



# 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. 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## 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

## Consistent and Robust data

3 statistically significant positive late-stage trials in TRD in over 1,000 participants

## Differentiated COMP360 Profile

Rapid onset, remarkable durability data out to 26 weeks from Phase 3 trials

## Clear accelerated regulatory path

Rolling NDA submission/review underway and FDA national priority review voucher awarded (TRD)

## Blockbuster opportunity<sup>1</sup>

Large underserved markets in TRD (4M<sup>2</sup> U.S. patients) & PTSD (13M<sup>3</sup> U.S. patients)

## Launch readiness

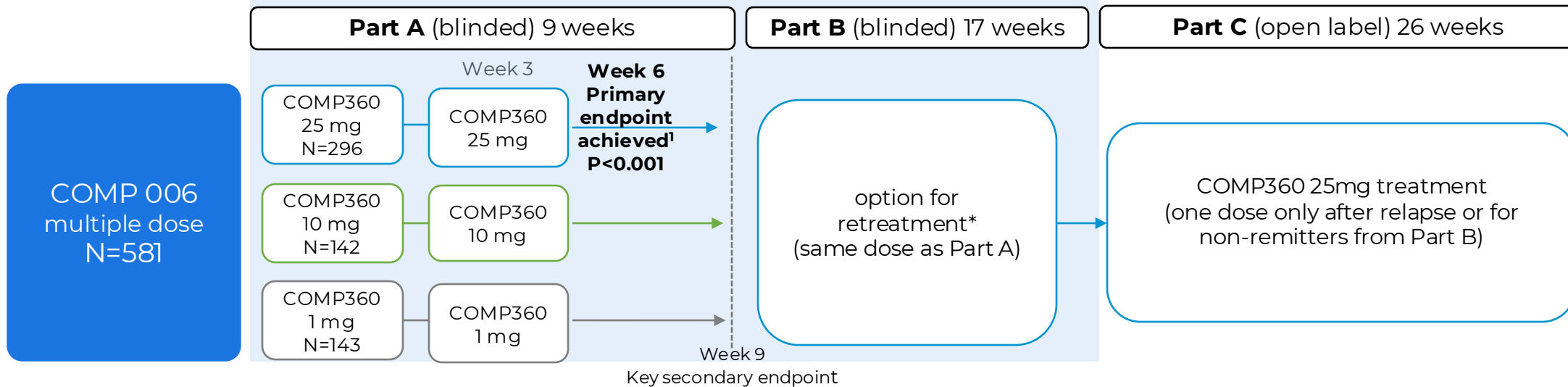
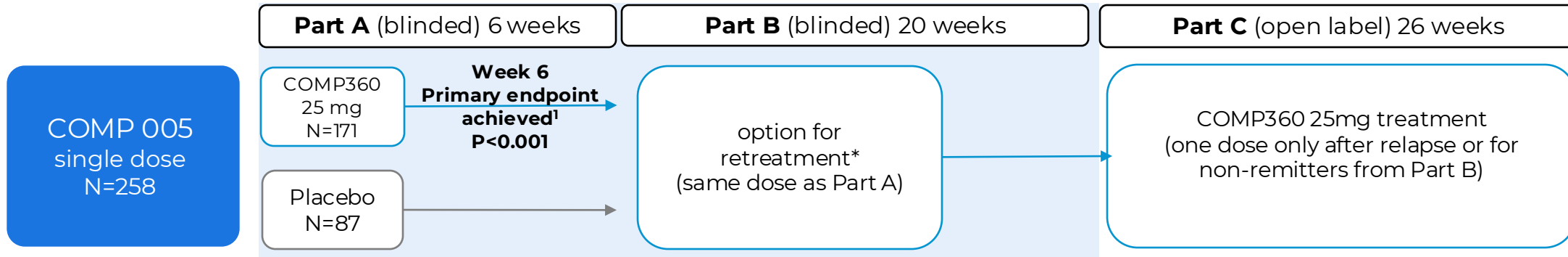
Established site-of-care infrastructure in place and best-in-class commercial team in place to deliver COMP360





# COMP006 Clinical Data

# Phase 3 Program in TRD: Trial Designs



<sup>1</sup>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.

