8 (11%)	0	2 (3%)	0
Feeling of Body Temperature Change	8 (11%)	0	1 (1%)	0
Hallucination, Visual	8 (11%)	0	1 (1%)	0
Insomnia	6 (8%)	2 (3%)	0	0

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

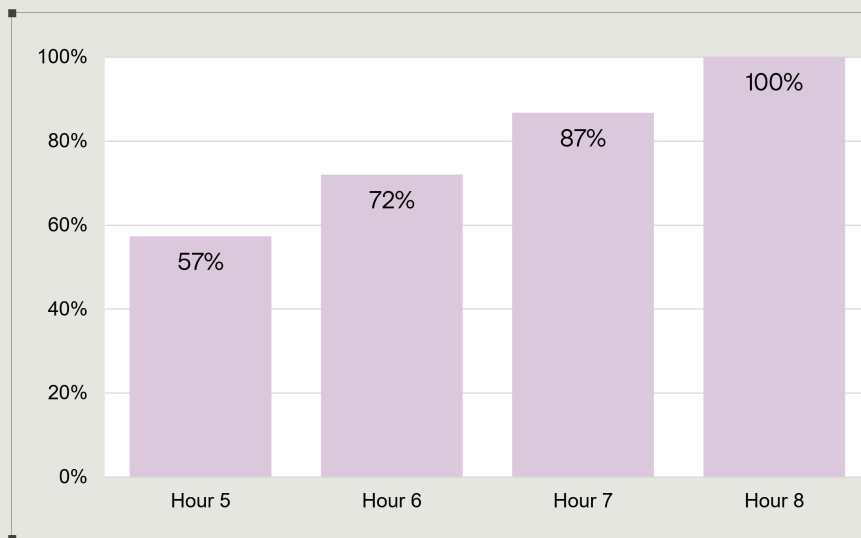
ODT: orally disintegrating tablet; TEAE: treatment-emergent adverse event

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◆

DT120 ODT Dosing Session Duration Supports Translation into Clinical Practice¹

Time to End of Session Checklist (EoSC) Clearance



Key Highlights

- Average time to clearance of EoSC of 5.8 hours
- Over half of participants cleared EoSC at hour 5
- All participants cleared EoSC by hour 8

1. Source: Emerge study documents. Safety population in study part A. Time at which participant first meets End of Session Checklist criteria.
ODT: orally disintegrating tablet; EoSC: End of Session Checklist

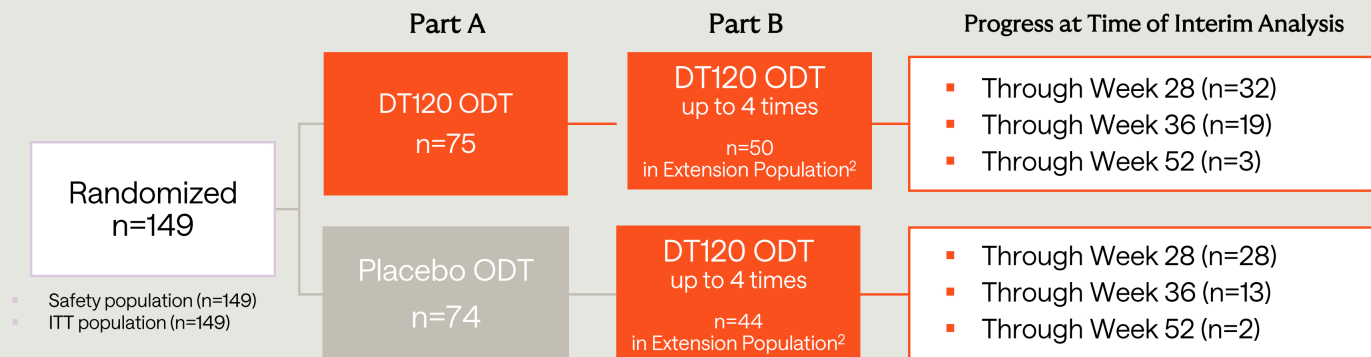
A large, stylized white number '3' is positioned on the left side of the slide, set against a dark purple background. The number is bold and has a modern, slightly rounded font style.

Phase 3 Emerge Topline Results

Part B – Interim Analysis

Dan Karlin, MD
Chief Medical Officer

Part B Disposition



1. Based on interim analysis as of May 21, 2026. Interim analysis based on partial data and subject to change.
2. Extension population includes participants with at least one Part B visit completed.

