



COMPASS Pathways Announces Second Quarter 2023 Financial Results and Business Highlights

August 3, 2023

LONDON, Aug. 03, 2023 (GLOBE NEWSWIRE) --

Highlights:

- COMP360 Phase 3 pivotal program ongoing and on track
- CPT® III code for in-person psychedelic therapy support accepted by the American Medical Association
- Cash position at June 30, 2023 of \$148.2 million
- Term loan facility up to \$50 million secured
- Conference call today at 8:00 am ET (1:00 pm UK)

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

Kabir Nath, Chief Executive Officer, said, "This has been another quarter of steady, strong progress across the business, including the continued execution of our COMP360 phase 3 trials in treatment-resistant depression, important progress in laying the commercial groundwork for COMP360 with the recent acceptance by the American Medical Association of a CPT III code to describe the support services required during administration of psychedelic drugs, and the FDAs recently issued guidance on psychedelic drug development that represents an important validation of our area of science. Further, the cash received from the draw down from our debt facility with Hercules and sales of equity through our ATM program lengthened our cash runway significantly and allows us to continue to invest in our COMP360 development programs at full speed."

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
- Current Procedural Terminology (CPT®) III code language for in-person support services during psychedelic therapy approved by the American Medical Association and aligns with expected COMP360 treatment support requirements.

Additional COMP360 development activities:

- Phase 2 trials in anorexia nervosa and post-traumatic stress disorder (PTSD) ongoing
- Investigator-initiated study data in depression in cancer patients following single dose of COMP360 psilocybin presented at ASCO 2023
- Investigator-initiated study demonstrating the potential for COMP360 psilocybin treatment in female patients with anorexia nervosa published in *Nature Medicine*
- Opinion paper on the definition of "psychedelic-assisted psychotherapy" using psilocybin published in *American Journal of Psychiatry*
- Data from an open-label study that suggest that the use of selective serotonin reuptake inhibitor (SSRI) anti-depressants does not interfere with the potential therapeutic effect of COMP360 published in *Neuropsychopharmacology*

Financial highlights

- Cash and cash equivalents were \$148.2 million as of 30 June 2023, compared with \$143.2 million as of 31 December 2022.
 - Runway lengthened through term loan facility and sales of shares under the At the Market ("ATM") facility
- Long-term debt was \$28.1 million as of 30 June 2023, compared with \$0 million as of 31 December 2022.
- Received \$26.9 million in net proceeds through our ATM facility in second quarter and entered into a term loan agreement with Hercules Capital, Inc. (NYSE: [HTGC](#)) in June 2023 for up to \$50 million, with net proceeds after issuance costs of

\$28.8 million received in the second quarter. Total net cash provided by financing of \$55.9 million in the second quarter.

- Net loss for the three months ended 30 June 2023 was \$28.3 million, or \$0.62 loss per share (including non-cash share-based compensation expense of \$4.6 million), compared with \$21.0 million, or \$0.50 loss per share, during the same period in 2022 (including non-cash-share-based compensation expense of \$3.2 million).
- Net loss for the six months ended 30 June 2023 was \$52.5 million, or \$1.19 loss per share (including non-cash share-based compensation expense of \$8.6 million), compared with \$42.2 million, or \$1.00 loss per share, during the same period in 2022 (including non-cash-share-based compensation expense of \$6.3 million).
- Research and development (R&D) expenses were \$19.8 million for the three months ended 30 June 2023, compared with \$15.9 million during the same period in 2022. Of this increase, \$2.7 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 \$1.8 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 \$1.0 million, which primarily related to a decrease in external consulting expenses.
- R&D expenses were \$38.9 million for the six months ended 30 June 2023, compared with \$31.3 million during the same period in 2022. Of this increase, \$4.1 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 \$3.0 million and \$0.8 million were attributable to personnel expenses and non-cash share-based compensation respectively, due to increased headcount. Other expenses decreased by \$0.3 million, which primarily related to a decrease in external consulting expenses.
- General and administrative (G&A) expenses were \$12.8 million for the three months ended 30 June 2023, compared with \$11.3 million during the same period in 2022. The increase was attributable to an increase of \$1.0 million and \$0.5 million in non-cash share-based compensation and personnel expenses respectively, due to increased headcount. There was a further increase of less than \$0.1 million in facilities and other expenses and a decrease of \$0.1 million in legal and professional fees.
- G&A expenses were \$25.6 million for the six months ended 30 June 2023, compared with \$21.4 million during the same period in 2022. The increase was attributable to an increase of \$2.8 million and \$1.5 million in personnel expenses and non-cash share-based compensation respectively, due to increased headcount. There was a further increase of \$0.9 million in facilities and other expenses and a decrease of \$1.0 million in legal and professional fees.

