

# Braxia Scientific Reports Second Quarter 2022 Financial Results and Provides Corporate Update

- Expanded clinical infrastructure to support a growing portfolio of clinical trials of novel interventions and for drug discovery; 14 registered clinical trials in depression, led by Company CEO and Chief Medical and Scientific Officer, completed or in process
- Excellent progress on only psilocybin trial in Canada actively recruiting study participants to receive psilocybin-assisted therapy
- Clinical footprint in Canada has administered ~4,900 ketamine treatments to date; focus on expansion opportunities in the U.S. and Europe

TORONTO, Nov. 29, 2021 /CNW/ - Braxia Scientific Corp. ("Braxia Scientific", or the "Company"), (CSE: BRAX) (OTC: BRAXF) (FWB: 496), a medical research company with clinics providing innovative ketamine treatments for persons with depression and related disorders, today announced the filing of its fiscal second-quarter results for the three-month period ending September 30, 2021. Complete financial statements along with related management discussion and analysis can be found in the System for Electronic Document Analysis and Retrieval (SEDAR), the electronic filing system for the disclosure documents of issuers across Canada, at [www.SEDAR.com](http://www.SEDAR.com).

"We have made tremendous progress on our strategic priorities, including increasing access to novel treatments for patients with depression through our clinics. We have also established a clinical research infrastructure required to execute on our growing pipeline of registered clinical trials alongside third-party sponsors, with 14 trials registered to date in the area of depression, including Canada's first and only psilocybin trial actively recruiting study participants to receive psilocybin-assisted therapy," said Dr. Roger McIntyre, CEO, Braxia Scientific.

"Looking ahead to our clinical research and development, our psilocybin trial is underway with newly trained therapists. These therapists have the required skills to execute a successful psilocybin-assisted therapy trial while ensuring patients receive treatments according to approved protocols and best practices – critical milestones that will create near-term value for Braxia Scientific in terms of patient access, drug development and implementation. While our product development pipeline is at an early stage, we have made progress in our goal to develop new ketamine derivatives and delivery formats underpinned by our large proprietary health database from administering ~4,900 ketamine treatments to date at our clinics."

"We continue to prioritize the expansion of our clinical footprint in Canada. We remain disciplined in our growth efforts and continue to actively assess a strong pipeline of opportunities to scale access to ketamine treatments for patients in North America."

## **Recent Operational Highlights and Corporate Update**

### **Established Clinical Infrastructure to Advance Research and Drug Development and Provide Patient Access to Ketamine, Psilocybin and other Potential Psychedelics in Future**

Building on management's extensive clinical expertise, the Company has expanded the necessary infrastructure to provide novel interventions that include ketamine, psilocybin and other potential future psychedelics that become available.

More specifically, the Company infrastructure has:

- Established access to a high-quality source of psilocybin that meets all regulatory requirements for human use in clinical research
- Received over 100 referrals for psilocybin-assisted therapy at our clinic in the first six weeks of opening patient recruitment approved protocols to collect treatment outcome data to allow for further optimization of treatment protocols and development of best practice guidelines
- Established well-trained medical and research staff to assess patients for psilocybin suitability. This includes twenty (20) therapists licensed to practice in Ontario with specialized training in psilocybin-assisted therapy
- Built physical space to safely provide psilocybin treatment with a comfortable living room-like environment with appropriate medical and psychological monitoring and evidence-based protocols

This infrastructure enables Braxia Scientific to provide psilocybin-assisted therapy as part of the current clinical trial, and importantly, if psilocybin is approved in the future, Braxia Scientific is positioned to provide access to psilocybin-assisted therapy treatment for eligible patients immediately.

**Fourteen (14) Clinical Trials Including Landmark Multi-Dose Psilocybin Study:** Dr. Joshua Rosenblat, Chief Medical and Scientific Officer for Braxia Scientific, recently commenced a landmark clinical trial to conduct Canada's first multiple-dose controlled psilocybin study for treatment-resistant depression (TRD). Through this trial, patients will be able to receive immediate access to psilocybin and be monitored by therapists with specialized training in psilocybin-assisted therapy. Whereas most other TRD studies limit participation to patients that have not found relief from a maximum of five other potential remedies, this trial does not impose an upper limit, and allows for patients that have endured dozens of unsuccessful medical treatments, including with ketamine and electroconvulsive therapy.

