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): August 12, 2026

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

British Columbia	**001-40360**	**98-1582438**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One World Trade Center **Suite 8500** **New York, New York**	**10007**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (212) 220-6633

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Shares	DFTX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company x

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 August 12, 2026, Definium Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing positive topline data from the Company's Phase 3 Voyage 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 8.01.

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 August 12, 2026, the Company posted a presentation discussing the Voyage 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 August 12, 2026
99.2	Voyage Topline Data Presentation, dated August 12, 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: August 12, 2026

By: /s/ Robert Barrow
Name: Robert Barrow
Title: Chief Executive Officer

Exhibit 99.1

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

Study met primary and all key secondary efficacy endpoints

Participants receiving DT120 ODT achieved a statistically significant reduction in Hamilton Anxiety Rating Scale (HAM-A) score, with a placebo-adjusted change of 5.4 points from baseline at Week 12 ($p<0.0001$, Cohen's $d=0.81$)

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

Company to host webcast today at 8:00 am EDT

NEW YORK-- (BUSINESS WIRE) -- Definium Therapeutics, Inc. (Nasdaq: DFTX) ("Definium" or the "Company"), a late-stage clinical biopharmaceutical company developing a new generation of therapeutics intended to address underlying causes of psychiatric and neurological disorders, today announced positive topline results from Voyage, its first Phase 3 study of DT120 (lysergide) Orally Disintegrating Tablet (ODT) 100 µg in adults with generalized anxiety disorder (GAD). The results mark the Company's second positive DT120 ODT Phase 3 readout, following the positive Emerge results in major depressive disorder (MDD) announced in June.

Voyage met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement from baseline compared with placebo, as measured by the change in 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 -11.6 compared with -6.2 for participants who received placebo, an LS mean difference of -5.4 points ($p<0.0001$), corresponding to a standardized effect size of $d=0.81$. Efficacy was rapid, with changes seen as early as Day 2 and sustained at all post-baseline timepoints in Part A.

"The unprecedented efficacy demonstrated in Voyage should raise the bar for what patients and clinicians expect from GAD treatments and reinforces our belief that DT120 has the potential to redefine care for the millions of patients in need," said Rob Barrow, Chief Executive Officer of Definium Therapeutics. "Importantly, the consistent, large effect size we've now observed across three studies underscores the potential of DT120 to transform psychiatry and usher in a new era of mental health care. With our Panorama topline results in GAD expected in September, we remain focused on bringing this potential new treatment to patients as quickly as possible. We are deeply grateful to the patients, investigators, site personnel, and our team whose commitment made this milestone possible."

DT120 ODT was generally well tolerated, with treatment-emergent adverse events mild to moderate in severity, transient, and predominantly occurring on the day of dosing in Part A. No new safety signals were identified, including no suicidality signal or suicidal behavior.

On the day of dosing, participants were assessed hourly beginning at hour 5 post-dose on a structured end-of-session checklist (EoSC). The average time to meeting EoSC criteria was 6.4 hours for participants receiving DT120 ODT in Part A, with a median of 6.1 hours and 92% of participants meeting the EoSC criteria by hour 8.
"GAD affects approximately 26 million adults in the United States, and when left untreated, can cause chronic, pervasive, and debilitating symptoms that can seriously impact a person's daily life. It is one of the most undertreated conditions in psychiatry," said Brian Barnett, MD, Vice Chair of Psychiatry at Cleveland Clinic, and a Voyage principal investigator. "Despite the burden of the disorder, the last new FDA-approved treatment for this condition was nearly two decades ago, and many of the patients I see have not found relief despite trying multiple therapies. A single-dose treatment option delivering meaningful benefits for 12 weeks is a promising step forward not found in today's therapies. If approved, it could give patients and their physicians a treatment option that works through an entirely different mechanism than anything currently used in clinical practice."

Highlights from Voyage Topline Results

The mean baseline HAM-A score at study entry was 28.4 in the DT120 ODT treatment group (n=107) and 27.4 in the placebo group (n=107).

Primary Endpoint	**DT120 ODT 100 µg**	**Placebo ODT**	**Placebo-Adjusted Difference**
HAM-A: LS mean change at Week 12	-11.6	-6.2	-5.4 (p<.0001)
Key Secondary Endpoints			
CGI-S: LS mean change at Week 12	-1.0	-0.4	-0.6 (p<.0001)
HAM-A: LS mean change at Week 1	-11.9	-4.2	-7.7 (p<.0001)
CGI-S: LS mean change at Day 2	-1.0	-0.2	-0.8 (p<.0001)
Other Secondary Endpoints			
HAM-A: response rate (≥50%) at Week 12	43%	16%	27% (p<0.0001)
HAM-A: remission rate (≤7) at Week 12	14%	4%	10% (p=0.0222)
HAM-A: mild or better (<16) at Week 12	51%	23%	28% (p<0.0001)

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

Webcast Details

Definium Therapeutics management will host a webcast at 8:00 a.m. EDT today to review the Phase 3 Voyage 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 Voyage

Voyage 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 adults with generalized anxiety disorder (GAD). The study consists of a 12-week double-blind 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 based on symptom severity.

The study enrolled 214 participants aged 18 to 74 years across approximately 35 sites in the United States with a DSM-5-confirmed diagnosis of GAD, based on clinical assessment and the Mini-International Neuropsychiatric Interview (MINI), and a Hamilton Anxiety Rating Scale (HAM-A) total score of at least 20 at screening and baseline.

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.

Voyage is one of two pivotal Phase 3 studies in GAD. Panorama, the second Phase 3 study in GAD, is aligned with Voyage, but includes a low-dose 50 µg dose arm. 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 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 Panorama is change from baseline in HAM-A total score at Week 12 between DT120 ODT 100 µg and placebo.

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 (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-HT2A) receptors. DT120 ODT is Definium's proprietary and pharmaceutically optimized formulation of LSD. DT120 ODT is an advanced formulation incorporating Catalent's Zydis® ODT fast-dissolve technology, designed to deliver several unique advantages, including faster absorption and onset of transient cognitive, perceptual, and affective changes, improved bioavailability, and a lower incidence of gastrointestinal side effects. Definium is developing DT120 ODT, the tartrate salt form of lysergide, for generalized anxiety disorder (GAD), major depressive disorder (MDD), and posttraumatic stress disorder (PTSD), and is exploring its potential applications in other serious brain health disorders. DT120 has received Breakthrough Therapy designation from the FDA for GAD. 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, 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-HT2A) 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 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; 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 or other regulatory approvals; the Company's beliefs regarding potential benefits of its product candidates; the Company's belief that DT120 ODT has the potential to transform psychiatry and usher in a new era of mental health care; and the ability of DT120 ODT to redefine care for the millions of patients in need. 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

1. Ringeisen, H., et al. (2023). Mental and substance use disorders prevalence study (MDPS): Findings report. RTI International and current U.S. Census data and internal company estimates.
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10. Liechti, ME. "Modern clinical research on LSD." Neuropsychopharmacology. 2017;42:2114-2127.

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

Media:
media@definiumtx.com

Phase 3 Voyage Study Topline Data Readout

Definium™ THERAPEUTICS

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 readouts for the 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 and 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, 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 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 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.

