Reunion Neuroscience Provides Business Update and Reports Fiscal Third Quarter 2023 Financial Results

Company Completed Phase 1 Interim Data Analysis for Lead Asset, RE104, Which Showed Strong Safety and Tolerability with Differentiated Profile; Final Data Anticipated in Mid-2023

Continued to Strengthen Executive Team; Named Dr. Robert Alexander as Chief Medical Officer

At December 31, 2022, Reunion Held CAD $32.4 Million in Cash and Cash Equivalents

TORONTO, Feb. 14, 2023 (GLOBE NEWSWIRE) -- Reunion Neuroscience Inc. (NASDAQ: REUN, TSX: REUN) ("Reunion" or "the Company"), a clinical-stage biopharmaceutical company committed to developing innovative and patented therapeutic solutions for underserved mental health conditions, today provided a business update and reported fiscal results for the third quarter ended December 31, 2022.

"This was a transformative quarter for Reunion. We enter 2023 well positioned with both encouraging clinical data and a highly experienced executive leadership team in place to execute on our mission to rapidly and efficiently develop RE104 as a potential therapeutic option for the millions of patients underserved by today's standard of care in depression and other mental health disorders," said Greg Mayes, President and Chief Executive Officer, Reunion. "We recently announced our first ever clinical data where RE104 showed encouraging pharmacokinetic, pharmacodynamic and safety data. The analysis included a dose that demonstrated the short-duration and robust pharmacodynamic effects we believe are needed for clinical efficacy in Phase 2."

Mr. Mayes added, "We also welcomed Dr. Robert Alexander as Chief Medical Officer, an accomplished pharmaceutical executive who brings to Reunion a proven track record in psychopharmacology. We remain on track to share the results of our Phase 1 study with the FDA in preparation for Phase 2 development in postpartum depression (PPD) later this year."

Recent Clinical Developments

RE104

Reunion continues to advance RE104, the Company's patented, serotonergic psychedelic compound – and the only 4-OH-DiPT prodrug in development – through the clinic as a potential fast-acting, durable treatment for patients suffering from PPD.

In January 2023, Reunion completed its Phase 1 interim data analysis, which showed that RE104 was safe and well tolerated, with no serious or severe adverse events. The interim analysis included 32 healthy volunteers across four ascending dose cohorts, with two of the eight subjects in each cohort receiving placebo. RE104 demonstrated robust and pervasive pharmacodynamic effects with a shorter duration of psychedelic experience relative to published data with psilocybin (approximately three to four hours for RE104 versus six to eight hours for psilocybin).

After completing the preplanned interim analysis, and per the recommendation of the Safety Review Committee, Reunion continued with dose escalation to seek additional safety, pharmacokinetic and pharmacodynamic data. Exploring further doses with the two additional planned cohorts will provide Reunion with valuable data to inform selection of a recommended Phase 2 dose.

The Company has also submitted the Phase 1 data to an upcoming 2023 medical congress and to the FDA in preparation for initiating a randomized Phase 2 study evaluating RE104 versus placebo in the treatment of women with PPD in the second half of 2023. It is anticipated that the multicenter trial will enroll approximately 40 patients from 20 centers across North America.

PPD represents a priority clinical development opportunity with a high unmet need for new therapeutic options. One in eight mothers experience PPD, and there remains only one FDA-approved treatment for the condition, which is administered by continuous infusion over a 60-hour inpatient hospital stay and has a black box safety warning due to excessive sedation and potential for sudden loss of consciousness. Selective serotonin reuptake inhibitors (SSRIs) are also commonly prescribed for PPD, but they frequently have delayed onset, are not specifically approved for use in this setting and may require multiple trials to find an effective treatment solution.

As a novel serotonergic psychedelic, single-dose RE104 could potentially provide mothers with fast relief and a quick return to mother-child bonding and breastfeeding (an estimated 24 to 48 hours) due to RE104's limited-duration psychoactive experience (less than four hours), durable efficacy and rapid washout period.

Once the PPD Phase 2 program is in progress, Reunion plans to share its continued RE104 development strategy in pursuit of treating additional indications.

RE200 Series

Reunion continues to develop its RE200 series. These novel molecules include preclinical compounds with enhanced receptor selectivity to address additional therapeutic applications. They are structurally similar to classic psychedelics but have selective potency at the target serotonin 2A receptor (5HT2A) and are devoid of 5HT2B receptor agonism. Reunion continues to evaluate this series of compounds and is on track to identify a lead clinical candidate later this year.

Leadership Expansion

Since the appointment of Greg Mayes as President and CEO in September 2022, Reunion has bolstered its leadership team with several key hires – most recently, Robert Alexander as Chief Medical Officer. Dr. Alexander was a former executive at Takeda, Pfizer, AstraZeneca, GSK and Merck, with extensive experience in psychopharmacology, having conducted or supervised clinical studies in a broad range of neurologic and psychiatric indications.

