

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 24, 2022

Lantern Pharma Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-39318

(Commission File Number)

46-3973463

(IRS Employer
Identification No.)

**1920 McKinney Avenue, 7th Floor
Dallas, Texas**

(Address of Principal Executive Offices)

75201

(Zip Code)

(972) 277-1136

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act: Common Stock

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, \$0.0001 par value	LTRN	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On January 24, 2022, Lantern Pharma Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted rare pediatric disease designation and orphan drug designation for the Company's drug candidate LP-184 for the treatment of atypical teratoid rhabdoid tumor (ATRT). A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 8.01, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filings, unless expressly incorporated by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press Release dated January 24, 2022 announcing grant of rare pediatric disease designation and orphan drug designation for Company drug candidate LP-184 for atypical teratoid rhabdoid tumor (ATRT).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Lantern Pharma Inc.,
A Delaware Corporation

Dated: January 24, 2022

By: /s/ David R. Margrave
David R. Margrave,
Chief Financial Officer



Lantern Pharma Receives Rare Pediatric Disease and Orphan Drug Designations for LP-184 for the Treatment of Atypical Teratoid Rhabdoid Tumor (ATRT) – an Aggressive and Rapidly Growing Form of Cancer of the Central Nervous System

- Designations reinforce unmet need for treatment options for patients, especially children with ATRT
- LP-184 for the potential treatment of ATRT is the third program of Lantern to receive orphan drug designation

DALLAS, January 24, 2022 /PRNewswire/ -- Lantern Pharma (NASDAQ: LTRN) a clinical stage biopharmaceutical company using its proprietary RADR[®] artificial intelligence (“A.I.”) platform to transform the cost, pace, and timeline of oncology drug discovery and development today announced that the U.S. Food and Drug Administration (FDA) has granted both Rare Pediatric Disease Designation and Orphan Drug Designation for the company’s drug candidate LP-184 for the treatment of pediatric patients with ATRT. LP-184 is being pursued as a potential new therapy across a range of genetically defined solid tumors, including pancreatic cancer, GBM (*Glioblastoma Multiforme*) and ATRT (*Atypical Teratoid Rhabdoid Tumor*).

“Historical approaches to treating pediatric ATRT such as surgery, radiation, and chemotherapy have had largely unfavorable long term outcomes for children, and new options are urgently needed,” said Kishor Bhatia, Ph.D., chief scientific officer of Lantern Pharma. “The gene SMARCB1 was included among several genes whose expression negatively correlated with LP-184 sensitivity in tumors. This in silico correlation was convincingly confirmed by in vitro and in vivo assessments of LP-184 in ATRT. The highest potency of LP-184 in-vivo has been seen in ATRT xenografts.” Dr. Bhatia continued, “Based on both the in-silico and in-vivo observations, LP-184 has the potential to become a critical part of the armamentarium of approved treatment options specifically for these patients. Receiving Rare Pediatric Disease Designation from the FDA underscores the critical value of our growing focus on pediatric oncology indications at Lantern and represents another significant milestone for the LP-184 program.”

The National Cancer Institute (NCI) classifies ATRT as Grade IV tumors, meaning they are malignant (cancerous), aggressive and fast-growing. ATRTs are very aggressive childhood malignancies of the central nervous system. The underlying genetic cause are inactivating bi-allelic mutations in SMARCB1 (also called INI1) or in SMARCA4. Nearly 90 percent of pediatric ATRTs are caused by changes in the gene known as SMARCB1.

The FDA grants rare pediatric disease designation for serious and life-threatening diseases that primarily affect children ages 18 years or younger and fewer than 200,000 people in the United States. The Rare Pediatric Disease Priority Review Voucher Program is intended to address the challenges that drug companies face when developing treatments for these unique patient populations. Under this program, companies are eligible to receive a priority review voucher following approval of a product with rare pediatric disease designation if the marketing application submitted for the product satisfies certain conditions, including approval prior to September 30, 2026 unless changed by legislation. If issued, a sponsor may redeem a priority review voucher for priority review of a subsequent marketing application for a different product candidate, or the priority review voucher could be sold or transferred to another sponsor.

Orphan drug designation is granted by the FDA Office of Orphan Products Development to investigational treatments that are intended for the treatment of rare diseases affecting fewer than 200,000 people in the United States. The program was developed to encourage the development of medicines for rare diseases, and benefits include tax credits and application fee waivers designed to offset some development costs, as well as eligibility for market exclusivity for seven years post approval.

www.lanternpharma.com

LP-184 is being developed for multiple targeted oncology indications. Lantern Pharma intends to further advance LP-184 as a new, potent treatment option in genetically defined subsets of patient populations in areas of high unmet clinical need, including pancreatic cancers, GBM, and other cancers that are DNA damage repair deficient. The U.S. Food and Drug Administration (FDA) has previously granted LP-184 Orphan Drug Designation for the treatment of pancreatic cancer, and for the treatment of malignant glioma, including GBM.

About Lantern Pharma

Lantern Pharma (LTRN) is a clinical-stage oncology-focused biopharmaceutical company leveraging its proprietary RADR[®] A.I. platform and machine learning to discover biomarker signatures that identify patients most likely to respond to its pipeline of genomically targeted therapeutics. Lantern is currently developing four drug candidates and an ADC program across eight disclosed tumor targets, including two phase 2 programs. 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. More information is available at: www.lanternpharma.com and Twitter @lanternpharma.

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; 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 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,” “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 A.I. 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, 2020, filed with the Securities and Exchange Commission on March 10, 2021. You may access our Annual Report on Form 10-K for the year ended December 31, 2020 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.

INVESTOR CONTACT:

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