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Lantern Pharma, Inc. (LTRN: NASDAQ)

Full Year 2022 Results

Based on our DCF model which uses a 15% discount rate, Lantern Pharma is valued at approximately $26.00 per share. 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 (3/21/2023)	$4.40
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 which was reacquired from Allarity Therapeutics, and LP-184 and LP-284 which are in preclinical development for multiple biomarker-defined tumors and hematological cancers, respectively.

Lantern uses AI & machine learning to rescue failed and 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 and saving time and 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 expected to begin Ph2 trials in defined advanced tumors in 2022.

SUMMARY DATA

52-Week High	**7.92**
52-Week Low	**4.05**
One-Year Return (%)	**-34.8**
Beta	**0.7**
Average Daily Volume (sh)	**39,245**
Shares Outstanding (mil)	**10.9**
Market Capitalization ($mil)	**48.0**
Short Interest Ratio (days)	**4.6**
Institutional Ownership (%)	**27.2**
Insider Ownership (%)	**23.4**
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 2022 Estimate	**N/A**
P/E using 2023 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)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.24 A	-$0.21 A	-$0.36 A	-$0.31 A	-$1.13 A
2022	-$0.38 A	-$0.41 A	-$0.21 A	-$0.31 A	-$1.31 A
2023					-$1.54 E
2024					-$2.42 E

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What's New?

2022 Financial and Operational Results

On March 20, 2023, Lantern Pharma, Inc. (NASDAQ: LTRN) announced 2022 financial and operational results, filed its Form 10-Q with the SEC and hosted a video webcast to review accomplishments. Since our previous update, Lantern has created the Starlight Therapeutics subsidiary, presented new data for LP-100, expanded its clinical leadership team, presented LP-184 at AACR and developed a roadmap for ADC development. The company also announced that it has activated five clinical trial sites and expects to enroll its first subjects in the HARMONIC trial in 2Q:23.

Highlights for 2022 and to-date include:

- FDA Authorization to start LP-300 trial – July 2022
- LP-184 data presented at AACR – September 2022
- KOL Webinar, Pediatric Cancers – September 2022
- LP-284 data for mantle cell lymphoma presented at SOHO – September 2022
- Publication in Frontiers in Drug Discovery – October 2022
- New patent issued for LP-300 – October 2022
- Positive data for LP-184 in GBM presented at SNO – November 2022
- Orphan drug designation for LP-284 in mantle cell lymphoma – January 2023
- AI collaboration with TTC Oncology – February 2023
- Addition of Dr. Reggie Ewesuedo M.D., VP of Clinical Development – March 2023
- Formation of Starlight Therapeutics – March 2023
- Refined direction for LP-100 with PARPi in prostate cancer – March 2023

Lantern generated no revenues in 2022 and incurred operating expense of $14.4 million, producing a net loss of ($14.3) million or ($1.31) per share.

For the year ending December 31, 2022 and versus the same comparable prior year period:

- Research & development expenses totaled $8.6 million, rising 14% from $7.6 million on account of rising consulting expenses as well as research and development payroll expenses. These increases were partially offset by decreases in product candidate manufacturing related expenses, decreases in licensing fees and a net decline in payments to licensing partners. Manufacturing related expenses fell as a result of a payment received from a service provider;
- General & administrative expenses were $5.8 million, rising 16% from $5.0 million. The following expense categories drove the increase: payroll and compensation, other professional fees, legal and patent expenses, travel expenses and other expenses. This was partially offset by decreases in business development expenses and corporate insurance;
- Interest income was $204,000 versus $68,000 while other (expense) income shifted to a loss of ($32,000) versus a gain of $161,000. The amount in other expense was attributable to increases in unrealized losses on investments, increase in foreign currency loses and a one-time gain from loan forgiveness among other minor items;
- Net loss was ($14.3) million, or ($1.31) per share, compared to ($12.4) million, or ($1.13) per share.