Corporate Structure and Basis of Presentation

On August 11, 2022, the Company completed its previously announced spinout of its clinics and botanical research operations (Clinic Operations) to Field Trip Health & Wellness with the resulting drug discovery and development business renamed Reunion Neuroscience Inc., which is listed on the NASDAQ Stock Market and Toronto Stock Exchange under the ticker symbol “REUN”.

Reunion accounted for the Clinic Operations as discontinued operations whose assets and liabilities are classified and presented separately as current items held for transfer in the statement of financial position and are measured at their carrying amount. Clinic Operations are excluded from the results of continuing operations and are presented as a single amount as a net loss from discontinued Clinic Operations in the unaudited interim condensed consolidated statements of loss.

For more details on the spinout transaction, please refer to the Key Highlights and Recent Developments – Reorganization and Spinout of Clinic Operations section of the Company’s management’s discussion and analysis, available under the Company’s SEDAR profile at www.sedar.com.

Financial Highlights

Selected Condensed Consolidated Financial Information

The following table sets forth selected financial information derived from the Company’s unaudited consolidated financial statements for the fiscal third quarter 2023 ended December 31, 2022, prepared in accordance with IAS 34 in a manner consistent with the Company’s annual audited financial statements, which are reported under International Financial Reporting Standards and in Canadian dollars. The following information should be read in conjunction with the financial statements and management’s discussion and analysis, which are available on the Company’s website at www.reunionneuro.com and under the Company’s SEDAR profile at www.sedar.com.

Overview of Operations

The Company incurred general and administrative expenses of $3.1 and $9.0 million for the three and nine month periods ended December 31, 2022 compared to $4.6 and $7.9 million for the same periods in 2021. Changes for the three and nine month periods included increased costs attributable to increased headcount and other costs associated with becoming a public company with an increased scale of operations due to the Company entering the clinical stage for its lead asset RE104. The three month period ended December 31, 2021 also included a reclassification of approximately $2.0 million of general and administrative costs from discontinued operations to continuing operations.

Research and development expenses of $3.4 and $8.6 million were incurred for the three and nine month periods ended December 31, 2022 compared to $1.1 and $4.7 million for the same periods in 2021. Increases were attributable to personnel and third-party manufacturing and clinical research costs associated with the ongoing Phase 1 clinical trial for RE104.

Other income and expenses include interest income on the Company's cash and cash equivalents balances and foreign currency gains primarily attributable to the Company’s United States dollar holdings. The Company also recognized $5.7 and $15.3 million in charges for the three and nine months ended December 31, 2022 in recognition of (i) a loss allowance for its financial guarantee of certain lease obligations associated with entities that were part of the spinout of Clinic Operations and (ii) the Company’s equity share of loss and impairment of its investment in Field Trip Health & Wellness.

The Company recognized a net loss from discontinued operations of $10.4 million for the nine month period ended December 31, 2022. No such loss was incurred during the three month period ended December 31, 2022. This compares to a $9.1 and $28.7 million loss for the three and nine months ended December 31, 2021. Discontinued operations are attributable to the spinout of Clinic Operations completed on August 11, 2022.

The Company incurred a net loss from continuing operations of $12.5 million or $1.07 per share and $31.6 million or $2.72 per share for the three and nine month periods ended December 31, 2022 compared to a loss of $5.9 million or $0.51 per share and $11.8 million or $1.02 per share for the three and nine month periods ended December 31, 2021.

At December 31, 2022, the Company held cash, cash equivalents and investments of $32.4 million.

Conference Call

Reunion will conduct a conference call and webcast to discuss its results on February 14, 2023, at 8:30 a.m. ET. To access the call, please dial 1-877-407-9716 (within the U.S.) or 1-201-493-6779 (outside the U.S.) and provide conference ID 13736225. A live webcast of the conference call can be accessed via the “Events and Presentations” section of the Reunion investor relations website here.

For those who are unable to attend the live call, a telephone replay will be available until February 28, 2023, at 11:59 p.m. ET. To access the replay, dial 1-844-512-2921 (within the U.S.) or 1-412-317-6671 (outside the U.S.) and provide the conference ID above. The webcast will be archived and available in the “Events and Presentations” section of the Reunion investor relations website approximately one hour after the conclusion of the live call.

About Reunion Neuroscience Inc.

Reunion is committed to developing innovative therapeutic solutions for underserved mental health conditions. The Company’s lead asset, RE104, a proprietary, novel, serotonergic psychedelic compound and the only 4-OH-DiPT prodrug in clinical development, is being developed as a potential treatment for postpartum depression that could provide rapid symptom relief and durable efficacy. RE104 is protected under U.S. Patent No. 11,292,765 issued on April 5, 2022 (priority June 30, 2020), with claims for composition of matter, methods of manufacturing, formulations and methods of use for a genus of hemi-ester tryptamines, including RE104, which could provide protection out to June 30, 2041. Reunion is also developing the RE200 series, which includes preclinical compounds with enhanced receptor selectivity to address additional therapeutic applications.

