

May 15, 2025



# Lantern Pharma Reports First Quarter 2025 Financial Results and Business Updates

- **Completion of LP-184 Phase 1a** clinical trial enrollment with 62-65 patients across a range of solid tumors expected by **end of June 2025**.
- Additional patient **data readout from the HARMONIC™ Trial** evaluating LP-300 in never-smokers with non-small cell lung cancer (NSCLC) anticipated in **Q3 2025**, including **initial readout for patients from the Asian expansion cohort**.
- **Strengthened AI intellectual property** portfolio with PCT publication of proprietary blood-brain barrier penetration prediction patent application; **favorable PCT search report** indicated no significant prior art.
- **Expanded RADR® platform with innovative AI-powered module** to improve the precision, cost and timeline of antibody-drug conjugate (**ADC**) **development, integrating a multiomic approach using proprietary algorithms** to design and optimize target, payload, and tumor selectivity.
- Planning **commercial availability and launch of select RADR® AI modules** for the scientific and research community to foster collaborative, **open-source innovation** in cancer drug development.
- Obtained further independent preclinical confirmation of **LP-184 hypersensitivity in rare pediatric brain tumors**, such as ATRT, by our collaborators at **Johns Hopkins** in support of **planned pediatric trial** in CNS tumors.
- Maintained **disciplined capital management**, with approximately \$19.7 million in cash, cash equivalents, and marketable securities as of March 31, 2025, providing expected **operating runway through at least May 15, 2026**.
- The [conference call and webcast](#) are scheduled for Thursday, May 15, 2025 at 9:00 a.m. ET.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), a clinical-stage biopharmaceutical company leveraging its proprietary RADR® artificial intelligence (AI) and machine learning (ML) platform to transform the cost, pace, and timeline of oncology drug discovery and development, today announced operational highlights and financial results for the first quarter 2025 ended March 31, 2025, and provided an update on its portfolio of AI-driven drug candidates, the RADR® platform for precision oncology drug development enhancements, and other operational progress.

***"This quarter represents a pivotal inflection point in our clinical and technological development. As we approach full enrollment in our LP-184 Phase 1a trial and prepare***

*for an additional data readout for our LP-300 Harmonic Trial, including initial data from our Asian expansion cohort, we are positioning ourselves for productive discussions with potential biopharma partners. Simultaneously, our RADR® AI platform has reached a crucial development milestone with a broad and validated range of oncology drug development modules powered by hundreds of billions of datapoints. These advancements further validate our AI-driven approach to cancer drug development, which is focused on addressing real-world, unmet patient needs while establishing a clear pathway toward commercialization focused on delivering value to patients and shareholders."* —Panna Sharma, CEO & President of Lantern Pharma

## **AI-Powered Drug Development Pipeline Highlights:**

### **LP-300**

Lantern's Phase 2 HARMONIC™ trial for LP-300 continued to advance during Q1 2025 with patients enrolled in Japan and Taiwan and ongoing enrollment in the US. Never-smokers with NSCLC in East Asia represent approximately 33% to 40% of new NSCLC cases as compared to the U.S., where never smokers account for approximately 15% of new NSCLC cases. **LP-300 is being evaluated in combination with standard-of-care chemotherapy (carboplatin + pemetrexed) in never-smokers with NSCLC adenocarcinoma who have progressed after TKI therapy.** The trial is designed to enroll approximately 90 patients across the U.S. and East Asia.

**Phase 2 Clinical Results:** [Preliminary data from the Phase 2 U.S. safety, lead-in cohort showed an 86% clinical benefit rate and a 43% objective response rate.](#) Additional patient data from the expansion cohort continues to support, at the current time, a similar patient response and clinical benefit rate trend. Lantern plans on sharing additional results, which will include updated data from patients enrolled in the lead-in cohort and new data from patients in the Asian expansion cohort, during Q3 of 2025.

