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): **July 7, 2026**

COMPASS PATHWAYS PLC

(Exact Name of Registrant as Specified in Its Charter)

England and Wales	**001-39522**	**Not applicable**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

33 Broadwick Street
London W1F 0DQ
United Kingdom
(Address of Principal Executive Offices; Zip Code)

+1 (716) 676-6461
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(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**
American Depositary Shares, each representing one ordinary share, nominal value £0.008 per share	CMPS	The Nasdaq Global Select Market

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

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation Fair Disclosure.

On July 7, 2026, Compass Pathways plc (the “Company” or "Compass") will be making an investor presentation (the "Presentation"). A copy of the Presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be “filed” for the 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 and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On July 7, 2026, the Company announced the 26-week results (Part B) from its second ongoing Phase 3 COMP006 trial of COMP360, a synthetic, proprietary formulation of psilocybin, for treatment-resistant depression, or TRD, which confirm COMP360’s rapid onset and durable profile. The 26-week findings in nearly 600 patients build on previously reported results from the first Phase 3 trial, COMP005, which demonstrated rapid onset and durable response to at least 6 months, with a generally well-tolerated and safe profile in people living with TRD.

The COMP360 Phase 3 program participants represent a highly chronic TRD population. In COMP006, participants had current depressive episodes lasting on average over three years and an average of more than six lifetime depressive episodes. Within the context of this severe population, 39% of participants in the 25 mg arm achieved a clinically meaningful reduction in Montgomery-Åsberg Depression Rating Scale (MADRS) (≥ 25%) by week 6, following two fixed doses of COMP360, and maintained durable response at least through Week 26. This compares favorably to the 25% in COMP005 following a single dose, supporting the potential value of a second dose in enhancing clinical benefit for some patients. COMP360 continues to demonstrate a generally well-tolerated and safe profile, with the vast majority of treatment-emergent adverse events (TEAEs) being transient and predominantly occurring on day of dosing.

A rolling New Drug Application, or NDA, submission and initial review with the U.S. Food and Drug Administration, or FDA, is underway and final submission remains on track to be completed in Q4, 2026. Compass anticipates the launch of COMP360 in the first half of 2027 subject to FDA approval and following Drug Enforcement Administration, or DEA, rescheduling.

Key findings from COMP006 Part B

Efficacy Profile

- COMP006 Part A (previously disclosed in February 2026) successfully met its primary endpoint at Week 6, delivering highly statistically significant and clinically meaningful results
- Rapid onset of effect was observed, with consistent separation between the 25 mg and the 1 mg arm maintained through the randomized, blinded Part B period to Week 26
- 39% of participants in the 25 mg arm achieved a clinically meaningful reduction in MADRS (≥ 25%) at Week 6, maintaining benefit, on average, through at least Week 26
    - Retreatment in Part B further enhanced benefit: nearly 30% of participants who achieved a clinically meaningful response at Week 6 later went into remission3 following retreatment in Part B
- Together with COMP005, the COMP006 26-week data confirm a consistent, differentiated profile for COMP360, with rapid onset and durable benefit observed across two large, well-controlled Phase 3 studies in TRD

Safety Profile

In a highly chronic TRD population with long-lasting depressive episodes, and consistent with previous studies, COMP360 continues to demonstrate a generally well-tolerated and safe profile with no new safety findings.

- Majority of TEAEs were transient and predominantly occurring on day of dosing
    - Most common adverse events were nausea, headache, anxiety and visual hallucination
- Serious adverse events (SAEs) were similar across arms (6.3% in the 1 mg arm and 5.7% in the 25 mg arm) over 26 weeks but low overall across the trial

The COMP360 program aims to evaluate the safety and efficacy of COMP360 psilocybin, a synthetic, proprietary formulation of psilocybin under investigation for difficult-to-treat mental health conditions. There are two pivotal Phase 3 trials, COMP005 and COMP006, evaluating the efficacy of COMP360 for TRD.

The ongoing COMP006 trial, running in parallel to the COMP005 trial, is a randomized, double-blind study with 581 dosed participants across North America and Europe and is comparing the efficacy and safety of two fixed doses, taken three weeks apart, of 25 mg COMP360 to 10 mg COMP360 and 1 mg COMP360 (25 mg: n=296; 10 mg: n=142; 1 mg: n=143). There is a potential for a total of 4 doses of COMP360 across a 52-week period. The trial is comprised of three parts: Part A, which was blinded through 9 weeks, Part B which recently concluded and remained blinded through week 26, and Part C, which contains an open-label treatment part from week 26 to 52.

The COMP005 trial is a randomized, double-blind, placebo-controlled study, with 258 dosed participants across the United States and is assessing the efficacy and safety of a single dose of 25 mg COMP360 versus placebo for reducing symptom severity in TRD (COMP360 25 mg: n=171; placebo: n=87). There is a potential for a total of 3 doses of COMP360 across a 52-week period. The trial is comprised of three parts: Part A, which was blinded through 6 weeks; Part B, which was blinded through week 26; and Part C, which contains an open-label treatment part from week 26 to 52.

Forward-looking statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, forward-looking statements can be identified by terminology such as “may”, “might”, “will”, “could”, “would”, “should”, “expect”, “intend”, “plan”, “objective”, “anticipate”, “believe”, “contemplate”, “estimate”, “predict”, “potential”, “continue” and “ongoing,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements relating to, among other things, statements regarding our business strategy and goals; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment for TRD or PTSD; our plans and expectations regarding our clinical trials, including our phase 3 trials in TRD and our phase 2b/3 trial in PTSD; any implication that preliminary results will be predictive of full safety and efficacy data from our phase 3 program; our expectations regarding the timing of our rolling submission of a new drug application, or NDA, for COMP360 psilocybin treatment in TRD and the timing of the review by the Food and Drug Administration, or FDA, of such NDA, including potential acceleration due to the grant of rolling review and award of a National Priority Voucher for COMP360 psilocybin treatment in TRD; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; our expectations regarding potential commercial launch timelines and our commercial readiness; our efforts and our ability to obtain regulatory approval and adequate coverage and reimbursement; our ability to transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained, on our expected, accelerated timeline or at all; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment, including as a treatment of TRD or PTSD. The forward-looking statements in this Current Report on Form 8-K are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Compass’s control and which could cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements.

