

August 9, 2023



Lantern Pharma Reports Second Quarter 2023 Financial Results and Operational Highlights

- Obtained FDA clearance of the IND application for LP-184 and activated initial clinical sites for the Phase 1 basket trial in relapsed/refractory advanced solid tumors and brain cancers - a patient population with unmet clinical needs.
- Completed IND-enabling studies for LP-284 and anticipate IND submission in August; first-in-human Phase 1 clinical trial targeted for Q4 in advanced non-Hodgkin's lymphomas.
- Dosed initial patients in the Phase 2 Harmonic™ clinical trial for never smokers with NSCLC, who make up 15-20% of all lung cancer cases; continued expansion of additional clinical trial sites in the US and increased patient recruitment activity.
- Initiated RADR® collaboration with Bielefeld University to design and develop breakthrough antibody drug conjugates (ADCs) with greater precision and efficacy.
- Received US Patent & Trademark Office notice of allowance for composition of matter patent for LP-284, extending commercial protection into early 2039.
- \$48.0 million in cash, cash equivalents, and marketable securities as of June 30, 2023, providing a cash runway into 2025.
- Conference call and webcast is scheduled for today at 4:30 p.m. ET / 1:30 p.m. PT.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), an artificial intelligence ("AI") company developing targeted and transformative cancer therapies using its proprietary RADR® AI and machine learning ("ML") platform with multiple clinical-stage drug programs, today announced operational highlights and financial results for the second quarter ended June 30, 2023.

"We made significant strides over the past quarter in executing our mission of transforming the oncology drug discovery and development process, especially with advancing our programs for LP-184 and LP-284 into the clinical setting and increasing our focus on developing next-generation ADCs. Our RADR® AI platform is revolutionizing the way we understand and predict drug-cancer interactions, enabling us to advance our newly developed drug programs from initial AI insights to first-in-human clinical trials in an average of two years and at a cost of roughly \$1-2 million per program - a milestone unheard of in the realm of oncology drug discovery," said Panna Sharma, CEO of Lantern Pharma.

Sharma continued, "Computational and AI-driven approaches are increasing their presence

and usage at both large and emerging pharma companies for all facets of drug discovery and development. Our leadership in the innovative use of AI and machine learning to transform costs and timelines in the development of precision oncology therapies should yield significant returns for investors and patients as our industry matures and adopts an AI-centric approach to drug development. Our top-ranked AI algorithms can predict any compound's blood-brain barrier permeability with 89-92% accuracy, a major breakthrough that could accelerate the timeline for developing treatments for brain and CNS cancers and also for other neurological disorders. We also presented breakthrough RADR[®] advancements at the AACR and ASCO annual meetings this quarter, demonstrating an 88% accuracy in predicting patient responses for our biopharma collaborator with a unique drug candidate."

"Our unwavering commitment to harnessing the power of AI for drug discovery has also led to the formation of a collaboration with Bielefeld University to develop the next-generation of ADCs that are designed and advanced using AI. This collaboration has the potential to pave the way for higher efficacy, faster development, and significantly reduced costs in this rapidly growing and emerging treatment modality. These specific instances of value creation along with the development of an entirely new company, Starlight Therapeutics, whose sole focus will be on CNS and brain cancers, demonstrate that Lantern continues to be at the forefront of a transformative approach to oncology drug discovery, and we look forward to sharing more breakthroughs and advancements as we move forward," Sharma concluded.

Highlights of AI-Powered Pipeline:

- **LP-184** – Received Food and Drug Administration (FDA) clearance of the investigational new drug (IND) application for LP-184 during the second quarter of 2023. LP-184 is the first of Lantern's drug candidates to be developed entirely internally, with the assistance of Lantern's AI and ML platform RADR[®], to advance to a first-in-human Phase 1 basket trial. Lantern has rapidly accelerated the clinical advancement of LP-184 and has activated the first two Phase 1 clinical trial sites and begun screening patients. Indications for the trial are anticipated to include relapsed/refractory advanced pancreatic cancer, glioblastoma (GBM), brain metastases (brain mets.), and multiple other solid tumor types with DNA damage response deficiencies.

The dosage and safety data obtained in the Phase 1 trial will be used to advance the central nervous system (CNS) indications for a future Phase 2 trial to be sponsored by Lantern's wholly-owned subsidiary, Starlight Therapeutics. Globally, the aggregate annual market potential of LP-184's target indications is estimated to be approximately \$10+ billion, consisting of \$5+ billion for CNS cancers and \$6+ billion for solid tumors.