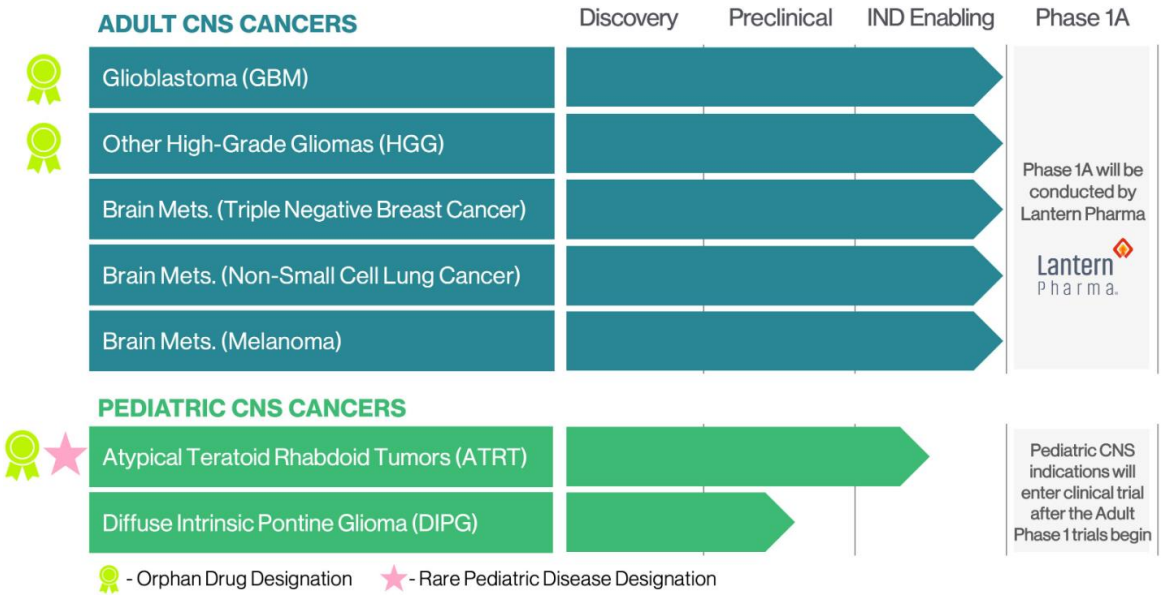
At the end of 2022 cash and marketable securities on the balance sheet totaled $55.2 million, declining $15.5 million compared to year end 2021. Cash burn for 2022 was ($12.8) million versus ($10.6) million in the prior year period. Cash used in financing was ($2.2) million with ($2.5) million of share repurchases partially offset by $0.3 million in warrant and option proceeds.

Starlight Therapeutics

In a March 6th press release, Lantern Pharma announced that it had created a new subsidiary that will hold rights to LP-184 for use in central nervous system (CNS) cancers. As part of the creation of the new entity, LP-184 will be renamed STAR-001 with the objective of pursuing CNS cancers with limited or no effective therapeutic options. Creating a subsidiary will make it easier to work with partners and potentially spin out this entity with its own funding, providing access for shareholders, patients and potential acquirors to an attractive segment of oncology that is not hindered by collateral indications.

Lantern expects to begin clinical trials in the designated cancer indications in late 2023 and 2024. In mid-2023, Lantern anticipates the start of a Phase Ia basket trial for LP-184 that will investigate recurrent brain cancers, metastatic CNS cancers, pancreatic cancer and solid tumors with DDR deficiencies. Starlight will have access to Lantern's RADR platform to advance targeted and efficient clinical development programs.

Exhibit I – Starlight Therapeutics Pipeline[1]



There are a number of potential benefits to creating a subsidiary to hold the CNS indications depending on the ultimate direction taken by the programs in Starlight. Flexibility, branding, access to resources and tax treatment are some of the primary benefits we see from the move. Starlight can also enter into its own agreements with partners and can be bought by another pharmaceutical company that wants access to CNS cancer therapeutics.

STAR-001

STAR-001 is the new designation for LP-184 when used in central nervous system (CNS) tumors under the Starlight Therapeutics banner. This asset is in preclinical development for multiple indications including glioblastoma (GBM), brain metastases in the lung, breast and skin, Atypical Teratoid Rhabdoid Tumors (ATRTs) and pediatric brain cancers. Several of these indications are eligible for orphan status including GBM, ATRT and pediatric brain cancers. ATRT has been granted a rare pediatric disease designation, which provides a priority review voucher if the pediatric indication is approved.

