

**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): **November 02, 2023**

COMPASS PATHWAYS PLC

(Exact Name of Registrant as Specified in Its Charter)

England and Wales
(State or other Jurisdiction of Incorporation)

001-39522
(Commission
File Number)

Not applicable
(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 2.02 Results of Operation and Financial Condition

On November 2, 2023, COMPASS Pathways plc (the “Company”) issued a press release announcing the Company's financial results for the nine months ended September 30, 2023. A copy of this press release is furnished herewith as Exhibit 99.1.

The information in Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed herewith:

Exhibit No.	Description
99.1	Press Release dated November 2, 2023
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: November 2, 2023

By: /s/ Mary-Rose Hughes
Mary-Rose Hughes
Interim Chief Financial Officer



COMPASS Pathways Announces Third Quarter 2023 Financial Results and Business Highlights

London, UK – November 2, 2023

Highlights:

- COMP360 Phase 3 pivotal program ongoing with expanding European clinical sites
- Secured up to \$285 million private placement financing with \$125 million upfront
- Cash position at September 30, 2023 of \$248.0 million
- Conference call on November 2 at 8:00 am ET (12:00 pm UK)

COMPASS Pathways plc (Nasdaq: CMPS) ("COMPASS"), a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health, today reported its financial results for the third quarter 2023 and provided an update on recent progress across its business.

Kabir Nath, Chief Executive Officer, said, "We continue to make progress in our COMP360 phase 3 program, most recently with the authorization to commence recruitment in a number of European clinical trial sites. Both phase 3 trials, COMP005 and COMP006, are on track, and we expect to have initial top-line data in less than a year for COMP005. We also expect to see top-line data in our phase 2 study in PTSD by the end of this year. The August financing, led by specialist healthcare investors, provides a strong financial foundation that permits COMPASS to move forward confidently with our clinical programs, as well as all supporting studies for a potential new drug application filing with the FDA. We also continue to invest in our pre-commercial work to ensure we are prepared for a successful COMP360 launch, if approved."

Business highlights

COMP360 psilocybin therapy in treatment-resistant depression (TRD):

- Phase 3 program underway, composed of two pivotal trials with an integrated, long-term outcomes component
 - Pivotal trial 1 (COMP 005): single dose monotherapy, n=255, topline data expected summer 2024
 - Pivotal trial 2 (COMP 006): fixed repeat dose monotherapy, n=568, topline data expected mid-2025
 - Long-term follow up in each trial will generate data on duration of response and potential effect of retreatment
 - Both phase 3 trials ongoing and on track

Additional COMP360 development activities:

- Phase 2 study in post-traumatic stress disorder (PTSD) top-line data expected by the end of 2023
- Phase 2 study in anorexia nervosa ongoing
- Publication of a paper in *Psychopharmacology* showing the potential of AI technologies to support investigational COMP360 psilocybin treatment in TRD

Team Updates

- Daphne Karydas appointed to the COMPASS Board of Directors
- Mary-Rose Hughes assumed the role of interim CFO after Mike Falvey departure; search for a permanent Chief Financial Officer commenced

Financial highlights

In August, COMPASS completed a private placement pursuant to which it issued and sold to a select group of specialist healthcare investors 16,076,750 American Depositary Shares (“ADSs”) and warrants to purchase up to 16,076,750 ADSs (the “PIPE Warrants”) at a purchase price of approximately \$7.78 per ADS and accompanying warrant to purchase one ADS. At closing, COMPASS received \$125 million in gross proceeds, before deducting placement agent commissions and offering expenses. COMPASS will receive up to an additional approximately \$160 million in gross proceeds if the PIPE Warrants are fully exercised. The PIPE Warrants have an exercise price of \$9.93 per ADS, which represented a 30% premium to the last sale price prior to the financing, and will be exercisable at the election of the investors beginning in February 2024 for a three-year period.

