

Compass Pathways Announces Second Quarter and First Half 2026 Financial Results and Business Highlights

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- Data from two positive Phase 3 trials demonstrated rapid onset of effect and durable benefit through at least 6 months, further validating COMP360's potential to establish a new standard of care in TRD
- COMP360 has a highly differentiated clinical profile and is expected to be a blockbuster opportunity, if approved
- Rolling NDA submission and initial review underway and final submission expected to be completed in Q4
- Commercial launch expected in first half of 2027
- COMP360 expected to fit seamlessly into current treatment infrastructure
- Late-stage PTSD trial underway
- Strong cash position of \$433 million at the end of second quarter, providing cash well beyond launch and into 2028
- Compass management will host a conference call on August 5 at 8:00 am ET

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to unlocking urgently needed new treatment options in mental health care, today reported the second quarter and first half 2026 financial results and business highlights.

"The first half of 2026 marked a defining period for Compass as we continued to build momentum across clinical, regulatory and commercial fronts in preparation for the potential approval and launch of COMP360," said Kabir Nath, Chief Executive Officer of Compass Pathways. "Over the past six months, we have strengthened – and further validated – the consistent evidence supporting COMP360's transformative potential, expanded our commercial readiness capabilities, deepened engagement across the treatment ecosystem, and advanced our rolling

submission in support of a regulatory filing in Q4. Our focus now is on disciplined execution - completing our filing activities and ensuring we are ready to deliver COMP360 to patients with TRD as quickly as possible, if approved. Our conviction in the potential of COMP360 has never been stronger. We are well positioned, confident in our ability to execute, and committed to bringing this transformative new treatment option to patients."

Business Highlights

COMP360's Highly Differentiated Profile as Demonstrated in First Half 2026

Rapid onset, sustained durability and infrequent dosing:

- COMP360 is leading a profound shift in the development of new treatment options in mental health care – moving beyond daily or frequent administration toward an option that could potentially provide strong efficacy with just a few treatments a year that could be life changing for patients
- Across two highly statistically significant positive Phase 3 trials, COMP360 is the first classic psychedelic ¹ to consistently demonstrate rapid onset, sustained durability and reproducibility of effect in TRD, one of the most difficult psychiatric conditions in which to demonstrate efficacy
 - Duration of current episode is the factor most strongly associated with failure to get relief from any treatment
 - Trial participants in the COMP360 Phase 3 program represent a highly chronic TRD population; across COMP005 and COMP006, participants had current depressive episodes lasting on average over three years and an average of more than six lifetime depressive episodes
 - For participants who achieved a clinically meaningful reduction in MADRS ²(≥ 25%), onset of effect was demonstrated from the day following administration
 - Across the trials, 39% in COMP006 and 25% of participants in 005, achieved a clinically meaningful reduction in MADRS (≥ 25%) at Week 6, maintaining benefit, on average, through at least Week 26

Generally well tolerated and safe profile:

- COMP360 demonstrated 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
- Serious adverse events (SAEs) were low overall across both trials

A blockbuster opportunity:

- Robust data from late-stage trials involving more than 1,000 participants living with TRD supports COMP360's potential to establish a new standard of care in TRD

- Approximately 4 million individuals in the US live with TRD ⁴, with only one marketed medicine that has captured <3% market share
- COMP360 offers a highly differentiated clinical profile and is expected to be a blockbuster opportunity

New evidence distinguishes COMP360 monitoring & support from psychotherapy:

- Peer-reviewed post-hoc analysis published in the **Journal of Psychopharmacology**, demonstrates that monitoring and support in COMP360 Phase 2b PTSD treatment sessions were minimal and non-directive with almost 80% of the administration session spent in silence, providing evidence that clinical outcomes are attributable to the COMP360 psilocybin treatment experience
- These findings are consistent with the standardized monitoring-and-support approach used across the COMP360 clinical development program, including the TRD trials

Regulatory Path Towards Approval

Final New Drug Application (NDA) submission on track for Q4:

- In April, the U.S. Food and Drug Administration (FDA) granted Compass NDA rolling submission and review request, based on strength of positive Phase 3 data
- Rolling submission and initial review are underway, with some modules of the NDA submitted and on track to complete all modules in Q4

Support and momentum:

- National Priority Voucher (NPV) awarded for COMP360, Compass' proprietary formulation of synthetic psilocybin for TRD, which has the potential to accelerate filing review time to be completed within 1-2 months
- White House Executive Order on psychedelics treatments directs the Drug Enforcement Administration (DEA) to initiate and complete review of psychedelic treatment that has successfully completed Phase 3 trials so that rescheduling may proceed as quickly as possible

Progressing Toward Potential Commercial Launch in First Half 2027

During the first half of 2026, Compass advanced key commercial readiness initiatives across organizational capabilities, strategic collaborations, policy engagement and infrastructure, positioning Compass for successful launch execution. Second half 2026 efforts are centered on operationalizing launch plans and ensuring launch readiness, with commercial launch expected in first half of 2027, subject to FDA approval and following Drug Enforcement Administration (DEA) rescheduling.