Favorable data has been observed for each of these indications. This includes the ability of STAR-001 to cross the blood brain barrier, induce tumor regression, and offer potent efficacy in specific cancer cell lines. The drug is amenable to combination therapies and has shown *in-vitro* potency with spironolactone

AACR Presentation

Lantern will present at the American Association for Cancer Research (AACR) Annual Meeting in Orlando, Florida on April 19th, 2023. The abstract for the presentation examines the role of DNA damage response (DDR) pathways and LP-184 in cancers that exhibit these characteristics. DDR pathways allow tumor cells to persist rather than un-

[1] Source: Lantern press release, March 6, 2023.

dergo apoptosis. The abstract notes that up to a third of solid tumor cancers have a deficiency in the DDR pathways and they are vulnerable to DDR inhibitors allowing next generation acylfulvenes such as LP-184 to produce synthetic lethality in tumor cells. Synthetic lethality is a concept in oncology that refers to the idea that cancer cells that carry certain mutations or genetic alterations can be selectively killed by targeting a second, functionally related gene or pathway. LP-184 can be synthetically lethal due to its ability to cause unresolvable DNA damage if tumor cells express high prostaglandin reductase 1 (PTGR1)[2] and are deficient in nucleotide excision repair (NER) / homologous repair (HR) genes. Unlike poly ADP-ribose polymerase inhibitors (PARPi), LP-184 can induce cell death in both NER deficient as well as HR deficient cancers.

LP-100 and PARP Inhibitors

LP-100 was recently reacquired from Allarity Therapeutics following the latter's Phase II work in prostate cancer. After evaluating all of the relevant data available including *in silico* analysis from patient data sets using RADR, Lantern has identified a promising indication in homologous repair (HR) deficient cancers such as metastatic prostate (mCRPC) and other cancers where PARPis are being used. A new clinical trial is being considered in cancers with mutations in DDR genes such as BRCA1/2 and ATM, which will build upon the prior Phase II work conducted in metastatic castration-resistant prostate cancer.

Lantern conducted prostate cancer mouse xenograft studies, showing synergistic potency of LP-100 when used with PARPi Olaparib. LP-100 was also synergistic with Olaparib, Rucaparib and Niraparib in ovarian cancer cell line studies. The combination's mechanism of action induces synthetic lethality by preventing repair of double strand breaks in the DNA leading to cell apoptosis. We expect to see further development efforts for LP-100 be conducted in combination with PARP inhibitors. The new approach is expected to expand the potential market size and position the drug in multiple genomically defined DDR cancers.

Antibody Drug Conjugate Development

In mid-February, Lantern provided a roadmap for the development of antibody drug conjugates (ADCs) for targeted delivery of cytotoxic drugs to tumor cells. ADCs are a class of drug that binds to target cells using an antibody to deliver a toxin or other small molecule. The conjugate combines the specificity of monoclonal antibodies with the cytotoxic potency of chemotherapy drugs. ADCs consist of three components: an antibody, a linker, and a cytotoxic drug molecule. ADCs allow for the selective delivery of cytotoxic drugs to cancer cells while sparing normal cells, thereby reducing off-target toxicity and improving the efficacy of chemotherapy.

The company plans to use the prestige of its AI and ML platform to enhance the development of novel and effective ADCs for the targeted delivery of potent anti-cancer small molecules to cancer cells. It expects to improve the cost, pace and timeline of drug discovery and development through the use of its RADR platform. A roadmap was provided highlighting several features of the effort. These include use of algorithms to 1) predict optimal combinations of ADC components, 2) generate biomarker signatures that can predict a cancer's sensitivity to an ADC, 3) identify potential synergies and 4) predict the immunogenicity of ADC antibodies to cancer cell surface antigens. The strategy will enable the large-scale analysis of thousands of high-performing model features through their SHAP[3] scores to efficiently identify key genes and pathways that are mechanistically important to drug resistance, quality of patient outcomes, and improved delivery of ADC drug payloads.