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Opening Remarks

Rob Barrow
Chief Executive Officer

Definium THERAPEUTICS

Thank you to our study participants, investigators and partners who made Voyage 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 years[1]

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

Second Positive Pivotal Readout for DT120 ODT

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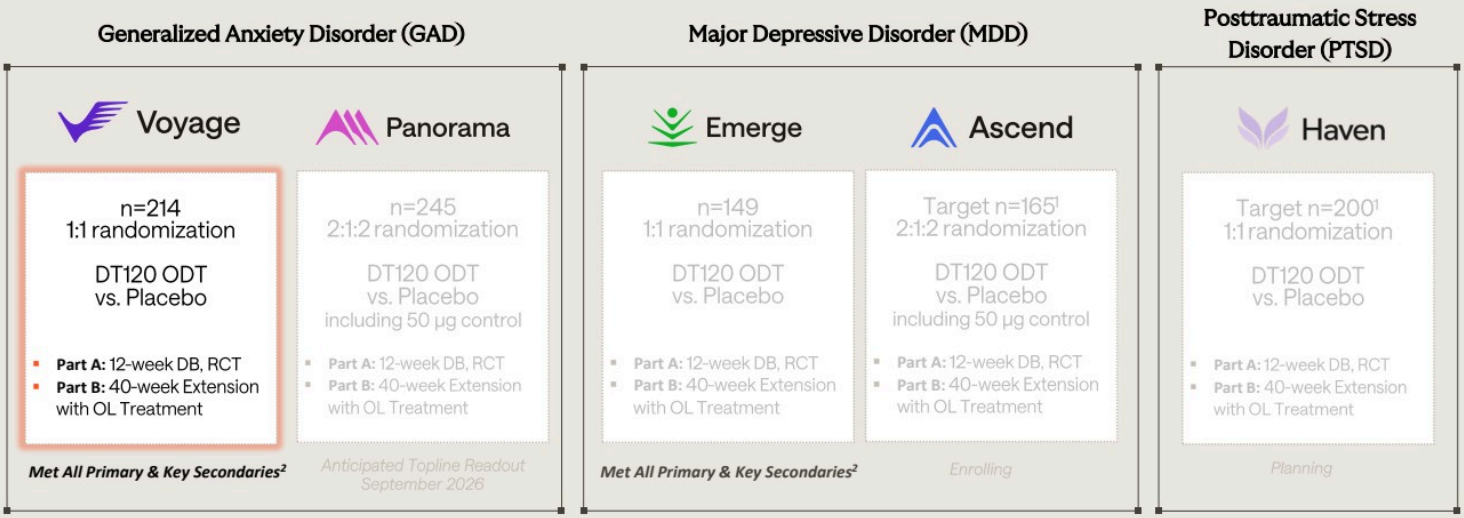

1. Clinical study designs subject to change based on ongoing regulatory discussion and review, including of Phase 3 clinical trial protocols
2. Includes the primary endpoint and all hierarchically controlled key secondary endpoints.

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

Voyage Results Demonstrate Potential Best-in-Class Efficacy in Generalized Anxiety Disorder[1]

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Rapid, robust and durable efficacy after single dose	▪ All primary and key secondary endpoints highly statistically significant ▪ 5.4 point HAM-A improvement over placebo at week 12 primary endpoint ($p<0.0001$) ▪ 7.7 point HAM-A improvement over placebo at week 1 ($p<0.0001$) ▪ 0.8 point CGI-S improvement over placebo at day 2 ($p<0.0001$)
Limited side effect burden	▪ DT120 ODT generally well tolerated and no new safety signals were identified[2] ▪ No suicidality signal observed or suicidal behavior
Efficient session dynamics	▪ 6.4 hour average time to clear End of Session Checklist (EoSC) ▪ 92% participants cleared EoSC by 8 hours

1. Source: Voyage study documents. Safety population in study part A (through week 12)
2. At the time of the analysis, a total of 13 participants reported a treatment emergent serious adverse event across all studies of DT120, including 1 SAE deemed treatment-emergent in Part B of Voyage, resulting in an SAE rate of approximately 1.7% across studies and populations. Part B safety data are expected to be shared in a future presentation.

AE: adverse event; CGI-S: Clinical Global Impression-Severity Scale; MADRS: Montgomery-Åsberg Depression Rating Scale; MDD: major depressive disorder; ODT: orally disintegrating tablet; SAEs: serious adverse events

Continuing to Build Potentially Practice-Changing Evidence[1]

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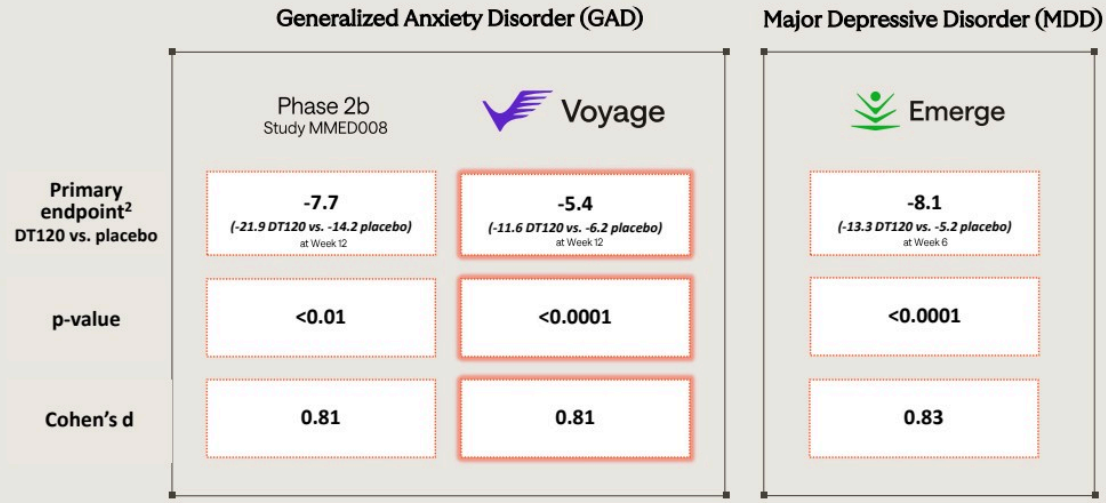
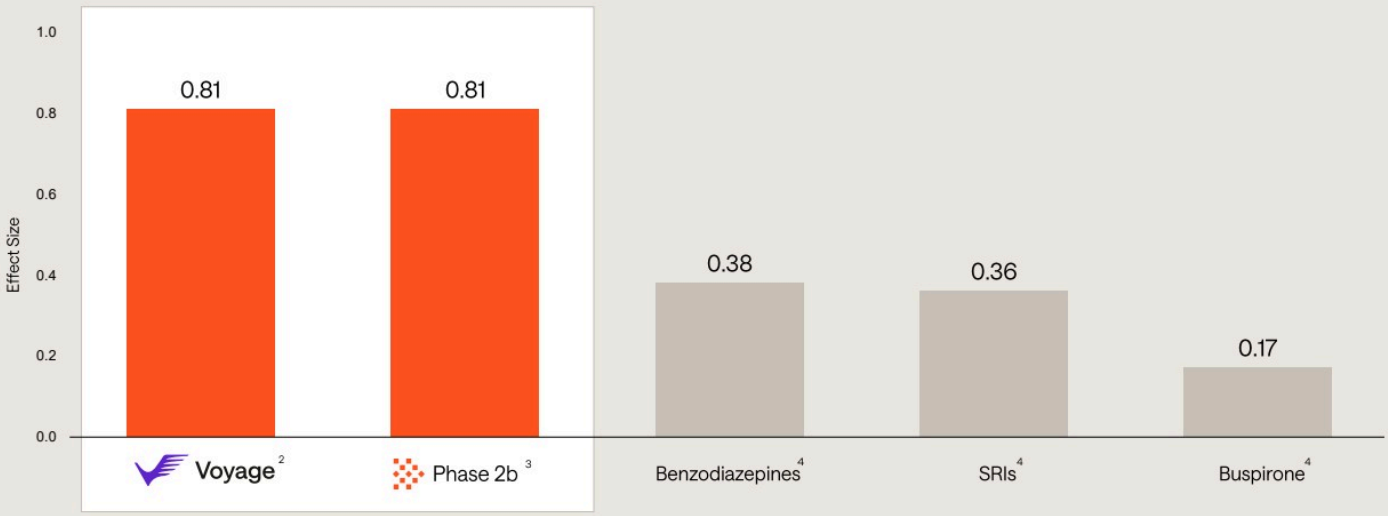


