



NEWS RELEASE

Lantern Pharma Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Operational Highlights

2023-03-20

- The Harmonic™ clinical trial, a Phase 2 study in never-smoker patients with non-small lung cancer, has activated 5 clinical trial sites, across 12 locations, and anticipates multiple additional sites in the US during the 1st half of 2023; first enrolled patients are anticipated for Q2 2023.
- IND-enabling studies for LP-184 are completed, and submission of the IND application to the FDA is anticipated for April 2023.
- Completion of IND-enabling studies for LP-284 and submission of the IND application to the FDA are anticipated in mid-2023.
- First-in-human Phase 1 clinical trials for LP-184, in genomically defined solid tumors, and for LP-284, in multiple non-Hodgkin's lymphomas, are targeted for launch in mid-2023.
- Starlight Therapeutics Inc., a wholly-owned Lantern subsidiary, was formed to focus exclusively on the clinical development of therapies for multiple CNS (central nervous system) and brain cancers; clinical trials for lead drug candidate, STAR-001, in CNS cancers are anticipated for late 2023/early 2024.
- RADR®, Lantern's oncology-focused AI drug development platform, surpassed 25 billion oncology-focused datapoints; future advancements will include AI-driven insights for the development of combination regimens, including immuno-oncology agents, and for the development of antibody drug conjugates (ADCs).
- \$55.2 million in cash, cash equivalents, and marketable securities as of December 31, 2022.
- Lantern has a cash runway into 2025.

- Conference call scheduled for 4:30 p.m. ET / 1:30 p.m. PT today.

DALLAS--(BUSINESS WIRE)-- Lantern Pharma Inc. (NASDAQ: LTRN), a clinical-stage biopharmaceutical company using 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 fourth quarter and fiscal year ended December 31, 2022.

"The Lantern team spent 2022 focused on preparing our unique drug candidates, LP-184 and LP-284, for the clinic, while at the same time advancing the clinical foundation and infrastructure for our Phase 2 Harmonic™ clinical trial for never-smokers with NSCLC. We have been working relentlessly towards the objective of leading the transformation of our industry's approach to the pace, risk, and cost of drug development by leveraging large scale data, machine learning, and leading-edge artificial intelligence technologies. We believe our capabilities in the development of precision oncology medicines and ADCs will establish us as a pioneer in the field of AI-based drug discovery," commented Panna Sharma, CEO and President of Lantern Pharma.

"During 2022 we also made significant advances in the field of CNS oncology, which resulted in several new indications for our drug candidate LP-184. We have gone from one CNS indication, GBM, to seven indications in less than 18 months and in a highly capital efficient manner. This unique achievement would have only been possible by combining our AI-driven approach along with our collaborative business model, where we engage with top-tier researchers and institutions to both validate and sharpen our development plans for specific cancer subtypes and patient populations. In 2023, we expect to launch multiple first-in-human clinical trials in targeted cancers, where there is an urgent patient need and clear evidence from both our in-silico and in-vivo studies of the potential to improve outcomes for patients. Ultimately, we believe that this will help to create significant value for investors and for the broader community of precision oncology," continued Sharma.

Portfolio Highlights:

- LP-184 – The investigational new drug (IND) enabling studies for LP-184 have been completed and the submission of the IND application to the US Food and Drug Administration (FDA) is anticipated during Q2 2023. Lantern is anticipating a Phase 1A basket trial for LP-184 in 2023, for recurrent brain cancers, including glioblastoma (GBM), brain metastases and other central nervous system (CNS) cancers, pancreatic cancer, and additional solid tumors with DNA damage response (DDR) deficiencies. Globally, the aggregate annual market potential of these programs is estimated to be approximately \$11.0-13.0 billion, consisting of \$5.0-6.0 billion for CNS cancers and \$6.0-7.0 billion for solid tumors.

At the 2022 San Antonio Breast Cancer Symposium (SABCS), Lantern scientists presented new research on the anti-tumor potential of LP-184 for Triple Negative Breast Cancer (TNBC), one of the most malignant forms

of breast cancer. The presentation highlighted results demonstrating that LP-184 treatment of 10 TNBC patient-derived xenograft (PDX) mouse models, led to complete and durable tumor regression of 107-141%. In addition to primary TNBC tumors, LP-184 may also have added therapeutic potential to treat brain metastases (brain mets.) from TNBCs, which are found in ~14% of TNBC patients at their initial diagnosis. In the US, there are approximately 28,000 newly diagnosed and relapsed TNBC patients per year, representing an estimated annual market potential of up to \$1.7 billion.