ADCs have been in the news recently with the announcement of Pfizer's (PFE) plans to acquire Seagen (SGEN) for $43 billion. Formerly Seattle Genetics, Seagen is a pioneer in the development of ADCs, and has successfully commercialized three ADC assets including Adcetris, Padcev and Tivdak. Other recent acquisitions in the space include Gilead's (GILD) buy of Immunomedics and Merck's (MRK) acquisition of VelosBio.

LP-184 Progress

SNO Poster for GBM

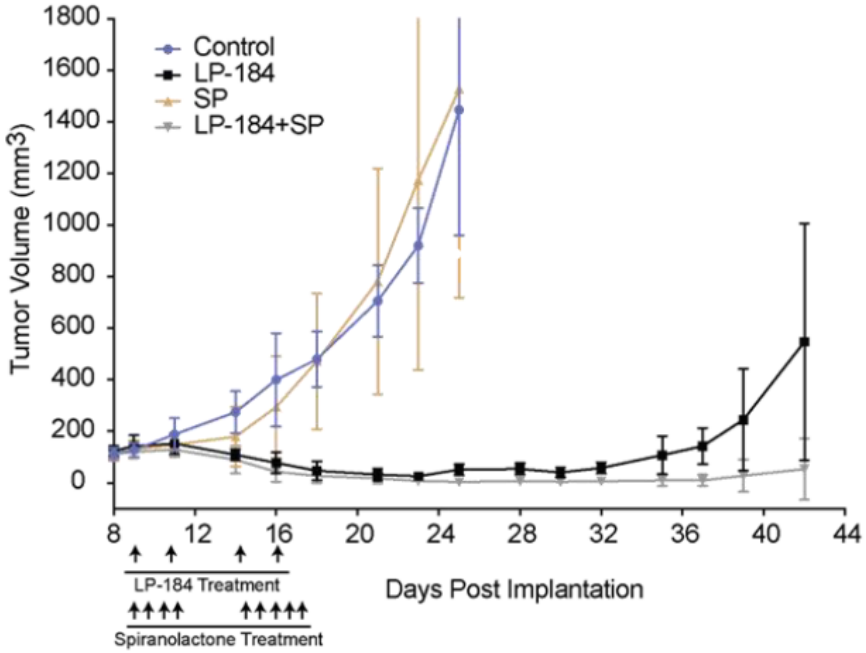
In late November, Lantern highlighted positive data around the anti-tumor potency of LP-184 in glioblastoma (GBM) at the Society for Neuro-Oncology Annual Meeting held in Tampa Bay, Florida. Positive preclinical data was presented for the use of LP-184 either alone or in combination with spironolactone for use against GBM. LP-184 pref-

[2] PTGR1 is an enzyme that is involved in the metabolism of prostaglandins, which are small lipid molecules that play important roles in various physiological and pathological processes, including inflammation and cancer.

[3] A Shapley Additive Explanation (SHAP) score is a method for explaining the output of machine learning models by measuring the contribution of each input feature to the model's prediction. It is based on the Shapley value from cooperative game theory, which measures the marginal contribution of each player to a coalition.

erentially damages DNA in cancer cells that harbor mutations in DNA damage repair (DDR) genes and that overexpress the enzyme PTGR1. The associated poster exhibited the *in vitro/in vivo* efficacy of LP-184 towards GBM as a single agent or in combination with spironolactone. This may provide an alternative to the standard of care agent temozolomide, which is ineffective in most patients.

Exhibit II – Tumor Volume for LP-184 + Spironolactone versus Control[4]



The presentation concluded that LP-184 is effective against temozolomide-resistant preclinical GBM models and is similarly effective independent of methylation status.[5] Common GBM tumor characteristics enhance the effectiveness of LP-184 in patients with intrinsic or spironolactone-induced nucleotide excision repair (NER) deficient tumors. Next steps for this program are to test LP-184 in combination with spironolactone in an intracranial xenograft model of GBM to assess survival, tumor response and pharmacokinetics. Additional investigational new drug (IND) enabling work is also planned.

SABCS Poster in TNBC

Lantern presented at the San Antonio Breast Cancer Symposium in December exhibiting LP-184's anti-tumor efficacy for triple negative breast cancer (TNBC) in comparison with standard of care agents. Many breast cancers lack the receptors for estrogen, progesterone or HER2 and drugs designed for these targets are ineffective. TNBC is a particularly deadly type of breast cancer with median survival of metastatic patients at less than one year.

