



COMPASS Pathways plc announces first quarter 2022 financial results and business highlights

May 10, 2022

LONDON, May 10, 2022 (GLOBE NEWSWIRE) --

Highlights:

- End of phase II meeting held with FDA
- Award of Innovation Passport as part of the UK MHRA Innovative Licensing and Access Pathway ILAP
- Finalising phase III in TRD program design to be ready for second half of 2022
- Pioneering collaboration with King's College London and South London and Maudsley NHS Foundation Trust, to create The Centre for Mental Health Research and Innovation in the UK
- Cash position at 31 March 2022 of \$243.7 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 first quarter 2022 and gave an update on recent progress across its business.

George Goldsmith, Chairman, CEO and Co-founder, COMPASS Pathways, said, "COMPASS made great progress this quarter including a productive end-of-phase II FDA meeting and we are actively working to finalise our phase III programme. Moreover, we continue to push the boundaries of brain health research as we broaden our pipeline and partnerships. This includes our clinical trial of COMP360 therapy in post-traumatic stress disorder, or PTSD, a condition of significant unmet need for improved patient outcomes. Our strong cash position enables us to move forward at pace."

Business highlights

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

- Positive results from groundbreaking phase IIb clinical trial
- Positive results from open-label study of 25mg COMP360 psilocybin therapy as adjunct to selective serotonergic reuptake inhibitor, or SSRI, antidepressants
- End-of-phase II meeting held with FDA in April 2022
- Award of Innovation Passport as part of the UK MHRA Innovative Licensing and Access Pathway (ILAP).
- Finalising Phase III in TRD programme to be ready for second half of 2022
- FDA granted breakthrough therapy designation
- 10 granted patents issued to date covering composition, formulation and method of use

Additional COMP360 development programmes:

- Phase II trial in PTSD ongoing at Kings College London
- Investigator-led study in adults with autism spectrum disorder (ASD) announced, the first ever study of psilocybin in adults with ASD, co-sponsored by Institute of Psychiatry, Psychology & Neuroscience (IoPPN) at King's College London and South London and Maudsley NHS Foundation Trust
- Positive early signals seen in investigator-initiated studies in anorexia nervosa and severe treatment-resistant depression, presented at the Society of Biological Psychiatry Annual Meeting in New Orleans
- Investigator-initiated studies underway across additional indications including new study in autism sponsored
- Identification of new potential novel drug candidates through the COMPASS Discovery Center and an exclusive research project with Dr Matthias Grill
- Strategic partnership formed to launch The Centre for Mental Health Research and Innovation to accelerate research and develop new models of mental healthcare in the UK

Financial highlights

- Net loss for the three months ended 31 March 2022 was \$21.2 million, or \$0.50 loss per share (after including non-cash share-based compensation expense of \$3.1 million), compared with \$12.7 million or \$0.35 loss per share, during the same period in 2021 (after including non-cash-share-based compensation expense of \$1.7 million).

- R&D expenses were \$15.4 million for the three months ended 31 March 2022, compared with \$6.9 million during the same period in 2021. Of this increase, \$5.1 million was attributable to increased external development expenses as COMPASS progresses its COMP360 psilocybin therapy in TRD, and continues to explore additional indications and therapeutic approaches. A further \$2.6 million and \$1.0 million were attributable to personnel expenses and non-cash share-based compensation respectively, due to increased headcount. This was partially offset by a decrease of \$0.2 million in other expenses.
- G&A expenses were \$10.1 million for the three months ended 31 March 2022 compared with \$6.7 million during the same period in 2021. The increase was attributable to an increase of \$1.0 million and \$0.5 million in personnel expenses and non-cash share-based compensation respectively, due to increased headcount. There was a further increase of \$1.4 million in legal and professional fees and \$0.4 million in facilities and other expenses.
- Cash and cash equivalents were \$243.7 million as of 31 March 2022 compared with \$273.2 million as of 31 December 2021.

Conference call

The COMPASS Pathways management team will host a conference call at 1.00pm UK (8.00am ET) on 10 May 2022. The call can be accessed by dialing 1-800-926-7358 from the United States, 1-212-231-2914 internationally, and 0800-496-0823 from the UK, followed by the conference ID: 22018578

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), for treatment-resistant depression (TRD), and we have completed a phase IIb clinical trial of psilocybin therapy for TRD, in 22 sites across Europe and North America. This 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 a phase II clinical trial of COMP360 psilocybin therapy for post-traumatic stress disorder (PTSD). 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, 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 Annual Report on Form 10-K filed with the US Securities and Exchange Commission (SEC) on 24 February 2022 and in subsequent filings made by COMPASS with the 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)

	March 31,	December 31,
	2022	2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 243,684	\$ 273,243
Restricted cash	104	104
Prepaid income tax	—	332
Prepaid expenses and other current assets	22,764	21,621
Total current assets	266,552	295,300
NON-CURRENT ASSETS:		
Investment	508	525
Property and equipment, net	415	398
Operating lease right-of-use assets	3,056	3,696
Deferred tax assets	1,232	766
Other assets	334	213
Total assets	\$ 272,097	\$ 300,898
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,054	\$ 2,564
Accrued expenses and other liabilities	7,480	10,308
Operating lease liabilities - current	2,146	2,235
Total current liabilities	11,680	15,107
NON-CURRENT LIABILITIES		
Operating lease liabilities - non-current	843	1,379
Total liabilities	12,523	16,486
Commitments and contingencies (Note 15)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 42,464,566 and 42,019,874 shares authorized, issued and outstanding at March 31, 2022 and December 31, 2021, respectively	440	435
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at March 31, 2022 and December 31, 2021	28	28
Additional paid-in capital	448,271	444,750
Accumulated other comprehensive income	1,647	8,840
Accumulated deficit	(190,812)	(169,641)
Total shareholders' equity	259,574	284,412
Total liabilities and shareholders' equity	\$ 272,097	\$ 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 March 31,	
	2022	2021
OPERATING EXPENSES:		
Research and development	\$ 15,362	\$ 6,884
General and administrative	10,058	6,718
Total operating expenses	25,420	13,602
LOSS FROM OPERATIONS:	(25,420)	(13,602)
OTHER INCOME (EXPENSE), NET:		
Other income	134	1

Foreign exchange gains (losses)	1,333	(643)
Benefit from R&D tax credit	2,922	1,557
Total other income, net	4,389	915
Loss before income taxes	(21,031)	(12,687)
Income tax expense	(140)	(28)
Net loss	(21,171)	(12,715)
Other comprehensive (loss) income:		
Foreign exchange translation adjustment	(7,193)	1,988
Comprehensive loss	(28,364)	(10,727)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (0.50)	\$ (0.35)
Weighted average ordinary shares outstanding—basic and diluted	42,036,563	36,569,290