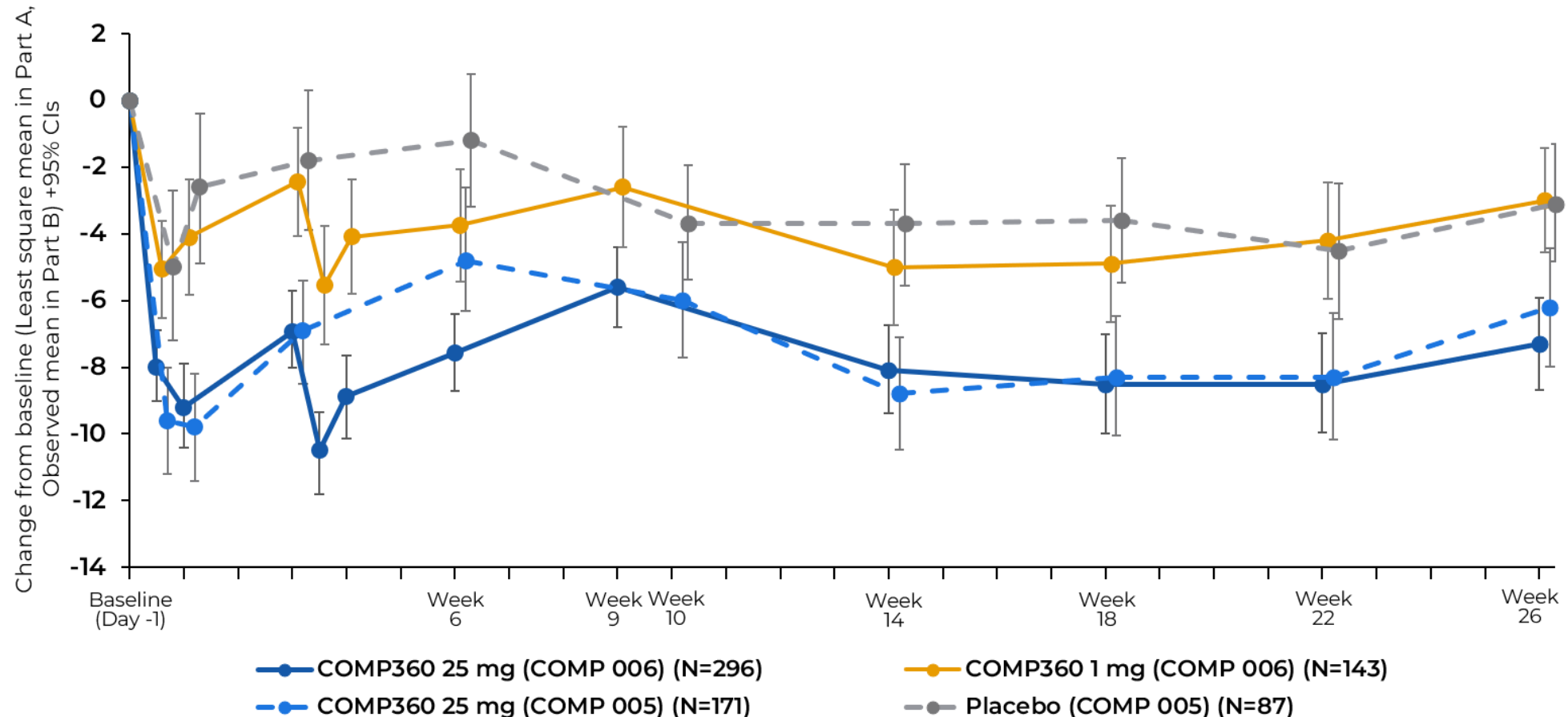


# Remarkable Consistency in COMP005 & COMP006 Through 6 Months\*

**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  $\pm$  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



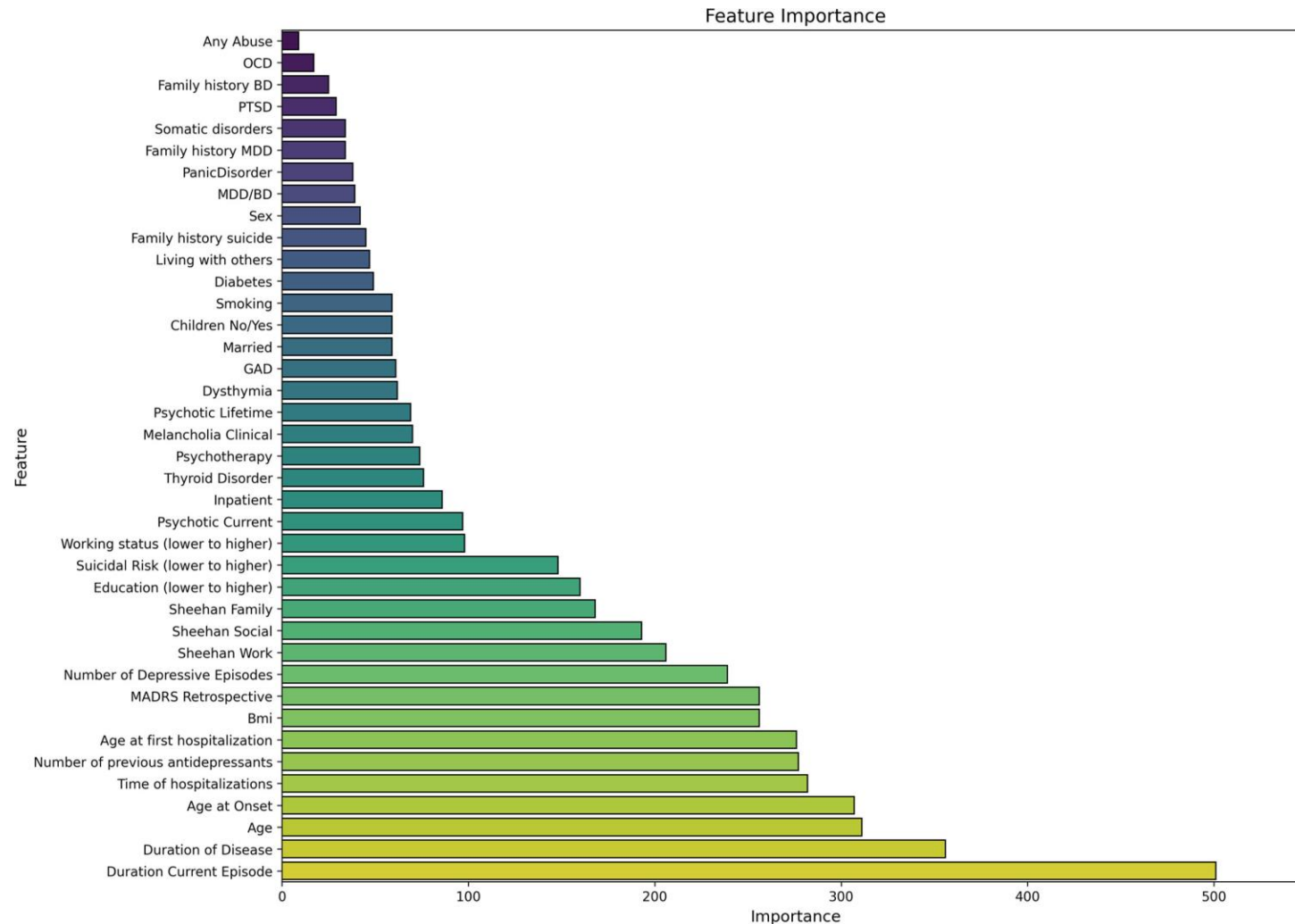
# COMP006 Enrolled a Highly Chronic TRD Population

	COMP360 25 mg (N=296)	COMP360 10 mg (N=142)	COMP360 1 mg (N=143)
<b>Number of failed treatments in current depressive episode, n (%)</b>			
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
<b>Number of treatments withdrawn from the screening period, n (%)</b>			
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 0.1 mg (N=143)
<b>Length of current depressive episode</b>			
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)
<b>Number of lifetime depressive episodes</b>			
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)



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



# 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)
<b>Female, n (%)</b>	160 (54.1)	68 (47.9)	69 (48.3)
<b>Race, n (%)</b>			
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)
<b>Age, years, mean (SD)</b>	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)
<b>MADRS total score at baseline, mean (SD)</b>	32.0 (5.8)	32.1 (5.8)	32.5 (5.4)
<b>MADRS total score severity at baseline, n (%)</b>			
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)
<b>Prior psilocybin experience, n (%)</b>	12 (4.1)	5 (3.5)	5 (3.5)
<b>Prior psychedelic experience including psilocybin*, n (%)</b>	20 (6.8)	8 (5.6)	9 (6.3)
<b>BMI kg/m<sup>2</sup>, mean (SD)</b>	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

