

COMPASS Pathways plc announces financial results and business highlights for the second quarter 2021

2021-08-11

Highlights:

- Phase IIb COMP360 psilocybin therapy trial for treatment-resistant depression (TRD) close to completion; on track to report data by end of 2021
- Partnership being developed with leading UK institutions to accelerate psychedelic research and develop new models of mental health care in the UK
- Guy Goodwin appointed Chief Medical Officer and Danielle Schlosser appointed Senior Vice-President, Clinical Innovation
- “Everyone has a story: talking about mental health” podcast launched to eliminate stigma and open up dialogue
- Conference call today at 1:00pm UK (8:00am ET)

LONDON, Aug. 11, 2021 (GLOBE NEWSWIRE) -- COMPASS Pathways plc (Nasdaq: CMPS), a mental health care company dedicated to accelerating patient access to evidence-based innovation in mental health, today reported its financial results for the second quarter 2021 and gave an update on recent progress across its business.

George Goldsmith, Chairman, CEO and Co-founder, COMPASS Pathways, said, “We have completed psilocybin therapy administration in our COMP360 phase IIb trial, a significant milestone in our journey to bring new therapies to patients suffering with treatment-resistant depression. This is the largest trial ever conducted in psilocybin therapy, and it was done amid the lockdowns and challenges of the COVID pandemic. We are well-positioned for recruitment to phase III, pending results from the phase IIb study, which are expected later this year.”

Mr Goldsmith added, “We continue to invest in the expansion of our portfolio through new indications for psilocybin therapy and the discovery of new psychedelic compounds. We expect to see data this year from the investigator-initiated study of COMP360 psilocybin therapy in cancer patients, currently underway at Maryland

Oncology Hematology at the Aquilino Cancer Center, and plan to begin new studies in other indications over the next few months.”

Business highlights

- Phase IIb clinical trial of COMP360 psilocybin therapy for TRD close to completion
 - COMP360 psilocybin therapy has now been given to 233 patients, exceeding 216 target
 - On track to report top-line data by end of 2021
 - Dose-finding study comparing 25mg and 10mg of COMP360 psilocybin with 1mg, given in conjunction with psychological support from specially trained therapists
 - World’s largest psilocybin therapy trial, taking place in 22 sites across 10 countries
- Continued investment in the expansion of the COMPASS portfolio, exploring new indications through investigator-initiated studies (IISs) and new compounds through our Discovery Center
 - IIS at Maryland Oncology Hematology at the Aquilino Cancer Center, in the US, for COMP360 psilocybin therapy in cancer, due to finish and report data this year
- Partnership being developed to accelerate psychedelic research and develop new models of mental health care in the UK
 - Memorandum of Understanding signed with South London and Maudsley NHS Foundation Trust and the Institute of Psychiatry, Psychology and Neuroscience at King’s College London
 - Partnership intended to include research into areas of unmet need such as depression, post-traumatic stress disorder (PTSD) and anorexia nervosa
 - COMPASS is part of the working group that helped to establish mental health as one of the seven critical missions of the UK Government’s new life sciences strategy
- Team strengthened by new hires in all functions, with significant expansion in R&D and Digital
 - Professor Guy Goodwin appointed Chief Medical Officer, bringing deep experience and leadership in psychiatry; Professor Goodwin is Emeritus Professor of Psychiatry at The University of Oxford
 - Danielle Schlosser PhD appointed Senior Vice-President, Clinical Innovation, to lead therapist research and training, bringing her clinical experience in behavioural health and expertise in digital health innovation. Dr Schlosser joins from Verily Life Sciences, a sister company to Google
 - Leadership hires in clinical science, regulatory affairs, clinical safety, quality and manufacturing, in preparation for phase III, new compounds and additional indications

- Eight patents now granted covering COMPASS's novel crystalline polymorphic psilocybin, psilocybin formulations, methods of manufacturing psilocybin, and use of psilocybin for the treatment of psychiatric and neurological indications
 - Numerous additional patent applications under review including three Patent Cooperation Treaty (PCT) applications
- New podcast launched: "Everyone has a story: talking about mental health"
 - Aims to encourage dialogue around mental health challenges, in order to eliminate stigma and secure better care for those who are suffering

Financial highlights

- Net loss for the three months ended 30 June 2021 was \$17.5 million, or \$0.44 loss per share, (after including non-cash share-based compensation expense of \$1.9 million) compared with \$16.2 million, or \$1.65 loss per share, during the same period in 2020 (after including non-cash share-based compensation expense of \$9.7 million)
- Net loss for the six months ended 30 June 2021 was \$30.2 million, or \$0.79 loss per share, (after including non-cash share-based compensation expense of \$3.6 million) compared with \$24.8 million, or \$2.61 loss per share, during the same period in 2020 (after including non-cash share-based compensation expense of \$11.4 million)
- Research and development (R&D) expenses were \$11.4 million for the three months ended 30 June 2021, compared with \$6.7 million during the same period in 2020. Of this increase, \$4.7 million reflected increased development activities and \$1.4 million related to hiring additional staff, as COMPASS progresses its COMP360 psilocybin therapy in TRD, and continues to explore additional indications and therapeutic approaches. There was a reduction of \$1.7 million in non-cash share-based compensation expense compared with the same period in the prior year
- R&D expenses were \$18.2 million for the six months ended 30 June 2021, compared with \$12.0 million during the same period in 2020. Of this increase, \$5.3 million reflected increased development activities and \$2.2 million related to hiring additional staff, as COMPASS progresses its COMP360 psilocybin therapy in TRD, and continues to explore additional indications and therapeutic approaches. There was a reduction of \$1.8 million in non-cash share-based compensation expense compared with the same period in the prior year
- General and administrative (G&A) expenses were \$8.2 million for the three months ended 30 June 2021, compared with \$11.0 million during the same period in 2020. The decrease was attributable to reductions of

