

**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 03, 2022**

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 3, 2022, COMPASS Pathways plc (the “Company”) issued a press release announcing the Company's financial results for the three months and nine months ended September 30, 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 November 3, 2022
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 3, 2022

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



COMPASS Pathways Announces Third Quarter 2022 Financial Results and Business Highlights

London, UK – November 3, 2022

Highlights:

- Phase 3 pivotal program design finalized and on track to start in 2022; several clinical sites have been initiated
- Phase 2b trial data published in The New England Journal of Medicine
- Cash position at 30 September 2022 of \$173.1 million
- Conference call today at 8:00am ET (12:00pm 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 third quarter 2022 and gave an update on recent progress across its business.

George Goldsmith, Executive Chairman of COMPASS Pathways, said, "With the announcement of our pivotal Phase 3 COMP360 program design for treatment-resistant depression, we are another important step closer to our goal of bringing COMP360 psilocybin therapy to the large number of patients who are not currently served by existing therapies and urgently need new treatment options. We are also thrilled with the publication of the COMP360 Phase 2b trial in The New England Journal of Medicine, the world's leading peer-reviewed medical publication, reinforcing the rigour and scale of this study."

Kabir Nath, Chief Executive Officer added, "The COMP360 Phase 3 pivotal program in treatment-resistant depression is designed to generate the evidence required for regulatory approval and to ensure commercial success through integration into healthcare systems. We are on track to start the Phase 3 program this year and we are making steady progress toward establishing the full global footprint for this program, which includes actively initiating new sites and training therapists. We are also advancing the other important elements of our business that are tied to the COMP360 program, namely commercial and digital, which we featured in our recent Capital Markets Day presentation. Beyond this Phase 3 program, we continue to expand our clinical development of COMP360 psilocybin therapy with ongoing Phase 2 trials in anorexia nervosa and PTSD."

Business highlights

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

- Phase 3 program on track to commence in 2022
- Program composed of two pivotal trials and one long-term outcomes study
 - Pivotal trial 1 (COMP 005): single dose monotherapy, n=378
 - Top line data expected end 2024
 - Pivotal trial 2 (COMP 006): fixed repeat dose monotherapy, n=568
 - Top line data expected mid 2025

- Goal is to provide the evidence needed for FDA approval and payor reimbursement
- Several clinical sites have been initiated
- Phase 2b trial published in The New England Journal of Medicine
- Phase 2b long-term follow up study complete
 - Results supportive of Phase 3 program design

Additional COMP360 development activities:

- Phase 2 trials in anorexia nervosa ongoing across four world-leading research institutes in the UK and US (University of California San Diego School of Medicine, Sheppard Pratt, King's College London and Columbia University Medical Center)
- Phase 2 trial in post-traumatic stress disorder (PTSD) ongoing at Mt. Sinai Hospital in New York City and King's College London
- Investigator-led study in adults with autism spectrum disorder (ASD) launched, the first ever mechanistic study of psilocybin in autistic adults, co-sponsored by Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London and South London and Maudsley NHS Foundation Trust
- 10 granted patents issued to date covering composition, formulation and method of use
- Investigator-initiated studies underway across numerous additional indications

Financial highlights

- Net loss for the three months ended 30 September 2022 was \$18.4 million, or \$0.43 loss per share (including non-cash share-based compensation expense of \$3.5 million), compared with \$15.8 million or \$0.38 loss per share, during the same period in 2021 (including non-cash-share-based compensation expense of \$2.3 million).
- Net loss for the nine months ended 30 September 2022 was \$60.6 million, or \$1.43 loss per share (including non-cash share-based compensation expense of \$9.8 million), compared with \$46.1 million or \$1.17 loss per share, during the same period in 2021 (including non-cash-share-based compensation expense of \$5.9 million).
- Research and development (R&D) expenses were \$14.0 million for the three months ended 30 September 2022, compared with \$12.2 million during the same period in 2021. Of this increase, \$1.1 million was attributable to an increase in other expenses, which primarily related to an increase in external consulting expenses. A further \$0.8 million and \$0.6 million were attributable to personnel expenses and non-cash share-based compensation respectively, due to increased headcount. External development expenses decreased by \$0.8 million overall, primarily attributable to decreased clinical trial expenses which are expected to increase substantially in the near future as the Phase 3 program initiates.
- R&D expenses were \$45.3 million for the nine months ended 30 September 2022, compared with \$30.4 million during the same period in 2021. Of this increase, \$5.1 million relates to an increase in personnel expenses, due to increased headcount. \$4.5 million relates to an increase in external development expenses as the Company continues to investigate COMP360 psilocybin therapy in clinical and pre-clinical trials. A further \$2.7 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 \$2.5 million, due to increased headcount.
- General and administrative (G&A) expenses were \$11.6 million for the three months ended 30 September 2022 compared with \$9.6 million during the same period in 2021. The increase was attributable to an increase of \$0.6

million in legal and professional fees. A further increase of \$0.6 million and \$0.4 million was attributable to non-cash share-based compensation and personnel expenses respectively, due to increased headcount. There was an additional increase of \$0.4 million in facilities and other expenses.