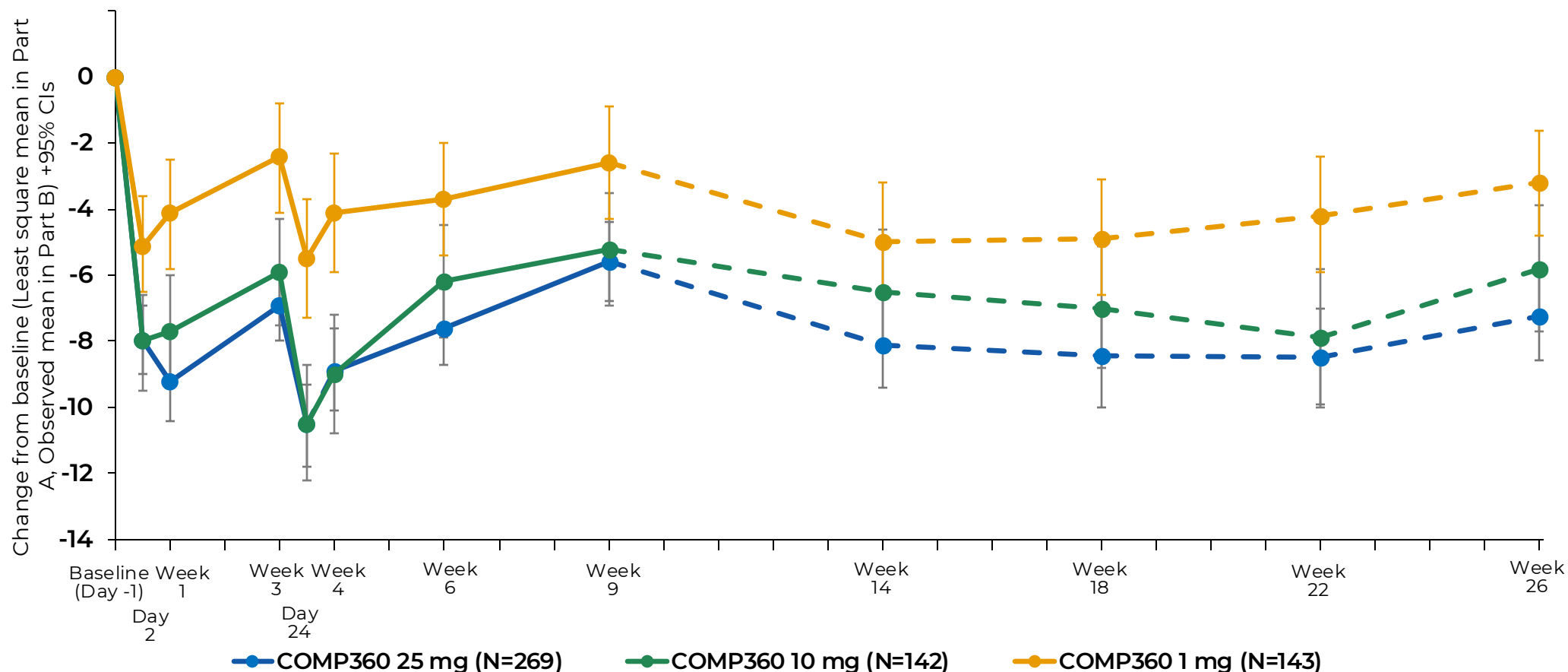


# COMP006 - Rapid Onset and Sustained Durability to Week 26

**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



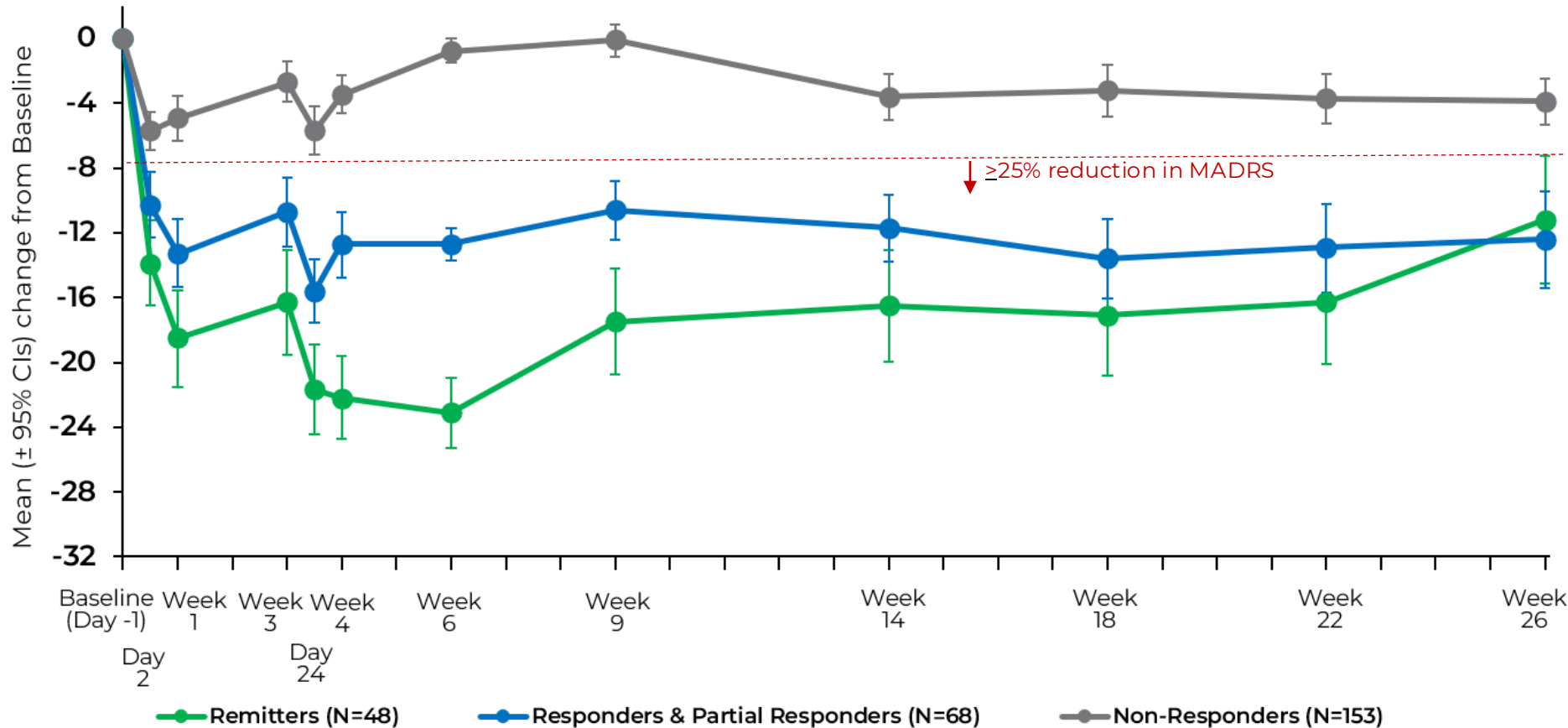
\*retreatment based on pre-specified criteria and receive either what they were randomized into or antidepressant  
 COMP 006 Part B results (post Week 9) are based on observed data only (CFB Mean  $\pm$  95% CI)  
 CI = Confidence Interval; LSM = Least Squares Mean; MADRS = Montgomery-Åsberg Depression 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  $\leq 12$  and no single item  $\geq 4$