**Developing the Next Generation of Clinicians:** The Braxia Institute, the Company's training centre focused on advancing psychiatric clinical practice and health services of ketamine and psychedelic treatment therapy, is set to graduate the first cohort of medical professionals from its psilocybin-assisted therapy training program. This multidisciplinary group of 20 therapists from diverse psychiatry and psychotherapy backgrounds experienced and learned, through pre-readings, didactic teaching, peer teaching, group discussion and simulations, which provided important background on the use of psilocybin for treating depression and practical considerations for providing psilocybin-assisted psychotherapy. All the enrolled therapists are also required to complete a practicum component, in which medical professionals gain experience in administering psilocybin-assisted therapy for participants with depression as part of an upcoming Health Canada-approved clinical trial.

The Company anticipates that, subject to the regulatory approval of psilocybin, therapists would also be trained to implement psychedelics in clinical practice.

**Growing Proprietary Ketamine Research Database:** As the Company continues to focus on developing novel ketamine derivatives, Braxia Scientific's team of researchers also continue to carry out multiple research trials adding to the Company's large database of proprietary data critical to future drug development efforts.

The Canadian Rapid Treatment Centre of Excellence (CRTCE), a wholly owned Braxia subsidiary, has comprehensive health data from administering approximately 4,900 ketamine treatments at CRTCE clinics. Braxia Scientific's researchers have published [39 ketamine-related manuscripts](#) in peer-reviewed biomedical journals.<sup>1</sup>

During the quarter, the Company reported encouraging preliminary findings of an important ketamine clinical study that suggest ketamine may be as effective as a standalone antidepressant, versus as an adjunctive therapy. The study, which was conducted at the CRTCE, showed comparable clinical benefits (e.g., antidepressant effects and reduction in suicidal thoughts) in a sample of 220 patients with treatment-resistant depression (TRD) who received intravenous (IV) ketamine infusions as a monotherapy, as compared with those receiving IV ketamine in addition to oral antidepressants.

Following the study protocols, participants in the ketamine monotherapy group achieved response and remission rates of 39.1% and 17.4%, respectively. Meanwhile, those receiving ketamine treatment adjunct to antidepressants, saw corresponding rates of 21.9% and 6.7%.

These initial findings support ketamine's effectiveness as a rapid-acting antidepressant treatment approach as evidenced by its ability to improve depression as a monotherapy, and the data is particularly important, because it shows that the benefits of ketamine may not be dependent on the co-prescription of other medications.

**Publishing timely studies:** Braxia Scientific was pleased to announce the publication of a new analysis led by the Company's CEO, Dr. Roger McIntyre, in the *Journal of the Royal Society of Medicine*. The study, which showed a decrease in the Canadian suicide mortality rate during the first year of the COVID-19 pandemic, was initiated to evaluate the impact on national suicide rates in Canada of federal, public health and social support programs that were put in place to mitigate the coinciding abrupt changes to social and financial provisions. The findings also underscore Braxia Scientific's core objective to develop derivatives of ketamine and other psychedelics as additional measures to further reduce suicidality.

**Growing Canadian Patient Treatments:** To accommodate increasing demand for ketamine treatments, the Company expects to commence expansion of its existing clinics in Toronto and Ottawa in the coming months, as well as ramp up personnel at its existing clinics. Through its four multidisciplinary, community-based Canadian clinics, the Company continues to see increased patient referrals and treatments which led to a year-over-year increase in revenue of nearly 55% in the second quarter of fiscal 2022.

**North American Clinic Expansion** – Following the publication by the *American Journal of Psychiatry* of the international guidelines and best practices for clinicians on the use of IV ketamine, which is based on research conducted by the Company's research team, including CEO Dr. Roger McIntyre and Chief Medical and Scientific Officer Dr. Joshua Rosenblat, at CRTCE, the Company remains focused on expanding its clinical footprint beyond Canada into the U.S. and Europe. The Company continues to be disciplined in deploying capital towards acquisition initiatives.

**Cultivating Name Recognition:** Braxia Scientific was featured in recent national and local news coverage, discussing access and promoting the use of ketamine to treat brain-based illnesses, bolstering the Company's brand awareness. Braxia Scientific CEO Dr. Roger McIntyre was featured on CTV's *W5*, Canada's most-watched current affairs and documentary program. The episode, entitled "Psychedelic Healing," aired on [October 23, 2021](#).