Consistent effect size greater than *d* = 0.8 across multiple studies & indications

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 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.

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; TBD: to be determined

DT120's Efficacy Stands Out Compared to Approved GAD Treatments[1]



DT120 effect size is more than double the GAD standard of care

1) The information presented in this slide is derived from multiple clinical trials, each conducted under distinct protocolsand 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) Source: Voyage study documents;3) R Robison, JAMA. 2025Sep4; e2513481. doi:10.1001/jama.2025.13481; 4) RB Hidalgo, JPsychopharmacol. 2007 Nov;21(8):864-72

GAD:generalizedanxietydisorder, SRI:serotoninreuptakeinhibitors

2

Phase 3 Voyage Study Results

Part A – Topline Results

Dan Karlin, MD
Chief Medical Officer

Voyage Trial Design

PHASE 3 STUDY[1]

Voyage

Part A
12 Week Randomized, Double-Blind

Single Dose

- n=107 DT120 ODT 100 µg
- n=107 Placebo

Part B
40 Week Extension with Opportunity for Open-Label Treatment

Up to four open-label doses of DT120 ODT 100 µg

Follow-up Observation
GAD-7 (ePRO): biweekly
HAM-A (central rater): monthly or when GAD-7 ≥ 10

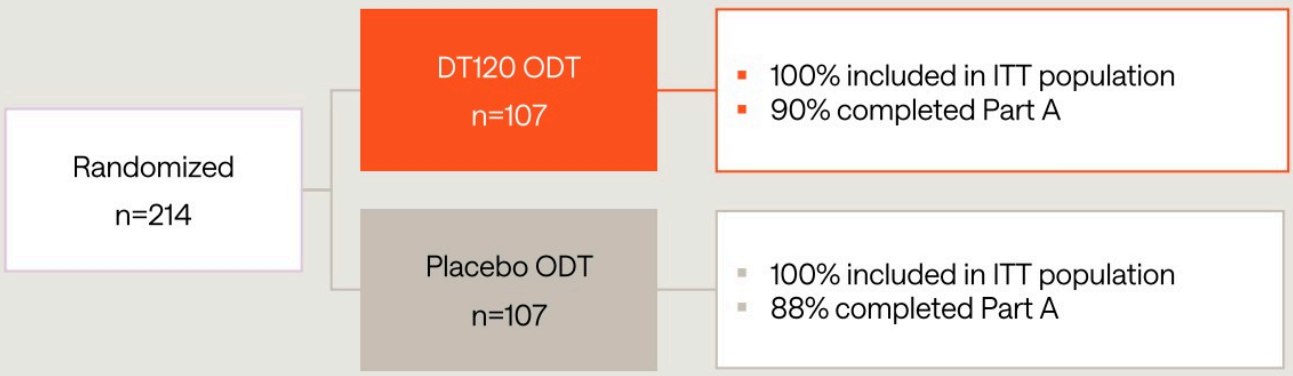
Potential Treatment
Eligible for open-label treatment if HAM-A ≥ 16

Primary Endpoint HAM-A at Week 12

1. Source: Definium internal study documents.

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



ITT: intent to treat; ODT: orally disintegrating tablet

Demographics & Baseline Characteristics[1]

Demographic	DT120 ODT n=107	Placebo ODT n=107	Overall n=214
Mean age (years)	41.5	42.8	42.1
Sex (% female)	59%	69%	64%
Race (% white)	73%	72%	72%
Baseline HAM-A score[2,3]	28.4 (5.9)	27.4 (5.5)	27.9 (5.7)
Baseline CGI-S score[2,4]	4.6 (0.6)	4.6 (0.6)	4.6 (0.6)
Past Psychedelic Use, n (%)			
Any psychedelic[5]	18 (17%)	27 (25%)	45 (21%)
LSD	10 (9%)	9 (8%)	19 (9%)

1. Based on ITT population.
2. Mean (SD).
3. The HAM-A is a 14-item clinician-rated outcome measure assessing various domains of anxiety with a range of 0-56. In Voyage, HAM-A 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; 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 Disease[1]

Diagnostic Trait	DT120 ODT n=107	Placebo ODT n=107	Overall n=214
HAM-A score[2]	28.4 (5.9)	27.4 (5.5)	27.9 (5.7)
HAM-A severity, n (%)			
Moderate (<24)[3]	26 (24%)	28 (26%)	54 (25%)
Severe (≥24)	81 (76%)	79 (74%)	160 (75%)
Number of past GAD treatments, n (%)			
0	35 (33%)	36 (34%)	71 (33%)
1	31 (29%)	34 (32%)	65 (30%)
2+	41 (38%)	37 (35%)	78 (36%)
Comorbid MDD, n (%)	43 (40%)	37 (35%)	80 (37%)
MADRS score[2]	13.6 (4.6)	13.5 (4.4)	13.5 (4.5)
Years since Diagnosis of GAD[2]	11.1 (10.1)	12.9 (11.6)	12.0 (10.9)
Years since Onset of GAD Symptoms[2]	21.9 (13.7)	25.7 (14.4)	23.8 (14.1)

1. Based on ITT population
2. Mean (SD)
3. Eligibility criteria required a baseline HAM-A score of 20 or greater; Moderate symptoms are defined as a HAM-A score of 16 – 23.

