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Lantern Pharma, Inc. (LTRN - NASDAQ)

New Programs, Pipeline Progress, Raise, and RADR

Based on our DCF model which uses a 15% discount rate, Lantern Pharma is valued at approximately $30.00 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 (3/11/2021)	$18.29
Valuation	**$30.00**

OUTLOOK

Lantern Pharma is a new type of drug development company using AI & data to identify patients most likely to respond and uncover mechanisms of action. It is developing lead candidate LP-300 for non- & never smoker NSCLC as well as two other candidates. LP-100 for mCRPC which has been outlicensed to Allarity Therapeutics and LP-184 which is in preclinical development for multiple tumors defined by biomarkers in combination with ADCs and as monotherapy in ATRT.

Lantern uses AI & machine learning to identify failed and abandoned compounds that may work in genomically defined subpopulations. RADR is the firm's AI platform which integrates diverse data to identify new candidates, mechanisms of action & drug combinations.

Lantern is planning to launch a Ph2 trial for LP-300 in 1H:21. We expect it to lead into a Ph3 study that will generate registrational data in 2024, US & EU regulatory submission in 2025 & commercialization in 2026. LP-184 is expected to begin Ph2 trials in multiple indications in 2021.

LP-300 targets a subpopulation of NSCLC which is not well served by standard of care & is genomically different from smoking related NSCLC. Lantern has identified a subpopulation in the indication that may benefit from the differentiated mechanism of action of LP-300.

SUMMARY DATA

52-Week High	**24.84**
52-Week Low	**10.40**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**201,700**
Shares Outstanding (mil)	**11.2**
Market Capitalization ($mil)	**205**
Short Interest Ratio (days)	**0.6**
Institutional Ownership (%)	**31.1**
Insider Ownership (%)	**27.1**
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 2020 Estimate	**N/A**
P/E using 2021 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)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.23 A	-$0.32 A	-$0.31 A	-$0.37 A	-$1.23 A
2020	-$0.24 A	-$0.31 A	-$0.27 A	-$0.47 A	-$1.37 A
2021					-$1.11 E
2022					-$1.42 E

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What's New

Fourth Quarter and Full Year 2020 Financial and Operational Results

On March 10, 2021, Lantern Pharma, Inc. (NASDAQ: LTRN) announced fourth quarter and full year 2020 financial and operational results, filed its form 10-K with the SEC and hosted a conference call to review the year's accomplishments. During 2020, Lantern completed its $26.3 million initial public offering, initiated an Antibody Drug Conjugate (ADC) program, identified and validated additional cancer indications for LP-184, made progress with its candidate LP-184 in glioblastoma, prostate and pancreatic cancers and accumulated over 1.2 billion curated datapoints to train its proprietary RADR platform. Following the end of the reporting period, Lantern also successfully executed a $69 million capital raise which is expected to fund the advancement of the pipeline over the next several years.

Lantern did not generate revenues in 2020 and expended $5.9 million in operational expense preparing pipeline candidates for clinical trials and identifying new indications for LP-184.

For the fiscal year ending December 31, 2020 and versus the fiscal year ending December 31, 2019:

- Research & development expenses totaled $2.24 million up 135% from $953,000 on an increase in R&D labor, research study expenses and stock option compensation expense;
- General & administrative expenses rose 147% to $3.66 million from $1.48 million driven by costs related to becoming a public company including corporate insurance, labor, and stock option compensation expense;
- Net loss was ($5.91) million, or ($1.37) per share, compared to ($2.43) million, or ($1.23) per share;

As of December 31, 2020, cash on the balance sheet was $19.2 million, compared to $1.2 million a year before. Following the end of the year, Lantern raised gross proceeds of $69 million in January 2021.

Phase II Clinical Trial For LP-300

Lantern expects to launch a Phase II trial for LP-300 in non-small cell lung cancer (NSCLC) patients that have never smoked in third quarter 2021. The company is interacting with the FDA and other regulatory bodies to refine the design of the trial and is seeking approval from investigators and institutional review boards. While not finalized, Lantern expects to use a combination treatment that includes doublet chemotherapy. The trial is expected to be a two-year, multi-center study enrolling from 40 to 75 patients diagnosed with adenocarcinoma NSCLC with little to no history of smoking and no prior chemotherapy. Beyond assessing the response to treatment in the target population, the trial will also serve to assess the efficacy of LP-300 in combination with chemotherapy on non-smokers, compare efficacy of LP-300 in non-smoking males and non-smoking females, further investigate safety, toxicity and tolerability, and investigate biomarkers. Endpoints are expected to be overall survival, progression-free survival, objective response rate, identification of gene signatures correlated with potential LP-300 efficacy from matched tumor tissue analysis and protection against chemotherapy-induced nephrotoxicity.