- Cash and cash equivalents were \$248.0 million as of September 30, 2023, compared with \$143.2 million as of December 31, 2022.
 - Runway lengthened to late 2025 through term loan facility, sales of shares under the At the Market (“ATM”) facility and private placement transaction (the “PIPE”).
- Long-term debt was \$28.4 million as of September 30, 2023, compared with \$0 million as of December 31, 2022.
- Received \$116.9 million in net proceeds through our PIPE offering in third quarter.
- Net loss for the three months ended September 30, 2023 was \$33.4 million, or \$0.67 loss per share (including non-cash share-based compensation expense of \$4.4 million), compared with \$18.4 million, or \$0.43 loss per share, during the same period in 2022 (including non-cash-share-based compensation expense of \$3.5 million).
- Net loss for the nine months ended September 30, 2023 was \$85.9 million, or \$1.81 loss per share (including non-cash share-based compensation expense of \$13.1 million), compared with \$60.6 million, or \$1.43 loss per share, during the same period in 2022 (including non-cash-share-based compensation expense of \$9.8 million).
- Research and development (R&D) expenses were \$21.5 million for the three months ended September 30, 2023, compared with \$14.0 million during the same period in 2022. Of this increase, \$6.2 million related to an increase in external development expenses as we continue to investigate COMP360 psilocybin treatment in clinical and pre-clinical trials. A further \$1.7 million and \$0.4 million were attributable to personnel expenses and non-cash share-based compensation respectively, due to increased headcount. Other expenses decreased by \$0.8 million, which primarily related to a decrease in external consulting fees.
- R&D expenses were \$60.4 million for the nine months ended September 30, 2023, compared with \$45.3 million during the same period in 2022. Of this increase, \$10.4 million related to an increase in external development expenses as we continue to investigate COMP360 psilocybin treatment in clinical and pre-clinical trials. A further \$4.7 million and \$1.2 million were attributable to personnel expenses and non-cash share-based compensation

respectively, due to increased headcount. Other expenses decreased by \$1.1 million, which primarily related to a decrease in external consulting fees.

- General and administrative (G&A) expenses were \$12.5 million for the three months ended September 30, 2023, compared with \$11.6 million during the same period in 2022. This was attributable to an increase of \$1.1 million in facilities and other expenses and \$0.6 million in non-cash share-based compensation, partially offset by a decrease of \$0.2 million in personnel expenses, primarily due to reductions in travel and employee benefit expenses. There was a further decrease of \$0.5 million in legal and professional fees.
- G&A expenses were \$38.1 million for the nine months ended September 30, 2023, compared with \$33.0 million during the same period in 2022. The increase was attributable to an increase of \$2.6 million and \$2.1 million in personnel expenses and non-cash share-based compensation respectively. There was a further increase of \$2.0 million in facilities and other expenses and a decrease of \$1.5 million in legal and professional fees.

Financial Guidance

Fourth quarter 2023 net cash used in operating activities is expected to be in the range of \$9 million to \$15 million. This range includes the amount receivable in respect of the R&D tax credit in the UK, the timing for which is uncertain. We are adjusting the full-year 2023 cash burn guidance downward and expect net cash used in operating activities to be in the range of \$79 million to \$85 million, which assumes the R&D tax credit is received in full in the fourth quarter.

Conference call

The COMPASS Pathways management team will host a conference call at 8.00am ET (12:00pm UK) on November 2, 2023.

Please register in advance [here](#) to access the call and obtain a local or toll-free phone number and personal pin.

A live webcast of the call will be available on COMPASS Pathway's website at: Third Quarter 2023 Financial Results. The webcast will also be available on the Investors section of the COMPASS Pathways website. The webcast will be archived for 30 days. The call will also be webcast on the COMPASS Pathways website and archived for 30 days. For more information, please visit the COMPASS Pathways website (ir.compasspathways.com).

About COMPASS Pathways

COMPASS Pathways plc (Nasdaq: CMPS) is a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health. Our focus is on improving the lives of those who are suffering with mental health challenges and who are not helped by current treatments. We are pioneering the development of a new model of psilocybin treatment, in which our proprietary formulation of synthetic psilocybin, COMP360, is administered in conjunction with psychological support. COMP360 has been designated a Breakthrough Therapy by the U.S. Food and Drug Administration (FDA) and has received Innovative Licensing and Access Pathway (ILAP) designation in the UK for treatment-resistant depression (TRD). We have commenced a phase 3 clinical program of COMP 360 psilocybin treatment in TRD, the largest randomised, controlled, double-blind psilocybin treatment clinical program ever conducted. Previously, we completed a phase 2b study with top line data showing a statistically significant ($p < 0.001$) and clinically relevant improvement in depressive symptom severity after three weeks for patients who received a single high dose of COMP360 psilocybin with psychological support. We are also conducting phase 2 clinical studies of COMP360 psilocybin treatment for

post-traumatic stress disorder (PTSD) and anorexia nervosa. COMPASS is headquartered in London, UK, with offices in New York and San Francisco in the United States. Our vision is a world of mental wellbeing.
www.compasspathways.com