These risks, uncertainties, and other factors include, among others: uncertainties associated with risks related to clinical development which is a lengthy and expensive process with uncertain outcomes, and therefore our clinical trials may be delayed or terminated and may be more costly than expected; the full results and safety data from our Phase 3 clinical trials in TRD may not be consistent with the preliminary results to date; our need for substantial additional funding to achieve our business goals and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our clinical trials; that the rolling review process and/or the National Priority Voucher pilot program may not actually lead to a faster FDA review or approval process; our efforts to obtain FDA approval, or approval from regulatory authorities in other jurisdictions, for our investigational COMP360 psilocybin treatment on an accelerated basis, or at all, may be unsuccessful; the timing and substance of decisions by the Drug Enforcement Administration and states to reschedule COMP360 psilocybin treatment, if approved by FDA, which contains Schedule I controlled substances and must be rescheduled before

commercializing COMP360 psilocybin in the U.S.; our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; and our ability to manage growth and retain key personnel; and those risks and uncertainties described under the heading "Risk Factors" in Compass's most recent annual report on Form 10-K or quarterly report on Form 10-Q, and in other reports we have filed with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Except as required by law, Compass disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this Current Report on Form 8-K in the event of new information, future developments or otherwise. These forward-looking statements are based on Compass's current expectations and speak only as of the date hereof.

Item 9.01. **Financial Statements and Exhibits.**

Exhibit No.	Description
99.1	Investor Presentation dated July 7, 2026.
104	Cover page interactive data file (embedded within 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.

COMPASS PATHWAYS PLC

Date: July 7, 2026

By: /s/ Teri Loxam
Teri Loxam
Chief Financial Officer



Compass Pathways
Phase 3 COMP006 data review

July 7, 2026

Disclaimer

Cautionary Note Regarding Forward-Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, you can identify forward-looking statements by terms such as "believe," "continue," "could," "estimate," "expect," "may," "might," "plan," "potential," "project," "target," "will," "would," or the negative of these terms, and similar expressions intended to identify forward-looking statements. However, not all forward-looking statements contain these identifying words. These forward-looking statements include express or implied statements relating to our strategic plans or objectives; our plans and expectations regarding our clinical trials, including our Phase 3 trials in TRD and our planned Phase 2b/3 trial in PTSD; any implication that preliminary results will be predictive of full safety and efficacy data from our phase 3 program; our expectations regarding the timing of our rolling submission of a new drug application, or NDA, for COMP360 psilocybin treatment in TRD and the timing of the review by the Food and Drug Administration, or FDA, of such NDA, including potential acceleration due to the grant of rolling review and award of a National Priority Voucher, for COMP360 psilocybin treatment in TRD; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; our expectations regarding the timing of federal and state rescheduling decisions; our expectations regarding potential commercial launch timelines and our commercial readiness; our efforts and our ability to obtain regulatory approval and adequate coverage and reimbursement; our ability to transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained, on our expected, accelerated timeline or at all; and our expectations regarding the benefits of our investigational COMP360 psilocybin treatment, including potential durability and dosing regimen. By their nature, these statements are subject to numerous risk and uncertainties, including the our need for substantial additional funding to achieve our business goals and if we are unable to obtain this funding when needed and on acceptable terms or at all, we could be forced to delay, limit or terminate our clinical development efforts; clinical development is lengthy and outcomes are uncertain, and therefore our Phase 3 clinical trials in TRD and our other clinical trials may be delayed or terminated; the full results and safety data from the Phase 3 trials may not be consistent with the preliminary results to date; that the rolling review process and/or the National Priority Voucher pilot program may not actually lead to a faster FDA review or approval process; our efforts to obtain FDA approval, or approval from regulatory authorities in other jurisdictions, for our investigational COMP360 psilocybin treatment on an accelerated basis, or at all, may be unsuccessful; potential for delayed or negative rescheduling decisions by the Drug Enforcement Administration and states regarding COMP360 psilocybin treatment, which contains Schedule I controlled substances and must be rescheduled, if FDA approved, before commercializing COMP360 psilocybin in the U.S.; our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; and our ability to manage growth and retain key personnel; our dependence on third parties in connection with our clinical trials; negative general economic and market conditions; unfavorable geopolitical conditions; changes in policy or resources of U.S. governmental agencies; and other factors beyond our control, that could cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied in our statements. For additional disclosure regarding these and other risks we may face, see the disclosure contained under the heading "Risk Factors" and elsewhere in the Company's most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and subsequent public filings with the US Securities and Exchange Commission (the "SEC"). You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we, nor any other person, assumes responsibility for the accuracy and completeness of these statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date such statements are made and should not be construed as statements of fact. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect any new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Market & Industry Data

Market & industry data projections, estimates, industry data and information contained in this presentation, including our general expectations about our market position and market opportunity, are based on information from third-party sources, publicly available information, our knowledge of our industry and assumptions based on such information and knowledge. Although we believe that our third party-sources are reliable, we cannot guarantee the accuracy or completeness of our sources. All of the projections, estimates, market data and industry information used in this presentation involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. In addition, projections, estimates and assumptions relating to our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including, but not limited to, those described above, that could cause future performance to differ materially from our expressed projections, estimates and assumptions or those provided by third parties.

