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Lantern Pharma, Inc. (LTRN: NASDAQ)

LTRN: M&A Illuminates GBM Value

Our approach uses a DCF model and a 15% discount rate for valuation. Our model applies a 25% probability of ultimate approval and commercialization for LP-300 in never-smoker NSCLC, for LP-184 in multiple tumors in combination with ADCs and as monotherapy in ATRT. The model includes contributions from the United States, EU and rest of world.

Current Price (3/7/2025)	$3.66
Valuation	**$26.00**

OUTLOOK

Lantern Pharma uses AI & data to identify drug responders, uncover mechanism of action & rescue failed drugs. It is developing LP-300 for non- & never smoker NSCLC in the Harmonic trial. Secondary candidates include LP-100 for mCRPC and LP-184 and LP-284 which are in clinical development for multiple biomarker-defined tumors and hematological cancers, respectively. Early-stage work emphasizes ADCs and orphan indications. STAR-001 is the lead candidate for Starlight Therapeutics, Lantern's CNS-focused subsidiary.

Lantern uses AI & machine learning to rescue failed & abandoned compounds by predicting response in biomarker-defined subpopulations. RADR is the firm's AI platform which analyzes proprietary, curated data to identify new candidates, mechanisms of action & patients most likely to respond to drug therapy, de-risking clinical trials to save time & cost.

Lantern launched its Ph2 trial for LP-300 in never-smoker NSCLC in late 2022. We expect it to lead into a Ph3 study that will generate registrational data followed by US & EU regulatory submission & commercialization. LP-184 is undergoing clinical trials in defined advanced tumors while LP-284 has been cleared for human trials.

SUMMARY DATA

52-Week High	**11.99**
52-Week Low	**2.79**
One-Year Return (%)	**-45.0**
Beta	**1.6**
Average Daily Volume (sh)	**98,122**
Shares Outstanding (mil)	**10.8**
Market Capitalization ($mil)	**39.5**
Short Interest Ratio (days)	**1.5**
Institutional Ownership (%)	**23.3**
Insider Ownership (%)	**14.7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2024 Estimate	**N/A**
P/E using 2025 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$0.36 A	-$0.44 A	-$0.29 A	-$0.39 A	-$1.47 A
2024	-$0.51 A	-$0.46 A	-$0.42 A	-$0.51 E	-$1.90 E
2025					-$1.86 E
2026					-$1.14 E

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What's New?

Lantern Pharma, Inc (NASDAQ: LTRN) continues to enroll its HARMONIC trial for LP-300 at sites around the globe with the most recent focus on Taiwan and Japan, where the prevalence of never-smoker non-small cell lung cancer (NSCLC) is from two to three times higher than in the United States. Lantern's RADR (Response Algorithm for Drug Positioning & Rescue) platform continues to break ground with new capabilities in predicting blood brain barrier (BBB) permeability of drug candidates and improving the development of antibody drug conjugate (ADC) design. Lantern's LP-184 gains another Fast Track designation for triple negative breast cancer (TNBC) following the receipt of the same designation for glioblastoma last October. The company also angled a spotlight towards its STAR-001 (LP-184) program at the Society for Neuro-Oncology (SNO) 2024 conference. The associated poster provided support for the combination of spironolactone with the next-generation acylfulvene in glioblastoma multiforme (GBM) and clarified the path forward for STAR-001 with the candidate's trial design. GBM also made an appearance in a recent transaction where Jazz Pharmaceuticals (JAZZ) made a bid to acquire Chimerix (CMRX) for its brain cancer drug for almost $1 billion. The deal should provide an additional framework for determining the value of Lantern's STAR-001 asset in GBM.

AI-Model Activity

Patent Application
Lantern's Patent Cooperation Treaty (PCT) patent application entitled Machine Learning System and Method for Predicting Blood Brain Barrier Permeability was published by the World Intellectual Property Organization (WIPO) as reported in a February 19th press release. The PCT application enables Lantern to pursue patent protection in major markets worldwide, with potential coverage extending 20 years from the filing date. The application describes a machine learning system and method for predicting blood-brain barrier permeability. It obtains samples of data associated with molecules from various data sources, converts the samples into structural representations, and generates features from the structural representations. Tests are conducted to determine blood-brain barrier permeability dependency. The system analyzes the ratio of permeable to non-permeable samples in the data and augments them with synthetic data to create a balanced dataset if an imbalance between the types of samples is detected. The system reduces the features utilized for training the machine learning utilizing a technique to create a selected set of features for the balanced dataset. The system trains a machine learning model using the balanced dataset, utilizing the machine learning model to predict blood-brain barrier permeability for the candidate molecule.

