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): **May 08, 2024**

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 8.01 Other Events.

Compass Pathways plc (the "Company") reported top-line results from an open-label phase 2 study evaluating the safety and tolerability of investigational COMP360 psilocybin treatment in 22 patients with post-traumatic stress disorder (PTSD). The study met its primary safety endpoint and available secondary efficacy endpoints. Study observations included meaningful and sustained symptom improvement from baseline in mean CAPS-5 total score, a measure of disease severity, and in Sheehan Disability Scale (SDS) score, a measure of functional impairment in daily life. Administration of COMP360 was well-tolerated, with a safety profile consistent with previous studies.

The key findings include:

• Administration was well tolerated, with no serious adverse events observed. There were no treatment-emergent serious adverse events. Treatment-emergent adverse events included headache (n=11 or 50.0%), nausea (n=8 or 36.4%), crying (n=6 or 27.3%), and fatigue (n=6 or 27.3%). There were two adverse events of suicidal ideation that resolved during the study. The first was a moderate and transient event which resolved on administration day in a patient who went on to be a responder, and it was deemed to be related to study drug. The second event was mild and occurred at week 7 in a non-responder, resolved during the study, and was deemed to be possibly related to study drug. Both participants had previous history of suicidality as measured by the Columbia-Suicide Severity Rating Scale.

• Durable improvement in symptoms from baseline observed following a single administration. Improvement in mean CAPS-5 total score from a baseline of 47.5 was observed (29.9 point reduction at week 4 and 29.5 point reduction at week 12).

• Improvement over time in Sheehan Disability Scale (SDS) measure of functional impairment over 12 weeks. From a mean SDS total score of 22.7 at baseline, there was a 11.7 point reduction at week 4 and a 14.4 point reduction at week 12.

• High and sustained rates of response and remission relative to baseline, with early onset of symptom improvement. Response, as defined by patients experiencing a ≥ 15-point improvement on CAPS-5 score, was 81.8% at week 4 and 77.3% at week 12. Remission, as defined by CAPS-5 total score of ≤ 20, was 63.6% at week 4 and 54.5% at week 12.

• No patients withdrew from the study and no patients returned to antidepressant medication treatment during the trial.

The open-label, multi-center, phase 2 safety study evaluated investigational COMP360 psilocybin treatment in 22 patients with PTSD resulting from trauma in adulthood. Participants received a single 25mg dose along with psychological support. Psychological support was provided by a licensed medical professional to ensure patient safety, which consisted of preparing participants for the treatment session, observing and being present with patients during the session and supporting them after the session. Primary endpoint was safety at week 12; available secondary endpoints were change in CAPS-5 from baseline and change in SDS total score from baseline.

The mean baseline severity of symptoms was a baseline of 47.5 (minimum of 25; maximum of 64) CAPS-5 total score, which is considered severe. The CAPS-5 assessment involves a structured interview that provides a PTSD diagnosis and measures symptom severity. The average age of participants at the time of screening was 39 and patients diagnosed with complex PTSD were excluded from study eligibility. The study was conducted at The Institute of Psychiatry, Psychology and Neuroscience at King's College London, Icahn School of Medicine at Mount Sinai in New York and Sunstone Therapies in Rockville, Maryland.

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: May 8, 2024

By: /s/ Teri Loxam

Teri Loxam
Chief Financial Officer