Welcome

Kabir Nath
Chief Executive Officer

Guy Goodwin, MD
Chief Medical Officer

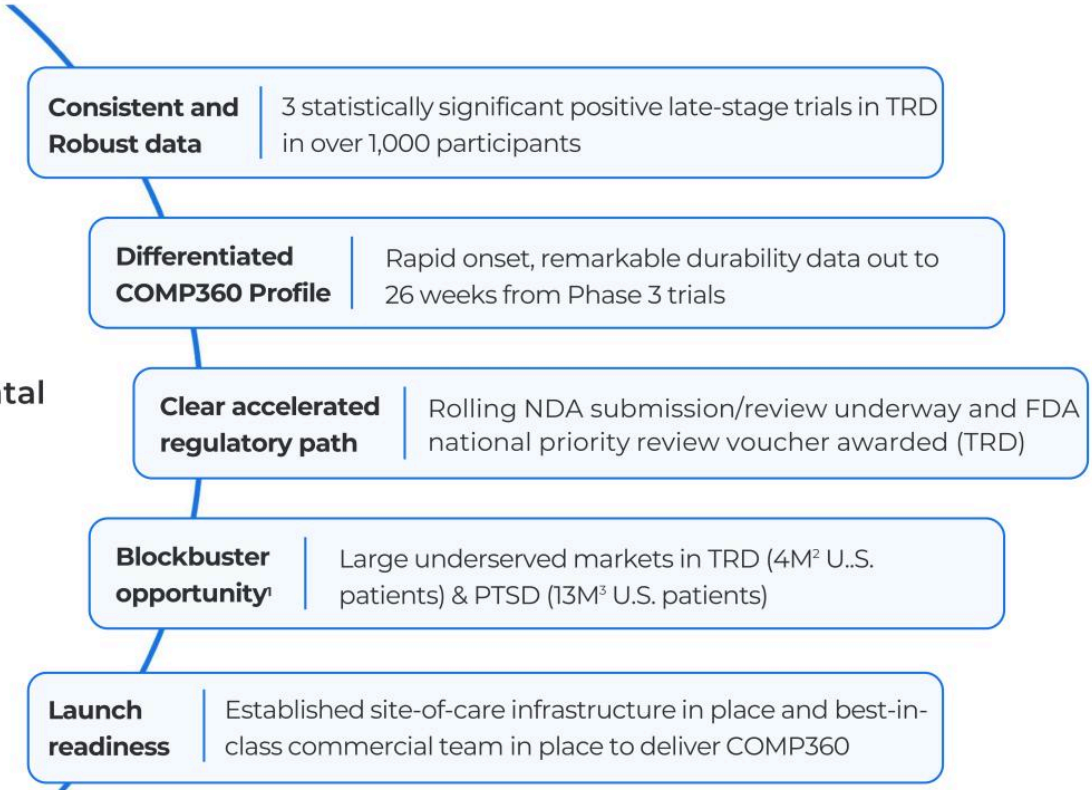
Lori Englebert
Chief Commercial Officer

Significant Progress Towards Potential Approval of COMP360 in TRD

- **Consistent Results across two highly statistically significant positive Phase 3 trials**
  - COMP006 and COMP005 26-week data demonstrate rapid onset and remarkable durability through at least 6 months further validating COMP360's differentiated profile in highly chronic TRD
  - COMP360 is generally well tolerated with a safe profile, with majority of adverse events transient and occurring on treatment day
- **Rolling NDA submission and initial review underway with final submission expected to be completed in Q4**
- **Commercial launch-readiness on track for end of 2026, with launch expected in first half of 2027**

We are convinced COMP360 will lead to a profound shift in mental health care - moving beyond daily or frequent administration - toward an option potentially involving just a few treatments in a year that could be life changing for patients

COMP360:
Transforming Mental Health Care

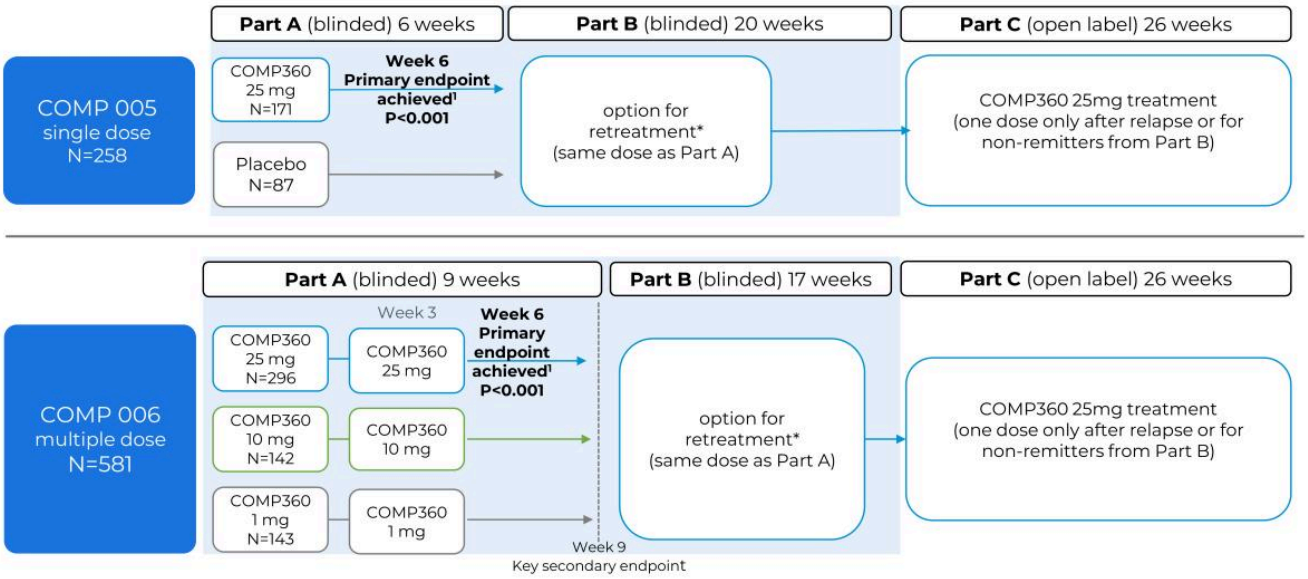


1. Expectation based on Compass estimates and current market conditions 2. Wing V, et al. Poster S97 Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. J Mood Anxiety Disord. Presentedat ADAA 2026.. 3. https://www.va.gov/columbia-south-carolina-health-care/stories/hope-and-healing-initiatives-for-ptsd-awareness-and-veteran-support/ (accessed July 6, 2026)