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

DT120 ODT Showed Statistically & Clinically Significant HAM-A Improvements at All Timepoints[1,2]

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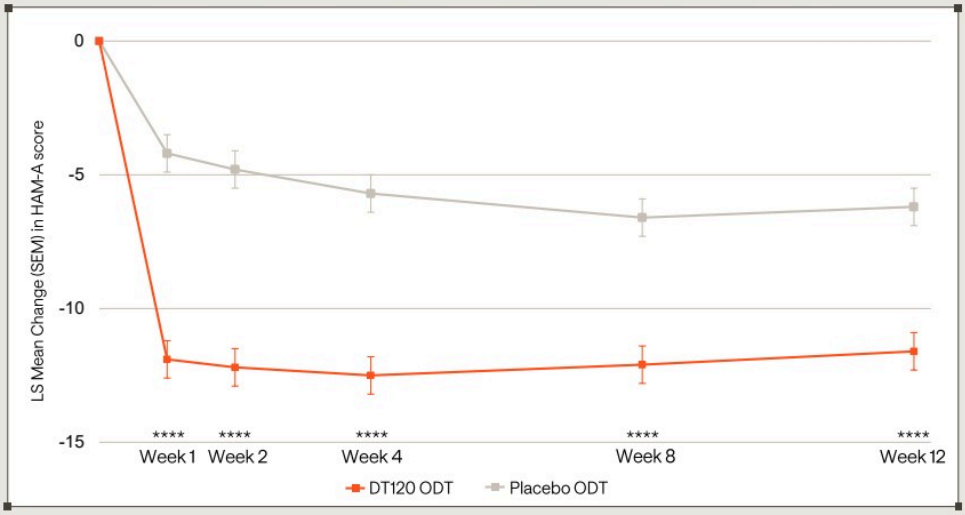
Primary Endpoint: HAM-A Change from Baseline to Week 12



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Highlights

Change from Baseline[2]

- Week 1: -11.9 points
- Week 4: -12.5 points
- Week 8: -12.1 points
- Week 12: -11.6 points

Improvement over Placebo[2]

- Week 1: -7.7 points
- Week 4: -6.8 points
- Week 8: -5.5 points
- Week 12: -5.4 points

1. Source: Voyage study documents. ITT population.
2. Primary endpoint of the study was change in HAM-A at week 12 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 Showed Statistically & Clinically Significant CGI-S Improvements on at All Timepoints[1,2]

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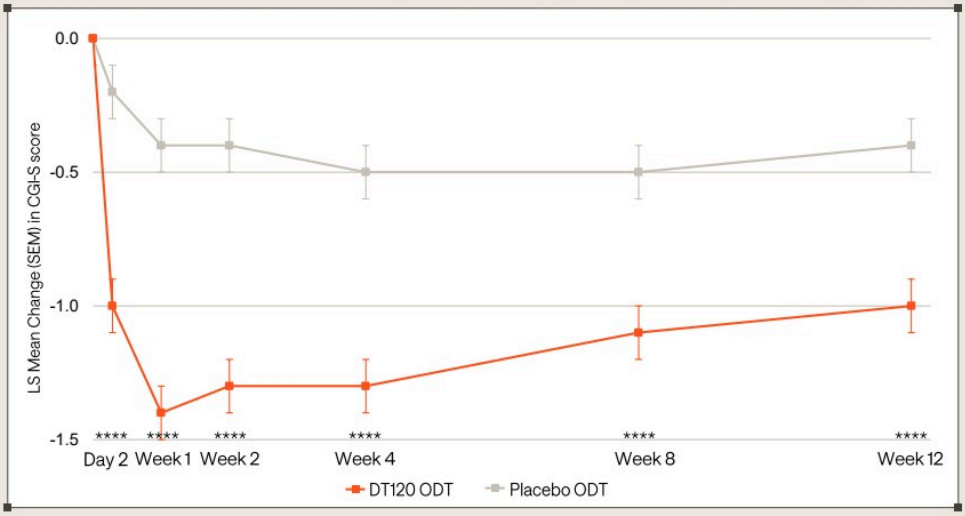
Key Secondary Endpoint: CGI-S Change from Baseline to Week 12



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Highlights

Change from Baseline[2]

- Day 2: -1.0 points
- Week 1: -1.4 points
- Week 4: -1.3 points
- Week 8: -1.1 points
- Week 12: -1.0 points

Improvement over Placebo[2]

- Day 2: -0.8 points
- Week 1: -1.1 points
- Week 4: -0.7 points
- Week 8: -0.6 points
- Week 12: -0.6 points

1. Source: Voyage study documents. ITT population.
2. Key secondary endpoints of the study was change in CGI-S at day 2 and week 12 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, Clinically Significant Response and Remission Rates[1]

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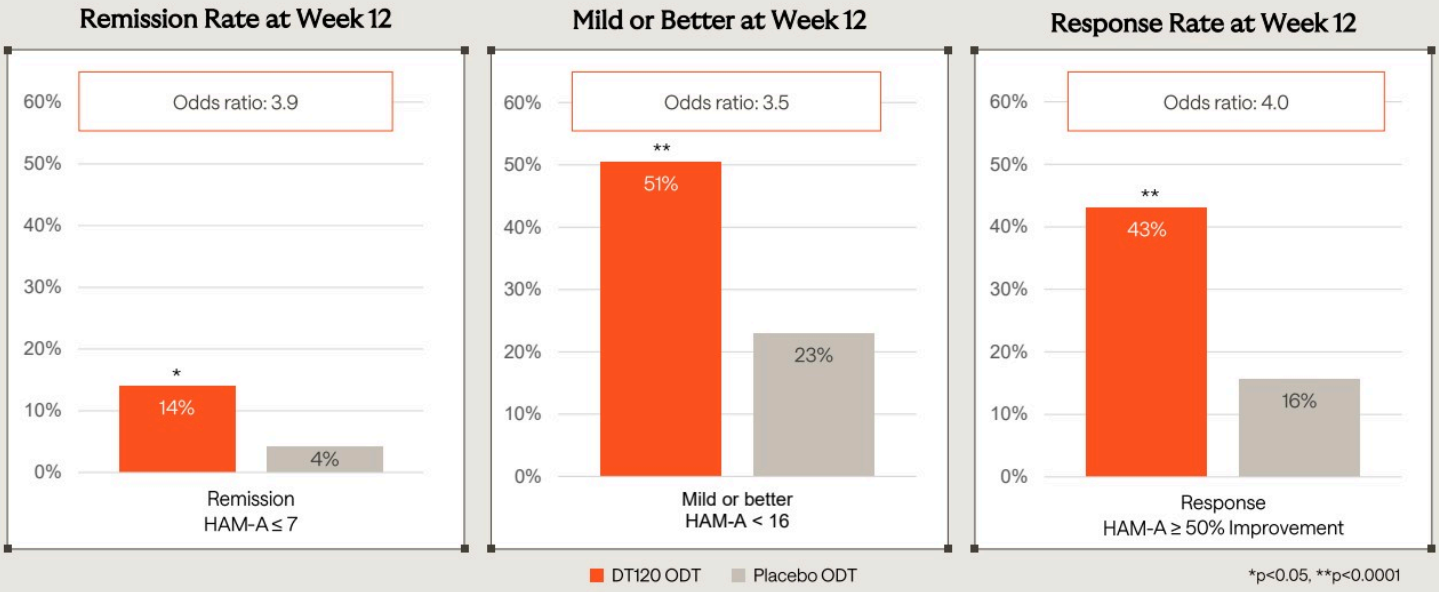

1. Source: Voyage study documents. ITT population. Pre-planned secondary endpoints.

HAM-A: Hamilton Anxiety Rating Scale; ODT: orally disintegrating tablet

Treatment Effect Maintained Across Key Subgroups – Including Those Failed by 2+ Prior Treatments[1]