The poster presented highlights LP-184's *in vitro* and *in vivo* anti-tumor potency across several breast cancer models, including those resistant to poly ADP-ribose polymerase (PARP) inhibitor Olaparib. Summary conclusions from the poster include:

- LP-184 demonstrates nanomolar potency in a panel of breast cancer cell lines;
- LP-184 dosed at 4 mg/kg was well tolerated in all TNBC PDX tumor models;
- Monotherapy LP-184 demonstrated high antitumor efficacy with complete tumor regression observed;
- LP-184 may be broadly efficacious in multiple other solid tumors with homologous repair and/or NER pathway defects, such as pancreatic, prostate, ovarian and bladder cancers.

[4] Source: Lantern Poster Preclinical efficacy of LP-184, a tumor site activated synthetically lethal therapeutic, in glioblastoma. November 2022.
[5] Methylation refers to the attachment of methyl groups to DNA. Methylation typically occurs on cytosine residues in the DNA molecule and can change the expression of genes by affecting the way that the genetic information is interpreted. Methylation is an epigenetic modification, meaning that it can alter gene expression without changing the underlying DNA sequence. MGMT (O6-methylguanine-DNA methyltransferase) is a DNA repair gene that is commonly methylated in glioblastomas. Methylation of the MGMT promoter is associated with the inactivation of the MGMT gene, which leads to chemotherapy resistance with alkylating agents, such as temozolomide. A methylated MGMT gene means that the gene is turned off, and the tumor is resistant to certain chemotherapy drugs. An unmethylated MGMT gene, on the other hand, means that the gene is turned on, and the tumor is sensitive to those drugs. The methylation status of the MGMT gene is therefore an important predictor of response to therapy in glioblastoma patients.

Pre-IND Feedback for LP-184
In mid-January, Lantern announced the receipt of feedback from the FDA regarding its anticipated LP-184 investigational new drug (IND) submission. In 4Q:22, Lantern requested the pre-IND meeting with the agency to ensure that the IND submission would address all of the FDA's concerns. The submission is expected in the near term, and if there are no outstanding questions, clearance could arrive in time for a trial to start in 2Q:23. The related study will look at a variety of solid tumors including those related to pancreatic cancer, solid tumors with DNA damage repair deficiency and malignant gliomas, including glioblastoma.

LP-284 Progress

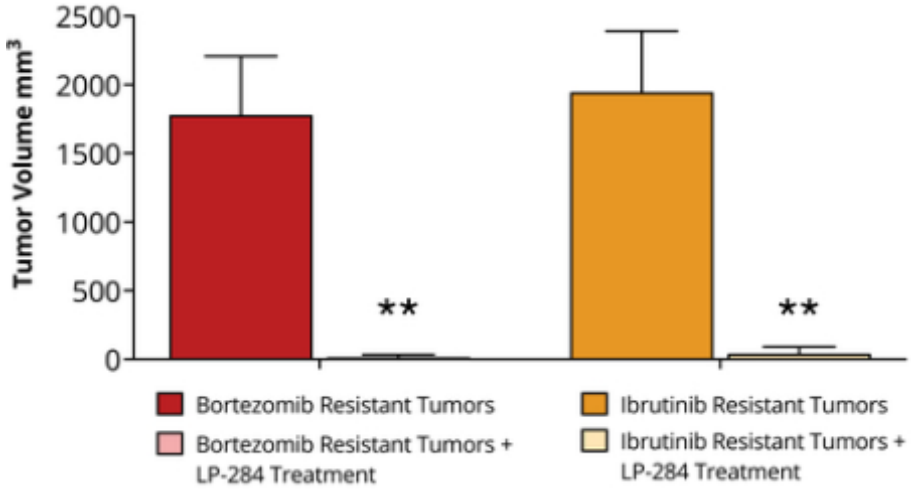
LP-284 Presentation at ASH
In mid-December, new data from Lantern's development work for LP-284 was presented at the American Society of Hematology (ASH) 2022 Annual meeting in New Orleans, Louisiana. The associated poster is entitled "Development of a Potent DNA Damaging Agent LP-284 for Treatment of Mantle Cell Lymphoma." Results in the poster demonstrated significantly greater tumor growth inhibition (TGI) in mice implanted with mantle cell lymphoma (MCL) cell derived xenograft tumors, when compared to treatment with the standard-of-care agents Ibrutinib or Bortezomib.

