# **PSYENCE GROUP CORPORATE UPDATE**

# Highlights:

- Drug development, Phase IIb clinical trial advanced planning underway in Australia
- Psyence granted worldwide licensing agreement to commercialize Filament's PEX010 (25 mg) in palliative care with exclusivity in key markets
- Successful completion of exports of medical grade psilocybin mushrooms to three key global markets
- Extraction capabilities enhanced at Psyence's production facility
- Christopher Bull appointed to the board of directors to drive Psyence's intellectual property strategy

## TORONTO, ON/ July 12, 2023 / Psyence Group Inc. (CSE: PSYG | OTCQB: PSYGF)

("**Psyence**" or the "**Company**") is pleased to provide the following corporate update on its strategic focus areas namely: **Psyence Therapeutics** and **Psyence Production**. The Psyence Group develops and provides innovative, safe, and effective psychedelic and nature-centered solutions for mental health and palliative care.

Since Psyence's corporate update issued in June 2022, the Company has made significant progress in its clinical trial programs and in upgrading its production facility and extraction capabilities. Psyence is executing on its strategy and is pleased to provide an update across the pillars of the business.

# **PSYENCE THERAPEUTICS**

Psyence is designing market-leading clinical trials in the field of palliative care, which will initially be conducted in Australia.

Psychiatrists in Australia will be able to prescribe psilocybin and Methylenedioxymethamphetamine (**MDMA**) for controlled clinical use for certain mental health disorders from 1 July 2023. Australia's medicines regulator, the Therapeutic Goods Administration, announced the change in February 2023.

## Phase IIb Clinical Trial in Australia

Psyence has partnered with iNGENū CRO Pty Ltd (**iNGENū**) to jointly design and conduct Psyence's Phase IIb clinical trial for psilocybin assisted psychotherapy in Australia. The Australian Federal Government's Research & Development tax incentive program makes Australia a very cost-effective environment to undertake clinical research.

The Phase IIb study will evaluate psilocybin assisted psychotherapy, using three different dose strengths of psilocybin in patients with adjustment disorder due to a recent terminal cancer diagnosis.

Psyence has submitted the Phase IIb study protocol to a Health Research Council Ethics Committee (**HREC**) in Australia for review and approval. Initial HREC feedback has been received and their suggestions are being addressed in the protocol. HRECs review research proposals that involve human participants in order to ensure that they meet ethical standards and guidelines.

A Principal Investigator and Chief Investigator have been contracted for the clinical trial. Potential clinical sites are currently being assessed, and thus far one site has been engaged. Patient recruitment will commence once the HREC's final approval for the study has been received.

Psyence has also submitted the study protocol to the United States Food and Drug Administration (**FDA**) as part of its pre-Investigational New Drug (**IND**) application. The pre-IND review provides commentary and direction for a clinical development program on what will be acceptable for a New Drug Application (**NDA**) and marketing approval by the FDA. Guiding comments have been received from the FDA and will be taken into account for the design of the Phase IIb study as well as for the planning of subsequent Phase III study design.

Upon successful completion of the Phase IIb study in Australia, Psyence aspires to conduct a multinational Phase III registrational program.

## Worldwide Licensing Agreement for Psilocybin Capsule for Palliative Care

In December 2022, Psyence and Filament Health Corp. (**Filament**), a clinical-stage natural psychedelic drug development company, signed a royalty-bearing, worldwide commercial licensing agreement, which expanded on its existing research licensing agreement announced previously in April 2022.

Under the terms of the initial agreement, Filament had licensed its natural psilocybin drug candidate, PEX010 (25 mg) and the associated intellectual property, to Psyence for use in Psyence's upcoming clinical trials. Filament has previously received authorisation from the FDA and Health Canada to enter into Phase I and Phase II human clinical trials for the PEX010 drug candidate.

The expanded agreement grants Psyence the worldwide right to commercialize PEX010, within the context of palliative care, with exclusivity in the USA, EU, and UK.

# **PSYENCE PRODUCTION**

Psyence operates one of the first government-licensed commercial psilocybin production facilities in the world. Its production facility, located in Southern Africa, is ISO22000 certified and is licensed to cultivate and export psilocybin mushrooms for the legal, global medical market and commercial medical research market.