\$6.1 million and \$0.5 million respectively in non-cash share-based compensation and legal and professional fees, offset against an increase of \$1.8 million and \$2.0 million respectively in personnel expenses and facilities and other expenses

- G&A expenses were \$14.9 million for the six months ended 30 June 2021, compared with \$14.4 million during the same period in 2020. The increase was attributable to an increase of \$3.3 million and \$3.1 million respectively in personnel expenses and facilities and other expenses, offset against a decrease of \$6.1 million in non-cash share-based compensation expenses
- Cash and cash equivalents were \$316.3 million as of 30 June 2021, compared with \$190.3 million as at 31 December 2020. In May 2021, we closed an underwritten public offering, including the full exercise of the underwriters' greenshoe option, and received net cash proceeds of approximately \$154.8 million, after deducting underwriting discounts and commissions and other offering expenses

Conference call

The COMPASS Pathways management team will host a conference call at 1.00pm UK (8.00am ET) on 11 August 2021. The call can be accessed by dialing (833) 665-0659 from the United States, +1 (914) 987-7313 internationally, and 0800 028 8438 from the UK, followed by the conference ID: 3495828.

The call will also be webcast on the investors section of the COMPASS Pathways website (ir.compasspathways.com) and archived for 30 days.

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 are currently conducting a phase IIb clinical trial of psilocybin therapy for TRD, in 22 sites across Europe and North America. We are headquartered in London, UK, with offices in New York, 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 our ongoing preclinical work and clinical trials, including the development of potential new compounds and the expansion of indications for COMPASS’s investigational psilocybin therapy, the success of partnerships with third parties and academic institutions, the success of our hiring strategy, and the timing of the release of clinical data, including from our ongoing phase IIb clinical trial and from investigator-initiated studies. 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 20-F filed with the US Securities and Exchange Commission (SEC) on 9 March 2021 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.

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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)

	June 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash	\$316,334	\$190,327
Restricted cash	29	29
Prepaid income tax	104	—
Prepaid expenses and other current assets	17,568	12,048
Total current assets	334,035	202,404
Investment	536	529
Property and equipment, net	326	245
Deferred tax assets	221	221
Other assets	43	57
Total assets	\$335,161	\$203,456
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$3,894	\$2,747
Accrued expenses and other liabilities	3,907	4,148
Total current liabilities	7,801	6,895
Total liabilities	7,801	6,895
Commitments and contingencies (Note 13)		
SHAREHOLDERS' EQUITY:		
Ordinary shares, £0.008 par value; 41,695,335 and 35,930,331 shares authorized, issued and outstanding at June 30, 2021 and December 31, 2020, respectively	431	367
Deferred shares, £21,921.504 par value; one share authorized, issued and outstanding at June 30, 2021 and December 31, 2020	28	28
Additional paid-in capital	438,825	279,480
Accumulated other comprehensive income	16,218	14,585
Accumulated deficit	(128,142)	(97,899)
Total shareholders' equity	327,360	196,561
Total liabilities and shareholders' equity	\$335,161	\$203,456

COMPASS PATHWAYS PLC
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
OPERATING EXPENSES:				
Research and development	\$ 11,353	\$ 6,724	\$ 18,237	\$ 11,947
General and administrative	8,175	10,963	14,893	14,445
Total operating expenses	19,528	17,687	33,130	26,392
LOSS FROM OPERATIONS:	(19,528)	(17,687)	(33,130)	(26,392)
OTHER INCOME (EXPENSE), NET:				
Other income, net	1	164	2	179
Foreign exchange (losses) gains	(550)	1,001	(1,193)	1,079
Fair value change of convertible notes	—	(407)	—	(1,023)
Fair value change of convertible notes - due to a related party	—	(285)	—	(717)
Benefit from R&D tax credit	2,558	1,008	4,115	2,083
Total other income (expense), net	2,009	1,481	2,924	1,601
Loss before income taxes	(17,519)	(16,206)	(30,206)	(24,791)
Income tax expense	(9)	(43)	(37)	(43)
Net loss	(17,528)	(16,249)	(30,243)	(24,834)
Other comprehensive income:				
Foreign exchange translation adjustment	(355)	(685)	1,633	(1,033)
Comprehensive loss	\$ (17,883)	\$ (16,934)	\$ (28,610)	\$ (25,867)
Net loss per share attributable to ordinary shareholders—basic and diluted	\$ (0.44)	\$ (1.65)	\$ (0.79)	\$ (2.61)
Weighted average ordinary shares outstanding—basic and diluted	39,802,532	9,866,428	38,194,822	9,528,596