

Compass Pathways Announces Fourth Quarter and Full-Year 2025 Financial Results and Business Highlights

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- COMP360 is the first classic psychedelic¹ to consistently achieve a highly statistically significant result and clinically meaningful effect in treatment resistant depression (TRD), with a generally well-tolerated and safe profile
- Across three large trials in TRD, including two positive Phase 3 studies, COMP360's differentiated profile is redefining rapidity and durability for TRD patients and demonstrating a consistent level of clinical effect that has never been achieved before
- Compass will meet with the FDA to confirm alignment on a rolling submission and review, and expects to complete the NDA submission in Q4
- Compass is rapidly advancing commercial readiness plans and expects COMP360 will fit seamlessly across diverse healthcare settings at launch
- Phase 2b/3 trial in PTSD initiating, following FDA acceptance of IND application
- Successful \$150 million financing in February and exercise of \$200 million in warrants extends cash runway into 2028

LONDON & NEW YORK--(BUSINESS WIRE)-- Compass Pathways plc (Nasdaq: CMPS), a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health, today reported the fourth quarter and full-year 2025 financial results and business highlights.

"COMP360 is shaping the future of mental healthcare, and we are moving the field of psychiatric medicine forward for the millions of people urgently needing better options. As the potential first classic psychedelic approved by the FDA, COMP360 is redefining rapidity and durability with response as early as the day after dosing and lasting

through at least 6 months with just one or two doses – an unmatched clinical profile and important advancement for those living with TRD,” said Kabir Nath, Chief Executive Officer of Compass Pathways. “We look forward to our upcoming FDA meeting to confirm our NDA submission strategy, and we continue to advance our commercial readiness to be launch-ready by the end of this year. We are also initiating our late-stage PTSD study, reinforcing our commitment to advancing innovative, science driven treatments for people facing the most challenging mental health conditions.”

Business Highlights

COMP360 in Treatment Resistant Depression (TRD)

FDA approval pathway

- Compass is scheduled to meet with the FDA to confirm the NDA submission strategy, including a rolling submission and review
- 26-week (Part B) data from COMP006 in early Q3 2026 is expected to be the final dataset for NDA submission
- Compass is rapidly advancing commercial readiness efforts to be launch-ready by the end of 2026

COMP360’s differentiated profile and commercial opportunity

- Of the approximately 4 million² TRD patients in the U.S., it is estimated that fewer than 200,000 (5%) of patients³ receive an FDA-approved treatment indicated for TRD
- Across three robust late-stage clinical trials in more than 1,000 participants, COMP360 has consistently achieved highly statistically significant results at the primary endpoint and demonstrated clinically meaningful efficacy in a patient population that has historically been failed by other treatment options
- COMP360 has the potential to redefine rapidity and durability for patients with TRD, offering a highly differentiated and transformative clinical profile unlike any other treatment available for this patient population today. As announced in **February**, the data demonstrate the following:
 - Extremely rapid onset of action with reduction in depressive symptoms as quickly as the day following administration at the first measured timepoint
 - The first pivotal, placebo-controlled trial COMP005 demonstrated extensive durability that lasts at least through 6 months after only 1 or 2 administrations for those participants in the 25 mg arm who achieved a clinically meaningful reduction in MADRS ($\geq 25\%$) at Week 6
 - A generally well-tolerated safety profile with a significant majority of treatment-emergent adverse events (TEAEs) being mild or moderate in severity, and the vast majority resolving within 24 hours
- Compass’ strategic collaborations are generating valuable insights into future implementation opportunities for COMP360 within the current infrastructure

- COMP360 is expected to fit seamlessly across diverse healthcare settings within the current infrastructure of over 7,300 centers ⁴ offering multi hour treatments
- Treatment centers are growing rapidly, and existing centers are already scaling in anticipation of a COMP360 launch and additional psychedelic treatments coming to market
- COMP360 will potentially offer a highly differentiated, patient friendly dosing schedule, compelling clinical profile and is expected to be a blockbuster opportunity

COMP360 in Post Traumatic Stress Disorder (PTSD)