Exhibit III – Tumor Growth Inhibition Comparison[6]

Agent (Dose; Administration)	LP-284 (4 mg/kg; i.v.)	LP-284 (2 mg/kg; i.v.)	Bortezomib (1 mg/kg; i.p.)	Ibrutinib (50 mg/kg; p.o.)
TGI (%)	113%	63%	22%	8%

In mouse tumors that had grown resistant to Bortezomib or Ibrutinib, subsequent administration of LP-284 resulted in substantial regression of the standard of care treated lesion. This effect is shown in the following exhibit.

Exhibit IV – Tumor Response to LP-284 in Standard of Care Resistant Tumors[7]



LP-284 treatment of MCL cell lines significantly down-regulated key cancer promoting genes and pathways. These new *in vitro* and *in vivo* preclinical data for LP-284 strongly support its anti-tumor activity in MCL over current standard of care agents.

[6] Source: Lantern Press Release, December 15, 2022.
[7] Source: Lantern Press Release, December 15, 2022.

Key conclusions from the poster are that LP-284:

- Significantly delays tumor progression and prolongs survival of the mouse models compared with Ibrutinib and Bortezomib;
- Shrinks and delays the progression of MCL xenograft tumors;
- Induces DNA damage.

Data shared in this presentation will support the preparation of an IND to pursue indications in MCL and double hit lymphoma. IND-enabling studies are expected to be complete in 1Q:23 and validation of LP-284 as a novel agent targeting oncogene addiction is ongoing.

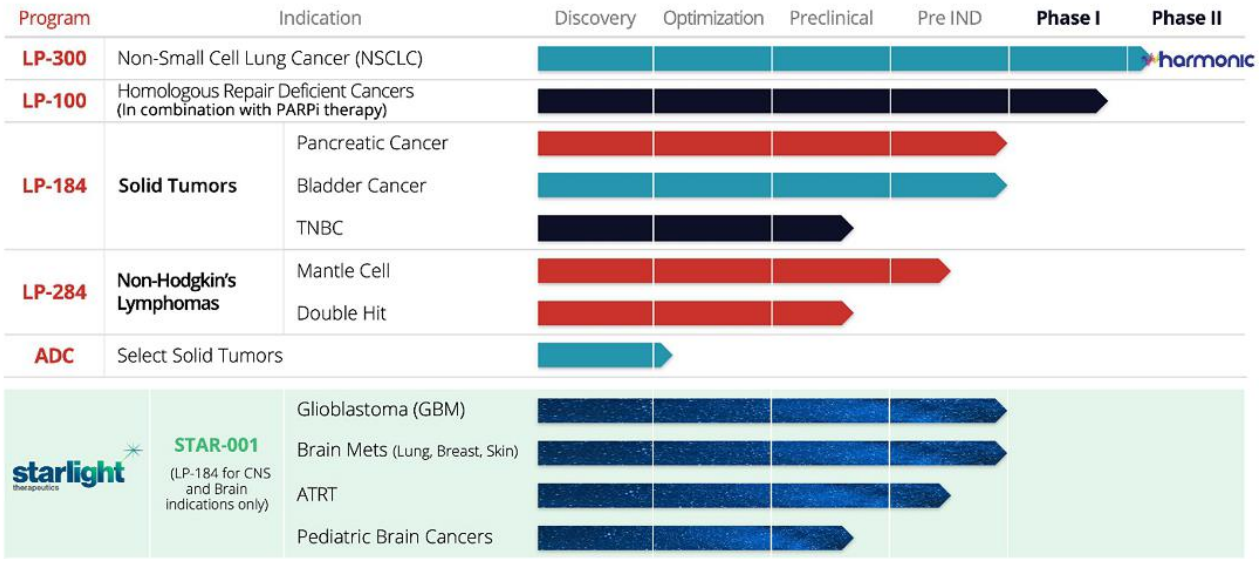
Orphan Drug Designation for LP-284 in MCL
Starting off the year with positive news, Lantern's first press release for 2023 announced the FDA's grant of orphan drug status to LP-284 in mantle cell lymphoma (MCL). According to the National Organization for Rare Disorders (NORD), MCL is a type of non-Hodgkin's lymphoma that affects every one out of 200,000 individuals or about 1700 persons. Lantern plans to file a related IND for LP-284 in B-cell non-Hodgkin's lymphomas, including MCL by mid-2023.