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

**Non-Responder (n=153)** = % CFB in MADRS  $\leq 25\%$

\*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)



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

MedDRA TEAE Preferred Term	COMP360	COMP360	COMP360
	25 mg	10 mg	1 mg
	N=296	N=142	N=143
	n (%)	n (%)	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	COMP360	COMP360
	25 mg	10 mg	1 mg
	N=296	N=142	N=143
	n (%)	n (%)	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

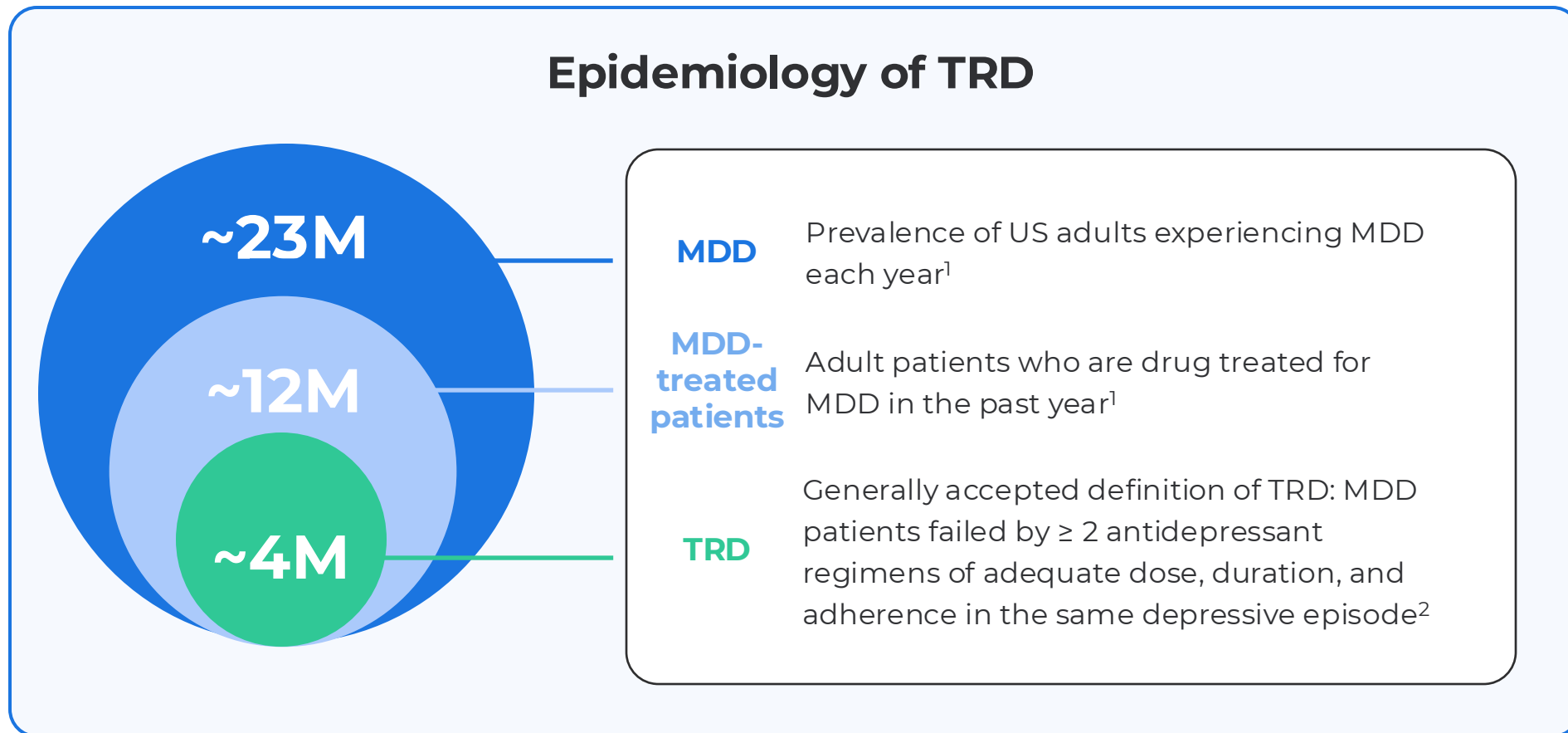
- ❖ COMP360 generally safe and well-tolerated
  - Majority of AEs transient and occurring on day of administration
- ❖ Safety data consistent with known profile of COMP360 psilocybin
  - No new safety signals identified
- ❖ SAEs similar in 25mg and 1mg arms and low overall across trial
- ❖ COMP360 emerging 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<sup>1</sup>