- FDA accepts Investigational New Drug (IND) Application for COMP360 for the treatment of post-traumatic stress disorder (PTSD), enabling initiation of Phase 2b/3 trial
- Previous Phase 2 open-label, safety and tolerability study in PTSD with 22 participants showed COMP360 is generally safe and well-tolerated, with no serious adverse events observed, and demonstrated both rapid and durable improvement in symptoms observed following a single administration of COMP360 out to 12 weeks. The results of this study were published in the September 2025 issue of the **Journal of Psychopharmacology**
- Affecting **13 million people** in the U.S. each year, PTSD remains an underserved condition. There are currently only two FDA-approved medications for PTSD. This limited pharmacological landscape underscores the urgent need to advance care for patients experiencing this debilitating condition

Financial Highlights

- Research and development expenses were \$29.9 million for the three months ended December 31, 2025, compared with \$32.1 million during the same period in 2024. The decrease was primarily attributable to a decrease in personnel and non-cash share-based compensation expenses due to decreased staffing levels associated with the reorganization that took place in the fourth quarter of 2024
- Research and development expenses were broadly stable at \$118.4 million for the year ended December 31, 2025, compared with \$119.0 million during the same period in 2024
- General and administrative expenses were broadly stable at \$16.0 million for the three months ended December 31, 2025, compared with \$16.3 million during the same period in 2024
- General and administrative expenses were \$60.6 million for the year ended December 31, 2025, compared with \$59.2 million during the same period in 2024. The increase was primarily attributable to an increase in legal and professional fees primarily due to issuance costs related to our January 2025 Financing as well as expenses associated with consulting, accounting and legal advice, partially offset by decreased personnel and non-cash share based compensation expenses due to decreased staffing levels associated with the reorganization that took place in the fourth quarter of 2024 as well as decreased facilities and other expenses as a result of lower insurance premiums and banking fees
- Net loss for the three months ended December 31, 2025, was \$93.9 million, or \$1.00 net loss per share: basic

and diluted, compared with \$43.3 million, or \$0.63 loss per share basic and diluted, during the same period in 2024. The increase in net loss for the quarter was primarily driven by a \$38.2 million non-cash loss on fair value adjustment related to our warrant liabilities, compared with \$0.0 million during the same period in 2024. As the fair value of the warrants fluctuates with our share price and other market inputs, this adjustment can result in significant variability in our reported net loss

- Net loss for the year ended December 31, 2025, was \$287.9 million, or \$3.08 net loss per share: basic and diluted, compared with \$155.1 million, or \$2.30 loss per share basic and diluted, during the same period in 2024. The increase in net loss for the period was primarily driven by a \$122.6 million non-cash loss on fair value adjustment related to our warrant liabilities, compared with \$0.0 million during the same period in 2024. As the fair value of the warrants fluctuates with our share price and other market inputs, this adjustment can result in significant variability in our reported net loss
- Cash and cash equivalents were \$149.6 million as of December 31, 2025, compared with \$165.1 million as of December 31, 2024
- Debt was \$31.6 million as of December 31, 2025, compared with \$30.2 million as of December 31, 2024 (and \$50.4 million as of March 24, 2026)

Financial Guidance

The cash position at March 24, 2026 is expected to be sufficient to fund operating expenses and capital expenditure requirements into 2028.

About Compass Pathways

Compass Pathways plc (Nasdaq: CMPS) is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. We are motivated by the need to find better ways to help and empower people with serious mental health conditions who are not helped by existing treatments. We are pioneering a new paradigm for treating mental health conditions focused on rapid and durable responses through the development of our investigational COMP360 synthetic psilocybin treatment, potentially a first in class treatment. COMP360 has Breakthrough Therapy designation from the US Food and Drug Administration (FDA) and has received Innovative Licensing and Access Pathway (ILAP) designation in the UK for treatment-resistant depression (TRD).

Compass is headquartered in London, UK, with offices in New York in the US. We envision a world where mental health means not just the absence of illness but the ability to thrive.