COMP006 Clinical Data

Phase 3 Program in TRD: Trial Designs



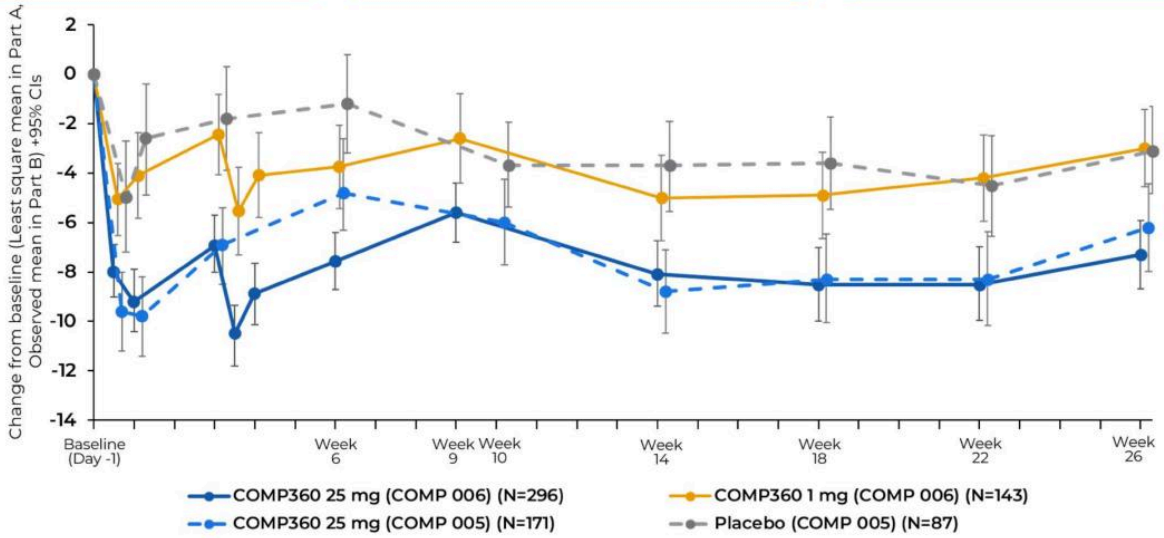
[1]Primary endpoint = change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 6. 1
*Retreatment for non-remitters from Part A or Part B could occur several weeks after transition to Part B or Part C, respectively, due to scheduling requirements. Participants were permitted to take protocol-allowed antidepressant treatments in Part B and C of the study.

Remarkable Consistency in COMP005 & COMP006 Through 6 Months*

Convincing separation between 25mg and control arms maintained **over 26-weeks** in both studies

Confirms validity, consistency and durability of efficacy signal over 26 weeks

Clear benefit of additional dose, either as fixed dose after 3 weeks (006) or later in 10-14 week timeframe (005)



*Cross-trial comparisons should be interpreted with caution. Differences between trials, including but not limited to study designs, protocols, timing of assessments, number or timing of doses and participant populations can meaningfully influence outcomes and limit the validity of any comparison.
COMP 005 Part B (post Week 6) and COMP 006 Part B (post Week 9) results are based on observed data only (CFB Mean ± 95% CI). retreatment in Part B based on pre-specified criteria and receive either what they were randomized into or antidepressant - CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery–Åsberg Depression Rating Scale

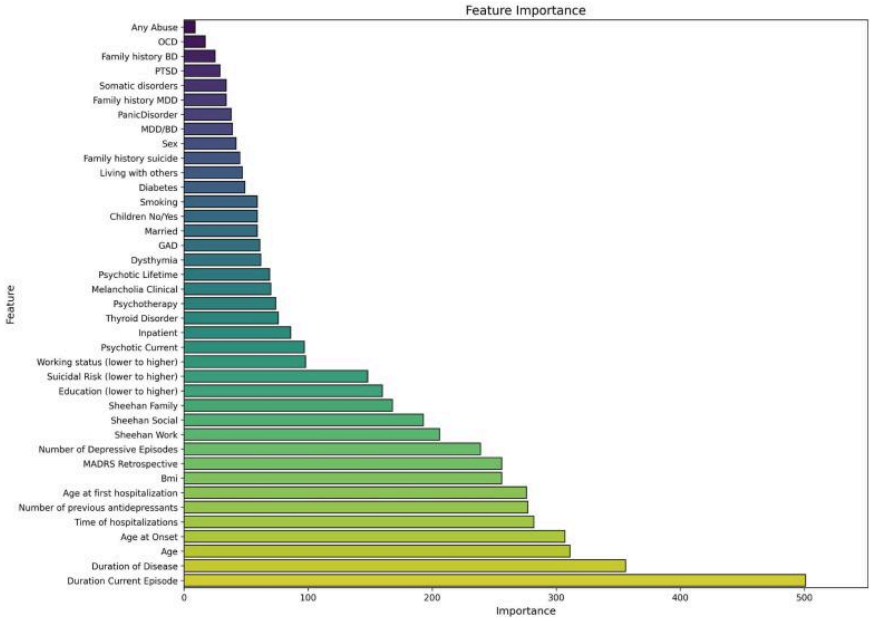
COMP006 Enrolled a Highly Chronic TRD Population

	COMP360 25 mg (N=296)	COMP360 10 mg (N=142)	COMP360 1 mg (N=143)
Number of failed treatments in current depressive episode, n (%)			
1	1 (0.3)	1 (0.7)	0
2	190 (64.2)	105 (73.9)	98 (68.5)
3	74 (25.0)	32 (22.5)	34 (23.8)
4	29 (9.8)	4 (2.8)	11 (7.7)
5	2 (0.7)	0	0
Number of treatments withdrawn from the screening period, n (%)			
0	68 (23.0)	30 (21.1)	36 (25.2)
1	127 (42.9)	62 (43.7)	62 (43.4)
2	68 (23.0)	34 (23.9)	31 (21.7)
>2	33 (11.1)	16 (11.3)	14 (9.8)

	COMP360 25 mg (N=296)	COMP360 10 mg (N=142)	COMP360 1 mg (N=143)
Length of current depressive episode			
Mean Months (SD)	45.5 (42.7)	37.7 (38.8)	38.4 (45.0)
< 1 year	53 (17.9)	37 (26.1)	30 (21.0)
1-2 years	73 (24.7)	35 (24.6)	41 (28.7)
>2 years	170 (57.4)	70 (49.3)	72 (50.3)
Number of lifetime depressive episodes			
Mean (SD)	6.3 (7.4)	5.4 (6.6)	7.0 (12.5)
1	1 (0.3)	0	0
2-5	199 (67.2)	109 (76.8)	99 (69.2)
6-10	61 (20.6)	21 (14.8)	30 (21.0)
>10	29 (9.8)	10 (7.0)	10 (7.0)

MADRS = Montgomery-Åsberg Depression Rating Scale; n=number of observed participants; SD = standard deviation.
n=number of observed participants; SD = standard deviation

Duration of Current Episode Strongest Predictor of Non-Response in TRD



Source: European Neuropsychopharmacology. Volume 98, September 2025, Pages 26-34 (https://www.sciencedirect.com/science/article/pii/S0924977X25001294)