Antibody Drug Conjugates (ADCs)

In January 2021 Lantern announced the launch of an antibody-drug conjugate (ADC) program through a partnership with San Diego-based Califia Pharma. ADCs are able to bind to a cancer cell, providing accurate delivery of a designated payload. Frequently, the ADC is endocytosed where the link is cleaved and the payload released. Lantern has matched several approved antibodies within its portfolio compatible with existing antibodies and linkers using its RADR[1] AI algorithm. Encouraged by Gilead's $21 billion acquisition of ADC leader Immunomedics,[2] Lantern forged a relationship with Califia to link its existing candidates with proven antibodies to address cancers where drug resistance has created an unmet need. Antibody conjugation allows cancer-cell specific targeting of nanomolar-potent LP-184 enabling further efficacy in treatment-resistant cancers.

Using Califia's linkers, Lantern conducted lab work that demonstrated improved efficacy at lower doses when LP-184 was combined with existing cancer-targeting antibodies. The lower levels of drug also resulted in decreased toxicity. Califia's patented linkers, payloads and conjugations provide a construct to combine approved immuno-

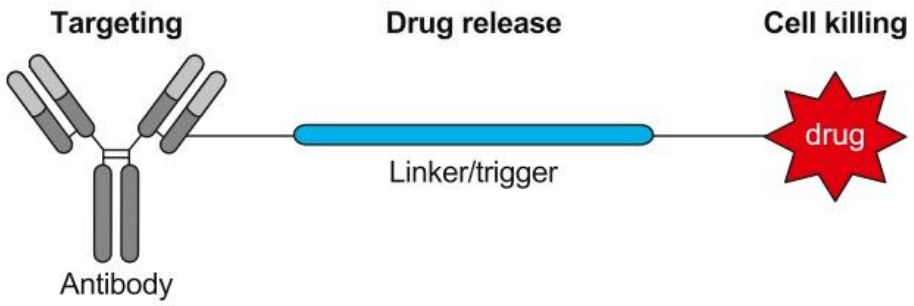
[1] Lantern's proprietary AI platform is entitled Response Algorithm for Drug Positioning and Rescue (RADR).
[2] Immunomedics developed next-generation ADC technology and obtained FDA approval for Trodelvy in metastatic triple negative breast cancer in April 2020.

oncology antibodies with Lantern's alkylating and DNA damaging agents. ADC development will target both solid tumors and blood cancers where drug resistance and systemic toxicity are key issues. Lantern's LP-100 is also being considered for the approach using ADCs.

Antibodies

Antibodies are proteins produced by B-lymphocytes in response to foreign antigens, most commonly bacteria and viruses as a part of the immune response. These biologics are often thought of as flags to mark pathogens for sequestering and destruction with the shape of the antibody binding site determining its specificity. Antibodies are engineered to target specific antigens, which include proteins, sugars or even nucleic acids. In addition to foreign immunogenic agents such as bacteria and viruses, antibodies can identify and bind to antigens, receptors or epitopes specific to cancer cells, allowing for targeted identification of malignant cells.

Exhibit I – Antibody Drug Conjugate[3]



Targeted antigen	Release mechanism	MOA
Tumor Specific	Cleaved by reduction	Microtubule disruption DM1, DM4, MMAE, MMAF
Minimal Normal Expression	Cleaved by low pH	DNA damage calicheamicin, duocarmicin, SN-38, D6.5, PDB dimers
Internalizing	Cleaved by proteases	Transcriptional Inhibitor amanitin
Prevalent in cancers	Non-cleavable	
Abundant in cancers		

Linkers

When the antibody is combined to a payload, which can be either a cytotoxic agent or a drug, the three part structure is termed an antibody drug conjugate (ADC). The bridge that holds together the antibody and the payload is a linker, which can be either cleavable or non-cleavable. Linkers attach to amino acids on the antibody, frequently via thiol chemistry with surface cysteines or lysines. Linkers are critical to the success of the ADC and their type determines when the cytotoxic payload will be released.