ITT: intent to treat; ODT: orally disintegrating tablet

Part B Enrollment & Baseline Characteristics¹

Demographic (Part B) ²	DT120 ODT n=50	Placebo ODT n=44	Total n=94
Mean age (years)	46.2	42.7	44.5
Sex, female (%)	50%	50%	50%
Race (% white)	62%	68%	65%
MADRS score at Part B Entry	23.5 (10.4)	29.7 (8.5)	26.5 (10.0)
CGI-S score at Part B Entry	3.6 (1.2)	4.4 (0.8)	4.0 (1.1)

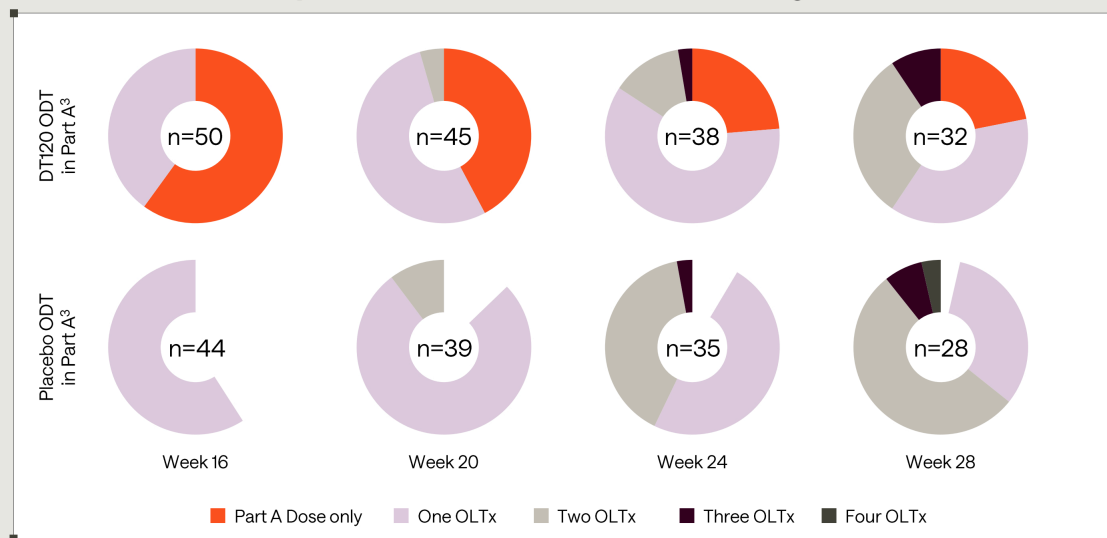
1. Based on interim analysis as of May 21, 2026. Extension population. Interim analysis based on partial data and subject to change.

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

CGI-S: Clinical Global Impressions - Severity Scale; ITT: intent to treat population; MADRS: Montgomery-Åsberg Depression Rating Scale; ODT: orally disintegrating tablet

Treatment Patterns in Part B Provide Early Insights into Paradigm beyond 12 Weeks^{1,2}