Learn more at https://www.reunionneuro.com, and follow us on LinkedIn, Twitter and Instagram.

To be added to the Reunion Neuroscience email list, please opt-in at https://investors.reunionneuro.com/resources/email-alerts.

Cautionary Note Regarding Forward-Looking Information

This release includes forward-looking information (within the meaning of Canadian securities laws and within the meaning of the United States Private Securities Litigation Reform Act of 1995) regarding Reunion and its business. Often but not always, forward-looking information can be identified by the use of words such as "expect", "intends", "anticipates", "plans", "believes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", "should" or "will" be taken, occur or be achieved. Such statements are based on the current expectations and views of future events of the management of Reunion and are based on assumptions and subject to risks and uncertainties, many of which are beyond Reunion's control. Although the management of Reunion believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect. The forward-looking events and circumstances discussed in this release may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting the companies, including the funds available to Reunion and the use of such funds, the timing, completion and potential outcome of testing and research on Reunion's drug trial candidates, RE104 and the RE200 Series, including the ability to recruit patients, to retain and identify clinical partners, and to optimize dosage amounts, the likelihood and ability of Reunion to complete an investigational new drug application and obtain regulatory approvals, as required, prior to initiating further clinical trials for RE104 and molecules within the RE200 Series, the ability of Reunion to meet eligibility requirements for clinical testing and through to more complex clinical trials, the ability of Reunion to protect and expand its intellectual property portfolio, the performance of Reunion's affiliate, Field Trip Health & Wellness Ltd., the ability of Reunion to produce and supply its drug trial candidates, market conditions, economic factors, management's ability to manage and to operate the business, the equity markets generally and this and other Risk Factors disclosed in Reunion's public filings available on the SEDAR website at www.sedar.com and on the EDGAR section of the SEC's website at www.sec.gov. Although Reunion has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Accordingly, readers should not place undue reliance on any forward-looking statements or information. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made (or such earlier date, if identified) and Reunion does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise. Additional information relating to Reunion, including its Annual Information Form and Risk Factors, can be located on the SEDAR website at www.sedar.com and on the EDGAR section of the SEC's website at www.sec.gov.

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities.

Neither the Toronto Stock Exchange, nor its Regulation Services Provider, have approved the contents of this release or accept responsibility for the adequacy or accuracy of this release.

Reunion Neuroscience:
Greg Mayes
President & CEO
(215) 696-9659
gmayes@reunionneuro.com

Media Contact:
Shana Marino
KCSA Strategic Communications
(347) 487-6189
reunion@kcsa.com

REUNION NEUROSCIENCE INC. (FORMERLY FIELD TRIP HEALTH LTD.)
UNAUDITED INTERIM CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	As at December 31, 2022	As at March 31, 2022
	$	$
ASSETS		
Cash and cash equivalents	31,870,745	63,720,102
Restricted cash	515,258	776,551
Other assets	4,218,391	5,408,853
Property, plant and equipment	-	4,462,175
Intangible assets	-	483,354
Right-of-use assets	-	27,285,334
TOTAL ASSETS	**36,604,394**	**102,136,369**
LIABILITIES AND EQUITY		
Accounts payable and accrued liabilities	4,423,598	5,846,672
Financial guarantees	5,465,707	-
Deferred revenue	-	278,717
Loan payable	-	31,163
Lease obligations	-	29,021,056
TOTAL LIABILITIES	**9,889,305**	**35,177,608**

TOTAL EQUITY	**26,715,089**	**66,958,761**
TOTAL LIABILITIES AND EQUITY	**36,604,394**	**102,136,369**

REUNION NEUROSCIENCE INC. (FORMERLY FIELD TRIP HEALTH LTD.)
UNAUDITED INTERIM CONSOLIDATED STATEMENTS OF LOSS

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2022	**2021**	**2022**	**2021**
	$	**$**	**$**	**$**
Operating Expenses				
General and administration	3,132,439	4,612,937	9,004,853	7,878,149
Research and development	3,440,697	1,102,175	8,573,180	4,656,376
Total operating expenses	**6,573,136**	**5,715,112**	**17,578,033**	**12,534,525**
Other Income (Expenses)				
Interest income	232,842	91,115	415,047	320,593
Foreign exchange gain (loss)	(390,397)	(266,690)	846,681	401,540
Share of loss, lease loss allowance and impairment of investment in associate	(5,723,983)	-	(15,293,689)	-
Net loss from continuing operations	**(12,454,674)**	**(5,890,687)**	**(31,609,994)**	**(11,812,392)**
Net loss from discontinued Clinic Operations	-	(9,080,483)	(10,390,695)	(28,708,453)
NET LOSS	**(12,454,674)**	**(14,971,170)**	**(42,000,689)**	**(40,520,845)**
Net Loss per Share - Basic and Diluted	(1.07)	(1.30)	(3.61)	(3.51)
Net Loss per Share from continuing operations - Basic and Diluted	(1.07)	(0.51)	(2.72)	(1.02)

Source: Reunion Neuroscience Inc.