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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Lantern Pharma, Inc. (LTRN: NASDAQ)

LTRN: Pediatric Rare Cancer in Focus

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 (11/11/2024)	$3.51
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	**3.04**
One-Year Return (%)	**6.4**
Beta	**1.6**
Average Daily Volume (sh)	**42,650**
Shares Outstanding (mil)	**10.8**
Market Capitalization ($mil)	**37.9**
Short Interest Ratio (days)	**4.7**
Institutional Ownership (%)	**24.1**
Insider Ownership (%)	**14.8**
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) reported third quarter 2024 financial results and achievements in a November 7th, 2024 press release. Since our previous report, the company has been granted three additional rare pediatric disease designations for LP-184, and Fast Track designation for glioblastoma. It has also announced inaugural members for Starlight Therapeutics' Scientific Advisory Board and participated in several conferences and presentations.

On November 7th, 2024, Lantern announced third quarter 2024 financial and operational results, filed its Form 10-Q with the SEC and hosted a video webcast to review accomplishments. In the financial sphere, Lantern generated no revenues in 3Q:24 and incurred operating expense of $5.2 million, producing a net loss of ($4.5) million or ($0.42) per share.

For the quarter ending September 30th, 2024 and versus the same comparable prior year period:

- Research & development expenses totaled $3.7 million, rising 68% from $2.2 million as spending on the LP-184 and, to a lesser extent, on the LP-300 program contributed to the increase. There were also spending jumps for LP-284, the RADR platform and other costs which were partially offset by lower spending on the LP-100 and ADC program. In terms of spending categories, Lantern experienced increases in research study material costs, higher salary and benefits and expanded consulting expenses;
- General & administrative expenses were $1.5 million, rising 11% from $1.3 million. Higher professional and patent fees combined with a rise in business development costs were partially offset by lower travel costs and salaries and benefits;
- Interest income was $191,000 versus $246,000 while other income rose to $483,000 from $116,000. Other income rose due to a fair value adjustment related to appreciation of securities ownership and foreign currency remeasurement gain. These were partially offset by a decrease in research and development tax incentives related to the Australian subsidiary;
- Net loss was ($4.5) million, or ($0.42) per share, compared to ($3.2) million, or ($0.29) per share.

As of September 30th, cash and marketable securities on the balance sheet totaled $28.1 million, compared to year end 2023 cash balances of $41.3 million. Cash burn for 3Q:24 was ($5.6) million versus ($3.6) million in the prior year comparable quarter. Year to date, cash burn was ($13.9) million vs. ($11.0) million for the first nine months of 2023. To date, cash from financing of $67,000 has been solely generated from warrant exercises. Management anticipates sufficient cash to support operations until late 2025.

FDA Actions

Lantern gained additional rare pediatric disease designations (RPDD) for LP-184 in malignant rhabdoid tumors, rhabdomyosarcoma and hepatoblastoma as detailed in a September 2024 press release. This builds on the RPDD that was announced back in January of 2022 for Atypical Teratoid Rhabdoid Tumors (ATRT). As we show in the following exhibit, these indications comprise very small numbers in the United States. Since these are rare diseases, predominantly occurring in a pediatric population, the sponsor is eligible for a priority review voucher. To refine the number of patients suffering from these cancers, we reviewed several sources[1,2,3,4,5] and consulted with Lantern's Chief Scientific Officer, Dr. Bhatia and Vice President of Clinical Development, Reggie Ewesuedo to refine our numbers.

The very low total patient count is less than 100 cases per year in each of these rare pediatric cancers. This limited number of potential subjects requires these patients to be grouped together based on similar characteristics of their cancer. The FDA wants to see safety and clinical activity and realizes that it would be near impossible to run a randomized controlled trial for these groups, which allows for surrogate endpoints to be used and grouping of patients.

[1] Heck, J.E. *et al*. Epidemiology of Rhabdoid Tumors of Early Childhood. Pediatric Blood Cancer, January 2014.
[2] OrphaNet Rare Disease database, orpha.net.
[3] Medscape, Malignant Rhabdoid Tumor. James Geller, MD. September 27, 2021.
[4] American Cancer Society
[5] Kahla, J.A. *et al*. Incidence and 5-year survival of children and adolescents with hepatoblastoma in the United States. Pediatric Blood Cancer, October 2022.

