

CEO Letter to Shareholders

From the desk of Nick Kadysh, Founding CEO, PharmAla Biotech

“Far and away the best prize that life offers is the chance to work hard at work worth doing.” – Theodore Roosevelt

With a year behind us, I wanted to reflect on where we are as a company and where we are going in 2023.

We formed PharmAla with two goals in mind:

1. To become the first commercial enterprise (other than MAPS) to make cGMP MDMA, and
2. to research and develop novel analogs of MDMA with an improved safety profile.

Our overarching vision was to create a regulatory-first organization which could not only fulfill the global demand by clinical researchers for Investigational Drug Product (IMP) of exceptional quality, but could accelerate acceptance of Psychedelic drugs in the MDXX class by providing evidence of improved safety.

Since forming PharmAla in (very) late 2020, we’ve achieved great things:

- The first publicly-traded company to make GMP MDMA in August 2022
- The submission of our 6 NCE patent applications in the Summer of 2022 (published in February 2023, [here](#))
- Closing nearly \$1m in 2022, our first year of sales
- Becoming the exclusive global reseller of synthetic GMP Psilocybin for our partners at Mindset Pharma.
- Launching [PsyCan](#) (Psychedelics Canada), the trade association for the for-profit medicinal Psychedelics industry.

I’m incredibly proud of the dedicated and nimble PharmAla team for overcoming the many challenges we faced in achieving these goals: Manufacturing challenges; R&D challenges, IP challenges. We also faced incredible pressure on our stock price due to macroeconomic difficulties in the market due to the central bank tightening cycle and conditions related to the war in Ukraine, as have many small Issuers on the Canadian stock markets.



PharmAla's LaNeo MDMA Clinical Trial Capsules (Not Released)

What changed over the past year?

In addition to our goals, we built this company with several strongly held beliefs about what was important in the Psychedelics business:

- 1) This industry is highly regulated, and so would rise or fall based on regulatory factors outside of any one company's control. Regulatory excellence is "*table stakes*" for this game.
- 2) Companies that have a product, that generate revenue, are more stable than companies that just burn capital in the hopes of one day creating a product.
- 3) Success will come to those that move fastest; Speed comes from focus not just spending the most money.

I hope that looking at PharmAla's progress over the past 12 months, our shareholders also see the value of these principles; They've informed some of the achievements of which I am most proud.

- We've built a small, lean team – but a team grounded in technical and regulatory excellence.
- We've not only completed significant preclinical research, but built a revenue-generating business in the manufacture of LaNeo MDMA, and the sales of Mindset's GMP Psilocybin.
- We're the only company in the world with stocks of both GMP Psilocybin and MDMA in inventory and ready to ship anywhere in the world, an achievement which required

intense focus and determination.

- Of course, regulatory change has helped us enormously along the way:
 - o The allowance of Controlled Substances in the Special Access Program by Health Canada in January 2022, and
 - o The recent changes to the Therapeutic Goods Agency's Poisons Code allowing for use of MDMA and Psilocybin to treat PTSD and Treatment-Resistant Depression (TRD) in Australia beginning July 1, 2023.

As a team, we hold the heartfelt belief that while no-one can predict the timing of such changes, it is crucial that we are ready for them. We see accelerating regulatory changes as a validation of our overarching strategy to manufacture products which fit with the views of regulators from a quality perspective; we are committed to building a company which can support and benefit from regulatory changes as they happen.

Outlook for 2023

The learnings from the challenges we faced as a company in 2022 have positioned our company for incredibly opportunities in the coming year, as the team has built the foundation for the execution of an exciting strategy which will alter how PharmAla is viewed on the world stage.