#### Successful Exports of Medical Grade Psilocybin Mushrooms to key Global Markets

Psyence has concluded three successful exports of medical grade psilocybin mushrooms to Canada, Portugal, and the UK.

In January 2023, Psyence successfully exported pharma-grade psilocybin extract to the UK and a further export is now underway. Psyence's Contract Development & Manufacturing Organisation (**CDMO**) partner is using the extract to develop standardised pharmaceutical grade psilocybin and psilocin extracts, which will be formulated into a final product for regulatory approval internationally.

Psyence previously exported medical grade psilocybin mushrooms to Psilo Pharma Inc. in Portugal, which is using the mushrooms to develop extraction methodologies. Psyence also exported psilocybin mushrooms to Canada-based Psilo Scientific Ltd, a wholly-owned subsidiary of Filament Health Corp. These mushrooms are being used for analysis and extraction and have shown to be compatible with the extract currently being used in Filament's drug development process.

The exports are in line with Psyence's aim to develop global partnerships for the supply of its pharmaceutical grade psilocybin products for research, clinical trials, and drug development.

#### Partnership with Eden Labs

Psyence has partnered with Eden Labs LLC (**Eden Labs**), a product development and extraction technology company. The extraction technology and IP is for the production of a stabilized, naturally derived psilocybin powder from the fruiting bodies of psilocybin-yielding mushrooms, which will be cultivated and processed at Psyence's production facility in Southern Africa.

#### **Production Facility Expanded to Facilitate Extraction Capability**

Progress is underway to upgrade Psyence's production facility and new extraction equipment will be installed. The equipment has been manufactured by Eden Labs and should arrive at the facility in Q3. The timeline to import, install, and commence extraction is as planned. The facility will be the headquarters for the Eden Labs and Psyence collaboration.

The upgrade will enable Psyence to undertake extraction at the facility, using Psyence's natural psilocybin mushrooms, which will be processed into a stabilized powder format. Psyence's extraction partners and CROs will then process this stabilized input material into an active pharmaceutical ingredient (**API**). There are multiple benefits to on-site extraction including increased product shelf life, a more stabilized format for export, and reduced transport costs.

#### **CORPORATE UPDATE**

#### SPAC Transaction, Psyence Biomed Business Combination Agreement

On 9 January 2023, Psyence announced that its wholly owned subsidiary, Psyence Biomed Corp., had entered into a business combination with Nasdaq listed Newcourt Acquisition Corp (**Newcourt**). Psyence Biomed, Psyence's clinical trial division, will become a public company (the "**Combined Company**") through the business combination (the "**Business Combination**"), leveraging natural psilocybin in the treatment of palliative care.

If the Business Combination is completed, Psyence Group Inc, will continue to be listed on the Canadian Securities Exchange and will own a significant portion of the Combined Company. The merger agreement for the Business Combination provides that at the closing of the Business Combination, the Combined Company will receive a minimum of USD\$20 million. Psyence will also continue to own and operate its other divisions.

The Business Combination is anticipated to conclude in the second half of 2023, with the resulting Combined Company being listed on the NASDAQ. The funds received from the Business Combination are expected to provide the Combined Company with the capital to advance its licensed natural psilocybin drug candidate (PEX010) into a Phase IIb clinical study in Australia.

#### **Agreement with Cantheon Capital**

Psyence entered into a brokered subscription agreement with Cantheon Capital, LLC (**Cantheon**) on 23 March 2023. Cantheon is a fund focussed on listed biotech stocks with near term catalysts. Cantheon will invest an aggregate amount of USD \$1,393,750 of which the first 50% tranche of CAD\$ 933,116 has closed.

## **Private Placement and Conversion of Debt Note**

Since Q4 2022, Psyence has raised more than CAD \$3.04 million ("**Aggregate Proceeds**") in numerous tranches. The Aggregate Proceeds raised triggered the conversion of the previously announced convertible debt note (announced December 2021). The Company does not have any debt on its balance sheet since the conversion of the note.