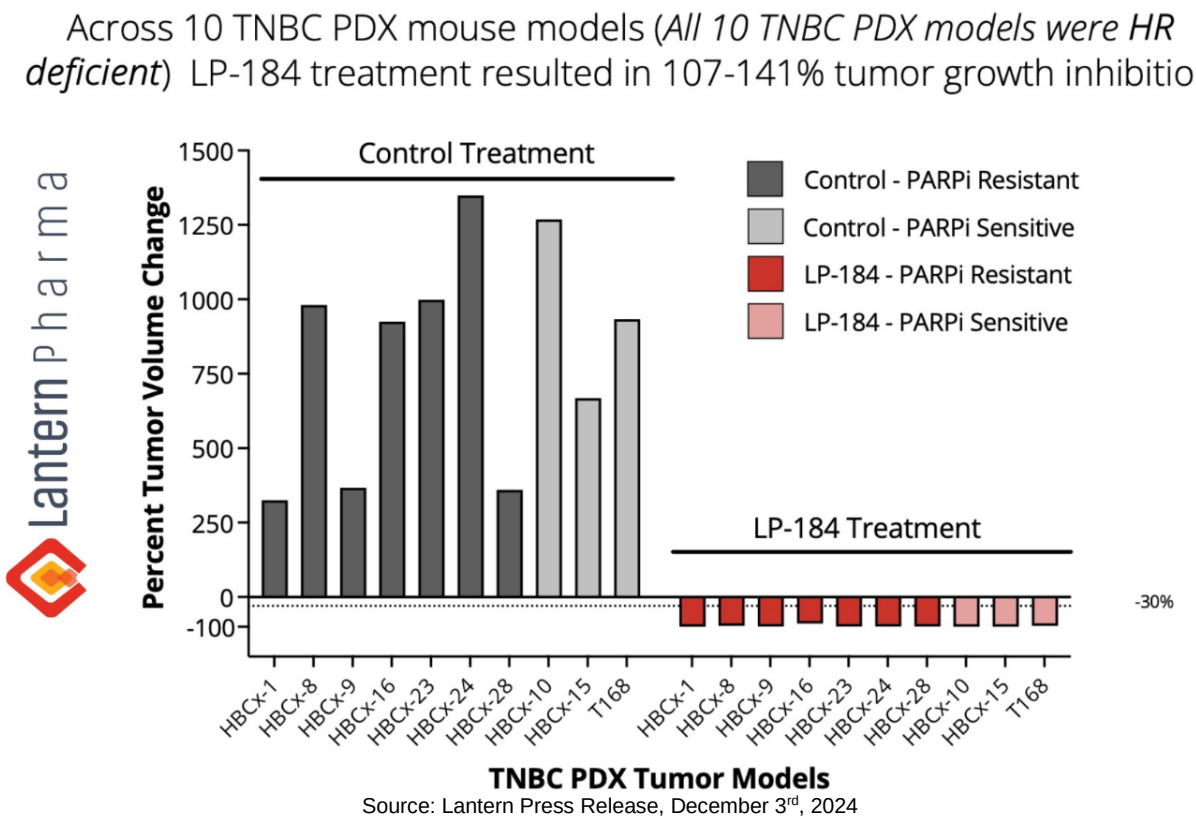
Lantern writes that the algorithm has performed well, processing up to 100,000 molecules per hour with notable accuracy. The technology can potentially accelerate drug development by identifying treatments that can enter the brain and central nervous system (CNS) thereby avoiding molecules that do not have this critical feature. The company plans to use the model to collaborate with pharmaceutical partners and biotechnology-driven companies to help them accelerate the advancement of their pipeline.

RADR Use in Identifying ADC Candidates
Lantern has also been developing an AI-powered module to improve the precision, cost and time to develop antibody drug conjugates (ADCs) for cancer. In late January the company announced that it had developed an AI-driven approach to identify ADC targets and target-indication combinations with a high degree of accuracy. 22 of the targets identified by the RADR platform have been validated in clinical or preclinical settings. Lantern has identified 60 additional targets that have potential for development. The company asserts that the AI-driven optimization capability could enhance the selective targeting and therapeutic window of the ADC payload candidates as well as reduce the time and cost of drug development. The team sees potential for partnership opportunities. The work was memorialized in a research article published in PLOS One entitled Expanding the repertoire of Antibody Drug Conjugate (ADC) targets with improved tumor selectivity and range of potent payloads through in-silico analysis.