Orphan drug designation grants several benefits to awardees including tax credits for qualified clinical trials, exemption from user fees and seven years of exclusivity after approval. In the United States, the status may be given to products that address diseases affecting fewer than 200,000 persons. Similar benefits are available in other regions outside the United States, and ten years of exclusivity is offered in the European Union. These incentives may be available if Lantern seeks and is granted orphan designations in these areas. This is the fourth orphan designation granted to Lantern with others for indications in malignant gliomas, atypical teratoid rhabdoid tumors and pancreatic cancer.

Harmonic Trial

In July 2022, Lantern announced the start of the Harmonic trial that will evaluate LP-300 in never smokers with non-small cell lung cancer (NSCLC). 90 subjects are expected to enroll in the Phase II study at 15 – 20 sites around the United States with enrollment expected to last from 12 to 16 months. It will target never smokers with lung adenocarcinoma who have relapsed after treatment with tyrosine kinase inhibitors (TKIs). The study will consist of two stages, the safety lead-in stage and the randomization stage. Patients on LP-300 + pemetrexed and carboplatin will be measured against patients on pemetrexed and carboplatin only in a 2:1 ratio. Primary endpoints are progression free survival (PFS) and overall survival (OS). Secondary endpoints include objective response rate (ORR), duration of objective response (DOR) and clinical benefit rate (CBR). The trial will also collect liquid biopsies and acquire genomic and transcriptomic data from patients. As of the 2022 report in late March 2023, Lantern has activated five clinical trial sites and expects to enroll first subjects in 1H:23.

Exhibit V – Lantern Pipeline[8]



[8] Source: Lantern Pharma 2022 10-K

Summary

Since the report of third quarter results, Lantern has activated additional trial sites for its HARMONIC study, continued screening efforts and anticipates first enrolled subjects in 2Q:23. The company also announced the creation of subsidiary Starlight Therapeutics, which will hold all of Lantern's CNS cancer assets, including the former LP-184, now designated STAR-001. Other efforts include preparation of INDs for LP-184 and LP-284. Our eyes are focused on the HARMONIC trial, which is the primary value driver for the company. Its indication in non-smoker NSCLC is an attractive niche which lacks other targeted therapies. We maintain our price target of $26.00 per share.

