



COMPASS Pathways Announces First Quarter 2023 Financial Results and Business Highlights

May 11, 2023

LONDON, May 11, 2023 (GLOBE NEWSWIRE) --

Highlights:

- COMP360 Phase 3 pivotal program underway, patients have been treated in both trials
- CPT® III code for in-person psychedelic therapy support accepted by the American Medical Association
- Cash position at 31 March 2023 of \$117.1 million, additional \$26.9 million net cash raised through ATM facility to date in the second quarter
- 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, reported its financial results for the first quarter 2023 and gave an update on recent progress across its business.

Kabir Nath, Chief Executive Officer, said, "Our phase 3 pivotal trials in treatment-resistant depression are now underway and on track, with treatment being administered to patients across numerous sites. This is significant progress, indicating that with the necessary approvals and licenses in place, these sites can now focus completely on training and recruitment.

We have also made 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 in its administration. It has been a quarter of steady, strong progress, including productive, ongoing dialogue about the design of our pivotal trials with FDA."

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, top line data expected summer 2024
 - Pivotal trial 2 (COMP 006): fixed repeat dose monotherapy, n=568, top line data expected mid-2025
 - Long-term follow up in each trial will generate data on duration of response and potential effect of retreatment
- As expected, FDA feedback received on the COMP 005 and COMP 006 trials and the phase 3 program is continuing in accordance with previously announced study design
- Current Procedural Terminology (CPT®) III code for in-person support services during psychedelic therapy accepted by the American Medical Association - code expected to go into effect when published on January 1, 2024

Additional COMP360 development activities:

- Phase 2 trials in anorexia nervosa and post-traumatic stress disorder (PTSD) ongoing
- Investigator-initiated studies ongoing across a number of additional indications

Financial highlights

- Net loss for the three months ended 31 March 2023 was \$24.2 million, or \$0.57 loss per share (including non-cash share-based compensation expense of \$4.1 million), compared with \$21.2 million or \$0.50 loss per share, during the same period in 2022 (including non-cash-share-based compensation expense of \$3.1 million).
- R&D expenses were \$19.0 million for the three months ended 31 March 2023, compared with \$15.4 million during the same period in 2022. Of this increase, \$1.4 million was attributable to an increase in external development expenses as the company continues to investigate COMP360 psilocybin therapy in clinical and pre-clinical trials. \$1.2 million relates to an increase in personnel expenses, due to increased headcount. A further \$0.6 million was attributable to an increase in other expenses primarily related to an increase in external consulting expenses. In addition, non-cash share-based payment compensation increased by \$0.5 million, due primarily to increased headcount.
- G&A expenses were \$12.8 million for the three months ended 31 March 2023 compared with \$10.1 million during the same period in 2022. The increase was attributable to an increase of \$2.2 million in personnel expenses, due to increased headcount. \$0.9 million relates to an increase in facilities and other expenses. A further \$0.5 million was attributable to an

increase in non-cash share-based compensation, due primarily to increased headcount. This was partially offset by a decrease of \$0.9 million in legal and professional fees.

- Cash and cash equivalents were \$117.1 million as of 31 March 2023, compared with \$143.2 million as of 31 December 2022.
- Additional \$26.9 million net cash raised through ATM facility to date in the second quarter

Financial Guidance

- Second quarter 2023 net cash used in operating activities is expected to be in the range of \$22 million to \$30 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 May 11, 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: [First 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 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, its expectations and projections about the company's future financial results, COMPASS's plans and expected timing for its phase 3 program in TRD, including its expectations regarding the amendments to the Phase 3 protocols, results of discussions with the Food and Drug Administration, or FDA, the timing of the completion of its Phase 3 trials for TRD, 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 therapy, including for treatment of TRD, anorexia nervosa, and PTSD, COMPASS's expectations regarding the potential impact of the CPT III codes on reimbursement for and access to COMP360 psilocybin therapy, 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: 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; the American Medical Association may change the scope of the CPT III code prior to publication in July 2023, which may negatively impact our expectations regarding reimbursement for COMP360 psilocybin therapy, if approved, and our efforts to obtain coverage and reimbursement for our investigational COMP360 psilocybin therapy, 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.

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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>March 31</u> | <u>December 31,</u> |
|--|------------------|---------------------|
| | <u>2023</u> | <u>2022</u> |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$117,103 | \$143,206 |
| Restricted cash | 271 | 175 |
| Prepaid income tax | 71 | 575 |
| Prepaid expenses and other current assets | 50,381 | 47,695 |
| Total current assets | <u>167,826</u> | <u>191,651</u> |
| NON-CURRENT ASSETS: | | |
| Investment | 469 | 469 |
| Property and equipment, net | 612 | 617 |
| Operating lease right-of-use assets | 1,593 | 2,006 |
| Deferred tax assets | 2,598 | 2,224 |
| Other assets | 212 | 327 |
| Total assets | <u>\$173,310</u> | <u>\$197,294</u> |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| CURRENT LIABILITIES: | | |
| Accounts payable | \$3,875 | \$4,761 |
| Accrued expenses and other liabilities | 6,267 | 9,325 |
| Operating lease liabilities - current | 1,112 | 1,510 |
| Total current liabilities | <u>11,254</u> | <u>15,596</u> |
| NON-CURRENT LIABILITIES | | |
| Operating lease liabilities - non-current | 412 | 418 |
| Total liabilities | <u>11,666</u> | <u>16,014</u> |
| SHAREHOLDERS' EQUITY: | | |
| Ordinary shares, £0.008 par value; 42,779,485 and 42,631,794 shares authorized, issued and outstanding at March 31, 2023 and December 31, 2022, respectively | 442 | 440 |
| Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at March 31, 2023 and December 31, 2022 | 28 | 28 |
| Additional paid-in capital | 463,973 | 458,825 |
| Accumulated other comprehensive (loss) | (17,445) | (16,867) |
| Accumulated deficit | (285,354) | (261,146) |
| Total shareholders' equity | <u>161,644</u> | <u>181,280</u> |
| Total liabilities and shareholders' equity | <u>\$173,310</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)

| | <u>Three months ended March 31,</u> | |
|------------------------------|-------------------------------------|-----------------|
| | <u>2023</u> | <u>2022</u> |
| OPERATING EXPENSES: | | |
| Research and development | \$19,035 | \$15,362 |
| General and administrative | 12,753 | 10,058 |
| Total operating expenses | <u>31,788</u> | <u>25,420</u> |
| LOSS FROM OPERATIONS: | <u>(31,788)</u> | <u>(25,420)</u> |
| OTHER INCOME, NET: | | |
| Other income, net | 709 | 134 |
| Foreign exchange gains | 2,685 | 1,333 |

| | | |
|--|------------|------------|
| Benefit from R&D tax credit | 4,316 | 2,922 |
| Total other income, net | 7,710 | 4,389 |
| Loss before income taxes | (24,078) | (21,031) |
| Income tax expense | (130) | (140) |
| Net loss | (24,208) | (21,171) |
| Other comprehensive loss: | | |
| Foreign exchange translation adjustment | (578) | (7,193) |
| Comprehensive loss | (24,786) | (28,364) |
| Net loss per share attributable to ordinary shareholders—basic and diluted | \$(0.57) | \$(0.50) |
| Weighted average ordinary shares outstanding—basic and diluted | 42,725,863 | 42,036,563 |