Summary of Cumulative DT120 ODT Doses through Week 28

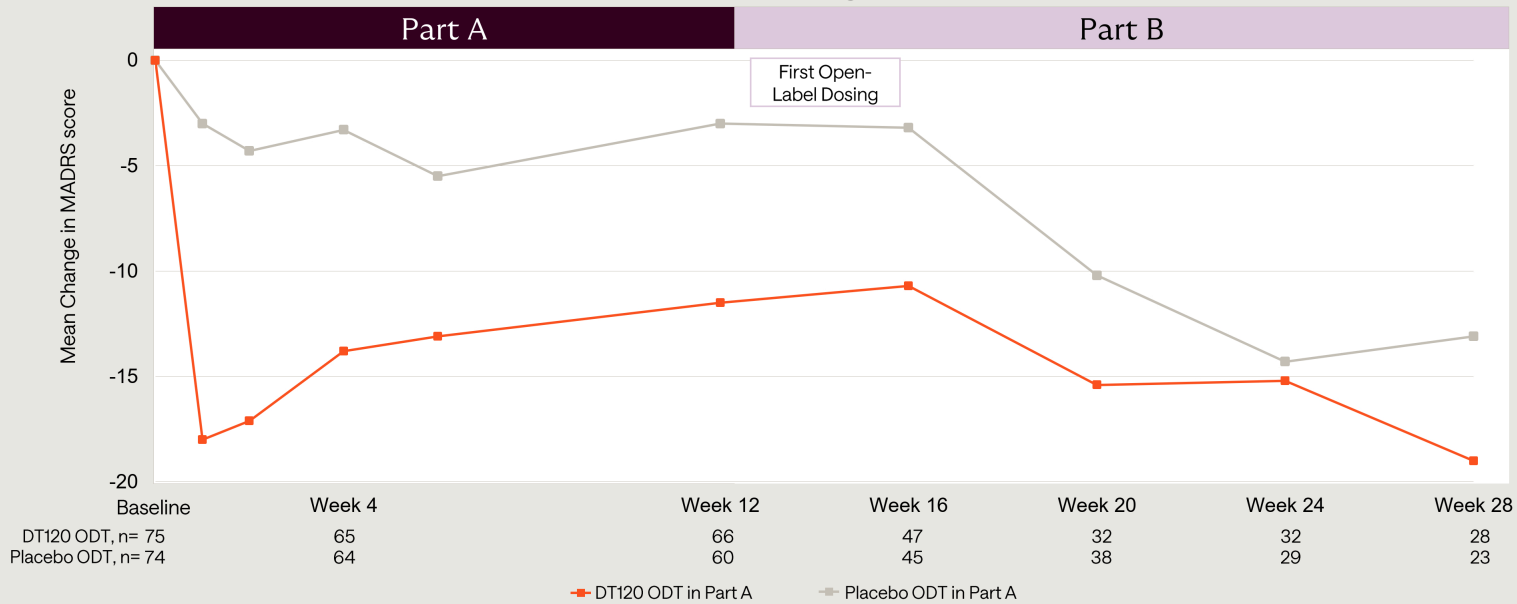


1. Based on interim analysis as of May 21, 2026. ITT Part A+B population. Interim analysis based on partial data and subject to change.
2. Only includes participants who received DT120 ODT in Part A.
3. n is the number of participants in the Extension population who had the specified number of doses up to the corresponding visit.

ODT: orally disintegrating tablet; OLTx: open-label treatment

MADRS Scores Improve Further with Additional Treatments in Part B

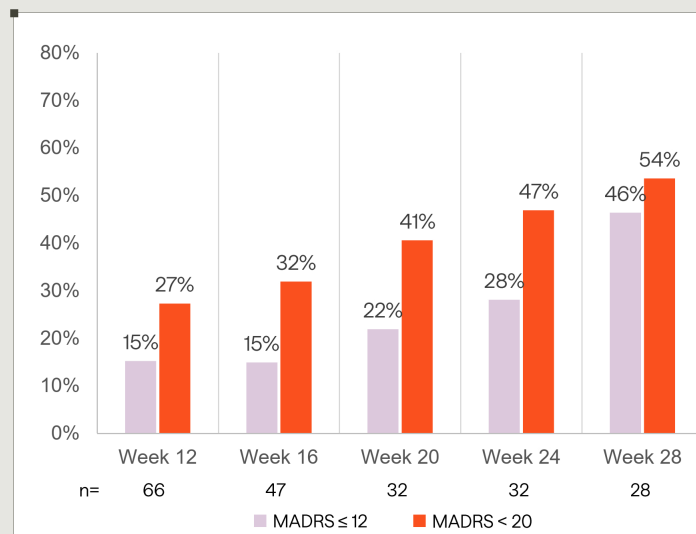
MADRS Scores through Week 28^{1,2}



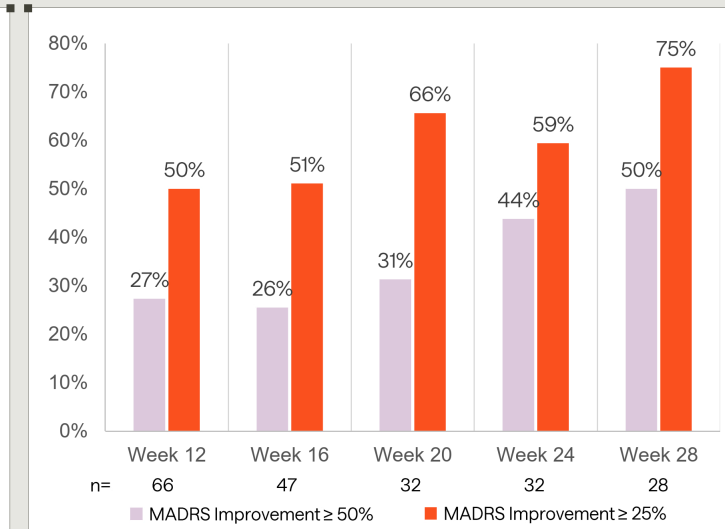
1. Based on interim analysis as of May 21, 2026. ITT Part A+B population with treatment policy strategy. Interim analysis based on partial data and subject to change.
2. n is the number of participants in the ITT Part A+B population with non-missing MADRS score at Baseline and the respective visit.
LS Mean: least squares mean; MADRS: Montgomery-Åsberg Depression Rating Scale; ODT: orally disintegrating tablet

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

Remission Rates in Part B



Response Rates in Part B



1. Source: Emerge study documents, ITT population.
2. Only includes participants who received DT120 CDT in Part A.
MADRS: Montgomery-Åsberg Depression Rating Scale

4

Next Steps

Rob Barrow
Chief Executive Officer

Building Potentially Practice-Changing Evidence

Generalized Anxiety Disorder (GAD)

Major Depressive Disorder (MDD)

