

**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): **FEBRUARY 28, 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 February 28, 2023, COMPASS Pathways plc (the “Company”) issued a press release announcing the Company's financial results for the fourth quarter and year ended December 31, 2022. 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 February 28, 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: February 28, 2023

By: /s/ Michael Falvey
Michael Falvey
Chief Financial Officer



COMPASS Pathways Announces Fourth Quarter and Year-End 2022 Financial Results and Business Highlights

London, UK – February 28, 2023

Highlights:

- Phase 3 pivotal program underway - important updates announced
- Phase 3 long term follow up defined
- Cash position at 31 December 2022 of \$143.2 million
- Conference call today at 8:00am ET (1:00pm UK)

COMPASS Pathways plc (Nasdaq: CMPS) ("COMPASS"), a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health, today reported its financial results for the fourth quarter and year-end 2022 and gave an update on recent progress across its business.

Kabir Nath, Chief Executive Officer said, "During this past quarter, we commenced our COMP360 phase 3 pivotal program in treatment-resistant depression, a significant milestone for our area of science as these are the first ever phase 3 trials of psilocybin. We have also announced important updates to this program that accelerate the placebo-controlled trial pivotal data read out and streamline the long-term follow up as an integrated component of the pivotal trials. We are confident that this phase 3 program should generate the evidence to support a regulatory filing and to support broad patient access through integration into healthcare systems."

Business highlights

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

- Phase 3 program underway, program composed of two pivotal trials with an integrated long-term outcomes component
 - Pivotal trial 1 (COMP 005): single dose monotherapy, n=255, top line data expected summer 2024
 - Updates to 005 accelerate data read out
 - Pivotal trial 2 (COMP 006): fixed repeat dose monotherapy, n=568, top line data expected mid-2025
 - Long term outcome component includes a single 25 milligram retreatment option for all qualifying patients
- Phase 2b trial published in *The New England Journal of Medicine*

Additional COMP360 development activities:

- Phase 2 trials in anorexia nervosa and post-traumatic stress disorder (PTSD) ongoing
- Investigator-initiated studies across numerous additional indications including:

- Bipolar disorder type II: data presented at ACNP showing treatment was well tolerated with 12 of 14 patients in remission at three months following a single 25 milligram administration of COMP 360 psilocybin therapy, and no subject having manic or hypomanic symptoms or an increase in suicidal ideation
- Anorexia nervosa: 6 of 10 participants in remission from Eating Disorder Psychopathology following a single 25 milligram administration of COMP 360, treatment was well tolerated and 9 of 10 participants endorsed the experience as meaningful and therapeutic; data presented at the Society of Biological Psychiatry annual meeting in April 2022.
- Major depressive disorder in adults: data from the University of Zurich published in *The Lancet* in December. This randomized blinded study enrolled 52 patients, comparing a weight based dose of COMP360 to true placebo, and demonstrated compelling efficacy results with no new safety signal.

Financial highlights

- Net loss for the year ended 31 December 2022 was \$91.5 million, or \$2.16 loss per share (including non-cash share-based compensation expense of \$13.1 million), compared with \$71.7 million or \$1.79 loss per share, during the same period in 2021 (including non-cash-share-based compensation expense of \$8.6 million).
- Net loss for the three months ended 31 December 2022 was \$30.9 million, or \$0.73 loss per share (including non-cash share-based compensation expense of \$3.3 million), compared with \$25.7 million or \$0.61 loss per share, during the same period in 2021 (including non-cash-share-based compensation expense of \$2.8 million).
- Research and development (R&D) expenses were \$65.1 million for the year ended 31 December 2022, compared with \$44.0 million during the same period in 2021. Of this increase, \$6.7 million relates to an increase in external development expenses as the Company continues to investigate COMP360 psilocybin therapy in clinical and pre-clinical trials. \$6.1 million relates to an increase in personnel expenses, due to increased headcount. A further \$5.4 million was attributable to increased other expenses primarily related to an increase in external consulting expenses. In addition, non-cash share-based compensation increased by \$2.8 million, due to increased headcount.
- R&D expenses were \$19.8 million for the three months ended 31 December 2022, compared with \$13.6 million during the same period in 2021. Of this increase, \$2.7 million was attributable to an increase in other expenses, which primarily related to an increase in external consulting expenses. A further \$2.3 million was attributable to an increase in external development expenses. Personnel expenses and non-cash share-based compensation increased by \$1.0 million and \$0.2 million respectively.
- General and administrative (G&A) expenses were \$45.4 million for the year ended 31 December 2022 compared with \$39.2 million during the same period in 2021. The increase was attributable to an increase of \$3.2 million in personnel expenses, due to increased headcount. A further \$2.8 million and \$1.7 million were attributable to legal and professional fees and non-cash share-based compensation respectively. The increases were offset by a decrease of \$1.5 million in facilities and other expenses.
- G&A expenses were \$12.4 million for the three months ended 31 December 2022 compared with \$14.7 million during the same period in 2021. The decrease was attributable to a decrease of \$2.6 million and \$1.0 million in facilities and other expenses and legal and professional fees respectively. This was partially offset by an increase of \$1.0 million in personnel expenses and an increase of \$0.3 million in non-cash share-based compensation expense, due to increased headcount.