- LP-300 – Harmonic™ is a Phase 2 clinical trial for never-smoker patients with relapsed non-small cell lung cancer (NSCLC) and will assess the effect of LP-300 in combination with standard-of-care chemotherapy, pemetrexed and carboplatin, on patient overall and progression-free survival. Lantern has activated 5 clinical trial sites at 12 different locations across the US, including **Gabrail Cancer Center, Northwest Oncology, New York Cancer and Blood Specialists, Texas Oncology**, and Cancer and Blood Specialty Clinic. Across the 5 Harmonic™ clinical trial sites, there is 1 consented patient that is anticipated to be dosed in Q1 2023 and 14 additional potential patients that have been pre-screened and are being monitored for possible enrollment. Multiple additional trial sites across the US are expected to be activated in the 1st half of 2023 and will bolster patient recruitment and enrollment. In the US, there are approximately 20,000-40,000 never-smokers with NSCLC diagnosed annually, representing an estimated annual market potential of \$1.5-2.0 billion. Additional information on the Harmonic™ trial can be found at the **Harmonic™ website** and the **clinicaltrials.gov website**.

This quarter, Lantern launched a first-of-its-kind iPhone app for the Harmonic™ clinical trial. The Harmonic™ app provides patients, caregivers, and the healthcare community with mobile access to up-to-date information on the Harmonic™ trial, including how NSCLC is different in never-smokers versus in tobacco users, what taking part in the Harmonic™ trial involves, the ability to contact the Harmonic™ clinical trial team, information on LP-300, and the locations of all currently active clinical trial sites. Download the Harmonic™ clinical trial app **here**.

- LP-284 – The completion of the LP-284 IND enabling studies and submission of the IND application to the US FDA are anticipated in mid-2023. A first-in-human Phase 1 clinical trial launch is anticipated in 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 NHL cancer subtypes. Nearly all MCL patients relapse from the MCL standard-of-care agents Bortezomib and Ibrutinib 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.

In January 2023, **the U.S. Food and Drug Administration (FDA) granted LP-284 an Orphan Drug Designation**

(ODD) for the treatment of MCL, based on LP-284's demonstrated anti-tumor activity across a comprehensive number of in vitro and in vivo models of mantle cell lymphoma (MCL). The ODD strengthens LP-284's clinical development path and provides the future potential opportunity for additional market exclusivity and commercial protection. In addition to the ODD granted for LP-284 in MCL, Lantern was previously granted ODDs by the FDA for its drug candidate LP-184 for the treatment of malignant gliomas, ATRT, and pancreatic cancer. Lantern has also been granted a Rare Pediatric Disease Designation for LP-184 in ATRT.

At the 2022 American Society of Hematology (ASH) annual meeting, Lantern scientists presented new research on LP-284 for MCLs. The poster presentation featured results demonstrating that LP-284 treatment had between 91-105% greater tumor growth inhibition (TGI) in mice implanted with MCL cell-derived xenograft (CDX) tumors, when compared to treatment with current MCL therapies Ibrutinib or Bortezomib.

- LP-100 – In LP-100's previous **Phase 2 trial in Denmark** for patients with metastatic castration resistant prostate cancer (mCRPC), the initial cohort of nine patients (out of a targeted enrollment of 27) experienced a median overall survival of 12.5 months, which is an improvement over other similar fourth-line treatment regimens for mCRPC.

Based on Lantern's recent in silico and in vivo results demonstrating the synergies of LP-100 with PARP inhibitors (PARPi), and the industry's development of entirely new classes of radio-ligand based therapy for mCRPC, the decision has been made to close the Phase 2 clinical trial in Denmark. Lantern believes that the strong anti-cancer synergy between LP-100 and PARPis will allow this drug combination to be positioned in earlier lines of therapy for treatment indications with larger market sizes.

Potential treatment indications for LP-100 and PARPi combination therapy may include homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer, first line platinum-responsive advanced ovarian cancer, and BRCA-mutated metastatic breast cancer. The total U.S. market size of these and other potential target development indications for the LP-100 and PARPi combination is estimated at between \$700 million and \$2 billion.

Formation of Starlight Therapeutics:

Lantern recently formed a wholly-owned subsidiary, Starlight Therapeutics Inc. ("Starlight"), to develop drug candidate LP-184's central nervous system (CNS) and brain cancer indications – including glioblastoma (GBM), brain metastases (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 programs being developed by Starlight were born from the analysis of billions of oncology-focused data points and by using Lantern's AI platform, RADR[®]. STAR-001's powerful anti-tumor mechanism of action, synthetic lethality, and collaborations with internationally recognized institutions, including the Kennedy Krieger Institute at Johns Hopkins and the Greehey Children's Cancer Research Institute at UT Health – San Antonio, make it well positioned to advance in targeted and efficient clinical development programs. Starlight intends to pursue human clinical trials for multiple CNS indications starting in late 2023, building on prior IND-enabling studies and the upcoming Phase 1A clinical testing that will be conducted by Lantern.

The clinical development of STAR-001 in CNS cancers beyond the Phase 1A trial will be conducted exclusively by Starlight. Following the launch of Starlight, Lantern will continue to advance LP-184's preclinical and clinical development for non-CNS indications (including pancreatic cancer and other solid tumors) and will also provide AI-driven bioinformatic and computational biology support to Starlight.

"The formation of Starlight as a wholly-owned subsidiary allows Lantern to sharpen the focus on advancing STAR-001 through targeted clinical trials and dedicate increased time, resources, and personnel to progress one of the most promising drug candidates for CNS cancer patients in decades," stated Panna Sharma, Lantern's CEO and President. "We believe that by focusing our efforts via Starlight Therapeutics we can accelerate and deepen our commitment to the CNS cancer patient community, while also creating the potential for meaningful additional upside for our investors," continued Sharma.