Triple Negative Breast Cancer Target

LP-184 Receives Fast Track Designation
The FDA granted Lantern's LP-184 a Fast Track designation in triple negative breast cancer (TNBC) late last year. This is the second such designation that the FDA has granted LP-184 in 2024. In October 2024, LP-184 was awarded Fast Track for a glioblastoma indication. Fast Track is granted to drug candidates that address serious or life-threatening conditions and an unmet medical need. The designation enables more frequent communication with the FDA, eligibility for rolling review and potential qualification for accelerated approval or priority review.

Exhibit I – Triple Negative Breast Cancer Supporting Evidence



Source: Lantern Press Release, December 3rd, 2024

LP-184 is being evaluated in a Phase Ia clinical trial in patients with advanced solid tumors (NCT05933265) including TNBC. The trial is also enrolling patients diagnosed with glioblastoma multiforme (GBM), which was also granted a Fast Track designation last October.

TNBC Poster

Several authors on behalf of Lantern presented a poster entitled LP-184, a Novel Acylfulvene, Sensitizes Immunorefractory Triple Negative Breast Cancers (TNBCs) to Anti-PD1 Therapy by Affecting the Tumor Microenvironment at the AACR Immuno-Oncology Conference in February. The poster summarized LP-184 work examining synergistic anti-tumor efficacy in a mouse TNBC model, gene expression at the single cell level as well as antigen presentation and interferon signaling in tumor cells among other preclinical studies in TNBC.

Conclusions from the poster found a synergistic anti-tumor response for LP-184 in combination with anti-PD-1 compared to monotherapies in mouse TNBC tumors that are non-hypermutated and IO agent resistant. LP-184 treatment appeared to reshape the tumor microenvironment by decreasing M2 macrophages, increasing T cell infiltration and enhancing individual T cell function when combined with immune checkpoint blockade therapy.

Transactions

A recent acquisition announcement in the oncology space between Jazz Pharmaceuticals (JAZZ) and its target, Chimerix (CMRX), valued the latter at $8.55 per share or $935 million for its lead clinical asset dordaviprone alongside other interests. Dordaviprone is an imipridone, a molecule discovered as a p53-independent inducer of TNF-related apoptosis-inducing ligand (TRAIL) gene transcription. It is in clinical-stage development for H3-K27M mutant diffuse glioma as its lead indication. Chimerix' candidate has been submitted to the FDA in a new drug application (NDA) and has been granted priority review with a target action date of August 18th, 2025.

H3 K27M-Mutant Diffuse Glioma

H3 K27M-mutant diffuse glioma is a significant and aggressive form of brain tumor Its genetic signature is the H3 K27M mutation which occurs in the histone H3 protein, which plays a crucial role in regulating gene expression. This mutation leads to changes in how genes are expressed, contributing to the uncontrolled growth of tumor cells. The cancer is highly malignant and the tumors typically arise in the midline structures of the brain, such as the pons (leading to diffuse intrinsic pontine glioma or DIPG), the thalamus, spinal cord and other locations of the brain.

The estimated incidence of H3-K27 mutated gliomas is from 2,000 to 2,200 patients in the United States,[1] which is markedly smaller than the estimated addressable market of 12,000 to 15,000 patients for STAR-001. Our research found a source that identified the H3-K27 mutation in 15% of cases.[2] The disease is more common in children and is highly malignant.[3]