Participant Baseline Demographics in Line with Known TRD Epidemiology

COMP006	COMP360 25 mg (N=296)	COMP360 10 mg (N=142)	COMP360 1 mg (N=143)
Female, n (%)	160 (54.1)	68 (47.9)	69 (48.3)
Race, n (%)			
White	255 (86.1)	123 (86.6)	129 (90.2)
Asian	14 (4.7)	6 (4.2)	6 (4.2)
Black or African American	8 (2.7)	3 (2.1)	4 (2.8)
American Indian or Alaska Native	0	0	1 (0.7)
Other/not reported	19 (6.4)	10 (7.0)	3 (2.1)
Age, years, mean (SD)	46.2 (13.7)	42.9 (12.8)	45.5 (13.1)
Min, Max	18, 79	19, 73	20, 75
Age ≥65 years old	29 (9.8)	9 (6.3)	13 (9.1)
MADRS total score at baseline, mean (SD)	32.0 (5.8)	32.1 (5.8)	32.5 (5.4)
MADRS total score severity at baseline, n (%)			
Subthreshold ≤10	2 (0.7)	0	0
Mild (11-19)	0	0	0
Moderate (20-30)	115 (38.9)	54 (38.0)	49 (34.3)
Severe (≥31)	179 (60.5)	88 (62.0)	94 (65.7)
Prior psilocybin experience, n (%)	12 (4.1)	5 (3.5)	5 (3.5)
Prior psychedelic experience including psilocybin*, n (%)	20 (6.8)	8 (5.6)	9 (6.3)
BMI kg/m² , mean (SD)	28.0 (6.2)	28.4 (6.4)	28.0 (6.5)

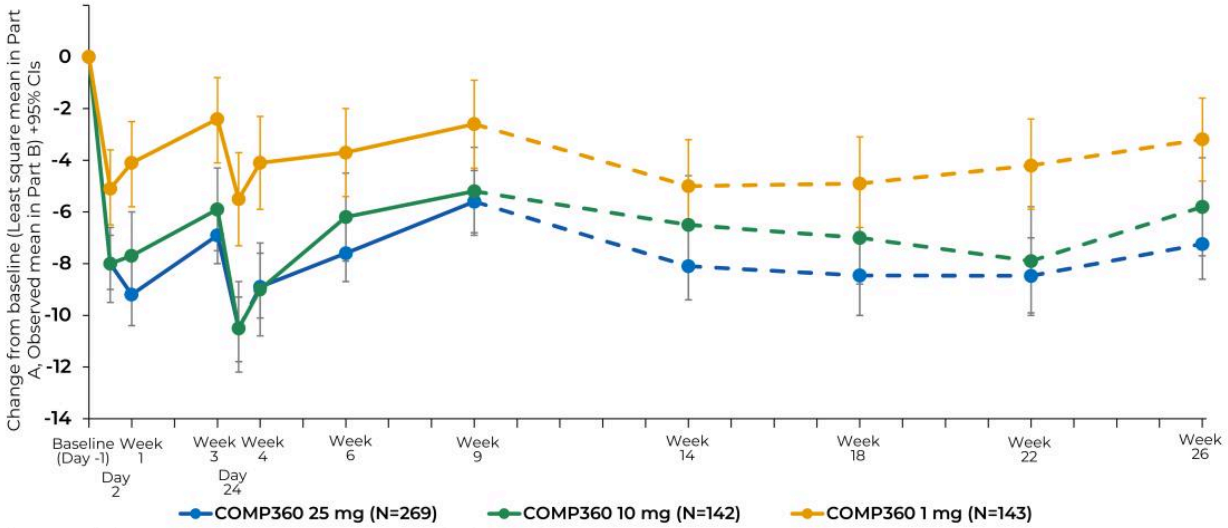
MADRS = Montgomery-Åsberg Depression Rating Scale; n=number of observed participants; SD = standard deviation.
*planned limit for prior psychedelic experience in trial was 15%
BMI = Body Mass Index; n=number of observed participants; SD = standard deviation

COMP006 - Rapid Onset and Sustained Durability to Week 26

Rapid effect from 25mg evident **from day after administration**: apparent after both first and second fixed doses in Part A

Persistent treatment effect of 25mg arm over full 26 weeks

58% of patients in 25mg arm received retreatment after Week 9

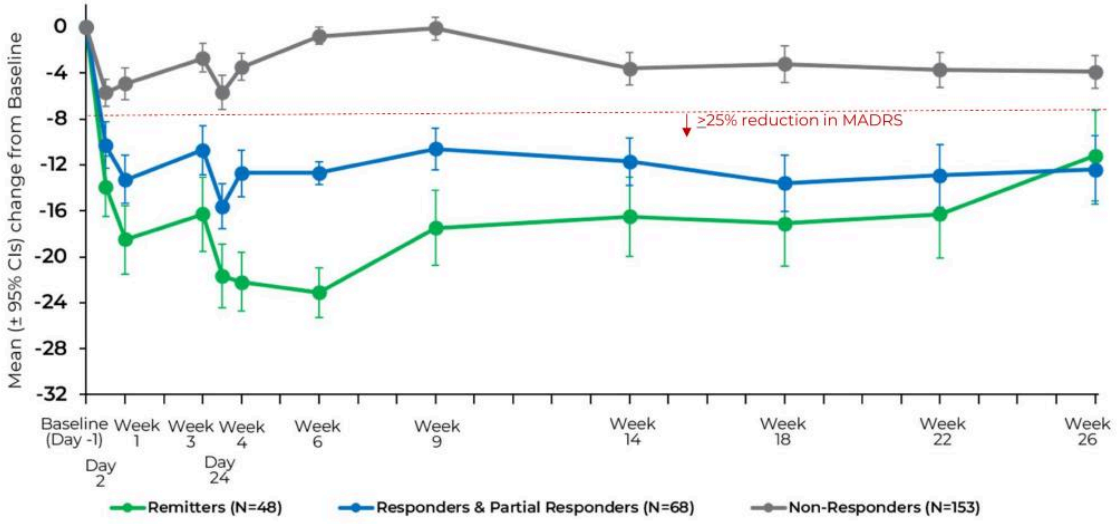


*retreatment based on pre-specified criteria and receive either what they were randomized into or antidepressant
COMP 006 Part B results (post Week 9) are based on observed data only (CFB Mean ± 95% CI)
CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery–Åsberg Depression Rating Scale

COMP006 - COMP360 Response Can Be Rapid and Durable – Unique in TRD

39% of participants in 25mg arm achieved **clinically meaningful reduction in MADRS*** at Week 6 and on average maintained response at least through Week 26

