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Lantern Pharma, Inc. (LTRN: NASDAQ)

LTRN: 2023 Results

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 (3/18/2024)	$9.96
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.

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 in 2025, US & EU regulatory submission in 2026 & commercialization in 2027. LP-184 is undergoing Ph2 trials in defined advanced tumors while LP-284 has been cleared for human trials.

SUMMARY DATA

52-Week High	**10.73**
52-Week Low	**2.38**
One-Year Return (%)	**99.2**
Beta	**1.3**
Average Daily Volume (sh)	**209,093**
Shares Outstanding (mil)	**10.7**
Market Capitalization ($mil)	**106.6**
Short Interest Ratio (days)	**0.7**
Institutional Ownership (%)	**22.3**
Insider Ownership (%)	**14.9**
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 2023 Estimate	**N/A**
P/E using 2024 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)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.38 A	-$0.41 A	-$0.21 A	-$0.31 A	-$1.31 A
2023	-$0.36 A	-$0.44 A	-$0.29 A	-$0.39 A	-$1.47 A
2024					-$1.98 E
2025					-$2.02 E

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What's New?

Lantern Pharma, Inc (NASDAQ: LTRN) reports full year 2023 financial results and achievements. Over the last few months, the company has been granted yet another orphan designation, strengthened its management team and progressed in its antibody drug conjugate (ADC) program. It has also participated in scientific and investor events, accumulated over 60 billion data points for RADR and dosed its first patient in the LP-284 trial for non-Hodgkin's lymphoma. We review these developments along with the company's 2023 financial results.

On March 18th, 2024, Lantern announced 2023 financial and operational results, filed its Form 10-K with the SEC and hosted a video webcast to review accomplishments. In the financial sphere, Lantern generated no revenues in 2023 and incurred operating expense of $17.9 million, producing a net loss of ($16.0) million or ($1.47) per share.

For the year ending December 31st, 2023 and versus the same comparable prior year period:

- Research & development expenses totaled $11.9 million, rising 38% from $8.6 million as spending for the LP-300 and LP-284 programs expanded materially. Spending on the ADC program expanded more than fivefold, but off of a small base. Product manufacturing expenses were lower and 2022 payments to Allarity Therapeutics did not recur in 2023;
- General & administrative expenses were $6.0 million, rising 3% from $5.8 million. Increases in professional fees, travel expenses, payroll and compensation and rent contributed to the rise. Some expenses declined including the categories of corporate insurance, legal and patent, business development and other office and administrative;
- Interest income was $765,000 versus $204,000 while other income (expense) shifted from $1.2 million to ($32,000). Higher interest rates led to the rise in interest income, while gains in investments and dividend income contributed to Other income;
- Net loss was ($16.0) million, or ($1.47) per share, compared to ($14.3) million, or ($1.31) per share.

At the end of 2023 cash and marketable securities on the balance sheet totaled $41.3 million, compared to year end 2022 cash balances of $55.2 million. Cash burn for 2023 was ($14.4) million versus ($12.8) million in the prior year. Cash used in financing was ($500,000) which was related to share repurchases. This compares to ($2.2) million of cash used in financing for 2022 with ($2.5) million used to repurchase shares.