- **LP-284** – IND-enabling studies for LP-284 have been completed, and Lantern expects to submit the IND application to the FDA in August. The first-in-human Phase 1 clinical trial launch of LP-284 is targeted for Q4 of 2023 for B-cell non-Hodgkin's lymphomas (NHL), where LP-284 has shown nanomolar potency across multiple in vitro and in vivo studies, including mantle cell lymphoma (MCL), double hit lymphoma (DHL), and other advanced NHL cancer subtypes with DNA damage response deficiencies, notably those with reduced expression of the ataxia-telangiectasia mutated (ATM) gene due to mutations or deletions.

Nearly all MCL patients relapse from the current MCL standard-of-care agents and there is an urgent and unmet need for novel improved therapeutic options for these patients. In the US and Europe, MCL and DHL are diagnosed in approximately 9,000 patients each year and have an estimated annual market potential of \$1.2 billion.

- **LP-300** – Dosed initial patients in the Phase 2 Harmonic™ trial, which is assessing the effect of LP-300 in combination with standard-of-care chemotherapy in never-smoker patients with relapsed non-small cell lung cancer (NSCLC). In addition to the dosed patients, more than two dozen potential patients have been pre-screened and are being monitored for possible enrollment across the multiple trial sites in the US. The Company is accelerating efforts to bolster recruitment, including activating multiple additional strategic sites across the US, potentially expanding the trial to countries in Asia that are known to have a significantly higher prevalence of never-smokers with NSCLC, and adding key experienced personnel to the clinical development and operations team.

[Dr. Joseph Treat MD of Fox Chase Cancer Center](#) has been appointed lead principal investigator of the Harmonic™ study. Dr. Treat is a leading expert in lung malignancies, including NSCLC in never smokers, and has dedicated his career, since 1991, to serving patients with lung cancer.

Globally, never-smokers with NSCLC are a growing population of patients and do not respond well to PD-1/PD-L1 based therapies, leaving them with reduced treatment options. In the US, there are approximately 20,000-40,000 never-smokers with NSCLC diagnosed annually, representing an estimated US annual market potential of \$1.5 billion and a global estimated annual market potential of over \$2.5 billion. Additional information on the Harmonic™ trial can be found at the [Harmonic™ website](#) and [clinicaltrials.gov](#).

RADR® Platform Growth and Development:

- RADR® continues to advance in size, scope, and capabilities to accelerate the Company's pipeline of precision therapeutics and also become a standard for AI-driven drug development in oncology. RADR® has now surpassed 34 billion oncology-focused datapoints and is projected to reach 50 billion datapoints by the end of 2023. The scope of RADR®'s data has broadened with a strategic focus on additional classes of compounds including antibodies, checkpoint inhibitors, and DNA damaging agents, and data from additional studies such as those being conducted clinically as a liquid biopsy for cancer diagnosis and treatment or those from preclinical combination studies that aim to define drug interaction and optimal dosage.

These datapoints and the associated advancements in automation have advanced RADR®'s drug development capabilities including 1) predicting patient responses and identifying optimal combination regimens for immuno-oncology (IO) drugs such as immune checkpoint inhibitors, 2) predicting the BBB permeability, with 89% to 92% accuracy, of any compound at a scale and speed that allows the analysis of tens of thousands of compounds a day, and 3) accelerating the design and development of

drug-conjugate templates for next-generation antibody-drug conjugates (ADCs) that have increased potential for improved safety and efficacy. These 3 modules exemplify the type of rapid and grounded progress the RADR[®] platform will make over the next several quarters as it aims to improve the speed and reduce the costs and risks associated with creating cancer therapies.

- Lantern initiated a [new collaboration with Bielefeld University](#) to develop breakthrough ADCs. The collaboration with Bielefeld University's Professor Norbert Sewald, Ph.D., a leading researcher in the field and head of the [Magicbullet::reloaded consortium](#), is focusing on the synthesis and evaluation of novel ADCs linked to cryptophycins, a promising group of potent antitumor molecules. The global ADC market, currently valued at over \$4 billion, is projected to reach \$14 billion by 2027 and Lantern is positioned to be at the forefront of this rapidly growing sector.

