News

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PharmaTher Reports Financial Results for the Third Quarter of Fiscal 2022 and Provides Recent Business Highlights and Update

Nearly $12 million in cash and investment

Fully funded for the Company's development programs, including ketamine injection and infusion product, ketamine microneedle patch and ketamine wearable pump device for mental health, neurological, and pain disorders

Seeking FDA approval for KETARX™ (ketamine injection and infusion product) for anesthesia and procedural sedation

TORONTO, April 25, 2022 -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a leader in specialty ketamine pharmaceuticals, today reported financial results for its third quarter ended February 28, 2022, and provided recent business highlights and update. All amounts are stated in Canadian dollars unless otherwise

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"We have made great progress with our product and clinical development programs for ketamine as a novel treatment use for near-rare and rare disorders, while also creating unique product profiles including injectables/infusions, microneedle patch and a proposed wearable pump device where each will provide a unique solution to treat various mental health, neurological and pain disorders in hospitals, clinics and homes," said Fabio Chianelli, Chief Executive Officer of PharmaTher. "We are focused on becoming a leader in advancing ketamine to treat unmet medical needs, and we are funded to complete our development programs for clinical studies and our expected submission for FDA approval of our ketamine injectable and infusion product for anesthesia and procedural sedation by the end of 2022."

Third-Quarter Financial Highlights

- Cash and cash equivalents totaled $10,165,170 and Investment totaled $1,666,667 for a total of $11,831,837 as at February 28, 2022; and
- Accounts payable and accrued liabilities totaled $140,947 as at February 28, 2022.

Recent Business Highlights

- Entered into a research collaboration agreement with Revive Therapeutics Ltd. (CSE: RVV) (OTCQB: RVVTF) for the development of a psilocybin microneedle patch;
- Granted U.S. Patent No. 11,213,495 and Japanese Patent No. 6967532 for the combination formulation of FDA-approved ketamine and betaine anhydrous ("KETABET™"), which has shown in research to enhance the antidepressant effect while having the potential to reduce the known negative side effects of ketamine significantly;
- Completed its first research study evaluating its proprietary microneedle patch for delivering lysergic acid diethylamide ("LSD") and psilocybin;
- Entered into a process development agreement with LTS LOHMANN Therapie-Systeme AG for the clinical trial scale-up of PharmaTher's proprietary ketamine microneedle patch product;
- The U.S. Food and Drug Administration ("FDA") accepted an investigator-initiated investigational new drug

Lateral Sclerosis, also known as Lou Gehrig's disease;

- The FDA granted orphan drug designation ("ODD") for ketamine to treat Status Epilepticus, a rare neurological disorder requiring emergency treatment for a seizure, which adds to the Company's current FDA ODD portfolio for ketamine to treat amyotrophic lateral sclerosis and complex regional pain syndrome;
- Announced positive topline results from the dose-finding and tolerability clinical study (the "Study") of ketamine for the treatment of levodopa-induced dyskinesia in patients with Parkinson's disease. The Study results are adequate to give an effect size in powering a Phase 3 clinical study; and
- Entered into an exclusive worldwide license agreement with Gesval S.A., a public limited company incorporated by the University of Liège, Belgium, for the development and commercialization of a patented continuous-flow process technology for the preparation of ketamine and ketamine analogs.

Business Update

PharmaTher is developing and commercializing novel uses, delivery forms and formulations of ketamine and ketamine analogs. Ketamine was approved by the FDA in 1970 and is clinically used for analgesia, sedation, and anesthetic induction. Ketamine is also emerging as a viable treatment option for various mental health, neurological and pain disorders.

As part of its short-term product strategy, the Company is developing its own ketamine injection and infusion product to support the Company's expected pivotal clinical studies for Parkinson's disease and Amyotrophic Lateral Sclerosis (Lou Gehrig's disease), future FDA 505(b)(2) regulatory submissions in mental health, neurological and pain disorders, and its commercialization plans in the U.S. via an FDA Abbreviated New Drug Application ("ANDA") for anesthesia and procedural sedation. The Company expects to file the ANDA in Q4-2022 for commercialization in the U.S.

The Company's long-term product strategy is to develop novel

device for the intradermal and subcutaneous delivery of ketamine, respectively, for specific indications including treatment-resistant depression, chronic pain and next-generation product profiles for neurological disorders.

The Company's clinical strategy includes supporting an investigator-initiated observational study to evaluate the impact of betaine anhydrous on the unwanted ketamine side effects seen post ketamine treatment for subjects with depression. The Company expects results to be reported in Q2-2022. In addition, the Company is preparing to engage the FDA to establish the next steps for a planned Phase 3 clinical study to allow for ketamine's approval for Parkinson's disease under the 505(b)(2) regulatory pathway. The Company plans to use its proprietary ketamine infusion product, KETARX™, for the planned Phase 3 clinical study. Full results of the Study are expected to be submitted for presentation at a medical congress by June 2022.

Furthermore, the Company expects to form partnerships with research labs, ketamine clinics and pharmaceutical companies that are: seeking a secure supply of cGMP ketamine and ketamine products for current portfolios; exploring alternative dosage forms of ketamine for multiple existing indications; developing novel ketamine analogs; and requiring support to develop and eventually commercialize specific ketamine products for new indications.

Lastly, the Company is engaged in partnering discussions for its microneedle patch delivery system to deliver psychedelics, such as LSD, DMT, MDMA, and mescaline, with specialty pharmaceutical companies.

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is focused on the development and commercialization of specialty ketamine pharmaceuticals for mental health, neurological, and pain disorders. Learn more at PharmaTher.com.

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Comments are closed.

Publicly-traded on the OTCQB: **PHRRF** and CSE: **PHRM**