## **Cancellation of Stock options**

The Company has cancelled 5,687,377 incentive stock options (the "**Options**") pursuant to its Stock Option Plan. The Options had been granted between December 31, 2020 and September 17, 2021 to certain directors, executive management, employees and consultants of the Company. The cancelled Options had an exercise price of C\$0.30 and an expiry date of December 31, 2025 in respect of 3,887,377 Options and June 30, 2026 in respect of 1,800,000 Options. The Options were voluntarily surrendered by the holders for no consideration.

## New board appointment

Christopher Bull was appointed to the board of directors of the Company on 10 July 2023. Mr. Bull is a qualified chemical engineer, attorney, patent attorney and Certified Licensing Professional<sup>®</sup>. He is also an alumnus of Saïd Business School, Oxford University (Private Equity and Venture Capital). Over his 30-year career, Mr. Bull has been an investor, director, founder and advisor to a range of successful companies in Europe and North America with novel technologies in the fields of pharmaceuticals, biotechnology, food sciences, chemical processing, and extraction technologies. Mr. Bull is recognised for his skills in relation to the development and execution of venture capital investment, patent and intellectual property strategies for high-technology companies and has received a number of international awards in recognition hereof.

"It gives me great pleasure reflecting on the strong progress we are making in executing on *Psyence's strategy," said* **Dr. Neil Maresky, Psyence Chief Executive Officer**. "The first phase of setting up our clinical trial in Australia is a significant milestone for our team, especially knowing that the work we do has the potential to significantly benefit patients in a palliative care setting. We are firmly on track to begin this study in the second half of this year. Together with the progress of our production strategy, we are looking forward to continuing along the path of executing our strategy for the remainder of 2023."

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# ABOUT PSYENCE GROUP: www.psyence.com

Psyence is a life science biotechnology company listed on the Canadian Securities Exchange (CSE: PSYG) and quoted on the OTCQB (OTCQB: PSYGF), with a focus on natural psychedelics. Psyence works with natural psilocybin products for the healing of psychological trauma and its mental health consequences in the context of palliative care. Our name "Psyence" combines the words *psychedelic* and *science* to affirm our commitment to producing psychedelic medicines developed through evidence-based research.

Informed by nature and guided by science, we built and operate one of the world's first federally licensed commercial psilocybin mushroom cultivation and production facilities in Southern Africa. Our team brings international experience in both business and science and includes experts in mycology, neurology, palliative care, and drug development. We work to develop advanced natural psilocybin products for clinical research and development.

Our key divisions, Psyence Production, Psyence Therapeutics and Psyence Function, anchor an international collaboration, with operations in Canada, the United Kingdom, Southern Africa and Australia, and a presence in the United States.

#### **Contact Information**

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#### FORWARD LOOKING STATEMENTS:

Certain statements in this news release related to Psyence Group Inc and its subsidiaries (collectively the "Company") are forward-looking statements and are prospective in nature. Forward-looking statements are not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as "may", "should", "could", "intend", "estimate", "plan", "anticipate", "expect", "believe" or "continue", or the negative thereof or similar variations. Forward-looking statements in this news release include statements regarding the approval of clinical trial applications by the relevant regulatory authorities, the receipt of all regulatory approvals for the Company's import and export activities, the fulfilment of the conditions required to close the business combination with Newcourt, and the results of the production facility upgrades. These forward-looking statements are based on a number of assumptions, including the assumptions that the Company's applications will be successful, the Company's research and development efforts will yield favourable results sufficient for product commercialisation and that there will be demand in the market for the Company's current product offering internationally. There are numerous risks and uncertainties that could cause actual results and the Company's plans and objectives to differ materially from those expressed in the forwardlooking information. These risks and uncertainties include demand for the Company's securities being less than anticipated, fluctuations in the price the Company's common shares, and the Company not raising the amount expected, or any funds at all. Actual results and future events could differ materially from those anticipated in such information. These and all subsequent written and oral forward-looking information are based on estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. Except as required by law, the Company does not intend to update these forward-looking statements.

The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The U.S. Food and Drug Administration, Health Canada or other similar regulatory authorities have not evaluated claims regarding psilocybin, psilocybin analogues, or other psychedelic compounds or nutraceutical products. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of psilocybin, psilocybin analogues, or other psychedelic compounds or nutraceuticals can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. The Company has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy, and safety of potential products do not imply that the Company verified such in clinical trials or that the Company will complete such trials. If the Company cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.

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