Choice of linkers depends upon both the antibody and payload. Califia has identified and documented many linkers amenable to conjugate LP-100 or LP-184. The choice of linkers is important for compatibility and internalizing the payload inside the cell.

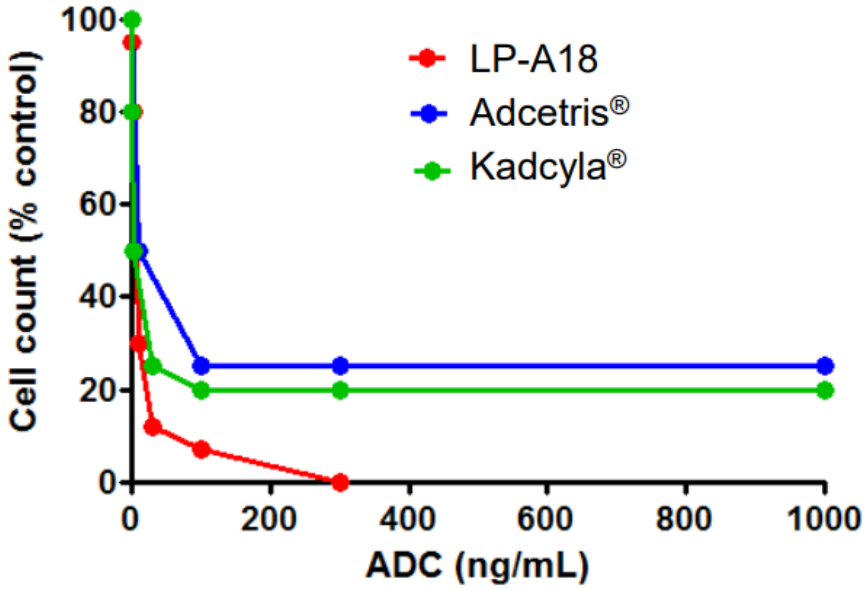
Califia Pharma

The original researcher for LP-184 is Michael Kelner, M.D., professor at the University of California San Diego Medical Center and CEO of Califia.[4] Califia Pharma offers a portfolio of linker strategies that complement Lantern's LP-100 and LP-184, allowing for lower concentrations and increased specificity. The antibodies that Lantern is considering in conjunction with its candidates are as yet unidentified but will soon be off patent, providing well-understood, battle-tested and potentially less-expensive biologics as part of the combination therapy for cancer indications.

Preliminary data from Lantern's ADC program shows promise when compared to other, well-known ADCs. Lantern's ADC, LP-A18, showed complete control at around 300 ng/mL when compared to Adcetris and Kadcyla, which were unable to control at doses as high as 1000 ng/mL.

[3] Polakis, Paul. Antibody Drug Conjugates for Cancer Therapy. Pharmacological Reviews, January 2016.
[4] https://ucsdnews.ucsd.edu/archive/newsrel/science/mdmushrm.htm

Exhibit II - LP-A18, Adcetris and Kadclya Compiled Data Comparison[5]



ADCs are not only therapeutically exciting, but also relevant. AstraZeneca and Daiichi Sankyo received FDA approval of Enhertu for gastric cancer on January 18, 2021, and received approval in the EU for breast cancer two days later. Enhertu had already been approved in the US for HER2+ metastatic breast cancer in December 2019.[6] ADC Therapeutics (ADCT) is expected to file a BLA for their lead candidate, loncastuximab tesirine (Lonca). Recent approvals for this drug construct should support investor enthusiasm and the value of the ADC program which is expected to enter the clinic as early as 4Q:21.

Lantern is considering the pursuit of multiple targets in the ADC combination program including colorectal, pancreatic, lung and ovarian cancer. From 5% to 10% of these cancers present the targeted biomarkers and compose the addressable market for the program.