- G&A expenses were \$33.0 million for the nine months ended 30 September 2022 compared with \$24.5 million during the same period in 2021. The increase was attributable to an increase of \$3.7 million in legal and professional fees. A further \$2.1 million and \$1.4 million were attributable to personnel expenses and non-cash share-based compensation respectively, due to increased headcount. There was an additional increase of \$1.2 million in facilities and other expenses.
- Cash and cash equivalents were \$173.1 million as of 30 September 2022, compared with \$273.2 million as of 31 December 2021.

Conference call

The COMPASS Pathways management team will host a conference call at 8.00am ET (1200 UK) on 3 November 2022.

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 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 US 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 completed a phase 2b clinical trial of psilocybin therapy for TRD, in 22 sites across Europe and North America and we are preparing to commence a phase 3 program by the end of 2022. This phase 2b trial was the largest randomised, controlled, double-blind psilocybin therapy clinical trial ever conducted, and our topline data showed 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 running phase 2 clinical trials 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 US. 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, the expected timing for starting our Phase 3 clinical program of COMP360 psilocybin therapy in TRD and expected timing for completing our Phase 3 program and providing top-line data, the safety or efficacy of its investigational COMP360 psilocybin therapy, including for treatment of TRD, anorexia nervosa or 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: preclinical and clinical development is lengthy and uncertain, and therefore our preclinical studies and clinical trials may be delayed or terminated, or may never advance to or in the clinic; 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
Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share amounts)

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

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 173,076	\$ 273,243
Restricted cash	155	104
Prepaid income tax	465	332
Prepaid expenses and other current assets	44,755	21,621
Total current assets	218,451	295,300
NON-CURRENT ASSETS:		
Investment	432	525
Property and equipment, net	555	398
Operating lease right-of-use assets	2,338	3,696
Deferred tax assets	2,445	766
Other assets	299	213
Total assets	\$ 224,520	\$ 300,898
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 19,885	\$ 2,564
Accrued expenses and other liabilities	7,817	10,308
Operating lease liabilities - current	1,831	2,235
Total current liabilities	29,533	15,107
NON-CURRENT LIABILITIES		
Operating lease liabilities - non-current	425	1,379
Total liabilities	29,958	16,486
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 42,554,384 and 42,019,874 shares authorized, issued and outstanding at September 30, 2022 and December 31, 2021, respectively	440	435
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at September 30, 2022 and December 31, 2021	28	28
Additional paid-in capital	454,957	444,750
Accumulated other comprehensive (loss)/income	(30,643)	8,840
Accumulated deficit	(230,220)	(169,641)
Total shareholders' equity	194,562	284,412
Total liabilities and shareholders' equity	\$ 224,520	\$ 300,898

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,	
	2022	2021	2022	2021
OPERATING EXPENSES:				
Research and development	\$ 13,977	\$ 12,197	\$ 45,259	\$ 30,434
General and administrative	11,559	9,571	32,953	24,464
Total operating expenses	25,536	21,768	78,212	54,898
LOSS FROM OPERATIONS:	<u>(25,536)</u>	<u>(21,768)</u>	<u>(78,212)</u>	<u>(54,898)</u>
OTHER INCOME, NET:				
Other income, net	3,206	—	3,580	2
Foreign exchange gains	1,096	3,364	4,387	2,171
Benefit from R&D tax credit	2,983	2,618	9,982	6,733
Total other income, net	7,285	5,982	17,949	8,906
Loss before income taxes	(18,251)	(15,786)	(60,263)	(45,992)
Income tax expense	(120)	(63)	(316)	(100)
Net loss	(18,371)	(15,849)	(60,579)	(46,092)
Other comprehensive loss:				
Foreign exchange translation adjustment	(15,156)	(8,401)	(39,483)	(6,768)
Comprehensive loss	(33,527)	(24,250)	(100,062)	(52,860)
Net loss per share attributable to ordinary shareholders—basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.38)</u>	<u>\$ (1.43)</u>	<u>\$ (1.17)</u>
Weighted average ordinary shares outstanding—basic and diluted	<u>42,525,855</u>	<u>41,708,220</u>	<u>42,377,895</u>	<u>39,378,824</u>