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; our expectations regarding the time periods the release of data from Part B of the COMP006 Phase 3 trial for TRD; our expectations regarding discussions with the FDA, including discussions regarding potential NDA acceleration strategies, including potential for rolling NDA submission and review for COMP360 psilocybin treatment in TRD; our expectations regarding timing for our NDA submission; our expectations regarding potential commercial launch timelines and our commercial readiness; the potential for the pivotal phase 3 program in TRD to support regulatory filings and approvals on an accelerated basis or at all; 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 an 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 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; our acceleration strategies for our NDA submission may not be successful; FDA may ultimately disagree with our proposal for a rolling NDA submission and may not permit us to utilize the rolling review process; our efforts to obtain marketing approval from FDA or regulatory authorities in any other jurisdiction for our investigational COMP360 psilocybin treatment may be unsuccessful; our efforts to commercialize and obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; 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, the prospectus supplement related to the proposed public offering we plan to file 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. Data on file
3. Data on file
4. Data on file

Enquiries

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COMPASS PATHWAYS PLC Consolidated Balance Sheets (in thousands, except share and per share amounts) (expressed in U.S. Dollars, unless otherwise stated)		
	December 31,	
	2025	2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 149,608	\$ 165,081
Restricted cash	379	389
Prepaid expenses and other current assets	41,503	35,821
Total current assets	191,490	201,291
NON-CURRENT ASSETS:		
Operating lease right-of-use assets	3,424	2,006
Deferred tax assets	3,751	3,774
Long-term prepaid expenses and other assets	11,684	6,595
Total assets	\$ 210,349	\$ 213,666

LIABILITIES AND SHAREHOLDERS' (DEFICIT)/EQUITY

CURRENT LIABILITIES:			
Accounts payable	\$	15,222	\$ 12,283
Accrued expenses and other liabilities		9,214	14,495
Debt, current portion		17,523	5,513
Operating lease liabilities - current		2,110	1,725
Warrant liabilities		203,726	—
Total current liabilities		247,795	34,016
NON-CURRENT LIABILITIES:			
Debt, non-current portion		14,110	24,652
Operating lease liabilities - non-current		1,292	303
Total liabilities		263,197	58,971
SHAREHOLDERS' (DEFICIT)/EQUITY:			
Ordinary shares, £0.008 par value; 96,085,785 and 68,552,215 shares authorized, issued and outstanding at December 31, 2025 and 2024, respectively		973	702
Additional paid-in capital		783,562	704,919
Accumulated other comprehensive loss		(14,789)	(16,194)
Accumulated deficit		(822,594)	(534,732)
Total shareholders' (deficit)/equity		(52,848)	154,695
Total liabilities and shareholders' (deficit)/equity	\$	210,349	\$ 213,666

COMPASS PATHWAYS PLC

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)
(expressed in U.S. Dollars, unless otherwise stated)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2025	2024	2025	2024
OPERATING EXPENSES:				
Research and development	\$ 29,906	\$ 32,141	\$ 118,436	\$ 119,039
General and administrative	16,046	16,273	60,601	59,166
Total operating expenses	45,952	48,414	179,037	178,205
LOSS FROM OPERATIONS:	(45,952)	(48,414)	(179,037)	(178,205)
OTHER (EXPENSE) INCOME, NET:				
Fair value change of warrant liabilities	(38,163)	—	(122,561)	—
(Expense) Benefit from R&D tax credit	(12,912)	10,203	3,747	21,097
Interest income	1,310	1,623	7,182	8,268
Interest expense	(1,137)	(1,132)	(4,517)	(4,479)
Foreign exchange (losses) gains	(128)	(4,926)	3,471	(1,032)
Other income	370	337	1,380	823
Total other (expense) income, net	(50,660)	6,105	(111,298)	24,677
Loss before income taxes	(96,612)	(42,309)	(290,335)	(153,528)
Income tax benefit (expense)	2,734	(1,023)	2,473	(1,594)
Net loss	\$ (93,878)	\$ (43,332)	\$ (287,862)	\$ (155,122)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (1.00)	\$ (0.63)	\$ (3.08)	\$ (2.30)
Weighted average ordinary shares outstanding—basic and diluted	93,636,285	68,395,343	93,504,836	67,482,902
Net loss	\$ (93,878)	\$ (43,332)	\$ (287,862)	\$ (155,122)
Other comprehensive loss:				
Foreign exchange translation adjustment	398	348	1,405	732
Comprehensive loss	\$ (93,480)	\$ (42,984)	\$ (286,457)	\$ (154,390)

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Source: Compass Pathfinder Limited