Exhibit I – Incidence of Select Rare Pediatric Cancer Indications

Indication	Incidence Rate	US Incidence	Date Granted
Rhabdoid Tumors	<1 per million	82	September 2024
Rhabdomyosarcoma	<1 per million	20	September 2024
Hepatoblastoma	<1 per million	12	September 2024
Atypical Teratoid Rhabdoid Tumor	<1 per million	60	January 2022

Source: Compiled by Zacks Analyst from Sources Cited Above

The general pathway forward is to first run a study that identifies the optimal pediatric dosage of LP-184. If these studies show strong evidence of clinical activity, then a Phase II pivotal trial could be designed that would use a basket approach for all of these patients with these tumors. Biomarkers may also be used to identify these patients. Since the population is so small and it is a serious cancer in a pediatric population, the FDA is interested in response rates rather than a randomized control trial showing statistically significant efficacy. The primary goal in this population is to understand the safety and make the drug available to the pediatric patients. Following an assumed accelerated approval by the FDA, the sponsor would then be required to run a post-approval Phase IV confirmatory trial while the drug is marketed.

To populate the trial, the sponsor would be best served to work with a large pediatric cancer group that could capture a broader swath of patients such as the Children's Oncology Group and Pediatric Oncology Experimental Therapeutics Investigators' Consortium (POETIC). Lantern is interacting with each of these two groups.

Priority Review Vouchers (PRVs) can be awarded if the indications are approved. In recent years, these vouchers have sold in the secondary markets for around $100 million. The vouchers provide the bearer with a priority treatment for a drug application which can reduce the FDA review time by four months. They can be sold to other companies and are valid for any future drug application.

SMARCB1

The common thread for all of these rhabdoid tumors[6] is the SMARCB1 gene. The SMARCB1 gene is a crucial tumor suppressor gene located on chromosome 22 that aids in the regulation of cell growth and development. It produces a protein that is part of the SWI/SNF chromatin remodeling complex, which helps control how DNA is packaged and accessed within cells, thereby influencing which genes are active or inactive. A normally functioning SMARCB1 gene helps prevent cells from growing and dividing too rapidly. Loss of SMARCB1 function, typically through genetic mutations, is strongly associated with the development of several rare cancers, most notably rhabdoid tumors in young children. These mutations can either be inherited (germline mutations) or occur spontaneously in specific cells (somatic mutations), and the complete loss of SMARCB1 function is particularly characteristic of malignant rhabdoid tumors.

Harmonic Lead-In Cohort Clinical Update

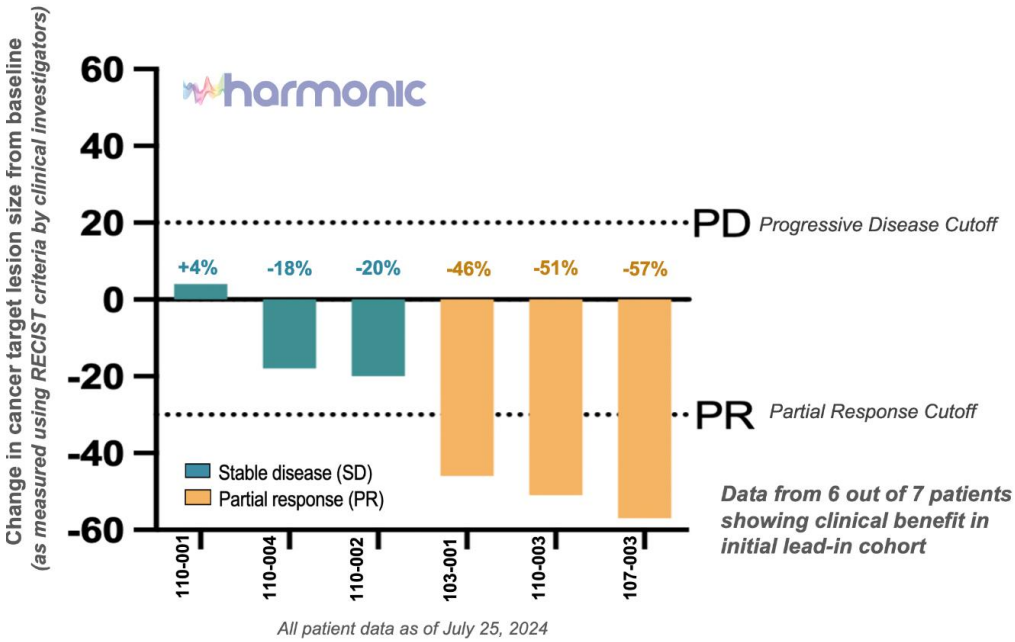
On August 5th, Lantern provided a clinical update to its Phase II Harmonic trial highlighting that six of seven (86%) patients experienced clinical benefit from LP-300 combination treatment. Of these patients comprising the lead-in cohort, three showed partial response (PR) and three others exhibit stable disease (SD). Average tumor size reduction for the partial responders was 51% and for those with stable disease, 13%. These results produce a clinical benefit[7] and disease control[8] rate of 86% and an objective response rate (ORR) of 43%.