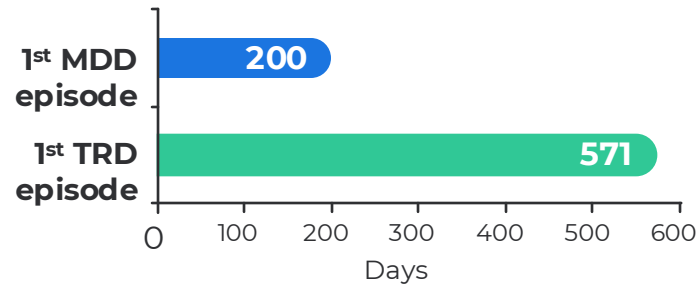
**Key:** M, million; MDD, major depressive disorder; TRD, treatment-resistant depression, US, United States

**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.



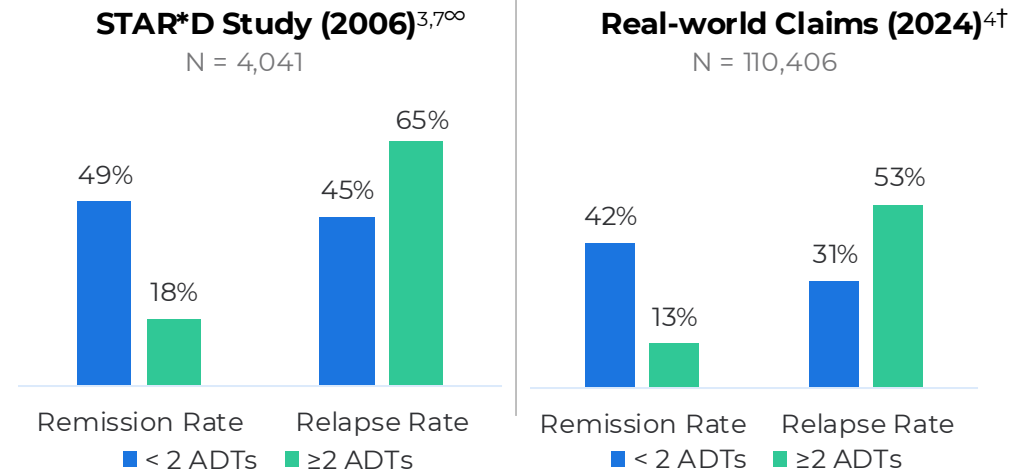
# TRD is Associated with a Greater Burden Compared to MDD