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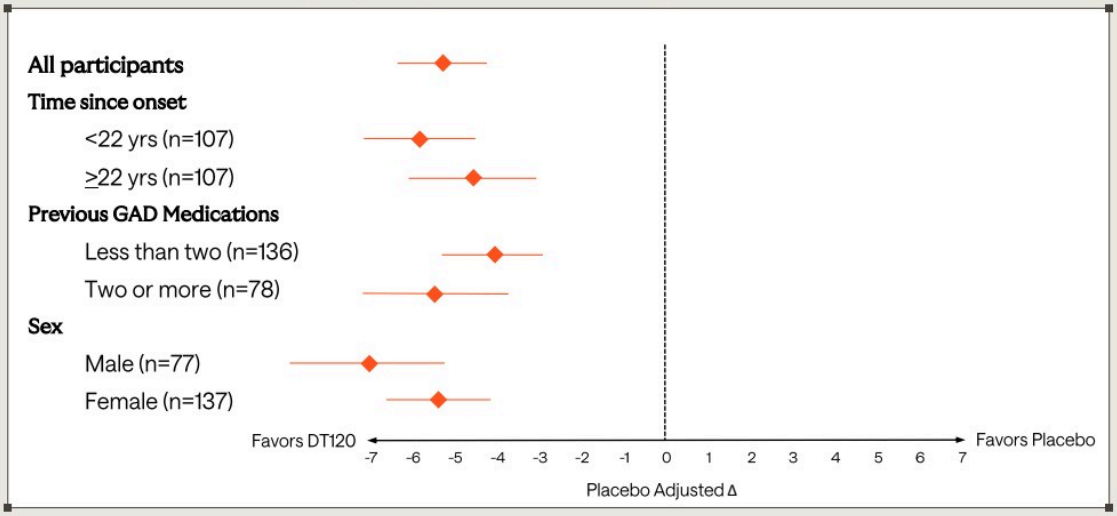
Subgroup Analysis of HAM-A Change at Week 12[2, 3]



1. Source: Voyage study documents. Subgroup analysis of ITT population.
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 ; HAM-A: Hamilton Anxiety Rating Scale; MMRM: Mixed-Effects Model Repeated Measures

DT120 ODT was Generally Well-Tolerated and Consistent with Prior Clinical Experience[1]

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Favorable tolerability profile	▪ AE profile consistent with prior studies of DT120 ▪ All adverse events (AEs) were mild-to-moderate in severity ▪ Most treatment emergent AEs (TEAEs) occurred and resolved on dosing day ▪ No serious adverse events (SAEs) in DT120 ODT arm[2]
No suicidal behavior or suicidality signal[3]	▪ No suicidal or self-injurious behavior ▪ No indication of increased suicide-related risk

1. Source: Voyage study documents. Safety population in study part A (through week 12).
2. At the time of the analysis, a total of 13 participants reported a treatment emergent serious adverse event across all studies of DT120 ODT, including 1 SAE deemed treatment-emergent in Part B of Voyage, resulting in an SAE rate of approximately 1.7% across studies and populations. Part B safety data are expected to beshared in a future presentation.
3. Participant suicidality assessment based on changes in C-SSRS.

ODT: orally disintegrating tablet

Adverse Events were Mild-to-Moderate in Severity[1,2]

Adverse Event	DT120 ODT n=107	Placebo ODT n=107
Any TEAE	106 (99%)	74 (69%)
Mild	65 (61%)	49 (46%)
Moderate	41 (38%)	24 (22%)
Severe	0	1 (1%)[3]
Any Study Drug-Related TEAE	102 (95%)	51 (48%)
Any Adverse Event of Special Interest (AESI)	100 (94%)	30 (28%)
Any Treatment-Emergent SAE	0	3 (3%)
Any TEAE Leading to Discontinuation	1 (1%)[4]	0
Any TEAE Leading to Death	0	0

1. Source: Voyage study documents. Safety population in study part A.
2. Adverse events were collected in accordance with FDA Final Guidance for Psychedelic Drug Development, which includes expected effects characterized as positive, favorable, or neutral.
3. Severe adverse event was diverticulitis occurring approximately 9 weeks after dose.
4. One participant discontinued due to a recurrence of depression 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 TEAEs Demonstrate Favorable Tolerability Profile of DT120 ODT[1,2]

TEAEs with Incidence ≥10%	Dosing Day		After Dosing Day	
	DT120 ODT (n=107)	Placebo ODT (n=107)	DT120 ODT (n=107)	Placebo ODT (n=107)
Illusion	80 (75%)	11 (10%)	2 (2%)	0
Nausea	41 (38%)	9 (8%)	3 (3%)	3 (3%)
Euphoric Mood	28 (26%)	4 (4%)	0	0
Headache	26 (24%)	7 (7%)	12 (11%)	7 (7%)
Feeling Abnormal	21 (20%)	3 (3%)	0	0
Disorientation	19 (18%)	2 (2%)	1 (1%)	0
Dizziness	14 (13%)	5 (5%)	1 (1%)	1 (1%)
Crying	13 (12%)	4 (4%)	0	0
Thinking Abnormal	12 (11%)	1 (1%)	0	0
Paraesthesia	12 (11%)	4 (4%)	0	0
Feeling of Body Temperature Change	12 (11%)	1 (1%)	0	0
Anxiety	11 (10%)	2 (2%)	3 (3%)	0
Feeling of Relaxation	8 (8%)	12 (11%)	1 (1%)	0
Hallucination, Visual	9 (8%)	2 (2%)	1 (1%)	0
Insomnia	7 (7%)	0	1 (1%)	6 (6%)
Emotional Disorder	6 (6%)	1 (1%)	1 (1%)	0

1. Source: Voyage 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 effectscharacterized as positive, favorable, or neutral.

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

DT120 ODT Dosing Session Duration Supports Translation into Clinical Practice[1]

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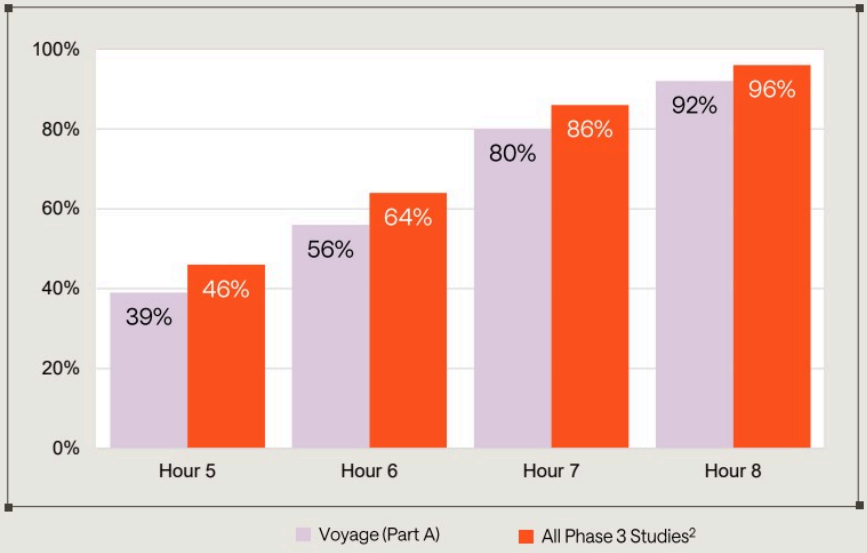
Time to End of Session Checklist (EoSC) Clearance