[6] A rhabdoid tumor is a rare and aggressive type of cancer that primarily affects infants and young children, typically under the age of two. These tumors are characterized by their unique "rhabdoid" cells, which under a microscope resemble developing muscle cells. The most common types are atypical teratoid/rhabdoid tumors (AT/RT) found in the brain and spinal cord, and malignant rhabdoid tumors (MRT) that typically develop in the kidneys, though they can occur in other soft tissues throughout the body. Nearly all rhabdoid tumors are caused by the loss of function in a tumor suppressor gene called SMARCB1, which normally helps regulate cell growth and division. Due to their fast-growing nature and tendency to spread quickly, these tumors require intensive treatment, usually involving a combination of surgery, chemotherapy, and sometimes radiation therapy.

[7] Clinical Benefit Rate (CBR) is the percentage of patients who had a complete response, partial response, or had stable disease for 6 months or more. This is the proportion of patients who received a benefit from the intervention.

[8] Disease control rate (DCR) is the proportion of patients who, according to internationally recognized criteria for alleviating evaluation, achieve tumor relief (PR+CR) and stable disease (SD) after treatment and can maintain for the minimum duration requirement.

Exhibit II – Percent Change in Cancer Lesion Size by Patient



Source: Lantern Pharmaceuticals August 5th, 2024 Press Release

Safety was another strong point for Harmonic. A preliminary analysis found no safety concerns, dose limiting toxicities or treatment related serious adverse events. The most common adverse events were a decrease in white blood cell count and thrombocytopenia.

Patients in this first stage of the trial were never smoker NSCLC patients who had failed on previous tyrosine kinase inhibitor (TKI) therapy. These individuals received treatment with LP-300 along with carboplatin and pemetrexed.

These results compare favorably to historical responses to other combination studies that measure an investigational drug with pemetrexed and carboplatin in non-small cell lung cancer (NSCLC) patients who have relapsed following TKI therapy.

Exhibit III – Historical Response Data for Pemetrexed + Carboplatin in NSCLC Patients Post TKI Treatment

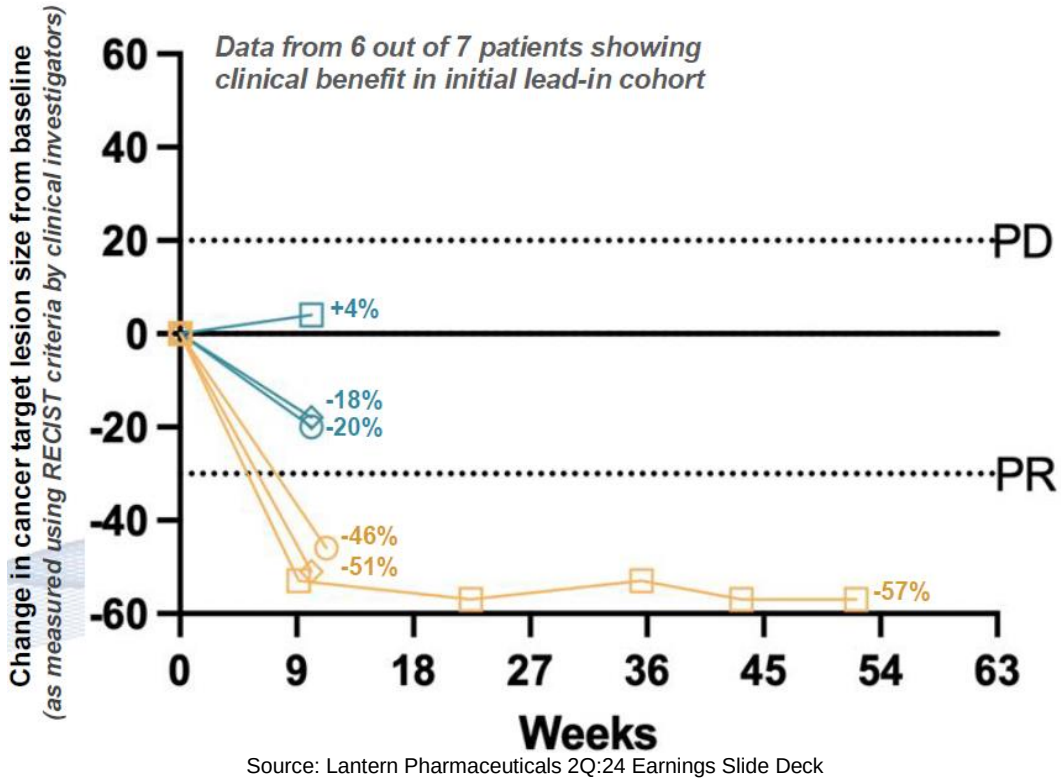
Trial Name	Sponsor	Intervention	Median ORR	Median DOR	Median PFS	HR for PFS
Mariposa-2	Janssen	Amivantamab lazertinib	36%	5.6	4.2	0.48
Keynote-789	Merck	Pembro-lizumab	27%	5.6	5.5	0.8
CheckMate-722	BMS	Nivolumab	27%	5.6	5.4	0.75
Herthena-Lung	Daiichi Sankyo	HER3-DXd	30%	6.4	5.5	
Harmonic	Lantern Pharma	LP-300	43%	Immature	Immature	Immature