## Longer depressive episodes<sup>6</sup>



2x longer episodes

## Increased relapse rates and decreased remission rates<sup>3,4,7</sup>



## Higher comorbidity burden<sup>2</sup>

61% vs 36%  
experience  
pain\*

50% vs 29%  
experience  
anxiety\*

35% vs 17%  
suffer  
migraines\*

## Decreased productivity<sup>5</sup> and increased mortality<sup>1</sup>

70%  
greater  
work time loss<sup>5</sup>

51%  
increased risk of  
mortality due to suicide<sup>1</sup>

17-30%  
increased risk of  
all-cause mortality<sup>1</sup>

**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.

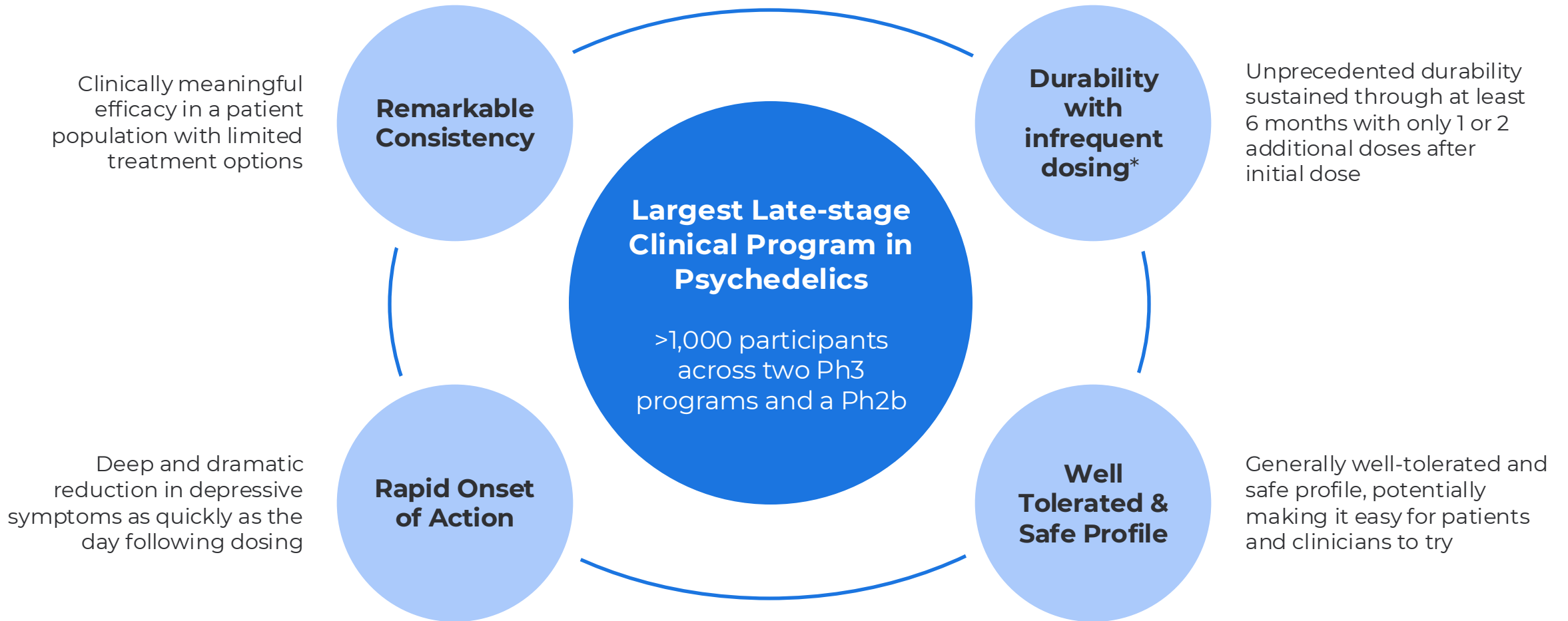
**Key:** ADT, antidepressant therapy; MDD, major depressive disorder; non-TRD MDD, non-treatment-resistant depression major depressive disorder; SDS, Sheehan Disability Scale; TRD, treatment-resistant depression.

**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



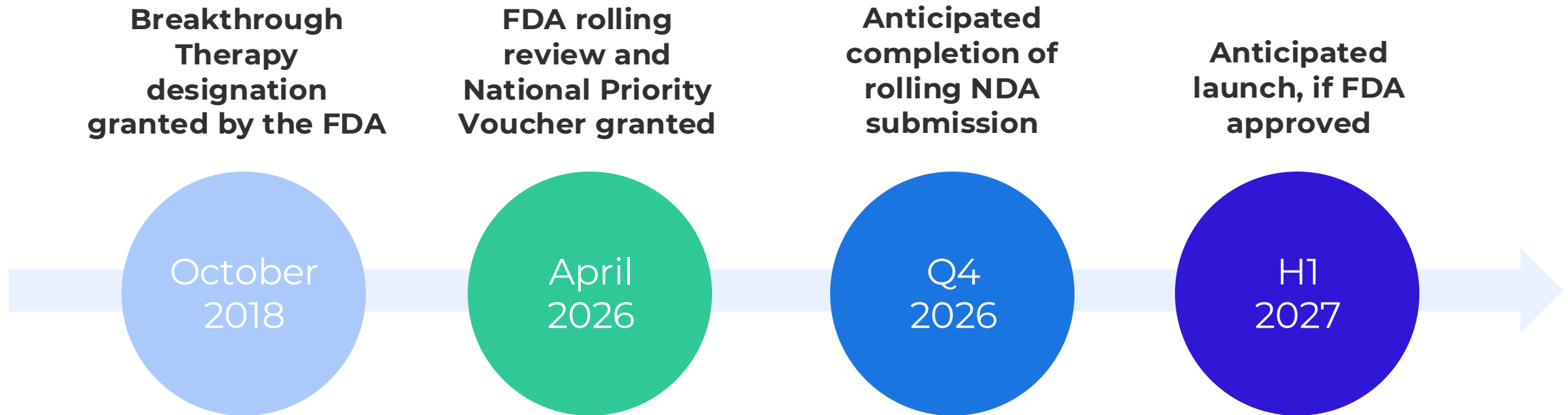
# Emerging Profile of COMP360 has Potential to Revolutionize how Mental Health Conditions are Treated