Starlight Therapeutics:

- In Q1 2023, Lantern formed a wholly-owned subsidiary, [Starlight Therapeutics Inc.](#) ("Starlight"), for the clinical development of drug candidate LP-184's central nervous system (CNS) and brain cancer indications – including GBM, brain mets., and several rare pediatric CNS cancers. Starlight will refer to the molecule LP-184, as it is developed in CNS indications, as "STAR-001".
- The company has begun discussions with leading clinicians and key opinion leaders at CNS-focused cancer centers to serve as clinical trial sites for upcoming clinical trials in adult and pediatric CNS cancers. Additionally, the formation of Starlight's Scientific/Clinical Advisory Board is advancing and will be announced in Q3. The Advisory Board members are anticipated to help sharpen the aims and heighten the awareness of upcoming Starlight clinical trials.

Additional Operational Highlights:

- New findings published in [Oncotarget](#) demonstrated that drug candidate LP-284 has in vitro and in vivo antitumor potency in over 15 NHL models, including MCL and DHL. The journal article titled "[LP-284 Targets Non-Hodgkin's Lymphoma and DNA Damage Repair Deficiency](#)" includes fundamental LP-284 findings demonstrating 1) LP-284 inhibited tumor growth in mice implanted with MCL xenografts at a level greater than current MCL standard of care (SOC) agents ibrutinib and bortezomib and 2) in MCL xenografts that had grown resistant to these SOC agents, subsequent LP-284 treatment led to near complete tumor regression.
- [Lantern Pharma received a notice of allowance from the United States Patent and Trademark Office \(USPTO\) for the composition of matter patent, no. 17/192,838, covering the molecule LP-284](#), including claims covering the new molecular entity. Lantern Pharma expects the resulting LP-284 patent will be Orange Book-listable with an anticipated expiration of early 2039.

Additionally during the quarter, five new patent applications were filed for LP-184 and LP-284, with claims covering the use of these drug candidates in combination regimens for specific tumor subtypes.

- New data and findings to be presented at several upcoming scientific conferences:
 - **Society of Neuro-Oncology/American Society of Clinical Oncology CNS Cancer Conference** in San Francisco, CA, on August 10th, 2023 from 5:30-7:30 p.m. PT. Link to conference registration [here](#).
Presentation Title: *LP-184, a novel acylfulvene-derived tumor site activated small molecule inhibits adult and pediatric CNS tumor cell growth*
 - **International Conference on Drug Conjugates for Directed Therapy** in Darmstadt, Germany on Thursday, August 24th, 2023 from 9:45-10:15 a.m. CEST. Link to conference registration [here](#).
Presentation Title: *In-silico Approach for the Identification of ADC Targets with Improved Tumor Selectivity*
 - **Society of Hematologic Oncology Annual Meeting** in Houston, TX on Wednesday, September 6th, 2023 at 6:00 p.m. CT. Link to conference registration [here](#).
Presentation Title: *Targeting Homologous Recombination Deficiencies in B-Cell Non-Hodgkin's Lymphomas with the Novel Anti-Tumor Small Molecule LP-284*

Second Quarter 2023 Financial Overview:

- **Balance Sheet:** Cash, cash equivalents, and marketable securities were approximately \$48.0 million as of June 30, 2023, compared to approximately \$55.2 million as of December 31, 2022. The quarterly cash burn rate continues to reflect our capital-efficient, collaborator-centered business model.
- **R&D Expenses:** Research and development expenses were approximately \$3.6 million for the quarter ended June 30, 2023, compared to approximately \$3.0 million for the quarter ended June 30, 2022.
- **G&A Expenses:** General and administrative expenses were approximately \$1.6 million for the quarter ended June 30, 2023, compared to approximately \$1.4 million for the quarter ended June 30, 2022.
- **Net Loss:** Net loss was approximately \$4.7 million (or \$0.44 per share) for the quarter ended June 30, 2023, compared to a net loss of approximately \$4.5 million (or \$0.41 per share) for the quarter ended June 30, 2022.

Earnings Call and Webinar Details:

Lantern will host its second quarter 2023 earnings call and webinar today, Wednesday, August 9, 2023, at 4:30 p.m. ET.