Source: Compiled by Zacks Analyst from Sources Cited Below[9,10,11,12]

Other highlights from the trial include a 57% reduction in tumor size for a patient that has been enrolled in the study for 14 months. The seventh patient that did not achieve a PR or SD experienced progressive disease. Investigators observed that the patients with low to intermediate tumor mutation burden were most responsive to LP-300 combination therapy.

[9] Passaro, A. *et al*. Amivantamab plus chemotherapy with and without lazertinib in EGFR-mutant advanced NSCLC after disease progression on osimertinib: primary results from the phase III MARIPOSA-2 study. Annals of Oncology. October 2023.
[10] Arter, Z.L., Nagasaka, M. The Nail in the Coffin?: Examining the KEYNOTE-789 Clinical Trial's Impact. Lung cancer. January 2024.
[11] Mok, T. *et al*. Nivolumab Plus Chemotherapy in Epidermal Growth Factor Receptor–Mutated Metastatic Non–Small-Cell Lung Cancer After Disease Progression on Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitors: Final Results of CheckMate 722. Thoracic Oncology. January 2024.
[12] Yu, H. *et al*. HERTHENA-Lung01, a Phase II Trial of Patritumab Deruxtecan (HER3-DXd) in Epidermal Growth Factor Receptor–Mutated Non–Small-Cell Lung Cancer After Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy and Platinum-Based Chemotherapy. Thoracic Oncology. September 2023.

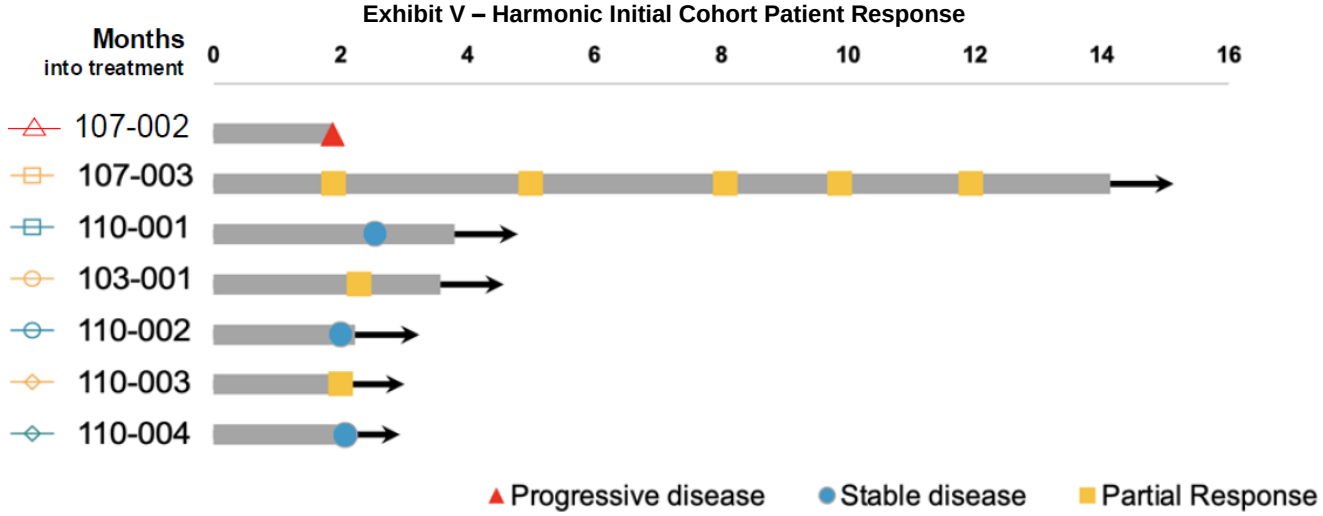
Exhibit IV – Change in Cancer Lesion Size by Patient