\* 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

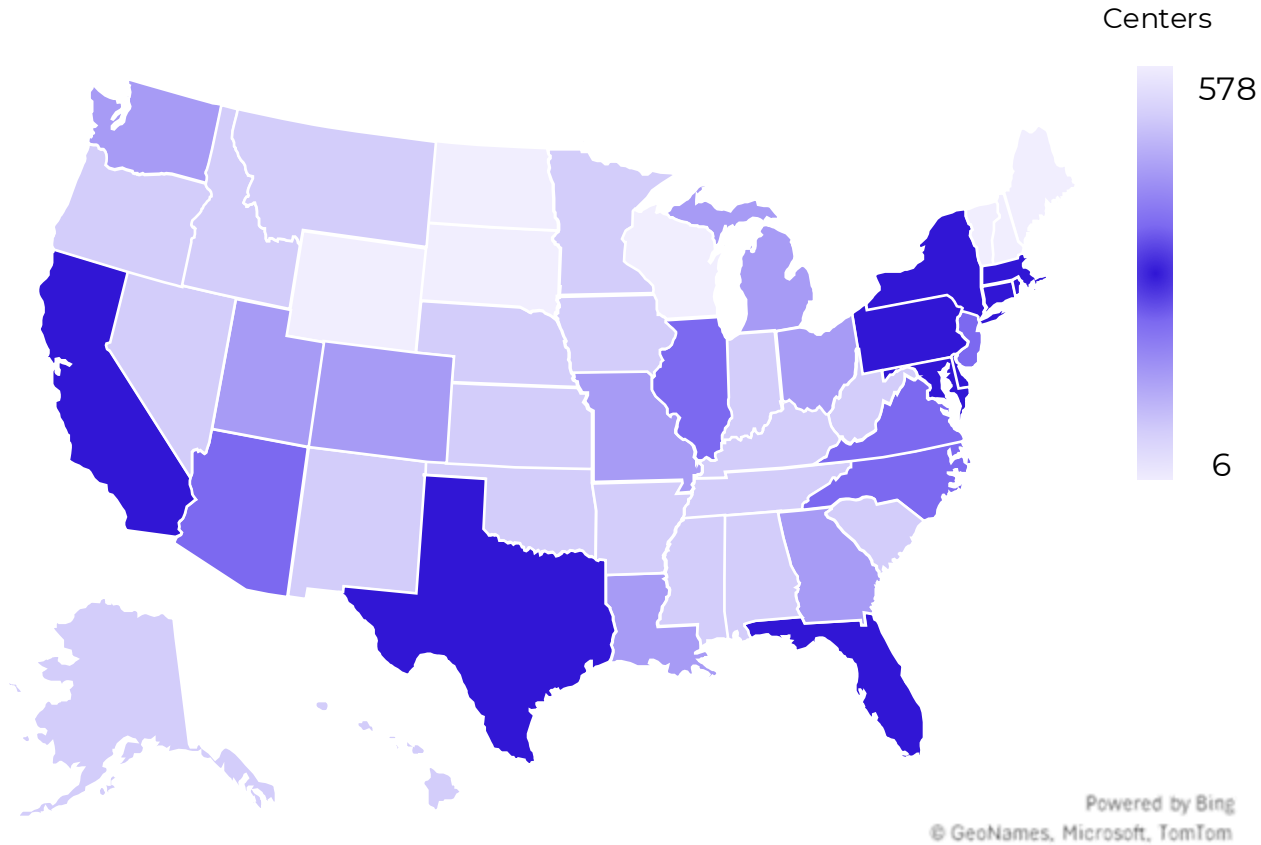


Advanced commercial launch prep work underway including payer discussions, enabling product distribution, setting up patient support mechanisms, preparing for field force execution and ongoing stakeholder education



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

~7,500 Spravato® treatment clinics in US<sup>1</sup>



## 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



# COMP360: Transforming Mental Health Care



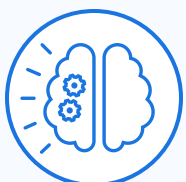
## Blockbuster Opportunity<sup>1</sup>

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





Thank you...

Q&A

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