First Patients Dosed in LP-284 Trial

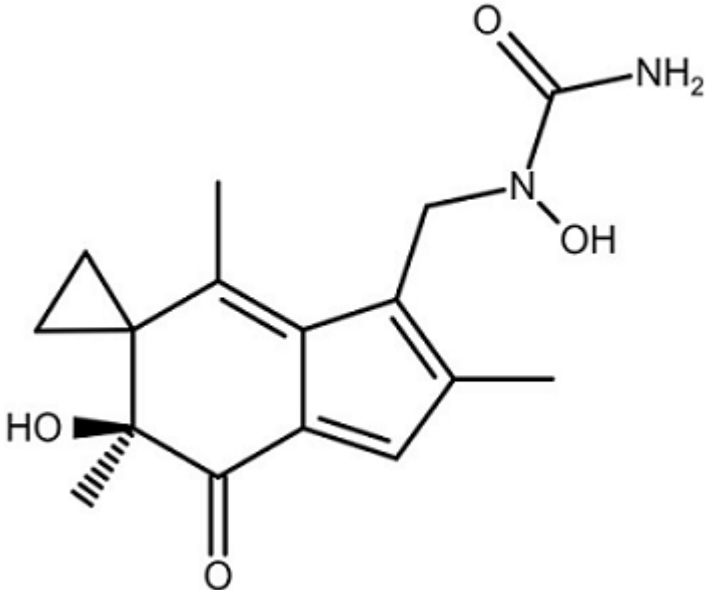
Following investigational new drug (IND) clearance by the FDA late last year for LP-284 in advanced, refractory non-Hodgkin's lymphoma (NHL) patients, Lantern announced that the first patients had been dosed in a March 15th press release. The study, listed under NCT06132503 on clinicaltrials.gov, will evaluate the safety and tolerability of LP-284 and determine the maximum tolerated dose of the drug to find the recommended Phase II dose. Up to 30 patients will be enrolled in the first part of the study and up to 40 patients will be enrolled in the second part which will include other cancers.[1] Lantern has activated two sites in the US thus far.

According to the American Cancer Society, about 81,000 people will be diagnosed with NHL in 2024. Some slow-growing types of NHL progress at a gradual pace and are easier to treat; however, other aggressive forms such as diffuse large B-cell lymphoma are more difficult and represent unmet needs. Mantle cell lymphoma is another aggressive type of NHL that is difficult to treat and usually presents at a later clinical stage. It is also resistant to many standard treatments. Lantern's addressable market will be relapsed or refractory NHL patients as well as other select solid tumors and sarcomas. The company estimates up to $4 billion of market potential from these indications.

LP-284
LP-284 (hydroxyureamethylacylfulvene) is the stereoisomer and positive enantiomer of LP-184. Preclinical work has demonstrated promising *in-vitro* and *in vivo* anticancer activity in multiple hematological cancers, which are distinct from the indications targeted by LP-184. The compound is a novel small molecule and DNA damaging agent being developed by Lantern for the treatment of several non-Hodgkin's lymphomas (NHL) including mantle cell lymphoma (MCL) and double hit lymphoma (DHL). LP-284 belongs to the new generation of acylfulvenes, a family of naturally derived anti-cancer drug candidates.

[1] Other indications include mantle cell, double-hit lymphomas and high-grade B-cell lymphoma (HGBL).

Exhibit I – Chemical Structure of LP-284[2]



New Orphan Drug Designation

Lantern was granted its first orphan drug designation in 2021 for LP-184 in pancreatic cancer. This was followed shortly after by the same designation in glioblastoma multiforme (GBM) and Atypical Teratoid Rhabdoid Tumor (ATRT) also for LP-184. Then in January 2023, another orphan designation was granted for LP-284 in Mantle Cell Lymphoma. Lantern's fifth orphan designation was recently awarded in December of last year, the second for LP-284, this time in high grade B-cell lymphomas (HGBL).

The associated press release notes that HGBL is a rare and aggressive form of B-cell non-Hodgkin's lymphoma with no established standard of care. While chemotherapy is used to treat the malignancy, up to a third do not respond and their cancer progresses. For relapsed or refractory patients, survival is usually less than 16 months.[3] The orphan designation for HGBL is the second for LP-284 which provides a broad array of advantages to the candidate to advance it to approval.

The FDA's orphan drug designation provides incentives for sponsors to develop drugs for rare diseases that affect fewer than 200,000 people in the U.S. Key features of the orphan drug designation include seven years of market exclusivity, tax credits, user fee waiver, assistance with clinical trial design and eligibility for grants among other features.

Starlight Adds Chief Medical Officer

A January 2024 press release informed investors that Starlight Therapeutics had appointed Marc Chamberlain, M.D. as Chief Medical Officer to oversee Starlight's clinical operations. His work will guide the development of STAR-001 (Lantern's LP-184) in several indications including GBM, brain metastases, ATRT and pediatric brain cancers.