28% of those who achieved clinically meaningful reduction in MADRS but had not remitted by 6 weeks **went into remission after additional dose** in Part B



Definitions (n at Week 6):

Remitters (n=48) = MADRS ≤12 and no single item ≥4

Responders and Partial Responders (n=68) = % CFB in MADRS ≥ 25% *and* do not meet remission criterion

Non-Responder (n=153) = % CFB in MADRS ≤ *25%*

*Clinically meaningful reduction in MADRS defined as a >25% reduction from baseline in MADRS total score at Week 6. This graph is a post hoc analysis. Total n at 6 weeks = 269 (based on ITT)
CI = Confidence Interval; CFB = change from baseline; MADRS = Montgomery–Åsberg Depression Rating Scale

COMP006 - Majority of AEs Transient and Occurred on Day of Administration

COMP006 Through 26 Weeks	COMP360 25 mg	COMP360 10 mg	COMP360 1 mg
	N=296	N=142	N=143
	n (%)	n (%)	n (%)
Any TEAE up to Week 26	280 (94.6)	132 (93.0)	124 (86.7)
Any Serious TEAE up to Week 26	17 (5.7)	5 (3.5)	9 (6.3)
Any TEAE with onset on day of dosing	265 (89.5)	119 (83.8)	88 (61.5)
Resolved ≤ 1 Day	255 (86.1)	113 (79.6)	78 (54.5)
Resolved > 1 and ≤ 2 Days	60 (20.3)	22 (15.5)	12 (8.4)
Resolved > 2 Days	80 (27.0)	32 (22.5)	21 (14.7)

COMP006 Through 26 Weeks (≥10% Incidence in 25mg) MedDRA TEAE Preferred Term	COMP360 25 mg	COMP360 10 mg	COMP360 1 mg
	N=296	N=142	N=143
	n (%)	n (%)	n (%)
Any TEAE	280 (94.6)	132 (93.0)	124 (86.7)
Nausea	133 (44.9)	50 (35.2)	18 (12.6)
Headache	118 (39.9)	53 (37.3)	49 (34.3)
Anxiety	83 (28.0)	38 (26.8)	29 (20.3)
Hallucination, visual	51 (17.2)	27 (19.0)	5 (3.5)
Fatigue	49 (16.6)	26 (18.3)	19 (13.3)
Illusion or Perceptual Disturbance*	48 (16.2)	19 (13.4)	4 (2.8)
Dizziness	47 (15.9)	25 (17.6)	9 (6.3)
Crying	41 (13.9)	15 (10.6)	6 (4.2)
Blood pressure increased	35 (11.8)	10 (7.0)	4 (2.8)

MedDRA = Medical Dictionary for Regulatory Activities; N=number of participants in the treatment group in the Safety Analysis Set by administration; n = number of participants.
*Illusion and Perceptual Disturbance categories have been combined in this presentation due to some recent changes in MedDRA classification

COMP006 - SAEs Similar in 25mg and 1mg Arms and Low in Number Overall

MedDRA TEAE Preferred Term	COMP360 25 mg N=296 n (%)	COMP360 10 mg N=142 n (%)	COMP360 1 mg N=143 n (%)
Any TESAE	17 (5.7)	5 (3.5)	9 (6.3)
Suicidal ideation	4 (1.4)	2 (1.4)	4 (2.8)
Suicidal behaviour	0	0	1 (0.7)
Suspected suicide*	1 (0.3)	0	0
Suicide attempt	0	0	1 (0.7)
Syncope	1 (0.3)	0	1 (0.7)
Major depression	1 (0.3)	0	0
Anxiety	1 (0.3)	0	0
Flashback	1 (0.3)	0	0
Cervical spinal stenosis	1 (0.3)	0	0
Renal neoplasm	0	0	1 (0.7)
Pelvic pain	1 (0.3)	0	0
Adjustment disorder with mixed disturbance of emotion and conduct	1 (0.3)	0	0

MedDRA TEAE Preferred Term	COMP360 25 mg N=296 n (%)	COMP360 10 mg N=142 n (%)	COMP360 1 mg N=143 n (%)
Pneumonia	0	1 (0.7)	0
Radius fracture	1 (0.3)	1 (0.7)	0
Road traffic accident	1 (0.3)	0	0
Tibia fracture	1 (0.3)	0	0
Ulna fracture	1 (0.3)	0	0
Alanine aminotransferase increased	1 (0.3)	0	0
Aspartate aminotransferase increased	1 (0.3)	0	0
Brain neoplasm	1 (0.3)	0	0
Thyroid neoplasm	1 (0.3)	0	0
Cerebrovascular accident	0	0	1 (0.7)
Toxic encephalopathy	0	1 (0.7)	0
Tremor	1 (0.3)	0	0

*Suspected Suicide determined by the investigator, based on the specific circumstances and timing, as not related to the treatment
MedDRA = Medical Dictionary for Regulatory Activities; N=number of participants in the treatment group in the Safety Analysis Set by administration; n = number of participants.

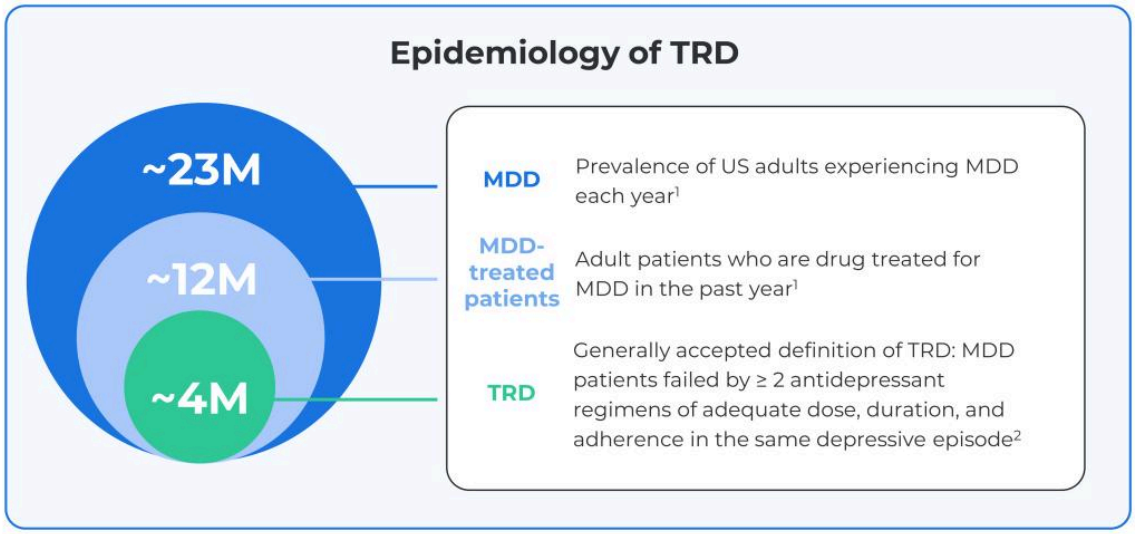
COMP360 Generally Well-Tolerated with Safe Profile