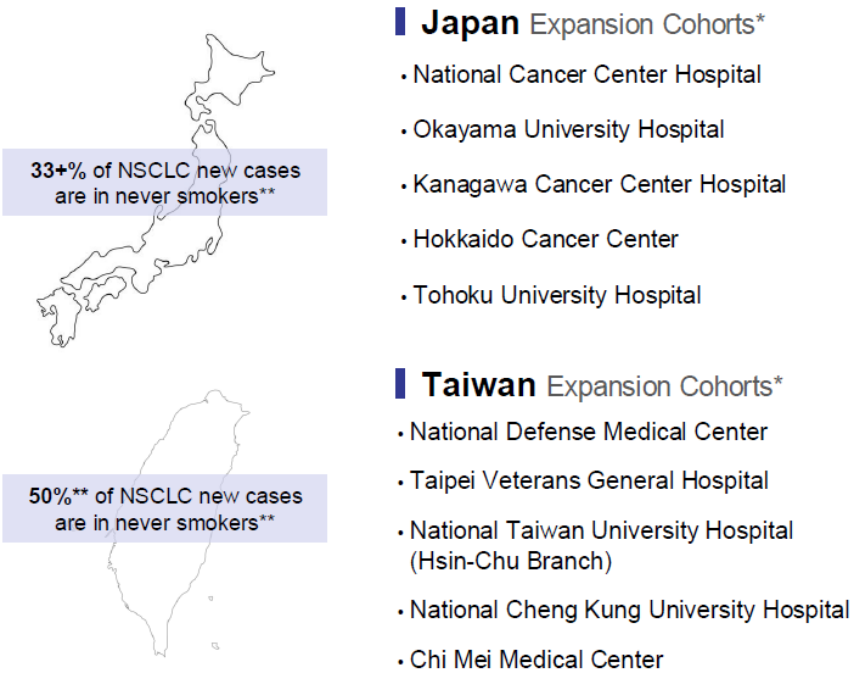
Acquisition activity is an important driver for valuations, especially for earlier stage companies such as Lantern Pharma. This deal is particularly relevant as Chimerix is pursuing a subset of brain cancer that is hard to treat and has no FDA approved therapies. With an addressable market of several thousand patients per year and a course of therapy priced at $300 to $500 thousand, global revenues could easily surpass $1 billion for dordaviprone.

While it is in an earlier stage of development and must still demonstrate efficacy in GBM, Lantern's STAR-101 may address a larger market in this indication. To place the two assets in context relative to their development stage, we generally apply a 10% probability of success to Phase I assets such as STAR-001 and up to a 90% probability of success for candidates that have been accepted for review by the FDA such as dordaviprone.

Expansion of Harmonic Trial to Asia

An April 22nd, 2024 press release informed investors that the Harmonic trial for non-small cell lung cancer (NSCLC) in never smokers will expand into Japan and Taiwan. A statistic from UCSF's cancer center found that over 50% of Asian American females diagnosed with lung cancer did not smoke. In Chinese females, the proportion went as high as 80%.[4] The susceptibility to lung adenocarcinomas from never-smoker females can be in part attributable to oncogenic mutations.[5] Lantern identified a source that finds one-third of all lung cancer patients in East Asia are non-smokers. Asia is an important market for LP-300 and clinical work in this region will provide the data necessary for regulatory approval in areas that require additional studies conducted in target ethnic populations. Success in these populations would be an important tailwind for LP-300 as there is a material unmet need. Expansion into Asia may also increase Lantern's attractiveness with global biopharma companies. Management has activated ten sites in the region and as of mid-November enrolled its first patient in Japan and by early December, enrolled its first patient in Taiwan. All sites are continuing to actively screen patients.

Exhibit II – Clinical Trial Sites in Japan and Taiwan



Source: Lantern Pharmaceuticals 2Q:24 Earnings Slide Deck

[1] Incidence provided by Lantern Pharma.
[2] Schreck, K.C., *et al*. Incidence and clinicopathologic features of H3 K27M mutations in adults with radiographically-determined midline gliomas. Journal of Neurooncology. March 2019.
[3] Zheng, L., *et al*. Diffuse Midline Gliomas With Histone H3 K27M Mutation in Adults and Children. American Journal of Surgical Pathology. April 2022.
[4] Addressing High Lung Cancer Rates Among Female Asian Non-Smokers. Karen Gehrman. January 13, 2022.
[5] Ha, S. *et al*. Lung cancer in never-smoker Asian females is driven by oncogenic mutations most often involving EGFR. Oncotarget. March 2015.

LP-284

LP-284 is also in a Phase Ia clinical trial for non-Hodgkin's Lymphomas in a trial entitled Safety, Pharmacokinetics, and Clinical Activity of LP-284 in Adult Patients with Relapsed or Refractory Lymphomas and Solid Tumors. This trial expects to enroll 30 to 35 subjects in the two US sites already activated. As of September 30, 2024, cohort 4 has been dosed with no dose-limiting toxicity observed.