Advanced launch readiness efforts:

- Highly experienced leadership team in place
- Continued proactive engagement with state-level stakeholders to facilitate timely post-approval rescheduling; currently, approximately 90% of the U.S. patient population live in states that intend to reschedule within 30 days after Federal DEA
- Expanded strategic collaborations, with the addition of Radial and Osmind in the first half of 2026. Compass' collaboration portfolio continues to inform key elements of the COMP360 treatment ecosystem including patient care pathways, patient and provider experience, support staff training, site economics, real-world initiatives and treatment model optimization

Delivery infrastructure readiness:

- COMP360 is expected to fit seamlessly across diverse healthcare settings within current infrastructure of more than 8,000 centers³ offering multi-hour treatments
- Treatment centers are growing rapidly, and existing centers are already scaling in anticipation of a COMP360 launch and additional multi-hour psychedelic treatments coming to market
- At approval, focus will be on site preparedness – including training, education, REMS certification, assistance with reimbursement and patient support

COMP360 PTSD Program

Compass continues to progress PTSD program, with late-stage trial underway. Affecting **13 million people** in the U.S. each year, PTSD remains an underserved condition and underscores the urgent need to advance care for patients experiencing this debilitating condition.

Financial highlights

Research and development expenses were \$29.2 million and \$55.7 million for the three and six months ended June 30, 2026, respectively, compared with \$30.3 million and \$61.2 million during the same periods in 2025, respectively. The decrease was primarily driven by lower development expenses, reflecting reduced clinical trial costs as our Phase 3 program for COMP360 psilocybin therapy in TRD progresses toward completion, as well as reduced discovery program expenses following the termination of certain programs in connection with the reorganization that took place in the fourth quarter of 2024 and the related contract terminations in 2025. This decrease was partially offset by an increase in facilities and other expenses primarily due to an increase in external consulting fees and contractors.

General and administrative expenses were \$23.2 million and \$39.6 million for the three and six months ended June 30, 2026, respectively, compared with \$12.6 million and \$31.3 million during the same periods in 2025, respectively.

The increase was primarily due to increased costs to support our commercial preparedness activities.

Net loss was \$253.8 million, or \$1.88 net loss per share, and \$162.6 million, or \$1.33 net loss per share, for the three and six months ended June 30, 2026, respectively, compared with of \$38.4 million, or \$0.41 net loss per share, and \$56.3 million, or \$0.62 net loss per share, during the same periods in 2025, respectively. The increase in net loss was primarily driven by non-cash fair value adjustments related to our warrants. The change in fair value was \$205.6 million loss and \$74.7 million loss, for the three and six months ended June 30, 2026, respectively, compared with \$2.5 million loss and \$16.9 million gain for the same periods in 2025, respectively. As the fair value of the warrants fluctuates with our share price, this adjustment can result in significant variability in our reported net income or net loss.

Cash and cash equivalents were \$433.3 million as of June 30, 2026, compared with \$149.6 million as of December 31, 2025.

Debt was \$50.7 million as of June 30, 2026, compared with \$31.6 million as of December 31, 2025.

Financial Guidance

The current cash position is expected to be sufficient to fund operating expenses and capital expenditure requirements into 2028.

Conference Call

The management team will host a conference call at 8:00 am ET (1:00 pm UK) on August 5, 2026. A live webcast of the call will be available on the Compass Pathways website at: <https://events.q4inc.com/attendee/246696001>

About Compass Pathways

We believe mental health patients deserve the possibility of a better future. Compass Pathways plc (Nasdaq: CMPS) is a biotechnology company dedicated to unlocking urgently needed new treatment options in mental health care. Our initial focus is developing COMP360 psilocybin, a proprietary, investigational, synthetic psilocybin treatment under evaluation for treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD). COMP360 is a potentially first-in-class treatment and has Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA), as well as Innovative Licensing and Access Pathway (ILAP) designation in the UK for TRD. We are leading the world's largest classic psychedelic clinical program in TRD, and building upon that robust foundation, we are executing a late-stage trial evaluating COMP360 for PTSD, another condition with high unmet need. Our goal is to advance treatments that move the field of psychiatry towards treatment options that offer

rapid onset and sustained durability with infrequent dosing.

Compass is headquartered in London, UK, with a U.S. office in New Jersey.

We are driven by our purpose of unlocking pathways to be – opening futures filled with possibility. Together, we are on an ambitious journey toward enabling people living with mental health conditions to find clarity through self-discovery, because every journey needs a Compass.

