



COMPASS Pathways announces financial results for the fourth quarter and full year 2021 and business highlights

February 24, 2022

LONDON, United Kingdom, Feb. 24, 2022 (GLOBE NEWSWIRE) --

Highlights:

- Positive results from phase IIb COMP360 psilocybin therapy trial for treatment-resistant depression (TRD); rapid and sustained response for patients receiving a single 25mg dose of COMP360 psilocybin with psychological support
- Positive results from open-label study of 25mg COMP360 psilocybin therapy as adjunct to SSRI antidepressants in TRD
- Launch of phase II study of COMP360 psilocybin therapy for post-traumatic stress disorder (PTSD)
- New senior executives appointed: Dr Guy Goodwin as Chief Medical Officer, Mike Falvey as Chief Financial Officer, and Matt Owens as General Counsel and Chief Legal Officer
- Well capitalised with year-end 2021 cash position of \$273.2 million
- Conference call today at 1:00pm UK (8:00am ET)

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 full year 2021 and gave an update on recent progress across its business.

George Goldsmith, Chairman, CEO and Co-founder, COMPASS Pathways, said, "With our end-of-phase II meeting now scheduled with the FDA, we will be finalising our phase III programme design for an expected start in the second half of the year. Moving into phase III is another important step towards providing a much-needed therapeutic option for patients suffering with treatment-resistant depression and extends our leadership in this area of science with the most extensive evidence package to date. At the same time, we continue to broaden our pipeline through a phase II trial in PTSD, ongoing investigator-initiated studies, and development of new compounds through our Discovery Center and our partnership with Dr Matthias Grill of MiHKAL GmbH."

Business highlights

COMP360 psilocybin therapy in treatment-resistant depression (TRD)

- Positive results from groundbreaking phase IIb clinical trial; additional data shows patient improvements beyond reduction of depression symptoms, including in positive affect and quality of life
- Positive results from open-label study of 25mg COMP360 psilocybin therapy as adjunct to SSRI antidepressants in TRD
- End-of-phase II meeting scheduled with FDA for late April 2022
- Phase III programme expected to begin in second half of 2022

Additional COMP360 development programmes

- Phase II trial in post-traumatic stress disorder (PTSD) launched at King's College London
- Positive results reported from two investigator-led clinical studies in major depressive disorder, one of which has been published in The New England Journal of Medicine
- Additional investigator-initiated studies ongoing in multiple indications

Pipeline development

- Development of new product candidates through exclusive research project with Dr Matthias Grill of MiHKAL GmbH, complementing work being done at COMPASS's Discovery Center

Commercial exclusivity and intellectual property

- 10 granted patents issued to date covering composition, formulation and method of use
- Several additional patent filings completed

Senior executive appointments

- New senior executives appointed, including Dr Guy Goodwin as Chief Medical Officer, Mike Falvey as Chief Financial Officer, and Matt Owens as General Counsel and Chief Legal Officer

Financial highlights

- Net loss for the year ended 31 December 2021 was \$71.7 million, or \$1.79 loss per share (after including non-cash share-based compensation expense of \$8.6 million), compared with \$60.3 million or \$3.55 loss per share, during the same period in 2020 (after including non-cash-share-based compensation expense of \$18.0 million)
- Net loss for the three months ended 31 December 2021 was \$25.7 million, or \$0.61 loss per share (after including non-cash share-based compensation expense of \$2.8 million), compared with \$18.8 million, or \$0.52 loss per share, during the same period in 2020 (after including non-cash share-based compensation expense of \$1.4 million)
- Research & development (R&D) expenses were \$44.0 million for the year ended 31 December 2021, compared with \$23.4 million during the same period in 2020. The increase was attributable to an increase of \$16.1 million, \$6.0 million and \$0.4 million respectively in development expenses, personnel expenses and other expenses, partially offset by a reduction of \$1.8 million in non-cash share-based compensation, as COMPASS progresses its COMP360 psilocybin therapy in TRD, and continues to explore additional indications and therapeutic approaches
- R&D expenses were \$13.6 million for the three months ended 31 December 2021, compared with \$4.5 million during the same period in 2020. The increase was attributable to an increase of \$7.3 million, \$2.1 million and \$1.0 million respectively in development expenses, personnel expenses and non-cash share-based compensation partially offset by a reduction of \$1.3 million in other expenses
- General & Administrative (G&A) expenses were \$39.1 million for the year ended 31 December 2021, compared with \$28.0 million during the same period in 2020. The increase was attributable to an increase of \$7.9 million, \$1.8 million and \$9.0 million respectively in personnel expenses, legal and professional fees and facilities and other expenses partially offset by a reduction of \$7.6 million in non-cash share-based compensation expenses
- G&A expenses were \$14.7 million for the three months ended 31 December 2021 compared with \$7.0 million during the same period in 2020. The increase was attributable to an increase of \$2.2 million, \$0.5 million, \$1.0 million and \$4.0 million respectively in personnel expenses, non-cash share-based compensation, legal and professional fees and facilities and other expenses
- Cash and cash equivalents were \$273.2 million as of 31 December 2021 compared with \$190.3 million as of 31 December 2020