The Phase Ia is expected to progress to a Phase Ib or II by early to mid-2025. LP-284 has shown nanomolar potency in preclinical work for a number of indications including mantle cell lymphoma (MCL), double hit lymphoma (DHL), and other advanced NHL cancer subtypes with DNA damage response deficiencies, notably those with compromised functioning of the ataxia-telangiectasia mutated (ATM) gene due to mutations or deletions.

Exhibit III – Lantern Pipeline

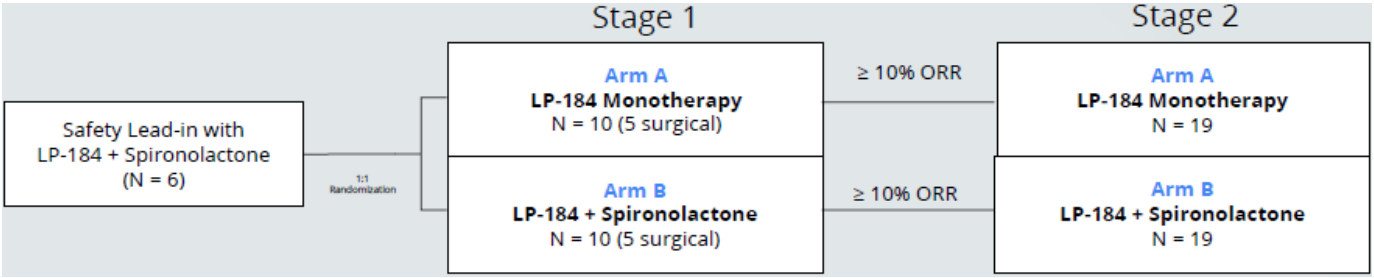


Source: Lantern Pharmaceuticals' 3Q:24 Corporate Presentation

STAR-001

Mouse model data for STAR-001, also known as LP-184 in the Lantern portfolio, has demonstrated potent anti-tumor efficacy in methylated and unmethylated glioblastoma (GBM). The candidate offers potency 3,000x higher in vitro compared to temozolomide, which is the standard of care for GBM. These results are independent of the repair enzyme O6-methylguanine-DNA methyltransferase enzyme (MGMT) status. In MGMT negative models, the inhibitory concentration 50% (IC50) value is 209 nmol/L in certain cell lines. In MGMT positive models, the IC50 value is below 100 nmol/L. STAR-001 in GBM is an attractive target as no effective single-agent therapy has been approved in decades and the candidate has shown effectiveness in preclinical models. Starlight is planning to launch a Phase Ib/II study in GBM. The trial design for the study was provided in a presentation and poster at the Society for Neuro-Oncology (SNO) meeting in late November. Conclusions from the poster found that LP-184 penetrates the brain well, with higher achieved penetration levels compared with the standard of care treatment temozolomide. Additionally, combining LP-184 with spironolactone increases GBM cell sensitivity to LP-184, allowing for increased damage after exposure compared with LP-184 alone. Furthermore, LP-184 is effective in temozolomide-resistant GBM models and is agnostic to O6-methylguanine-DNA methyltransferase (MGMT) methylation status.