- COMP360 generally safe and well-tolerated
  - Majority of AEs transient and occurring on day of administration
- Safety data consistent with known profile of COMP360 psilocybin
  - No new safety signals identified
- SAEs similar in 25mg and 1mg arms and low overall across trial
- COMP360 emerging efficacy and safety profile differentiated and if approved, a good new option for the millions of patients suffering with TRD



Commercial Update

1 in 3 Patients Drug-Treated for MDD are Considered Treatment Resistant[1]

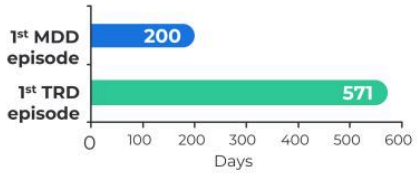


Key: M, million; MDD, major depressive disorder; TRD, treatment-resistant depression, US, United States

References: 1. Wing V, et al. Poster S97 Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. J Mood Anxiety Disord. Presented at ADAA 2026.. 2. US Food and Drug Administration. Major Depressive Disorder (MDD): Developing Drugs for Treatment. Guidance for Industry. June 2018. https://www.fda.gov/media/113988/download. Accessed March 26, 2026.

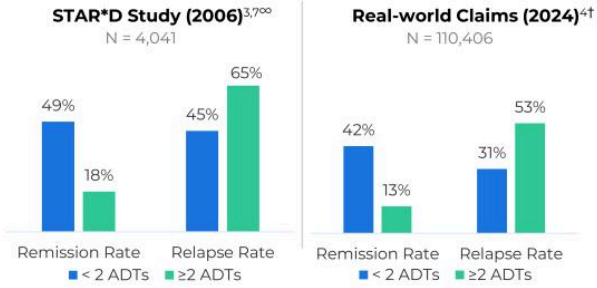
TRD is Associated with a Greater Burden Compared to MDD

Longer depressive episodes[6]



2x longer episodes

Increased relapse rates and decreased remission rates[3,4,7]



Higher comorbidity burden[2]

61% vs **36%** experience **pain***

50% vs **29%** experience **anxiety***

35% vs **17%** suffer **migraines***

Decreased productivity[5] and increased mortality[1]

70% greater **work time loss[5]**

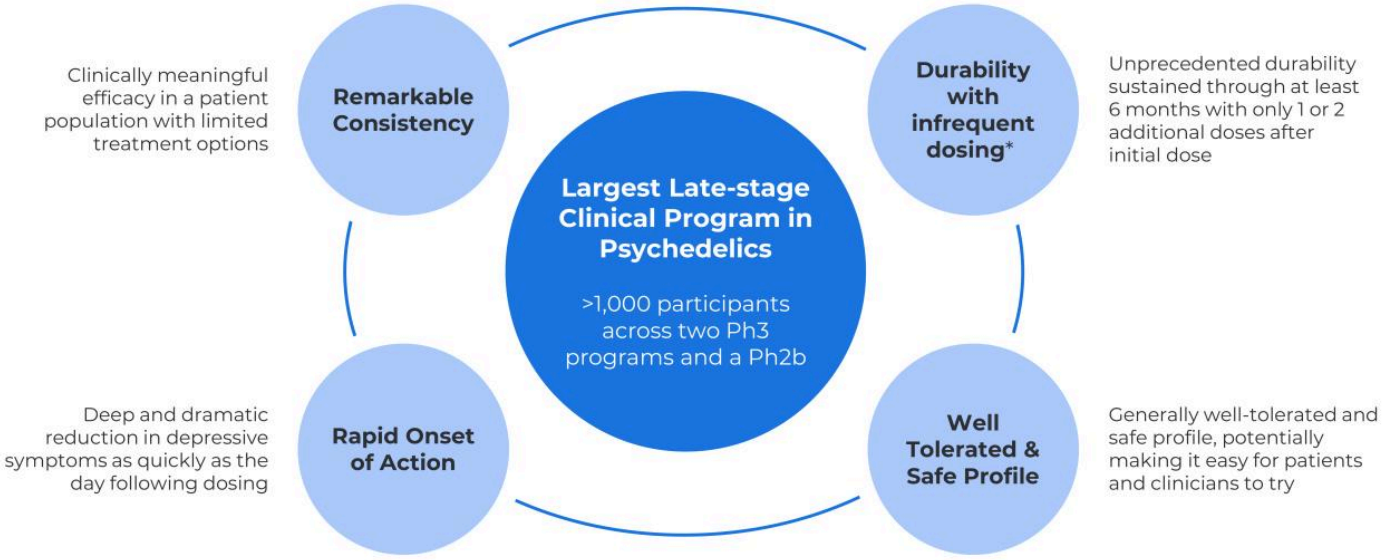
51% increased risk of **mortality due to suicide[1]**

17-30% increased risk of **all-cause mortality[1]**

Note: * p < 0.0001, **Data calculated for "<2 ADTs" by combining steps 1 and 2 and for "≥2 ADTs" by combining steps 3 and 4. †Real-world claims data from Discover-NOW Health Data Research Hub for Real World Evidence in the United Kingdom.
Key: ADT, antidepressant therapy; MDD, major depressive disorder; non-TRD MDD, non-treatment-resistant depression major depressive disorder; SDS, Sheehan Disability Scale; TRD, treatment-resistant depression.
References: 1. Gustafsson TT, et al. *J Affect Disord*. 2025;368:136-142 . **2.** Kubitz N, et al. PLoS One. 2013;8(10):e76882. **3.** Rush AJ, et al. Am J Psychiatry. 2006;163(11):1905-17 **4.**. Pappa S, et al. *BJPsych Open*. 2024;10(1):e32.. **5**. Amos TB, et al. *J Clin Psychiatry*. 2018;79(2):17m11725. **6.** Wu B, et al. *PLoS One*. 2019;14(8):e0220763. **7**. Compass Pathways data on file.