Dr. Chamberlain's background has been focused on adult and pediatric neurology and neuro-oncology in four NCI-designated cancer centers: Moores Cancer Center at UC San Diego, Norris Cancer Center at USC, Moffit Cancer Center at the University of South Florida and Fred Hutchinson Cancer Center at the University of Washington. He has also served as medical director for Cascadian Therapeutics, Seattle Genetics, SystImmune, Angiochem, and Pionyr Immunotherapeutics. Dr. Chamberlain has published more than 300 neurology-focused papers in peer-reviewed journals.

[2] Lantern Pharma's 2023 Form 10-K.
[3] Laude, M.C., *et al*. First-line treatment of double-hit and triple-hit lymphomas: Survival and tolerance data from a retrospective multicenter French study. December 2020. (p.15/40)

Advance of ADC Program

Antibody Drug Conjugates (ADCs) have been one of the most in-demand technologies in recent years. There have been at least four major acquisitions[4] of ADC-focused companies since the beginning of 2023. ADCs are drugs designed as a targeted therapy for cancer which consist of three components: a monoclonal antibody (mAb), a cytotoxic drug and a linker which connects the other two. The mAb is designed to specifically bind to antigens found on the cancer cell surface. This targets the ADC to the cancer cells and minimizes binding to healthy cells. The cytotoxic drug is a chemotherapeutic agent that can kill cancer cells. The linker connects the two components and breaks down after payload delivery. It is designed to be stable in the bloodstream but release when the drug is endocytosed inside the cancer cell. By combining the targeting ability of antibodies with the cancer-killing ability of cytotoxic drugs, ADCs allow chemotherapy to selectively bind to and kill cancer cells while reducing side effects on healthy cells. Several ADCs are FDA approved including Kadcyla, Adcetris, Polivy, Padcev and Enhertu among others.

Lantern has been developing its own ADC program for some time in collaboration with partner Universitat Bielefeld in Germany. Its work is in the preclinical stage, but the program recently received a boost with its development of a new class of highly specific ADC which carries a cryptophycin[5] drug payload. In a recent press release, Lantern shared with investors its work on the development, synthesis and preclinical proof-of-concept for its cryptophycin-based ADC. RADR has been a part of the process to select targets, characterize molecular payload and conjugate payloads to improve ADC performance. Next steps for the program are preparation for investigational new drug (IND) development this year centered on solid tumors unresponsive or refractory to current therapies.

Lantern's approach uses cysteine-engineered antibodies which provides for more uniform and homogenous ADCs that can precisely control the drug to antibody ratio. The drug payload for its ADC is cryptophycin which offers several features that can improve its performance. These include improving the anti-tumor potency of the ADC molecule and overcoming drug resistance. In preclinical work, the cryptophycin ADC produced an 80% cancer cell kill rate which is in excess of other ADC drug payloads.

LP-300

Limited new information was provided for LP-300 beyond the announcement of an increase in the number of sites in the US to 12 and plans to open new sites in Asia. Lantern is seeking regulatory clearance for trials to begin in Japan, Taiwan and South Korea where about one-third of all lung cancer cases are non-smokers with NSCLC. Lantern noted in their press release that the LP-300 program is half enrolled but facing patient enrollment challenges in the US which may be alleviated by new Asia sites where prevalence of non-smoker NSCLC is higher.