- https://us06web.zoom.us/webinar/register/1016902973506/WN_h4QZ0ZyxR3mZZbNQx
- Related presentation materials will be accessible at: <https://ir.lanternpharma.com>
- A replay of the second quarter earnings call and webinar will be available at <https://ir.lanternpharma.com>

About Lantern Pharma:

Lantern Pharma (NASDAQ: LTRN) is an AI company transforming the cost, pace, and timeline of oncology drug discovery and development. Our proprietary AI and machine learning (ML) platform, RADR[®], leverages over 34 billion oncology-focused data points and a library of 200+ advanced ML algorithms to help solve billion-dollar, real-world problems in oncology drug development. By harnessing the power of AI and with input from world-class scientific advisors and collaborators, we have accelerated the development of our growing pipeline of therapies including eleven cancer indications and an antibody-drug conjugate (ADC) program. On average, our newly developed drug programs have been advanced from initial AI insights to first-in-human clinical trials in 2-3 years and at approximately \$1.0-2.0 million per program.

Our lead development programs include two Phase 2 clinical programs and multiple upcoming Phase 1 clinical trials anticipated for 2023. We have also established a wholly-owned subsidiary, Starlight Therapeutics Inc., to focus exclusively on the clinical execution of our promising therapies for CNS and brain cancers, many of which have no effective treatment options. Our AI-driven pipeline of innovative product candidates is estimated to have a combined annual market potential of over \$15 billion USD and have the potential to provide life-changing therapies to hundreds of thousands of cancer patients across the world.

Please find more information at:

Website: www.lanternpharma.com

LinkedIn: <https://www.linkedin.com/company/lanternpharma/>

X/Twitter: [@lanternpharma](https://twitter.com/lanternpharma)

Newsletter – The Spark: Sign-up [here](#)

Forward-looking Statements:

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, among other things, statements relating to: future events or our future financial performance; the potential advantages of our RADR[®] platform in identifying drug candidates and patient populations that are likely to respond to a drug candidate; our strategic plans to advance the development of our drug candidates and antibody drug conjugate (ADC) development program; estimates regarding the development timing for our drug candidates and ADC development program; expectations and estimates regarding clinical trial timing and patient enrollment; our research and development efforts of our internal drug discovery programs and the utilization of our RADR[®] platform to streamline the drug development process; our intention to leverage artificial intelligence, machine learning and biomarker data to streamline and transform the pace, risk and cost of oncology drug discovery and development and to identify patient populations that would likely respond to a drug candidate; estimates regarding patient populations, potential markets and potential market sizes; sales estimates for our drug candidates and our plans to discover and develop drug candidates and to maximize their commercial potential by advancing such drug candidates ourselves or in collaboration with others. Any statements that are not statements of historical fact (including, without limitation, statements that use words such as "anticipate," "believe," "contemplate," "could," "estimate," "expect," "intend," "seek," "may," "might," "plan," "potential," "predict," "project," "target," "model," "objective," "aim," "upcoming," "should,"

"will," "would," or the negative of these words or other similar expressions) should be considered forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by the forward-looking statements, such as (i) the risk that our research and the research of our collaborators may not be successful, (ii) the risk that none of our product candidates has received FDA marketing approval, and we may not be able to successfully initiate, conduct, or conclude clinical testing for or obtain marketing approval for our product candidates, (iii) the risk that no drug product based on our proprietary RADR[®] AI platform has received FDA marketing approval or otherwise been incorporated into a commercial product, and (iv) those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 20, 2023. You may access our Annual Report on Form 10-K for the year ended December 31, 2022 under the investor SEC filings tab of our website at www.lanternpharma.com or on the SEC's website at www.sec.gov. Given these risks and uncertainties, we can give no assurances that our forward-looking statements will prove to be accurate, or that any other results or events projected or contemplated by our forward-looking statements will in fact occur, and we caution investors not to place undue reliance on these statements. All forward-looking statements in this press release represent our judgment as of the date hereof, and, except as otherwise required by law, we disclaim any obligation to update any forward-looking statements to conform the statement to actual results or changes in our expectations.

Lantern Pharma Disclosure Channels to Disseminate Information:

Lantern Pharma's investors and others should note that we announce material information to the public about our company and its technologies, clinical developments, licensing matters and other matters through a variety of means, including Lantern Pharma's website, press releases, SEC filings, digital newsletters, and social media, in order to achieve broad, non-exclusionary distribution of information to the public. We encourage our investors and others to review the information we make public in the locations above as such information could be deemed to be material information. Please note that this list may be updated from time to time.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20230809925278/en/>

Nicole Leber
Investor Relations Associate
ir@lanternpharma.com

Source: Lantern Pharma Inc.