Source: Lantern Pharmaceuticals 2Q:24 Earnings Slide Deck

The randomization and expansion phase of the trial is underway where 84 additional patients will be placed in the LP-300 + SoC or SoC arms of treatment. The randomization proportion will be 2:1. The study's co-primary end-points are progression-free survival (PFS) and overall survival (OS). Results from this portion of the study will be provided when 31 clinical events have been observed. If the data are supportive, Lantern will consider applying for a Breakthrough Therapy designation.

Exhibit V – Harmonic Initial Cohort Patient Response



Source: Lantern Pharmaceuticals 2Q:24 Earnings Slide Deck

Expansion of Harmonic Trial to Asia

An April 22nd 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%.[13] The susceptibility to lung adenocarcinomas from never-smoker females can be in part attributable to

[13] Addressing High Lung Cancer Rates Among Female Asian Non-Smokers. Karen Gehrman. January 13, 2022.

oncogenic mutations.[14] Lantern identified a source that finds one-third of all lung cancer patients in East Asia are non-smokers. Clearly, this is an important market for LP-300 and expansion into this region will provide the data necessary for regulatory approval in areas that require additional studies conducted in target ethnic populations. These studies are frequently done in Asian populations, particularly in countries such as Japan, China and South Korea. 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 the attractiveness of Lantern with global biopharma companies. Management has activated 5 sites in Japan and 5 sites in Taiwan, which should be sufficient to achieve a sufficient representation.

Exhibit VI – Clinical Trial Sites in Japan and Taiwan



Source: Lantern Pharmaceuticals 2Q:24 Earnings Slide Deck

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.

Poster Presentations

Lantern Pharmaceuticals along with M.D. Anderson's Dr. Yong Du and Dr. Shiaw-Yih Lin presented a poster at the 2024 Immuno-Oncology Summit. The August 7th event was held in Philadelphia and provided a venue for the poster entitled LP-184, a Novel Acylfulvene, Sensitizes Immuno-Refractory Triple Negative Breast Cancers (TNBCs) to Anti-PD1 Therapy by Affecting the Tumor Environment. 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 ICB therapy. Other testing for LP-184 is expected to address whether or not the candidate elevates cytoplasmic ssDNA, induces immunostimulatory cytokine expression and creates replication stress. In the clinical realm, LP-184 is now the subject of a Phase I trial, evaluating the agent in patients with advanced solid tumors.

[14] Ha, S. *et al*. Lung cancer in never-smoker Asian females is driven by oncogenic mutations most often involving EGFR. Oncotarget. March 2015.

Poster conclusions:

- LP-184 combined with an anti-PD1 agent elicited a greater anti-tumor response than monotherapies in mouse TNBC tumors that are non-hypermutated and IO resistant;
- LP-184 can synergize with an anti-PD1 agent in a TNBC mouse model;
- LP-184 plus anti-PD1 combination treatment led to larger T cell population in the tumor microenvironment along with higher activity of these T cells.

Lantern also presented at the Society of Hematologic Oncology (SOHO) 2024 annual meeting beginning September 4th. The associated poster was entitled Phase I Clinical Trial of LP-284 in Relapsed or Refractory B-Cell Non-Hodgkin Lymphomas and Solid Tumors. The document summarized the design of the Phase Ia/Ib study which sought to determine the safety and tolerability of LP-284. The trial further served to determine the maximum tolerated dose of the agent and to identify Phase II dosing in patients. The poster reported progress of the study having completed dose levels 1 to 3 and starting dose level 4 in August. So far, LP-284 has been well tolerated and no serious adverse events have occurred. Of the six patients who were evaluable, four had stable disease and two had progressive disease.