Exhibit II – Lantern Pipeline[6]



[4] This includes Pfizer for Seagen ($43B), AbbVie for Immunogen ($10B), Lonza for Synaffix & J&J for Ambrx ($2B).
[5] Cryptophycins are a class of cytotoxic cyclic depsipeptides with anti-cancer properties. Cryptophycins have a similar mechanism of action to other microtubule-disrupting agents like paclitaxel. They bind to tubulin and inhibit microtubule formation, thus interrupting mitosis & cell division.
[6] Source: Lantern Pharma March 2024 Corporate Presentation

Webinar Wednesdays

Lantern will host a series featuring world-class collaborators and researchers titled "*Webinar Wednesdays*" that will address company-related technologies and indications. As the title suggests, the webinars will be held on Wednesdays in coming months to enhance communications with investors and other stakeholders. Upcoming topics include:

- LP-300 in non-smoker NSCLC with Dr. Joseph Treat of Fox Chase Cancer Center
- STAR-001 in Brain & CNS cancers with Dr. Marc Chamberlain, CMO of Starlight Therapeutics
- LP-84 in Pancreatic Cancer & Other Solid Tumors with Dr. Igor Astsaturov of Fox Chase Cancer Center
- Discussions addressing Lantern's AI Platform

Milestones

- LP-284 trial launched – 4Q:23
- Three new patent applications submitted (LP-284 in HGBL) – 4Q:23
- Further disclosure on cryptophycin-based ADC – January 2024
- RADR exceeds 60 billion data points – March 2024
- Participation in AI-based drug discovery and development conference – March 2024
- LP-184 Phase Ia continued enrollment – 1H:24
- Expansion of trial sites for Harmonic throughout the US and Asia – 1H:24
- AACR presentation for LP-284 – April 2024
- ADC program IND development – 2024
- Begin combination studies for LP-184 and LP-284 - 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 – 2H:24

Summary

Lantern provided financial and operational results for 2023 and brought us up to date for its three clinical candidates and preclinical programs. LP-284 is the latest asset to dose patients in a clinical trial and is advancing with an orphan designation under its belt. We expect to see an initial readout later this year. The LP-184 program has continued to dose patients and is also expected to provide a readout in 2024. LP-300 should benefit from new site openings in the US and in Asia which offers a higher prevalence of non-smoker NSCLC. Starlight is shining bright with a new Chief Medical Officer who will shepherd STAR-001 through a Phase Ib/II study in 2H:24 focusing on GBM, brain metastases and other rare pediatric CNS cancers.

Lantern enters 2024 with an attractive treasure chest of $41 million which is expected to support operations through at least the end of 2025. The company offers an attractive artificial intelligence platform that may soon become self-aware. RADR offers multiple modules that evaluate mechanism of action, identify drug combinations, prioritize indications, enhance selection of ADC components and many other features. The system has evolved to accumulate and curate data on its own. Additionally, the company brings its orphan designation count to five, adding HGBL to its stable of rare diseases recognized by the FDA. Development work is also moving forward with identification of the toxic payload used in Lantern's ADCs and we expect to see IND development on this program later in 2024. We maintain our price target of $26.00 per share.