RADR[®] Platform Growth and Development:

- RADR[®], Lantern's AI and ML platform, continues to rapidly expand its 25+ billion oncology-focused datapoints. Lantern expects the platform to reach 50 billion datapoints in the coming year and to include new datasets with an increased focus on immuno-oncology and antibody drug conjugates. Additional advancements are simultaneously occurring in platform automation, scalability, and security.
- An expanded RADR[®] product development roadmap was recently announced, which will enhance RADR[®]'s capabilities for the development of novel and effective antibody drug conjugates (ADCs), which are highly specific cancer-targeted antibodies linked to potent anti-tumor small molecules. Globally, ADCs are one of the fastest growing drug development markets and are estimated to have a market potential of over \$14 billion by 2027.

RADR[®] and Scientific Collaborations Update:

- **Lantern recently established a new RADR[®] and AI-driven collaboration with TTC Oncology** to enhance the development of TTC's Phase 2 ready drug candidate TTC-352. TTC-352 is a novel, first- and best-in-class selective human estrogen receptor (ER) partial agonist (ShERPA) for the treatment of patients with metastatic

ER+ breast cancer. The initial aims of the collaboration will be to identify biomarker or gene signatures to power potential patient selection for an upcoming TTC-352 Phase 2 clinical trial and to discover additional treatment indications for TTC-352. Under the terms of the collaboration, Lantern is receiving an exclusive right to license TTC-352, including any collaboration intellectual property (IP), during an exclusive option period.

- On March 21st, 2023 at 12:00 p.m. ET, Lantern will host a KOL webinar on synthetic lethality, the unique mechanism of action of Lantern's drug candidates LP-184, LP-284, and LP-100. Synthetic lethality can exploit vulnerabilities in cancer cells, known as DNA damage repair deficiencies, which are estimated to be present in 25-30% of solid tumors. The webinar will feature an internationally recognized expert in synthetic lethality, Zoltan Szallasi, M.D., who serves joint appointments as principal investigator at The Danish Cancer Research Center and as assistant professor of pediatrics at Boston Children's Hospital, a Harvard Medical School affiliate. Register for the webinar [here](#).

Operational Highlights:

- Lantern has expanded its clinical leadership team with several key additions, including Reggie Ewesuedo M.D., M.Sc., MBA, as Vice President of Clinical Development. Combined, the new clinical leadership team members represent over 40 years of proven success in clinical operations and bringing drugs to market. The expansion of the clinical development team will continue to advance the Harmonic™ trial, as well as the upcoming first-in-human Phase 1 clinical trials for LP-184 and LP-284.

Fourth Quarter and Fiscal Year 2022 Financial Overview:

- Balance Sheet: Cash, cash equivalents, and marketable securities were \$55.2 million as of December 31, 2022, compared to \$70.7 million as of December 31, 2021. The quarterly and annual cash burn for 2022 reflects our capital-efficient, collaborator-centered business model.
- R&D Expenses: Research and development expenses were \$2.3 million and \$8.6 million for the quarter and year ended December 31, 2022 compared to \$2.2 million and \$7.6 million for the quarter and year ended December 31, 2021.
- G&A Expenses: General and administrative expenses were \$1.6 million and \$5.8 million for the quarter and year ended December 31, 2022, compared to \$1.4 million and \$5.0 million for the quarter and year ended December 31, 2021.
- Net Loss: Net losses were \$3.4 million (or \$0.31 per share) and \$14.3 million (or \$1.31 per share) for the quarter and year ended December 31, 2022, compared to a net loss of \$3.5 million (or \$0.31 per share) and \$12.4 million (or \$1.13 per share) for the quarter and year ended December 31, 2021.

Earnings Call and Webinar Details:

Lantern will host its fourth quarter and fiscal year 2022 earnings call and webinar today, Monday, March 20, 2023 at 4:30 p.m. ET.

- https://us06web.zoom.us/webinar/register/3616775268267/WN_94qgn_1IRnuRALmciLu0CQ
- Related presentation materials will be accessible at: <https://ir.lanternpharma.com>
- A replay of the fourth quarter and fiscal year 2022 earnings call and webinar will be available at <https://ir.lanternpharma.com>.

About Lantern Pharma:

Lantern Pharma (NASDAQ: LTRN) is a clinical-stage oncology-focused biopharmaceutical company leveraging its proprietary RADR[®] AI and machine learning platform to discover biomarker signatures that identify patients most likely to respond to its pipeline of genomically-targeted therapeutics. By targeting drugs to patients whose genomic profile identifies them as having the highest probability of benefiting from the drug, Lantern's approach represents the potential to deliver best-in-class outcomes.

Please find more information at:

Website: www.lanternpharma.com

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

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

Lantern Pharma 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 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 impact of the COVID-19 pandemic, (ii) the risk that our research and the research of our collaborators may not be successful, (iii) 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, (iv) 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 (v) 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.

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