Publications

In August 2024, Lantern research was published in PLOS ONE in an article entitled Expanding the repertoire of Antibody Drug Conjugate (ADC) targets with improved tumor selectivity and range of potent payloads through in-silico analysis. The study summarized the work done where the RADR platform was employed to identify ADC targets with improved tumor selectivity. The results identified a diverse range of both targets and payloads that can serve to facilitate multiple choices for precise ADC targeting.

Exhibit VII – Lantern Pipeline



Source: Lantern Pharmaceuticals' 3Q:24 Corporate Presentation

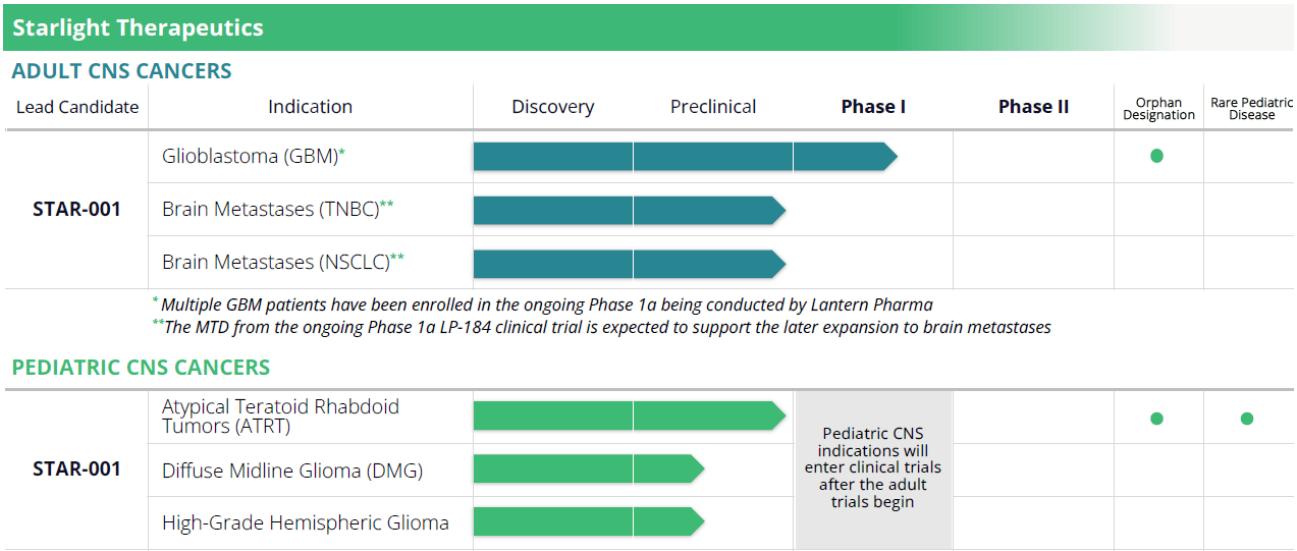
STAR-001

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 in 2H:24.

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 communica-

tion 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 activated. As of September 30th, cohort 9 has been dosed and no dose-limiting toxicity has been observed. 40-50 patients are expected to be enrolled.

Exhibit VIII – 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
- Initial readout for LP-184 – late summer/early fall 2024
- Initial readout for LP-284 – 2024
- STAR-001 (LP-184) Phase Ib/II clinical trial – 2H:24
- Initial readout for Harmonic – August 2024
- HARMONIC LP-300 interim readout of 30+ subjects – mid-2025

Summary

Lantern has had a busy second half so far, with updates on its HARMONIC trial and expansion of enrollment into 10 sites in East Asia. The FDA also looked favorably on Lantern with a fast-track designation for STAR-001 in GBM and three rare pediatric disease designations. The company was also busy communicating with the scientific community and investors through its attendance at the Immuno-Oncology Summit and the Society of Hematologic Oncology among others. Efforts to distinguish Starlight Therapeutics have progressed with continued work on STAR-001 and the appointment of inaugural Scientific Advisory Board members. In this report, we took a deeper look at some of the rare pediatric diseases that the company is pursuing, narrowed down their incidence and reviewed the pathway forward for them. We maintain our price target of $26.00 per share.