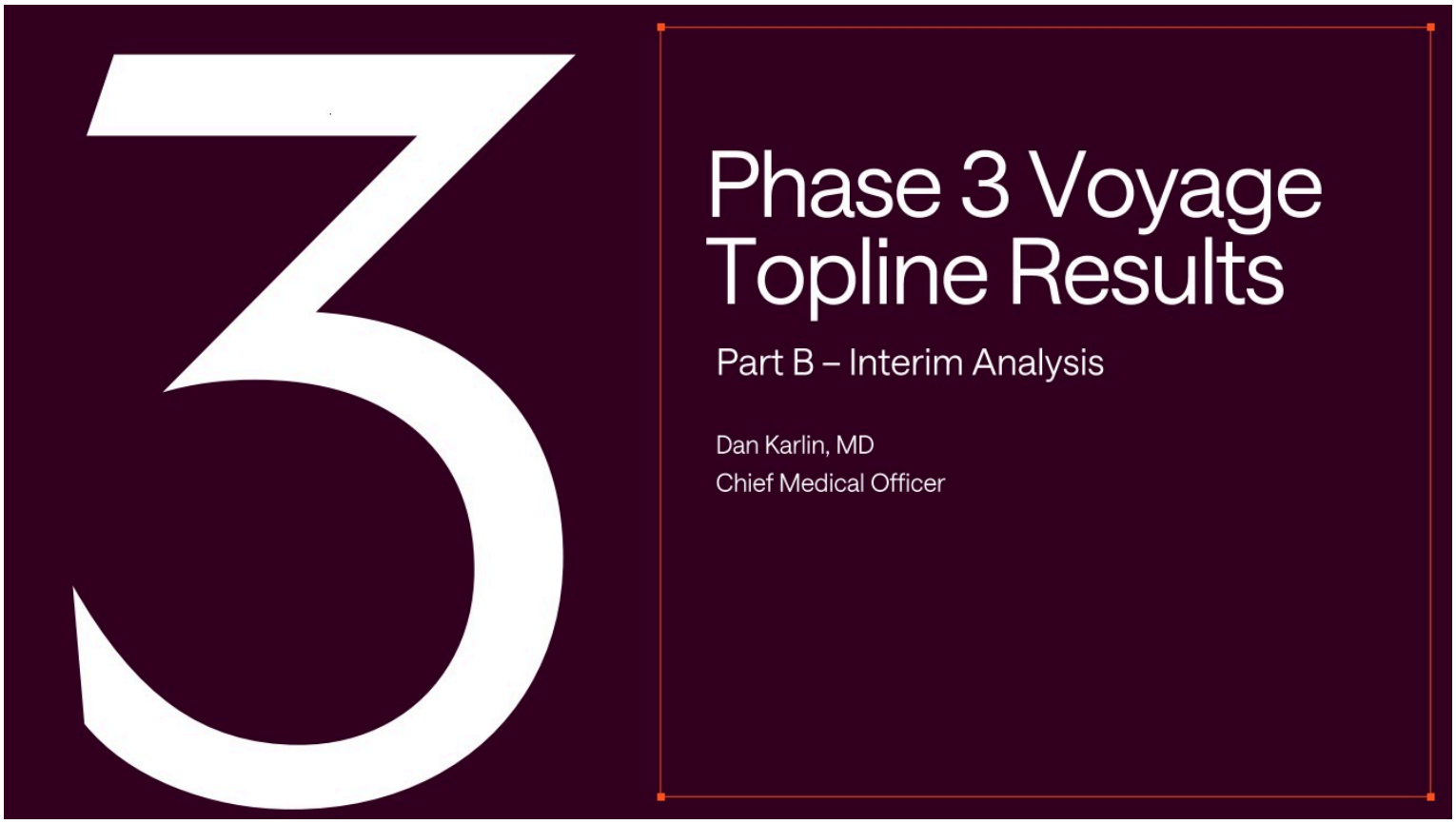


Key Highlights

- Average time to clearance of EoSC of 6.4 hours in Voyage
- More than half of participants clear EoSC at hour 6
- Over 90% participants clear EoSC by hour 8
- Emerging evidence of predictable 5 to 8 hour sessions

1. Source: Voyage study documents. Safety population in study part A. Time at which participant first meets End of Session Checklist criteria.
2. Based on Interim analysis ofEoSCas of August 10, 2026 from all dosing sessions in Emerge and Voyage and open-label dosing sessions in Panorama.

ODT: orally disintegrating tablet;EoSC: End of Session Checklist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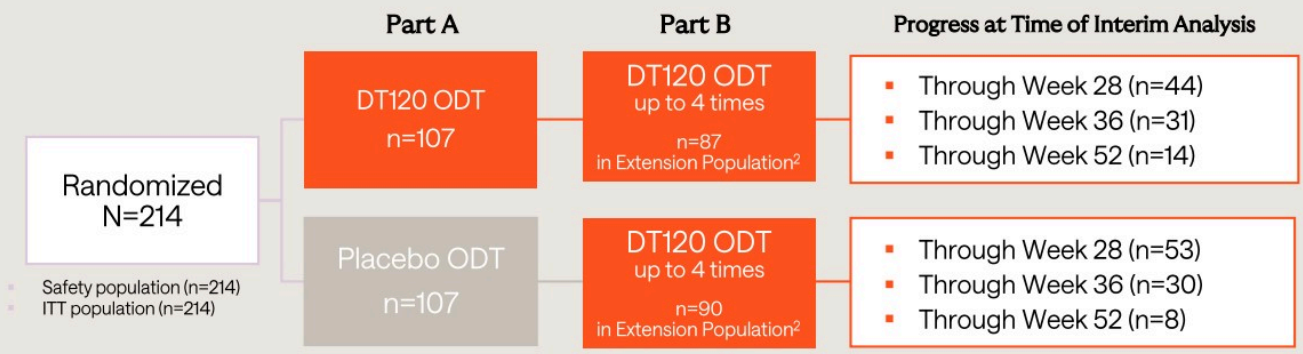
Phase 3 Voyage Topline Results
Part B – Interim Analysis
Dan Karlin, MD
Chief Medical Officer

Part B Disposition[1]



1. Based on interim analysis as of July 15, 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 Characteristics[1]

Demographic (Part B)[2]	DT120 ODT n=62	Placebo ODT n=75	Total n=137
Mean age (years)	40.9	43.6	42.3
Sex, female (%)	52%	68%	61%
Race (% white)	76%	76%	76%
HAM-A score at Part B Entry	16.8	21.2	n/a
CGI-S score at Part B Entry	3.6	4.2	n/a

1. Based on interim analysis as of July 15, 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; 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 Weeks[1]

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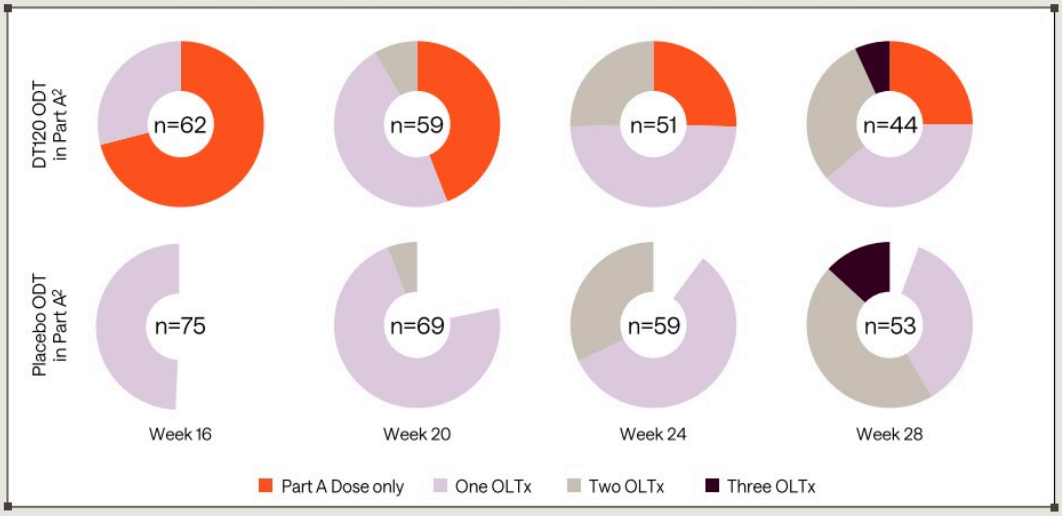
Summary of Cumulative DT120 ODT Doses through Week 28