TRD MDD
MDD defined as non-TRD MDD

Emerging Profile of COMP360 has Potential to Revolutionize how Mental Health Conditions are Treated



* Durability data across the two phase 3 programs (COMP005 and COMP006)
Based on clinical trial results to date; Label has not been determined as COMP360 is not yet approved by the FDA

Anticipated Timeline to COMP360 Launch, if FDA Approved

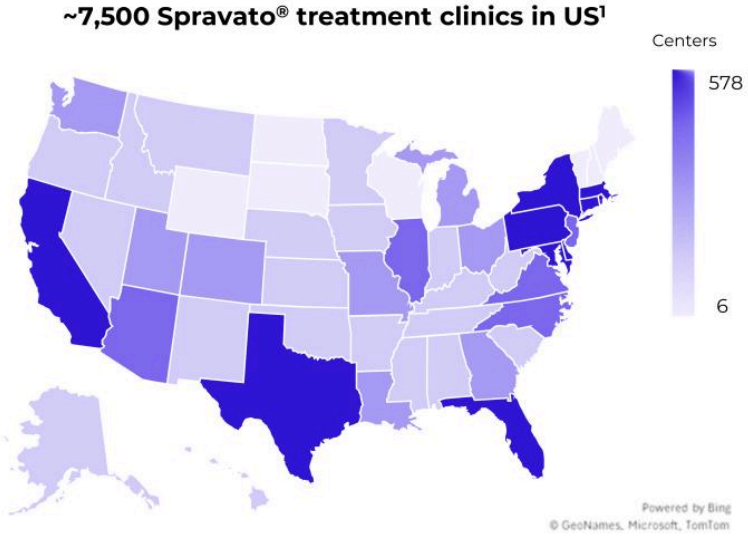


Advanced commercial launch prep work underway including payer discussions, enabling product distribution, setting up patient support mechanisms, preparing for field force execution and ongoing stakeholder education

Key: FDA, Food and Drug Administration; NDA, new drug application; Q, quarter

Well-established Infrastructure of Interventional Psychiatry Treatment Centers in Place and Preparing to Offer COMP360

~7,500 Spravato® treatment clinics in US[1]



Established Practice Patterns

Dedicated rooms/areas for treatments that require multi-hour monitoring

Operational and scheduling capabilities with team-based workforce

Scaling to meet patient demand

At approval, our top priority is site and patient experience:

- Training & education
- REMS certification
- Reimbursement assistance
- Patient support

1. www.spravatohcp.com/find-treatment-center – data pulled 03/19/2026

COMP360: Transforming Mental Health Care

Blockbuster Opportunity[1]
Large underserved markets in TRD (4M U..S. patients) & PTSD (13M U.S. patients)

Upcoming Catalysts
Completion of NDA submission in Q4 2026: Expected launch H1 2027

Compelling Data
2 successful Ph3 TRD trials: rapid effect, durable efficacy, highly differentiated in TRD

Provider Scalability
Established site-of-care infrastructure in place and ramping to potentially deliver COMP360

Clear Accelerated Regulatory Path
Rolling NDA review underway and FDA National Priority Review Voucher awarded (TRD)

Confidence
Exclusivity protection & extensive IP expected >2038;
Cash runway into 2028

1. Expectation based on Compass estimates and current market conditions

Thank you...

Q&A

For more information:
Stephen Schultz
SVP, Investor Relations
stephen.schultz@compasspathways.com
+1 401-290-7324

COMP006 – Safety Data Through Week 26 - TEAEs

(≥5% Incidence in 25 mg arm) **MedDRA TEAE Preferred Term**	**COMP360 25 mg** N=296 **n (%)**	**COMP360 10 mg** N=142	**Placebo** N=143 **n (%)**
Any TEAE	280 (94.6)	132 (93.0)	124 (86.7)
Nausea	133 (44.9)	50 (35.2)	18 (12.6)
Headache	118 (39.9)	53 (37.3)	49 (34.3)
Anxiety	83 (28.0)	38 (26.8)	29 (20.3)
Hallucination, visual	51 (17.2)	27 (19.0)	5 (3.5)
Fatigue	49 (16.6)	26 (18.3)	19 (13.3)
Dizziness	47 (15.9)	25 (17.6)	9 (6.3)
Crying	41 (13.9)	15 (10.6)	6 (4.2)
Blood pressure increased	35 (11.8)	10 (7.0)	4 (2.8)
Perceptual disturbance	33 (11.1)	18 (12.7)	3 (2.1)
Insomnia	28 (9.5)	20 (14.1)	12 (8.4)
Major depression	25 (8.4)	13 (9.2)	7 (4.9)
Tearfulness	23 (7.8)	7 (4.9)	4 (2.8)
Back pain	21 (7.1)	10 (7.0)	11 (7.7)

(≥5% Incidence in 25 mg arm) **MedDRA TEAE Preferred Term**	**COMP360 25 mg** N=296 **n (%)**	**COMP360 10 mg** N=142 **n (%)**	**Placebo** N=143 **n (%)**
Paraesthesia	18 (6.1)	8 (5.6)	8 (5.6)
Illusion	18 (6.1)	3 (2.1)	1 (0.7)
Feeling cold	17 (5.7)	13 (9.2)	4 (2.8)
Vomiting	17 (5.7)	2 (1.4)	1 (0.7)
Nasopharyngitis	16 (5.4)	11 (7.7)	11 (7.7)
Upper respiratory tract infection	16 (5.4)	9 (6.3)	10 (7.0)
Mood altered	16 (5.4)	8 (5.6)	3 (2.1)
Euphoric mood	16 (5.4)	6 (4.2)	1 (0.7)
Diarrhoea	16 (5.4)	5 (3.5)	11 (7.7)
Suicidal ideation	15 (5.1)	12 (8.5)	14 (9.8)
Abdominal pain	15 (5.1)	4 (2.8)	3 (2.1)
Hallucination	15 (5.1)	4 (2.8)	2 (1.4)
Abdominal discomfort	15 (5.1)	3 (2.1)	3 (2.1)

MedDRA = Medical Dictionary for Regulatory Activities; N=number of participants in the treatment group in the Safety Analysis Set by administration; n = number of participants.
Table shows TEAEs occurring in ≥ 5% in each treatment period.