PROJECTED FINANCIALS

Lantern Pharma, Inc. - Income Statement

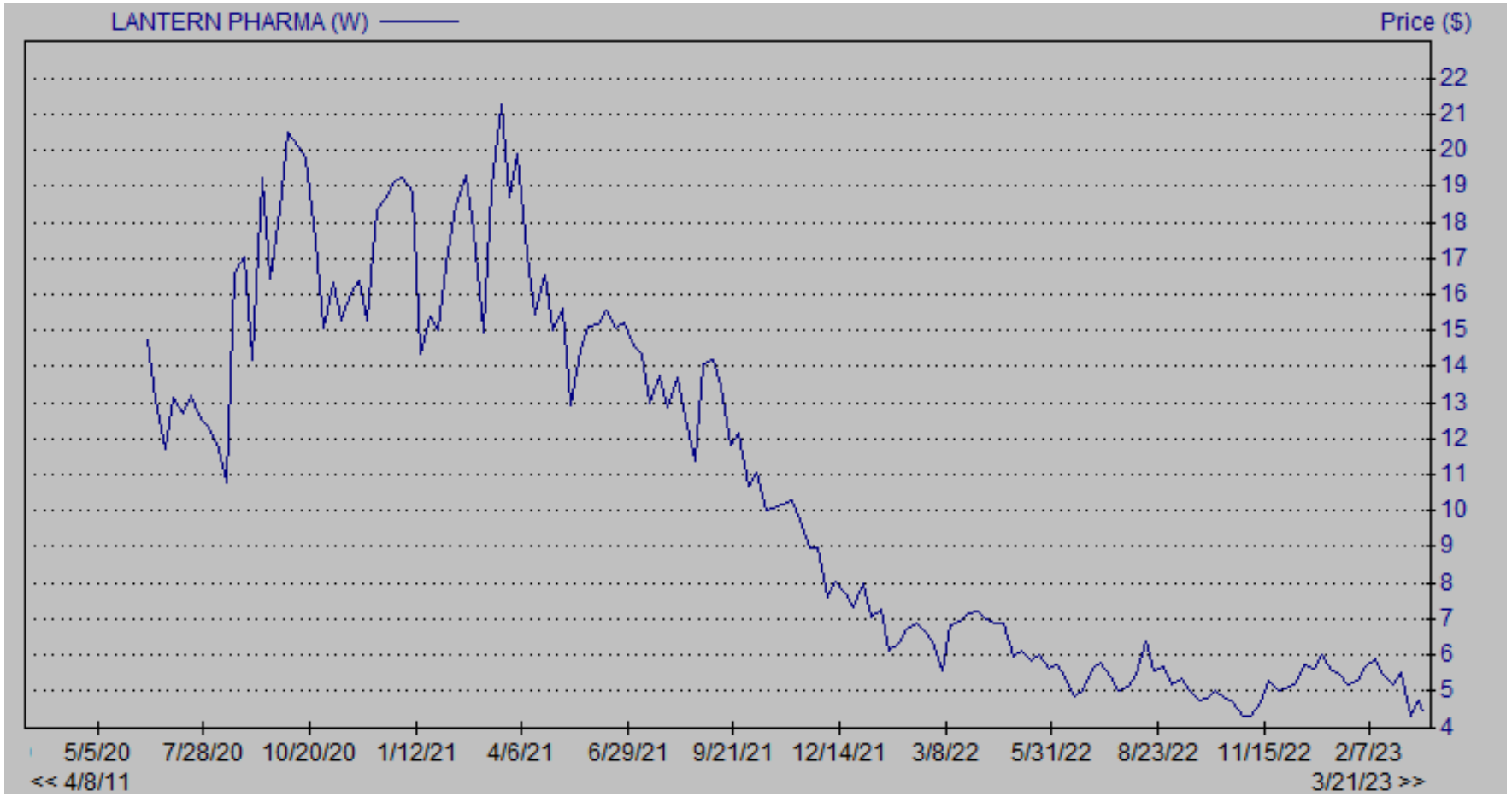
Lantern Pharma Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
General & Administrative	$5,021	$1,406	$1,406	$1,443	$1,575	$5,830	$5,976	$6,500
Research & Development	$7,571	$2,660	$2,989	$702	$2,252	$8,603	$11,614	$23,100
Income from operations	($12,592)	($4,066)	($4,395)	($2,145)	($3,826)	($14,433)	($17,590)	($29,600)
Operating Margin								
Interest Income	$68	$22	$55	$52	$75	$204	$80	$50
Other Income	$161	($78)	($153)	($172)	$370	($32)	$0	$0
Pre-Tax Income	($12,363)	($4,122)	($4,492)	($2,265)	($3,381)	($14,260)	($17,510)	($29,550)
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	**($12,363)**	**($4,122)**	**($4,492)**	**($2,265)**	**($3,381)**	**($14,260)**	**($17,510)**	**($29,550)**
Net Margin	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*
Reported EPS	**($1.13)**	**($0.38)**	**($0.41)**	**($0.21)**	**($0.31)**	**($1.31)**	**($1.54)**	**($2.42)**
YOY Growth	*-17%*	*55.7%*	*100.2%*	*-42.6%*	*-2%*	*16%*	*17%*	*58%*
Basic Shares Outstanding	10,905	10,876	10,831	10,839	10,857	10,851	11,400	12,200

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

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HISTORICAL STOCK PRICE

Lantern Pharma, Inc. – Share Price Chart[9]



[9] Source: Zacks Research System

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