- 1) In the first half (H1) of 2023, we will work to develop a distribution network in Australia to serve the new medicinal MDMA and Psilocybin market there, while continuing to support our clinical trial and SAP customers around the world.**
- 2) PharmAla will continue developing our Novel Chemical Entities (NCEs), with the goal of launching a clinical trial into one of our ALA series molecules within 12 months. We will utilize existing data to supercharge our clinical research program, and work with best-in-class researchers to get the best possible data for assessment by regulators.**
- 3) PharmAla will prepare for the next major international regulatory change affecting MDMA, and be ready to capitalize on that change.**

In more detail:

- 1) The reason we believe that the Australian regulatory change is a permanent, structural change to the psychedelics industry: for the first time, a government has allowed for a *scalable* medical pathway to utilizing these molecules clinically. To date, nowhere else in the world do we have a regulatory regime that allows for an authorized prescriber to issue diagnostic prescriptions for these molecules, and where there is no arbitrary limit on the number of prescriptions that can be written for properly diagnosed, deserving patients. Moreover, these are psychotherapy-enabling protocols – one Authorized

Prescriber psychiatrist can support a multitude of psychotherapists or clinics which are executing treatments.

We agree with the TGA's decision, as we believe it is a critical step in improving lives for patients and creating acute benefits for reimbursement entities.

There are a multitude of challenges that have to be overcome before this dream can become reality, but as the foremost GMP Drug Manufacturer in Psychedelics, we know that we have a valuable and important role to play as a supplier for these patients. We will work to engage with all stakeholders – the TGA, the College of Psychiatrists, Distributors, and Clinic Operators – to ensure that on July 1st, authorized prescribers can get access to the drugs they need to help them improve their patients' lives.

- 2) We believe strongly that our ALA series of molecules represents a substantial improvement over traditional, generic MDMA. These molecules have been shown in preclinical research to have less of a stimulant effect, and to produce fewer adverse events. At PharmAla, we have never forgotten that the key to opening MDMA treatments to the world is to help prove that these molecules are safe for human use.

Focusing on product safety isn't a popular area of research – we know that the majority of funding for research in psychedelics has gone towards other areas: non-hallucinogenic molecules, shorter durations of effect, or analogues that provoke stronger or more potent 'trips' as part of the therapeutic process. We have taken a different approach.

Improved safety, for Psychedelic drug developers, is good business. It represents the ability to open treatment in new modalities, and for new indications. It helps unlock new patient populations. Most importantly, focusing on drug safety helps regulators gain comfort with molecules which, until recently, were considered some of the most dangerous in the world. We do not have to agree with this risk assessment to acknowledge the existence of this perception.

More importantly, focusing on base molecules like MDMA as our starting point allows us to rely on decades of drug research by a multitude of talented scientists. We believe that this focus will yield positive results in our clinical research program, which we would like to kick off as quickly as possible. We hope to be able to share more information about our discussions with regulators on this topic soon.

- 3) The regulatory changes in Australia represent the first in a wave of legal changes for our category, but they will not be the last. We're gratified and thankful to the TGA for following the latest science on these molecules, but we are confident that the example of Australia will lead more regulators to the same conclusions. We intend to be first-in-market not only in Australia, but in the next jurisdiction as well, and the next after that.

Moreover, we do not intend to wait for regulatory change: through our work with PsyCan, where I sit as founding board chair, we will share positive data about the impact of Psychedelic molecules like MDMA and Psilocybin with the Canadian government. We will also work with partners around the world, including charitable initiatives like Heroic Hearts Project and Reason for Hope, to share data with emerging jurisdictions.

These regulatory changes will generate a new wave of scientific research, which represent a sales opportunity for us as a retailer of investigational drug product.

Finally, we will build on our success as a drug products manufacturer by building a “regulatory moat” around the quality of our products both in Canada and abroad. There is no excuse for having subpar drug products in use for these treatments, and we intend to ensure that all drug product manufacturers both in Canada and abroad meet or exceed the high quality standards which we have set for ourselves. Only by doing so can we know that bad actors will not erase the progress our industry has made in gaining the trust of so many hopeful patients around the world.

I don't believe that any of these goals will be easy, or quick, to achieve. I do however believe that they are all achievable, and represent a world of possibility for both PharmAla, our shareholders, and customers around the world.

To our initial funders, our current shareholders, and our diligent board members: thank you for your confidence in us as we continue to break new ground.

Sincerely, on behalf of the PharmAla Team,

Nicholas Kadysh
Founding CEO
PharmAla Biotech