Availability of other information about COMPASS Pathways

Investors and others should note that we communicate with our investors and the public using our website (www.compasspathways.com), our investor relations website (ir.compasspathways.com), and on social media (LinkedIn), including but not limited to investor presentations and investor fact sheets, US Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in us to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include additional social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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, COMPASS’s financial guidance, COMPASS’s business strategy and goals, its expectations and projections about the company’s future cash needs and financial results, the anticipated proceeds to be received, if any, from the exercise of warrants issued in the private placement, COMPASS’s plans and expectations regarding its phase 3 trials in TRD, including its expectations that the trials are on track and the period during which the results of the Phase 3 trials will become available, the potential for these Phase 3 trials or other trials to support regulatory filings and approvals, the safety or efficacy of its investigational COMP360 psilocybin treatment, including for treatment of TRD, anorexia nervosa, and PTSD, and COMPASS’s expectations regarding its ongoing preclinical work and clinical trials, development efforts and innovation labs. 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: we will require substantial additional funding to achieve our business goals, including to repay the term loan facility, 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 product development efforts; the availability of future tranches under the term loan facility is dependent, in part, on the approval of the lender, achievement of certain milestones and other factors; clinical development is lengthy and outcomes are uncertain, and therefore our clinical trials may be delayed or terminated; our efforts to obtain marketing approval from the applicable regulatory authorities in any jurisdiction for COMP360 or any of future product candidates may be unsuccessful; our development efforts and our business strategy to set up research facilities and innovation labs involves significant costs and resources and may be unsuccessful; and our efforts to obtain coverage and reimbursement for our investigational COMP360 psilocybin treatment, if approved, may be unsuccessful; 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.

Enquiries

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 248,038	\$ 143,206
Restricted cash	331	175
Prepaid income tax	427	575
Prepaid expenses and other current assets	36,010	47,695
Total current assets	284,806	191,651
NON-CURRENT ASSETS:		
Investment	469	469
Property and equipment, net	309	617
Operating lease right-of-use assets	4,165	2,006
Deferred tax assets	3,406	2,224
Long-term prepaid expenses and other assets	5,878	327
Total assets	<u>\$ 299,033</u>	<u>\$ 197,294</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 4,248	\$ 4,761
Accrued expenses and other liabilities	8,998	9,325
Operating lease liabilities - current	2,104	1,510
Total current liabilities	15,350	15,596
NON-CURRENT LIABILITIES		
Long-term debt	28,431	—
Operating lease liabilities - non-current	1,997	418
Total liabilities	<u>\$ 45,778</u>	<u>\$ 16,014</u>
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 61,884,785 and 42,631,794 shares authorized, issued and outstanding at September 30, 2023 and December 31, 2022, respectively	634	440
Deferred shares, £21,921.504 par value; nil and one share authorized, issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	28
Additional paid-in capital	617,165	458,825
Accumulated other comprehensive loss	(17,466)	(16,867)
Accumulated deficit	(347,078)	(261,146)
Total shareholders' equity	<u>253,255</u>	<u>181,280</u>
Total liabilities and shareholders' equity	<u>\$ 299,033</u>	<u>\$ 197,294</u>

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 September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
OPERATING EXPENSES:				
Research and development	\$ 21,526	\$ 13,977	\$ 60,379	\$ 45,259
General and administrative	12,536	11,559	38,135	32,953
Total operating expenses	34,062	25,536	98,514	78,212
LOSS FROM OPERATIONS:	(34,062)	(25,536)	(98,514)	(78,212)
OTHER INCOME, NET:				
Other income, net	1,127	3,206	2,463	3,580
Interest expense	(1,080)	—	(1,080)	—
Foreign exchange (losses) gains	(1,997)	1,096	2,064	4,387
Benefit from R&D tax credit	2,685	2,983	9,521	9,982
Total other income, net	735	7,285	12,968	17,949
Loss before income taxes	(33,327)	(18,251)	(85,546)	(60,263)
Income tax expense	(62)	(120)	(386)	(316)
Net loss	(33,389)	(18,371)	(85,932)	(60,579)
Other comprehensive (loss) income:				
Foreign exchange translation adjustment	(738)	(15,156)	(599)	(39,483)
Comprehensive loss	(34,127)	(33,527)	(86,531)	(100,062)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (0.67)	\$ (0.43)	\$ (1.81)	\$ (1.43)
Weighted average ordinary shares outstanding—basic and diluted	49,633,104	42,525,855	47,355,992	42,377,895