### **LP-184**

LP-184 continued advancements through a Phase 1a trial in multiple solid tumors, which is targeted to **finish enrollment during June of 2025.** LP-184 has received Fast Track Designations from the FDA for [GBM \(Glioblastoma Multiforme\)](#) and [TNBC \(Triple Negative Breast Cancer\)](#). Additionally, [LP-184 has four Rare Pediatric Disease Designations](#) for hepatoblastoma, rhabdomyosarcoma, and malignant rhabdoid tumors, and ATRT (atypical teratoid, rhabdoid tumors).

**Phase 1a Results: Safety, Tolerability, Pharmacokinetics including MTD Determination** - The trial has **now enrolled through cohort 12**, and early indications of clinical activity have been observed at higher dose levels, consistent with preliminary PK data. During Q1 2025, the Safety Review Committee (SRC) along with the Company, made the decision to backfill dose levels 10 and 11 to ensure clarity on the maximum tolerated dose (MTD) while ensuring the safety of study participants, and assessing the clinical activity of the dose to guide future LP-184 clinical trials. Enrollment at dose level 9 and higher has been focused on inclusion of advanced solid tumor patients that have identified DNA damage repair mutations. A broader clinical data update is slated for Q3 of 2025, when complete safety, pharmacokinetic and dose response data along with biomarker correlations is expected to be available.

**Future Planned Phase 1b/2 Trials:** Lantern has **recently cleared two clinical trial protocols** with the FDA that can provide a path towards a regulatory approval.

The first, announced on May 5th, is for a Phase 1b/2 study in **TNBC evaluating LP-184 in both a combination regimen with the PARP inhibitor, Olaparib and as monotherapy in the same indication**. The FDA has raised no objections to the protocol, and Lantern plans to initiate this trial in both the US and at leading academic cancer centers in Nigeria and India, subject to clinical priorities and funding. The average survival for newly diagnosed, metastatic **TNBC** is estimated at 8 to 13 months and presents an annual market opportunity in excess of **\$4 billion USD**.

The second, announced on May 12th, is for a Phase 1b/2 study in a biomarker defined subset of **drug-resistant non-small cell lung cancer that has mutations in the STK11 and/or KEAP1 genes**. This unique trial is aimed at addressing a critical unmet clinical need in lung cancer care: the median overall survival in **newly diagnosed, advanced NSCLC patients with KEAP1 and/or STK11 mutations** treated with chemo-immunotherapy averages 15 months, substantially lower than outcomes in mutation negative populations. For patients that fail earlier lines of therapies the overall survival tends to skew even lower at approximately 6.3 months. This represents a market opportunity **exceeding \$2 billion annually**, given the prevalence and poor prognosis for patients with these mutations.

Additionally, an **investigator-led, exploratory clinical trial of LP-184 for recurrent bladder cancer** is planned to begin in Denmark during Q3 of 2025. This clinical trial is designed to test LP-184 as a monotherapy specifically in advanced, recurrent bladder cancer patients with DNA damage repair mutations with the **potential to create a path towards data to support usage in the 3rd line setting**.

### **RADR®-A.I. Platform:**

Lantern's proprietary RADR® **platform has grown during Q1 2025 to approximately 200 billion** oncology-focused data points across multiple sources (proprietary, collaborative and public) of oncology, molecular, clinical, biochemical, and preclinical datasets.

RADR® continues to **play an important role in advancing:**

- drug candidate optimization,
- development and validation of clinically relevant drug-candidate combinations,
- identification of mechanism(s) of action,
- identification of optimal indications for drug-candidate advancement,
- creation of biomarker signatures to support patient selection,
- optimization and characterization of molecular features, and
- prediction of the blood brain barrier (BBB) potential of a molecule.

AI and platform-driven insights contributed to LP-184's clinical biomarker strategy, including a qPCR assay for PTGR1 to guide patient stratification, and aided in the identification of multiple indications leading to orphan and rare pediatric disease designations. Additionally, RADR® also underpinned combination strategies, such as

LP-184 with PARP inhibitors and LP-284 with rituximab. Future plans and proposed developments include additional collaborations with leading oncology development groups and biopharma companies in both adult and pediatric cancers. **Lantern expects to publicly release multiple modules (validated A.I. frameworks) that can be accessed by Lantern collaborators and the research community** for specific needs in oncology drug development—such as prediction of certain molecular features including the BBB penetrability of a molecule, identification of potential cancer indications that are more likely to show a higher sensitivity to a molecule or drug-candidate, and aiding the development of optimized paths to demonstrate potential therapeutic utility of a molecule in a rare cancer.