1. Based on interim analysis as of July 15, 2026. Extension population. Interim analysis based on partial data and subject to change.
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 Improve Further with Additional Treatments in Part B

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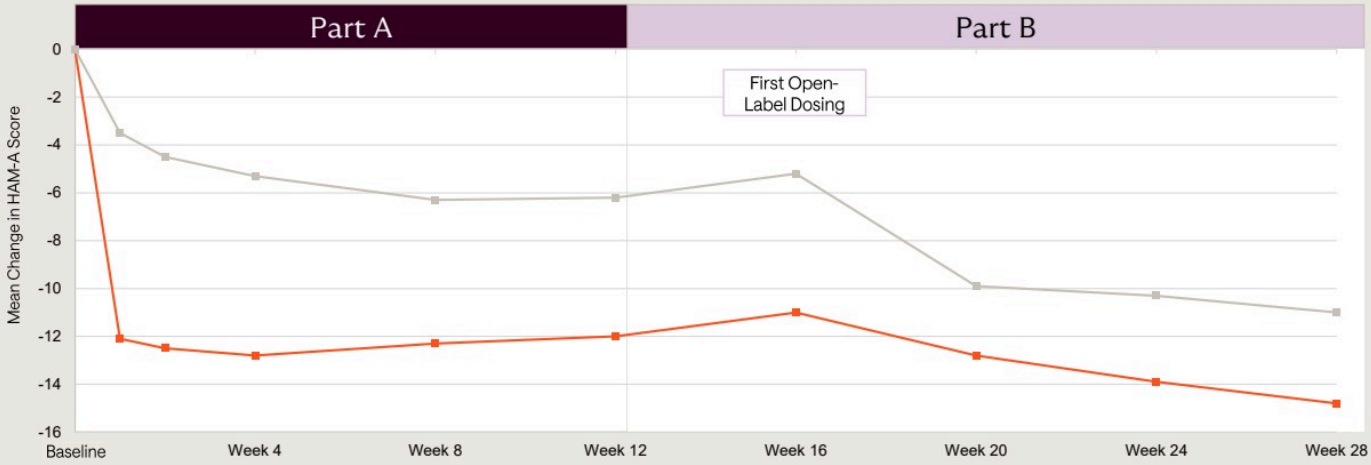
HAM-A Scores through Week 28[1,2]



	Baseline	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Week 28
DT120 ODT, n=107	101	98	94	62	55	41	37	
Placebo ODT, n=107	101	96	97	77	51	49	34	

DT120 ODT in Part A Placebo ODT in Part A

1. Based on interim analysis as of July 15, 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 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 Improve Response and Remission Rates through Week 28[1,2]

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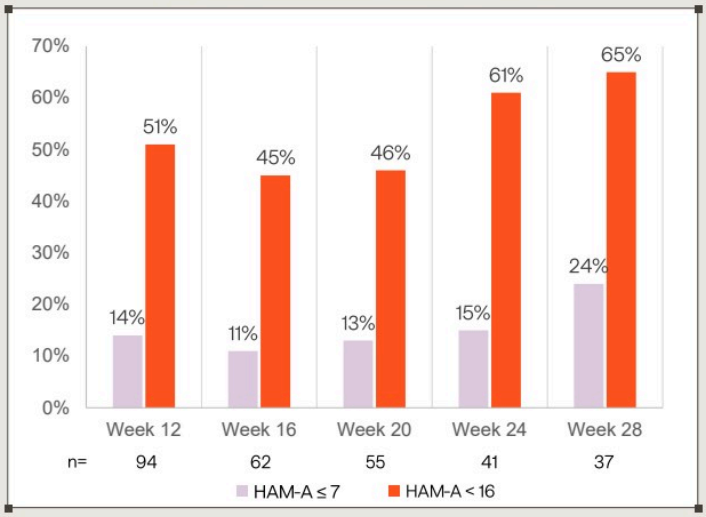
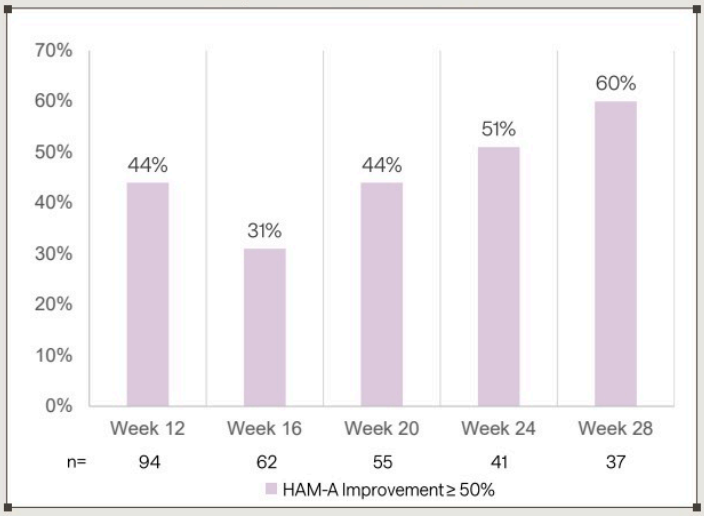
Mild and Remission Rates in Part B



Response Rates in Part B



1. Source: Voyage study documents. Based on interim analysis as of July 15, 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 Three Late-Stage Trials

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	Generalized Anxiety Disorder (GAD)			Major Depressive Disorder (MDD)	
	Phase 2b Study MMED008	Voyage	Panorama	Emerge	Ascend[2]
Primary endpoint[1] DT120 vs. placebo	**-7.7** ***(-21.9 DT120 vs. -14.2 placebo)*** at Week 12	**-5.4** ***(-11.6 DT120 vs. -6.2 placebo)*** at Week 12	*Anticipated Topline Readout September 2026*	**-8.1** ***(-13.3 DT120 vs. -5.2 placebo)*** at Week 6	*Anticipated Topline Readout 2027*
p-value	**<0.01**	**<0.0001**	TBD	**<0.0001**	TBD
Cohen's d	**0.81**	**0.81**	TBD	**0.83**	TBD

Robust data package supporting advancement of potential NDA submission for DT120 ODT

1. Primary endpoint in Voyage 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 and Ascend is the change from baseline in MADRS score at Week 6.
2. Clinical study designs subject to change based on ongoing regulatory discussion and review, including of Phase 3 clinical trial protocols

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; TBD: to be determined

Opportunity to Deliver Significant Impact and Value Creation[1]