Phase 2b
Study MMED008



Voyage



Panorama



Emerge



Ascend

n=198
1:1:1:1 randomization
Positive Study

n=214
1:1 randomization
Enrollment Complete

n=245
2:1:2 randomization
Enrollment Complete

n=149
1:1 randomization
Positive Study

Target n=165¹
2:1:2 randomization
Enrolling

4 Doses of DT120
vs. Placebo

DT120 ODT
vs. Placebo

DT120 ODT
vs. Placebo
including 50 µg control

DT120 ODT
vs. Placebo

DT120 ODT
vs. Placebo
including 50 µg control

**-7.7 HAM-A at Week 12
(p<0.01)**

*Primary endpoint:
HAM-A at Week 12*

*Primary endpoint:
HAM-A at Week 12*

**-8.1 MADRS at Week 6
(p<0.0001)**

*Primary endpoint:
MADRS at Week 6*

*Anticipated Topline Readout
Early 3Q 2026*

*Anticipated Topline Readout
Late 3Q 2026*

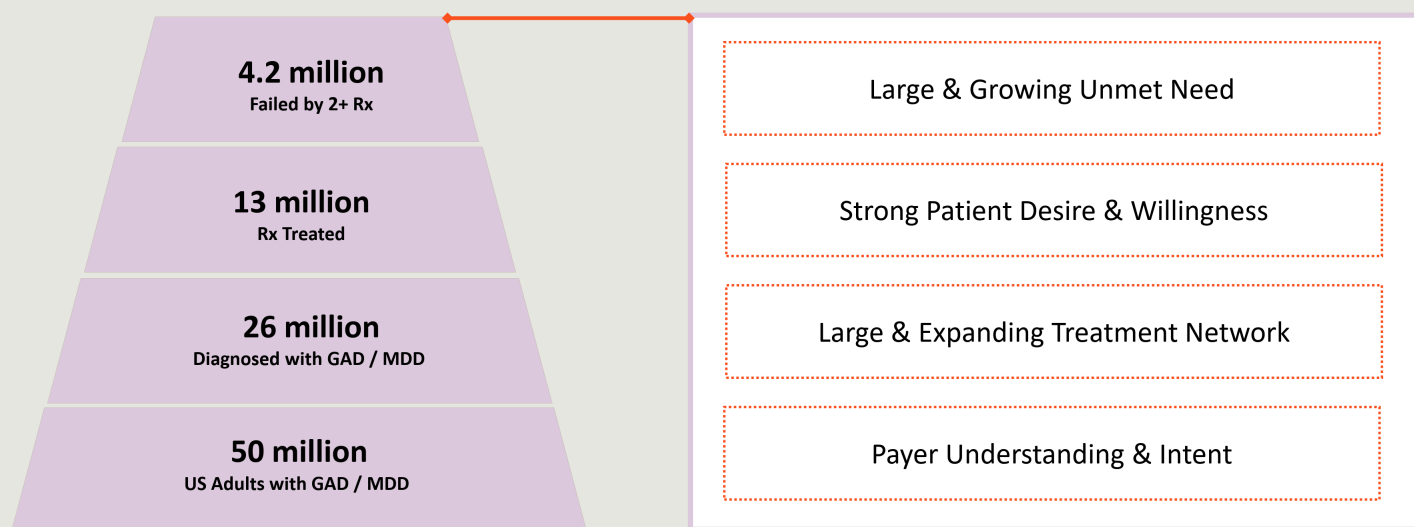
Continued momentum across complementary studies heading into upcoming Phase 3 readouts

¹ Clinical study designs subject to change based on ongoing regulatory discussion and review, including of Phase 3 clinical trial protocols

DB: double blind; HAM-A: Hamilton Anxiety Rating Scale; MADRS: Montgomery-Åsberg Depression Rating Scale; ODT: orally disintegrating tablet; OL: open-label; RCT: randomized controlled trial; Δ: placebo-adjusted delta

Opportunity to Deliver Significant Impact and Value Creation¹

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Addressable market means potential 42,000 patient impact & \$2 billion revenue opportunity per 1% 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.

Building a Psychiatry Powerhouse with Two Distinct Drivers¹

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Clinical & Regulatory Execution

★
Positive Emerge
Topline Data

◆
Voyage TLR
early 3Q 2026

◆
Panorama TLR
late 3Q 2026

◆
Initial DT402 Data
in ASD (2026)

◆
NDA for
DT120 ODT

◆
Ascend TLR

Value Creation

Optimizing Patient
Care Model

Expanding Site of Care
Engagement &
Commercial Footprint

Accelerating
Scheduling &
Reimbursement

◆
Commercial Launch
GAD & MDD

Commercial Execution

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

ASD: autism spectrum disorder; GAD: generalized anxiety disorder; MDD: major depressive disorder; ODT: orally disintegrating tablet; TLR: topline data readout

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Precise science. Boundless impact.