### **Starlight Therapeutics:**

Lantern's wholly owned subsidiary focused on CNS and brain cancers, Starlight Therapeutics, made key advances towards the design, development and approval of adult and pediatric trials, **including potential investigator-initiated clinical trials** for STAR-001. LP-184, referred to as STAR-001 for CNS indications, was highlighted at the Society for Neuro-Oncology (SNO) 2024 conference, with a Phase 1b/2 trial in recurrent GBM anticipated to begin in late 2025 subject to successful additional funding and clearance of the protocol. Additionally, further preclinical studies led by Lantern's collaborators at Johns Hopkins provided independent confirmation of **LP-184 hypersensitivity in rare pediatric brain tumors**, in support of **a clinical trial being planned with a pediatric consortium** in CNS tumors.

### **Additional Operational Highlights:**

Lantern also advanced a proprietary BBB permeability prediction algorithm with a favorable PCT patent application report, advancing our AI leadership with Lantern's algorithms now holding five of the top ten positions on Therapeutic Data Commons (TDC) Leaderboard. The company is developing a **publicly available tool to predict the BBB permeability** of any molecule that can be readily accessed by the research and drug development community, which is planned for initial launch during the second half of 2025.

### **First Quarter 2025 Financial Highlights:**

- **Balance Sheet:** Cash, cash equivalents, and marketable securities were approximately \$19.7 million as of March 31, 2025, compared to approximately \$24.0 million as of December 31, 2024.
- **R&D Expenses:** Research and development expenses were approximately \$3.3 million for the quarter ended March 31, 2025, compared to approximately \$4.3 million for the quarter ended March 31, 2024.
- **G&A Expenses:** General and administrative expenses were approximately \$1.5 million for the quarter ended March 31, 2025, essentially unchanged from approximately \$1.5 million for the quarter ended March 31, 2024.
- **Net Loss:** Net loss was approximately \$4.5 million (or \$0.42 per share) for the quarter ended March 31, 2025, compared to a net loss of approximately \$5.4 million (or \$0.51

per share) for the quarter ended March 31, 2024.

- **Warrant Exercises:** There were no warrants exercised during the three months ended March 31, 2025. The company has warrants to purchase 70,000 shares of common stock outstanding and exercisable as of March 31, 2025 at a weighted-average exercise price of \$18.75 per share. These warrants will expire on June 10, 2025.

### **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 200 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 drug-candidates that span multiple cancer indications, including both solid tumors and blood cancers and an antibody-drug conjugate (ADC) program. On average, our newly developed programs have been advanced from initial AI insights to first-in-human clinical trials in 2–3 years and at approximately \$1.0 – \$2.5 million per program.

Our lead development programs include a Phase 2 clinical program and multiple Phase 1 clinical trials. We have also established a wholly-owned subsidiary, Starlight Therapeutics, 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.

### **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 genomic 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 we may not be able to secure sufficient future funding when needed and as required to advance and support our existing and planned clinical trials and operations, (ii) the risk that observations in preclinical studies and early or preliminary observations in clinical studies do not ensure that later observations, studies and development will be consistent or successful, (iii) the risk that our research and the research of our collaborators may not be successful, (iv) the risk that we may not be successful in licensing potential candidates or in completing potential partnerships and collaborations, (v) 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, (vi) the risk that no drug product based on our proprietary RADR<sup>®</sup> AI platform has received FDA marketing approval or otherwise been incorporated into a commercial product, and (vii) those other factors set forth in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission on March 27, 2025. You may access our Annual Report on Form 10-K for the year ended December 31, 2024 under the investor SEC filings tab of our website at [www.lanternpharma.com](http://www.lanternpharma.com) or on the SEC's website at [www.sec.gov](http://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.

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