- Cash and cash equivalents were \$143.2 million as of 31 December 2022, compared with \$273.2 million as of 31 December 2021.

Financial Guidance

- First quarter 2023 net cash used in operating activities is expected to be in the range of \$24 million to \$32 million and the full-year 2023 to be in the range of \$85 million to \$110 million.

Conference call

The COMPASS Pathways management team will host a conference call at 8.00am ET (1:00pm UK) on February 28, 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: Fourth Quarter and Year End 2022 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 therapy, 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 therapy in TRD, the largest randomised, controlled, double-blind psilocybin therapy 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 therapy 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 business strategy and goals, our expectations and projections about the company’s future financial results, the Company’s plans and expected timing for its phase 3 program in TRD and the potential for that or other trials to support regulatory filings and approvals, the Company’s expectations regarding amendments to its phase 3 protocols and results of ongoing discussions with FDA, the safety or efficacy of its investigational COMP360 psilocybin therapy, including for treatment of TRD, anorexia nervosa, PTSD, bipolar type II and major depressive disorder, 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: 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 will involve significant costs and resources and 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

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	December 31,	
	2022	2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 143,206	\$ 273,243
Restricted cash	175	104
Prepaid income tax	575	332
Prepaid expenses and other current assets	47,695	21,621
Total current assets	191,651	295,300
NON-CURRENT ASSETS:		
Investment	469	525
Property and equipment, net	617	398
Operating lease right-of-use assets	2,006	3,696
Deferred tax assets	2,224	766
Other assets	327	213
Total assets	\$ 197,294	\$ 300,898
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 4,761	\$ 2,564
Accrued expenses and other liabilities	9,325	10,308
Operating lease liabilities - current	1,510	2,235
Total current liabilities	15,596	15,107
NON-CURRENT LIABILITIES		
Operating lease liabilities - non-current	418	1,379
Total liabilities	16,014	16,486
Commitments and contingencies (Note 15)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 42,631,794 and 42,019,874 shares authorized, issued and outstanding at December 31, 2022 and 2021, respectively	440	435
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at December 31, 2022 and 2021	28	28
Additional paid-in capital	458,825	444,750
Accumulated other comprehensive (loss)/income	(16,867)	8,840
Accumulated deficit	(261,146)	(169,641)
Total shareholders' equity	181,280	284,412
Total liabilities and shareholders' equity	\$ 197,294	\$ 300,898

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,	
	2022	2021	2022	2021
OPERATING EXPENSES:				
Research and development	\$ 19,794	\$ 13,593	\$ 65,053	\$ 44,027
General and administrative	12,397	14,730	45,350	39,194
Total operating expenses	32,191	28,323	110,403	83,221
LOSS FROM OPERATIONS:	<u>(32,191)</u>	<u>(28,323)</u>	<u>(110,403)</u>	<u>(83,221)</u>
OTHER INCOME (EXPENSE), NET:				
Other income, net	481	38	4,061	40
Foreign exchange gains (losses)	(3,566)	(181)	821	1,990
Benefit from R&D tax credit	4,442	2,915	14,424	9,648
Total other income (expense), net	1,357	2,772	19,306	11,678
Loss before income taxes	<u>(30,834)</u>	<u>(25,551)</u>	<u>(91,097)</u>	<u>(71,543)</u>
Income tax expense	(92)	(99)	(408)	(199)
Net loss	<u>(30,926)</u>	<u>(25,650)</u>	<u>(91,505)</u>	<u>(71,742)</u>
Other comprehensive loss:				
Foreign exchange translation adjustment	13,776	1,076	(25,707)	(5,745)
Comprehensive loss	<u>(17,150)</u>	<u>(24,574)</u>	<u>(117,212)</u>	<u>(77,487)</u>
Net loss per share attributable to ordinary shareholders—basic and diluted	<u>\$ (0.73)</u>	<u>\$ (0.61)</u>	<u>\$ (2.16)</u>	<u>\$ (1.79)</u>
Weighted average ordinary shares outstanding—basic and diluted	<u>42,436,292</u>	<u>39,997,587</u>	<u>42,436,292</u>	<u>39,997,587</u>