PROJECTED FINANCIALS

Lantern Pharma, Inc. - Income Statement

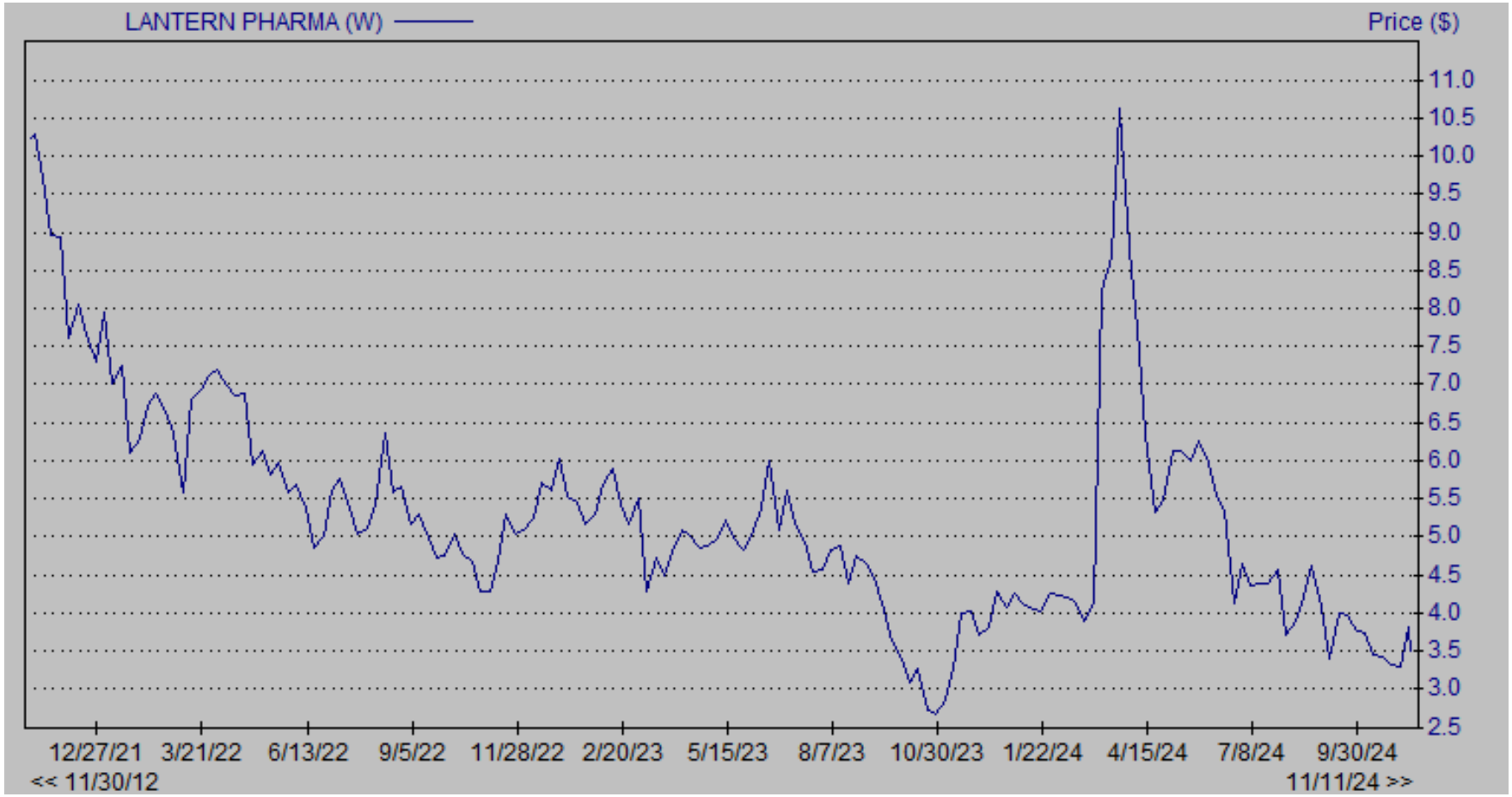
Lantern Pharma Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
General & Administrative	$5,983	$1,481	$1,520	$1,463	$1,724	$6,188	$6,581	$3,600
Research & Development	$11,894	$4,251	$3,889	$3,717	$3,890	$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[15]



[15] Source: Zacks Research System

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