Financial Guidance

Third quarter 2023 net cash (provided by)/used in operating activities is expected to be in the range of (\$2 million) to \$18 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 expect the full-year 2023 net cash used in operating activities to be in the range of \$80 million to \$90 million.

Conference call

The COMPASS Pathways management team will host a conference call at 8.00am ET (1:00pm UK) on August [3], 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: [Second 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, 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, PTSD and depression, COMPASS’s expectations regarding the potential impact of the CPT III codes on reimbursement for and access to COMP360 psilocybin treatment, if FDA approval is obtained 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>June 30,</u>	<u>December</u>
	<u>2023</u>	<u>31,</u>
		<u>2022</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$148,234	\$143,206
Restricted cash	251	175
Prepaid income tax	—	575
Prepaid expenses and other current assets	45,116	47,695
Total current assets	193,601	191,651
NON-CURRENT ASSETS:		
Investment	469	469
Property and equipment, net	482	617
Operating lease right-of-use assets	4,784	2,006
Deferred tax assets	3,054	2,224
Long-term prepaid expenses and other assets	7,444	327
Total assets	<u>\$209,834</u>	<u>\$197,294</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$1,982	\$4,761
Accrued expenses and other liabilities	8,617	9,325
Operating lease liabilities - current	2,176	1,510
Total current liabilities	12,775	15,596
NON-CURRENT LIABILITIES		
Long-term debt	28,124	—
Operating lease liabilities - non-current	2,539	418
Total liabilities	<u>\$43,438</u>	<u>\$16,014</u>
SHAREHOLDERS' EQUITY:		

Ordinary shares, £0.008 par value; 45,760,250 and 42,631,794 shares authorized, issued and outstanding at June 30, 2023 and December 31, 2022, respectively	471	440
Deferred shares, £21,921.504 par value; nil and one share authorized, issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	28
Additional paid-in capital	496,342	458,825
Accumulated other comprehensive (loss)	(16,728)	(16,867)
Accumulated deficit	<u>(313,689)</u>	<u>(261,146)</u>
Total shareholders' equity	<u>166,396</u>	<u>181,280</u>
Total liabilities and shareholders' equity	<u>\$209,834</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		Six months ended	
	June 30,		June 30,	
	2023	2022	2023	2022
OPERATING EXPENSES:				
Research and development	\$19,818	\$15,920	\$38,853	\$31,282
General and administrative	12,846	11,336	25,599	21,394
Total operating expenses	<u>32,664</u>	<u>27,256</u>	<u>64,452</u>	<u>52,676</u>
LOSS FROM OPERATIONS:	<u>(32,664)</u>	<u>(27,256)</u>	<u>(64,452)</u>	<u>(52,676)</u>
OTHER INCOME, NET:				
Other income, net	627	240	1,336	374
Foreign exchange gains	1,376	1,958	4,061	3,291
Benefit from R&D tax credit	2,520	4,077	6,836	6,999
Total other income, net	<u>4,523</u>	<u>6,275</u>	<u>12,233</u>	<u>10,664</u>
Loss before income taxes	<u>(28,141)</u>	<u>(20,981)</u>	<u>(52,219)</u>	<u>(42,012)</u>
Income tax expense	<u>(194)</u>	<u>(56)</u>	<u>(324)</u>	<u>(196)</u>
Net loss	<u>(28,335)</u>	<u>(21,037)</u>	<u>(52,543)</u>	<u>(42,208)</u>
Other comprehensive (loss) income:				
Foreign exchange translation adjustment	717	(17,134)	139	(24,327)
Comprehensive loss	<u>(27,618)</u>	<u>(38,171)</u>	<u>(52,404)</u>	<u>(66,535)</u>
Net loss per share attributable to ordinary shareholders—basic and diluted	<u>\$(0.62)</u>	<u>\$(0.50)</u>	<u>\$(1.19)</u>	<u>\$(1.00)</u>
Weighted average ordinary shares outstanding—basic and diluted	<u>45,565,991</u>	<u>42,474,987</u>	<u>44,153,772</u>	<u>42,110,161</u>