Conference call

The COMPASS Pathways management team will host a conference call at 1.00pm UK (8.00am ET) on 24 February 2022. The call can be accessed by dialling (833) 665-0659 from the United States, (914) 987-7313 internationally, and 0800 028 8438 from the UK, followed by the conference ID: 2825279. The call will also be webcast on the COMPASS Pathways website and archived for 30 days. For more information, please visit the COMPASS Pathways investor relations 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. 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; 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 Consolidated Balance Sheets

(in thousands, except share and per share amounts)
(expressed in US dollars, unless otherwise stated)

	<u>December 31,</u>	
	<u>2021</u>	<u>2020</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 273,243	\$ 190,327
Restricted cash	104	29
Prepaid income tax	332	—
Prepaid expenses and other current assets	21,621	12,048
Total current assets	<u>295,300</u>	<u>202,404</u>
NON-CURRENT ASSETS:		
Investment	525	529
Property and equipment, net	398	245
Operating lease right-of-use assets	3,696	—
Deferred tax assets	766	221
Other assets	213	57
Total assets	<u>\$ 300,898</u>	<u>\$ 203,456</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,564	\$ 2,747
Accrued expenses and other liabilities	10,308	4,148
Operating lease liabilities - current	2,235	—
Total current liabilities	<u>15,107</u>	<u>6,895</u>
NON-CURRENT LIABILITIES		
Operating lease liabilities - non-current	<u>1,379</u>	<u>—</u>
Total liabilities	<u>16,486</u>	<u>6,895</u>
Commitments and contingencies (Note 15)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 42,019,874 and 35,930,331 shares authorized, issued and outstanding at December 31, 2021 and 2020, respectively	435	367
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at December 31, 2021 and 2020	28	28
Additional paid-in capital	444,750	279,480
Accumulated other comprehensive income	8,840	14,585
Accumulated deficit	<u>(169,641)</u>	<u>(97,899)</u>

Total shareholders' equity	284,412	196,561
Total liabilities and shareholders' equity	<u>\$ 300,898</u>	<u>\$ 203,456</u>

COMPASS PATHWAYS PLC
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(expressed in US dollars, unless otherwise stated)

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
OPERATING EXPENSES:				
Research and development	\$ 13,593	\$ 4,544	\$ 44,027	\$ 23,366
General and administrative	14,730	6,975	39,194	28,027
Total operating expenses	<u>28,323</u>	<u>11,519</u>	<u>83,221</u>	<u>51,393</u>
LOSS FROM OPERATIONS:	<u>(28,323)</u>	<u>(11,519)</u>	<u>(83,221)</u>	<u>(51,393)</u>
OTHER INCOME (EXPENSE), NET:				
Other income, net	38	17	40	319
Foreign exchange gains (losses)	(181)	(8,450)	1,990	(11,702)
Fair value change of convertible notes	—	(10)	0	(1,041)
Fair value change of convertible notes - due to a related party	—	(7)	0	(730)
Benefit from R&D tax credit	2,915	1,070	9,648	4,245
Total other income (expense), net	<u>2,772</u>	<u>(7,380)</u>	<u>11,678</u>	<u>(8,909)</u>
Loss before income taxes	<u>(25,551)</u>	<u>(18,899)</u>	<u>(71,543)</u>	<u>(60,302)</u>
Income tax expense	(99)	93	(199)	(32)
Net loss	<u>(25,650)</u>	<u>(18,806)</u>	<u>(71,742)</u>	<u>(60,334)</u>
Other comprehensive income:				
Foreign exchange translation adjustment	1,076	10,910	(5,745)	14,683
Comprehensive loss	<u>\$ (24,574)</u>	<u>\$ (7,896)</u>	<u>\$ (77,487)</u>	<u>\$ (45,651)</u>
Net loss per share attributable to ordinary shareholders—basic and diluted	<u>\$ (0.61)</u>	<u>\$ (0.52)</u>	<u>\$ (1.79)</u>	<u>\$ (3.55)</u>
Weighted average ordinary shares outstanding—basic and diluted	<u>41,833,697</u>	<u>35,912,333</u>	<u>39,997,587</u>	<u>16,991,664</u>