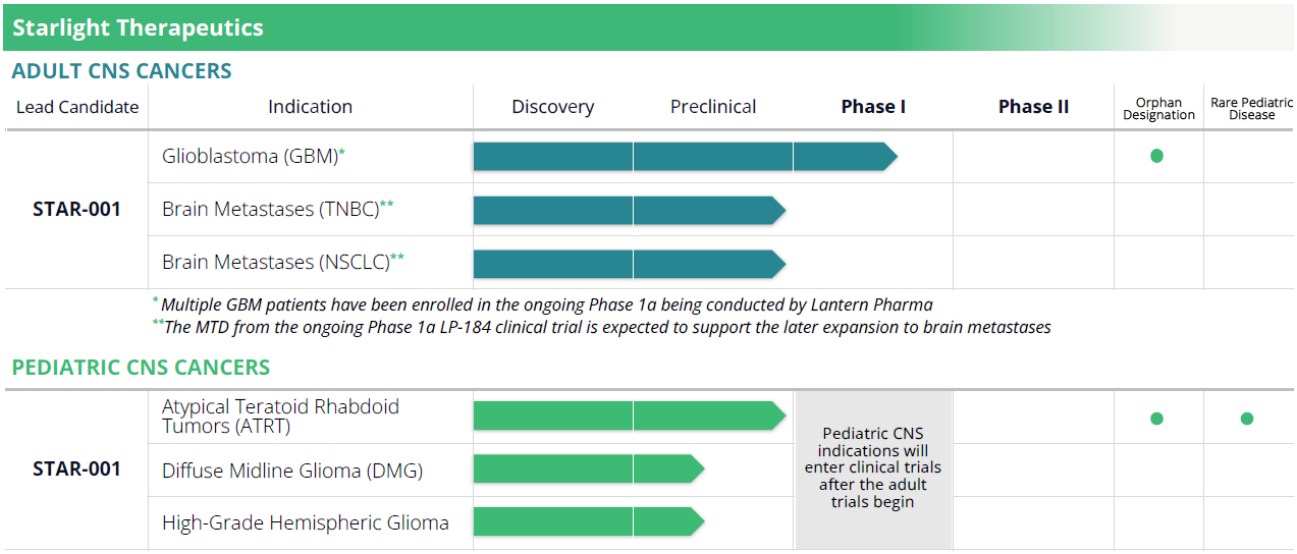
Exhibit IV – LP-184/STAR-001 GBM Trial Design



Source: Lantern's November 2024 SNO Poster

Lantern continues to develop STAR-001 as LP-184 in its Phase Ia basket trial called Study of LP-184 in Patients with Advanced Solid Tumors. On October 15th the drug candidate received a fast-track designation in glioblastoma (GBM) from the FDA which will allow for a streamlined path towards approval. Fast track allows more communication with the FDA, ability to submit using a rolling review, eligibility for accelerated treatment and more flexibility in clinical trial design among other benefits. The trial has been launched and multiple US sites are active. As of September 30th, cohort 9 has been dosed and no dose-limiting toxicity had been observed. 40-50 patients are expected to be enrolled.

Exhibit V – Starlight Therapeutics Pipeline



Source: Lantern Pharmaceuticals' 3Q:24 Corporate Presentation

Milestones

- LP-184 Phase Ia continued enrollment – 1H:24
- Expansion of trial sites for Harmonic throughout the US and Asia – 2024
- AACR presentation for LP-284 – April 2024
- ADC program IND development – 2024
- Begin combination studies for LP-184 and LP-284 – 2024
- Certificate of Patent for LP-284 Composition of Matter granted in Japan – July 2024
- STAR-001 (LP-184) Phase Ib/II clinical trial – 2H:24
- Initial readout for Harmonic – August 2024
- Report of 2024 financial and operational results – mid to late March 2025
- HARMONIC LP-300 interim readout of 30+ subjects – mid-2025

Summary

Lantern is enrolling patients in Asia for the HARMONIC trial, now with 10 sites in East Asia. RADR continues to identify features in candidate drugs that reduce cost and time to approval, now identifying molecules that will more easily cross the BBB and represent feasible ADC candidates. The FDA granted Lantern another fast-track designation for STAR-001 in TNBC, which can better guide the candidate's regulatory voyage. We also saw a transaction by Jazz for Chimerix, valuing the company at almost $1 billion, largely for its H3-K27 mutated glioma asset dordaviprone. We anticipate that Lantern will report its 2024 results and provide an update to investors in the next week or two. We maintain our price target of $26.00 per share.