Forward-looking statements

This press release 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 expectations regarding our financial guidance; our business strategy and goals; our expectations and projections about the company's future cash needs and financial results; our expectations regarding the safety or efficacy of our investigational COMP360 psilocybin treatment, including as a treatment of 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 expected timing of our commercial launch for COMP360 psilocybin treatment in TRD, if approved by the FDA, including the timing and substance of decisions by the U.S. Drug Enforcement Administration, or the DEA, 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 and our ability to obtain regulatory approval and adequate coverage and reimbursement; our ability to grow our organization and transition from a clinical-stage to a commercial-stage organization and effectively launch a commercial product, if regulatory approval is obtained; our expectations regarding market adoption and commercial potential for COMP360; 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 press release 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 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; the risk that, if approved, our COMP360 psilocybin treatment may not achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large and market adoption may be limited; the risk that our strategic collaborations will not continue or will not be successful; and our ability to 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 press release 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.

References

1. For the definition of classic psychedelic, see Vollenweider, F.X. and Smallridge, J.W., 2022. Classic psychedelic drugs: update on biological mechanisms. *Pharmacopsychiatry*, 55(03), pp.121-138
2. Montgomery-Åsberg Depression Rating Scale
3. www.spravatohcp.com/find-treatment-center – data pulled 07/31/2026
4. Wing V, et al. Poster S97 Contemporary Estimate of the National Prevalence of Treatment-Resistant Depression in the United States. Presented at ADAA 2026

Enquiries

Media: Dana Sultan-Rothman, media@compasspathways.com

Investors: Stephen Schultz, stephen.schultz@compasspathways.com, +1 401 290 7324

COMPASS PATHWAYS PLC
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	June 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 433,295	\$ 149,608
Restricted cash	425	379
Prepaid expenses and other current assets	41,954	41,503
Total current assets	475,674	191,490
NON-CURRENT ASSETS:		
Operating lease right-of-use assets	3,937	3,424
Deferred tax assets	4,555	3,751
Long-term prepaid expenses and other assets	20,395	11,684
Total assets	\$ 504,561	\$ 210,349
LIABILITIES AND SHAREHOLDERS' EQUITY/(DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	\$ 12,240	\$ 15,222
Accrued expenses and other liabilities	15,701	9,214
Debt, current portion	—	17,523
Operating lease liabilities - current	1,885	2,110
Warrant liabilities	337,459	203,726
Total current liabilities	367,285	247,795
NON-CURRENT LIABILITIES:		
Debt, non-current portion	50,727	14,110
Operating lease liabilities - non-current	2,016	1,292
Total liabilities	\$ 420,028	\$ 263,197
SHAREHOLDERS' EQUITY/(DEFICIT):		
Ordinary shares, £0.008 par value; 135,722,306 and 96,085,785 shares authorized, issued and outstanding at June 30, 2026 and December 31, 2025, respectively	1,401	973
Additional paid-in capital	1,083,059	783,562
Accumulated other comprehensive loss	(14,741)	(14,789)
Accumulated deficit	(985,186)	(822,594)
Total shareholders' equity/(deficit)	\$ 84,533	\$ (52,848)
Total liabilities and shareholders' equity/(deficit)	\$ 504,561	\$ 210,349

COMPASS PATHWAYS PLC
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	Three Months ended June 30, 2026	2025	Six Months ended June 30, 2026	2025
OPERATING EXPENSES:				
Research and development	\$ 29,175	\$ 30,325	\$ 55,655	\$ 61,205
General and administrative	23,197	12,608	39,621	31,344
Total operating expenses	52,372	42,933	95,276	92,549
Loss from operations:	(52,372)	(42,933)	(95,276)	(92,549)
OTHER (EXPENSE) INCOME, NET:				
Fair value change of warrant liabilities	(205,577)	(2,540)	(74,661)	16,920
Interest income	3,744	1,898	6,163	4,284
Benefit from R&D tax credit	2,583	4,287	5,060	12,735

Interest expense	(1,483)	(1,151)	(2,948)	(2,275)
Foreign exchange (losses) gains	(904)	2,349	(1,640)	4,482
Other income (expense)	546	(176)	1,030	627
Total other (expense) income, net	(201,091)	4,667	(66,996)	36,773
Loss before income taxes	(253,463)	(38,266)	(162,272)	(55,776)
Income tax expense	(331)	(137)	(320)	(491)
Net loss	<u>\$ (253,794)</u>	<u>\$ (38,403)</u>	<u>\$ (162,592)</u>	<u>\$ (56,267)</u>
Net loss per share attributable to ordinary shareholders: basic and diluted	\$ (1.88)	\$ (0.41)	\$ (1.33)	\$ (0.62)
Weighted average ordinary shares outstanding: basic and diluted	135,039,810	93,341,594	122,679,123	91,278,385
Net loss	<u>\$ (253,794)</u>	<u>\$ (38,403)</u>	<u>\$ (162,592)</u>	<u>\$ (56,267)</u>
Other comprehensive income:				
Foreign exchange translation adjustment	54	1,729	48	1,612
Comprehensive loss	<u>\$ (253,740)</u>	<u>\$ (36,674)</u>	<u>\$ (162,544)</u>	<u>\$ (54,655)</u>

Enquiries

Media: Dana Sultan-Rothman, media@compasspathways.com

Investors: Stephen Schultz, stephen.schultz@compasspathways.com, +1 401 290 7324

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