PROJECTED FINANCIALS

Lantern Pharma, Inc. - Income Statement

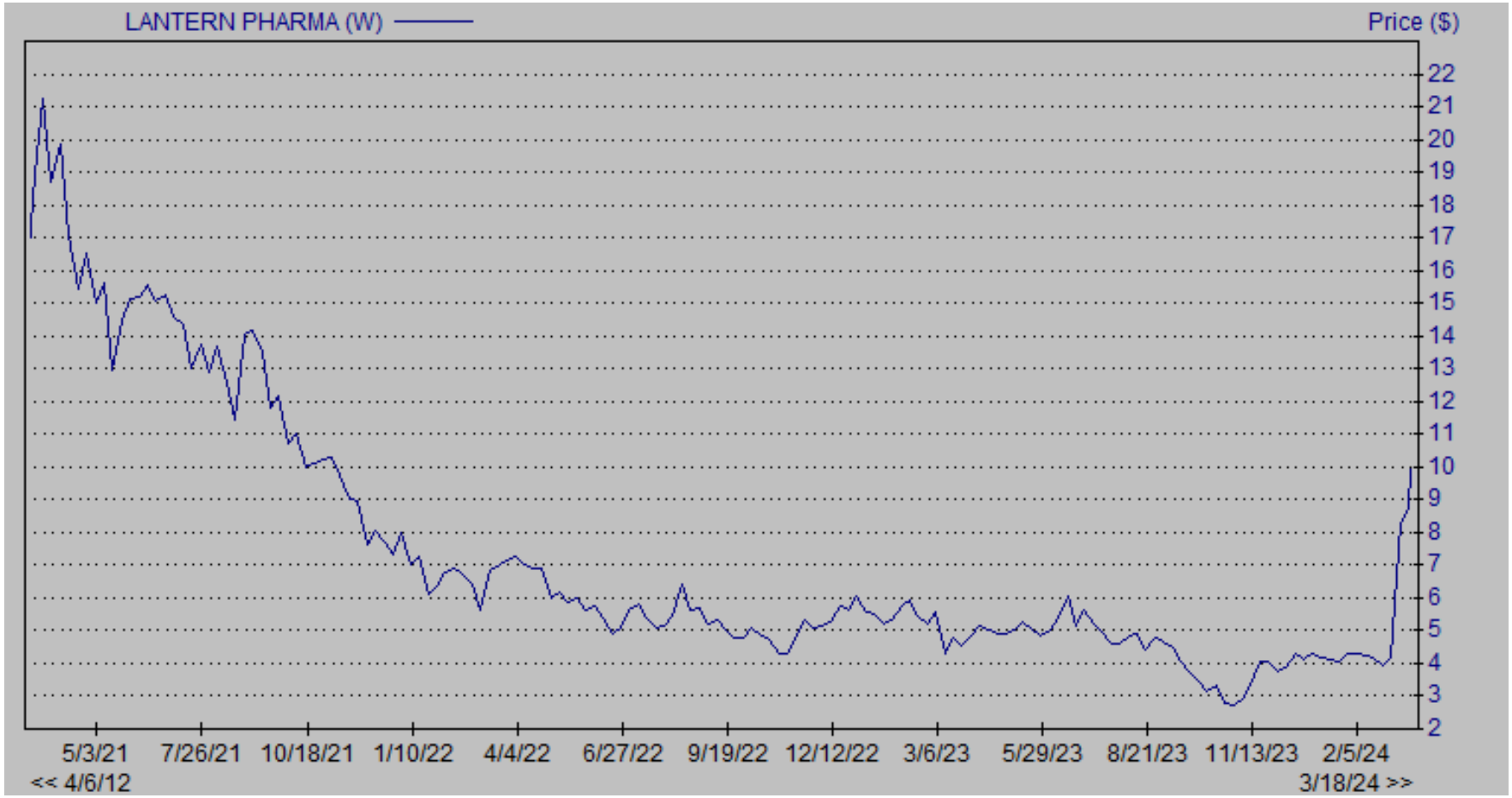
Lantern Pharma Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 A	2023 A	2024 E	2025 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
General & Administrative	$5,830	$1,733	$1,632	$1,314	$1,304	$5,983	$6,500	$6,581
Research & Development	$8,603	$2,553	$3,558	$2,210	$3,573	$11,894	$18,100	$18,643
Income from operations	($14,433)	($4,286)	($5,190)	($3,524)	($4,877)	($17,878)	($24,600)	($25,224)
Interest Income	$204	$134	$118	$246	$267	$765	$500	$10
Other Income	($32)	$285	$326	$116	$424	$1,151	$0	$0
Pre-Tax Income	($14,260)	($3,868)	($4,746)	($3,161)	($4,186)	($15,962)	($24,100)	($25,214)
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	**($14,260)**	**($3,868)**	**($4,746)**	**($3,161)**	**($4,186)**	**($15,962)**	**($24,100)**	**($25,214)**
Reported EPS	**($1.31)**	**($0.36)**	**($0.44)**	**($0.29)**	**($0.39)**	**($1.47)**	**($1.98)**	**($2.02)**
Basic Shares Outstanding	10,851	10,857	10,857	10,857	10,860	10,842	12,200	12,500

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

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HISTORICAL STOCK PRICE

Lantern Pharma, Inc. – Share Price Chart[7]



[7] Source: Zacks Research System

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