PROJECTED FINANCIALS

Lantern Pharma, Inc. - Income Statement

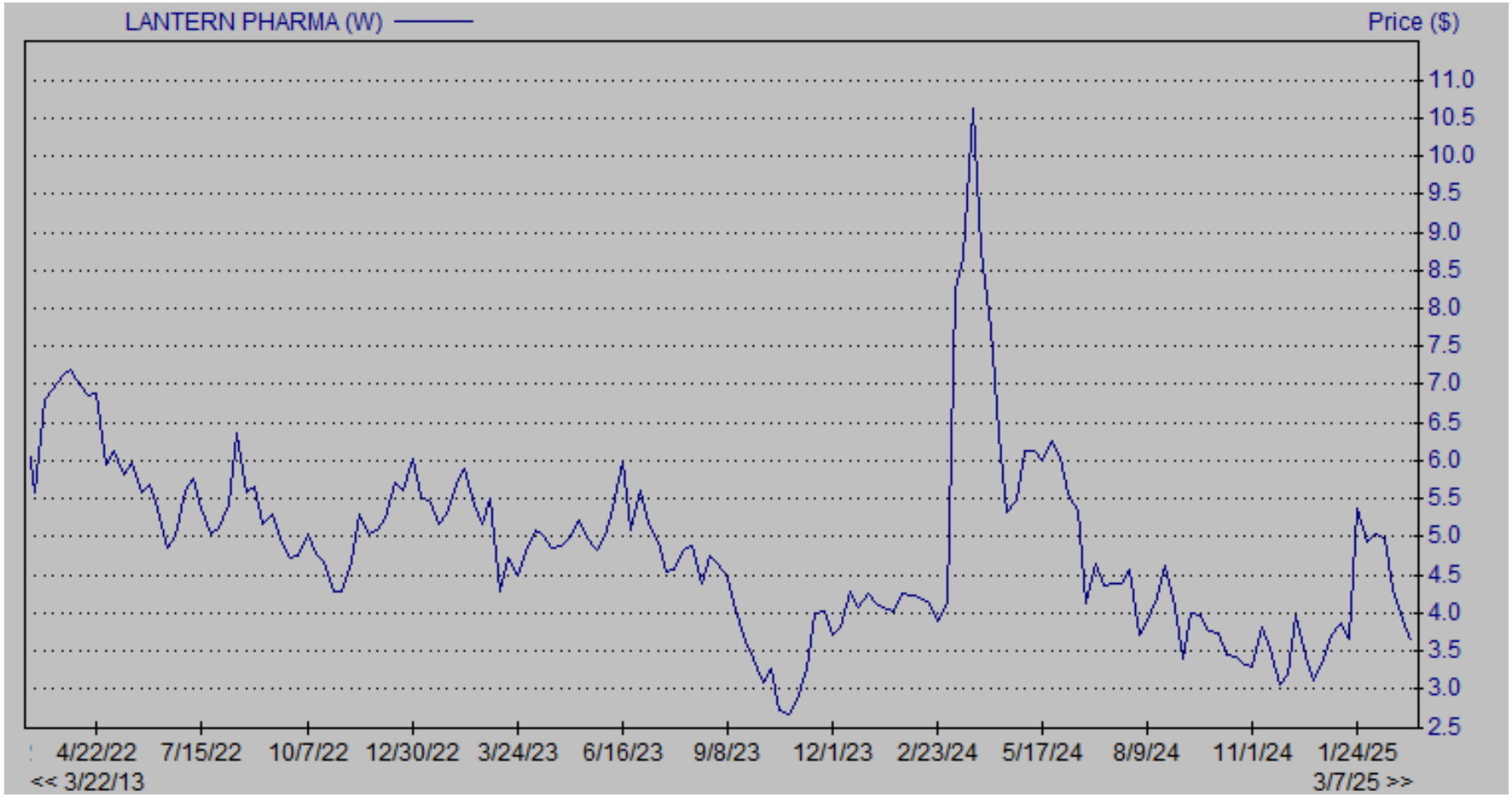
Lantern Pharma Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
General & Administrative	$5,983	$1,481	$1,520	$1,463	$1,724	$6,188	$6,581	$3,600
Research & Development	$11,894	$4,251	$3,889	$3,717	$3,890	$15,746	$16,643	$14,988
Income from operations	($17,878)	($5,732)	($5,408)	($5,180)	($5,614)	($21,934)	($23,224)	($18,588)
Operating Margin								
Interest Income	$765	$201	$189	$191	$50	$631	$10	$0
Other Income	$1,151	$90	$260	$483	$0	$833	$0	$0
Pre-Tax Income	($15,962)	($5,441)	($4,960)	($4,506)	($5,564)	($20,470)	($23,214)	($18,588)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($15,962)**	**($5,441)**	**($4,960)**	**($4,506)**	**($5,564)**	**($20,470)**	**($23,214)**	**($18,588)**
Net Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*
Reported EPS	**($1.47)**	**($0.51)**	**($0.46)**	**($0.42)**	**($0.51)**	**($1.90)**	**($1.86)**	**($1.14)**
YOY Growth	*12%*					*29%*	*-2%*	*-38%*
Basic Shares Outstanding	10,842	10,743	10,759	10,763	10,822	10,772	12,500	16,250

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Lantern Pharma, Inc. – Share Price Chart[6]



[6] Source: Zacks Research System

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