Braxia Scientific and the CRTCE were also highlighted in a recent article by *Toronto Life*, a monthly magazine. In the piece, Dr. McIntyre and Dr. Rosenblat discussed the benefits of ketamine therapy to rapidly treat mental disorders like treatment-resistant depression (TRD) and the access to the treatments Braxia Scientific provides through its clinics.

## Second Quarter Financial Summary

The Company's cash and cash equivalents as of September 30, 2021, was \$9,614,977, compared with \$10,257,750 at June 30, 2021.

The Company recorded revenue of \$385,525 for the second quarter fiscal 2022, ended September 30, 2021 compared with revenue of \$249,049 in the second quarter ended September 30, 2020, reflecting 54.8% increase year-over-year. Second quarter 2022 gross margin was \$57,140, compared with \$3,603 in the prior year period. Revenues consisted primarily of sales from the administering of ketamine infusion treatments at the CRTCE clinics in Ontario.

Net loss for the quarter decreased 16%, to \$1,709,942 including a non-cash share-based compensation expense of \$821,748, compared to a net loss of \$2,052,580 in the second quarter of the prior year period.

## Looking Ahead

"Braxia Scientific's value proposition rests in our superior human capital, well established clinical infrastructure and large proprietary health database," said Dr. McIntyre. "Our team includes three researchers ranked among the world's top 25 in [depression](#), as well as mood disorders research. Having conducted or registered 14 clinical trials for depression, we believe Braxia Scientific has a distinct competitive advantage among the leading groups endeavouring to research and develop new psychedelic treatments. With this expertise and data, we will work to enhance our intellectual property, including and developing new chemical entities, while providing patients with access to new pathways to treat their mental health disorders."

## About Braxia Scientific Corp.

Braxia Scientific is a medical research company with clinics that provide innovative ketamine treatments for persons with depression and related disorders. Through its medical solutions, Braxia aims to reduce the illness burden of brain-based disorders, such as major depressive disorder among others. Braxia is primarily focused on (i) owning and operating multidisciplinary clinics, providing treatment for mental health disorders, and (ii) research activities related to discovering and commercializing novel drugs and delivery methods. Braxia seeks to develop ketamine and derivatives and other psychedelic products from its IP development platform. Through its wholly owned subsidiary, the Canadian Rapid Treatment Center of Excellence Inc., Braxia currently operates multidisciplinary community-based clinics offering rapid-acting treatments for depression located in Mississauga, Toronto, Ottawa, and Montreal.

## ON BEHALF OF THE BOARD

"Dr. Roger S. McIntyre"  
Dr. Roger S. McIntyre

Chairman & CEO

The CSE has not reviewed and does not accept responsibility for the accuracy or adequacy of this release.

## Forward-looking Information Cautionary Statement

This news release contains forward-looking statements within the meaning of applicable securities laws. All statements that are not historical facts, future estimates, plans, programs, forecasts, projections, objectives, assumptions, expectations, or beliefs of future performance are "forward-looking statements."

Forward-looking statements include statements about the intended promise of ketamine-based treatments for depression and the potential for ketamine to treat other emerging psychiatric disorders, such as Bipolar Depression. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, events, or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements. Such risks and uncertainties include, among others, the failure of ketamine, psilocybin and other psychedelics to provide the expected health benefits and unanticipated side effects, dependence on obtaining and maintaining regulatory approvals, including acquiring and renewing federal, provincial, municipal, local or other licenses and engaging in activities that could be later determined to be illegal under domestic or international laws. Ketamine and psilocybin are currently Schedule I and Schedule III controlled substances, respectively, under the

Controlled Drugs and Substances Act, S.C. 1996, c. 19 (the "CDSA") and it is a criminal offence to possess such substances under the CDSA without a prescription or a legal exemption. Health Canada has not approved psilocybin as a drug for any indication, however ketamine is a legally permissible medication for the treatment of certain psychological conditions. It is illegal to possess such substances in Canada without a prescription. These factors should be considered carefully, and readers are cautioned not to place undue reliance on such forward-looking statements.

Although the Company has attempted to identify important risk factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other risk factors that cause actions, events or results to differ from those anticipated, estimated or intended. Additional information identifying risks and uncertainties that could affect financial results is contained in the Company's filings with Canadian securities regulators, including the Amended and Restated Listing Statement dated April 15, 2021, which are available at [www.sedar.com](http://www.sedar.com). There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in forward-looking statements.

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