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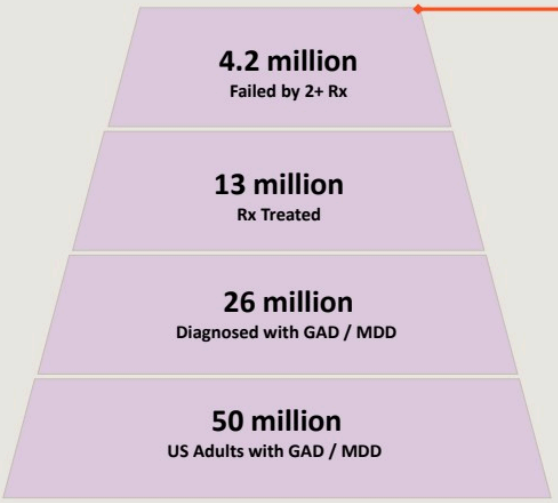

- Large & Growing Unmet Need
- Strong Patient Desire & Willingness
- Large & Expanding Treatment Network
- Payer Understanding & Intent

Addressable market means potential 42,000 patient impact & $2 billion revenue opportunity per 1% penetration[2]

1. Ringeisen, 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

Building a Psychiatry Powerhouse with Two Distinct Drivers[1]

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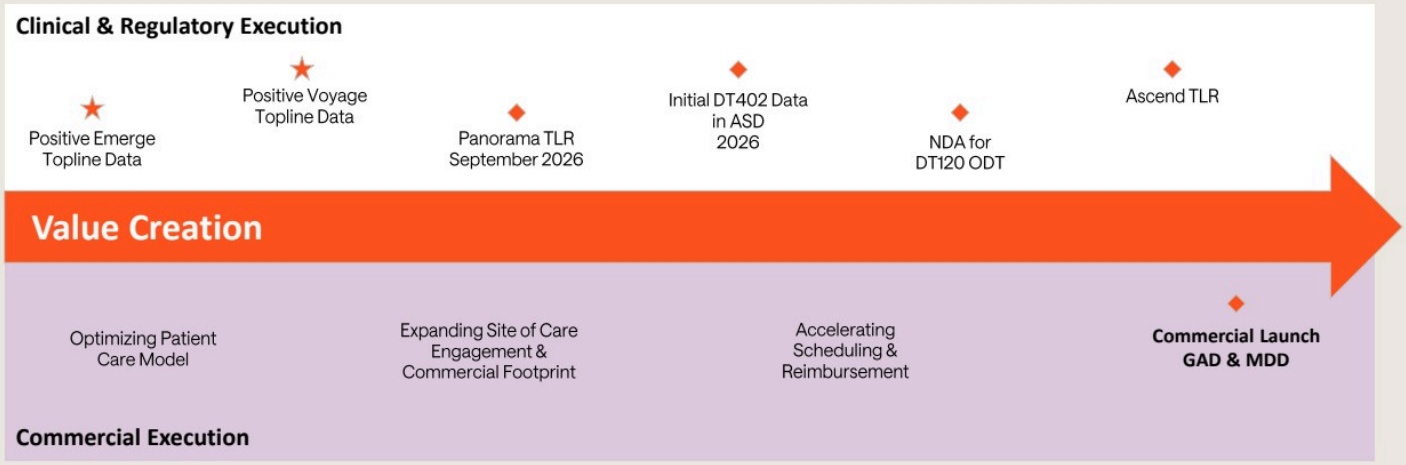
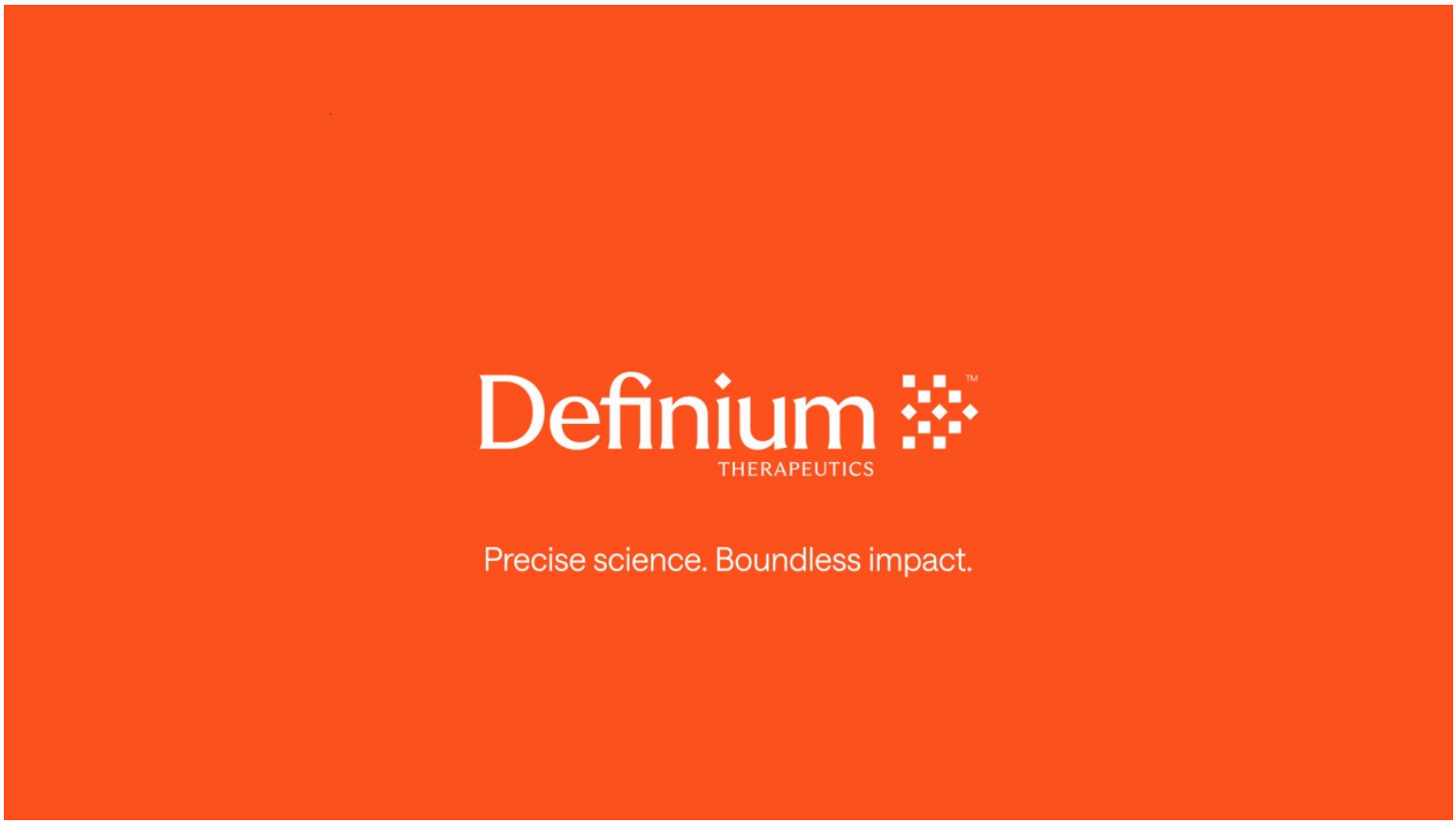


1. Timing estimates subject to clinical progress and regulatory interactions.

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

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