New Indications For LP-184 - Atypical Teratoid Rhabdoid Tumors (ATRT)

Atypical teratoid rhabdoid tumors (ATRT) belong to a family of rhabdoid tumors (RT) that can arise in the liver, brain or central nervous system (CNS). 66% of RT arise in the brain and CNS and are known as ATRT. ATRT are a rare and rapidly proliferating cancer (Grade IV) of the brain and spinal cord. ATRT is considered ultra-rare. There are an estimated 58 pediatrics patients diagnosed per year, and an estimated 596 people below the age of majority with the disease in the US.[7] Another 10 to 15 cases appear in adults each year. Estimates of the percentage of ATRT originating in the brain vary considerably, with estimates between 15%[8] and 50%.[9] The cancer occurs in less than 10% of pediatric brain tumors and is most frequently in children aged 3 and under. Symptoms of ATRT include morning headaches or headaches that are less painful after vomiting, change in activity levels and lethargy, loss of balance or trouble walking, asymmetric eye movements, and increased head size. Treatment is multi-modal including surgery, chemotherapy and radiation. Due to the location in the brain, the tumor is often unresectable. Survival rates are poor which are estimated to be 32.2% at five years.[10] Most ATRT are caused by mutations in the SMARCB1 gene. This gene is responsible for tumor growth suppression and when mutated, it is no longer able to suppress tumor formation.

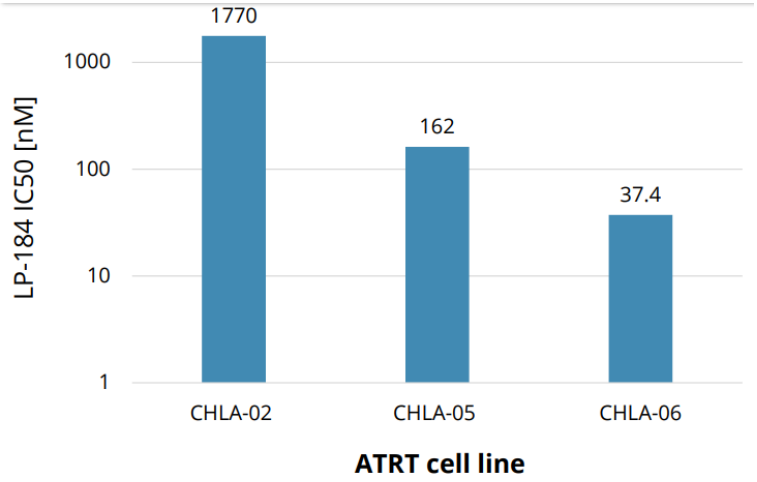
Lantern began its focus on brain and CNS cancers after confirming that its candidate LP-184 readily penetrated the blood-brain barrier. Because LP-184 is able to cross, it can act on cancers in the brain and CNS. Lantern enriched RADR's dataset with 100 million genomic, transcriptomic and drug sensitivity datapoints specific to brain and CNS cancers leading to the identification of ATRT as a potential target for LP-184. Lantern has been collaborating with researchers from Johns Hopkins for LP-184 in GBM. ATRT is also a research interest for the Johns Hopkins group.

[5] Lantern Pharma Company Overview January 11, 2021
[6] FDA approves new treatment option for patients with HER2-positive breast cancer who have progressed on available therapies | FDA
[7] Atypical Teratoid Rhabdoid Tumors (ATRT) Diagnosis and Treatment - National Cancer Institute
[8] Rhabdoid tumor | Genetic and Rare Diseases Information Center (GARD) – an NCATS Program (nih.gov)
[9] Atypical Teratoid Rhabdoid Tumor (ATRT) - St. Jude Children's Research Hospital
[10] Atypical Teratoid Rhabdoid Tumors (ATRT) Diagnosis and Treatment - National Cancer Institute

Several other companies have programs that include ATRT. Epizyme (EPZM) has a Phase II trial enrolling multiple rhabdoid tumors. Vyriad (private) has an open label Phase I for brain tumors. Novartis (NVS) has a Phase I in 55 brain tumors. And Cellectar Biosciences (CLRB) has a Phase I open label in malignant brain tumors. Istari Oncology (private) has sponsored a study in recurrent malignant glioma in pediatric populations. Takeda (TAK) and Millennium Pharmaceuticals (private) also are collaborating on a Rhabdoid Tumor trial.

In vitro evaluation has already shown nanomolar potency of LP-184 across multiple ATRT cell lines as measured by IC50, or the concentration required to decrease the intended biochemical function by half.

Exhibit III - LP-184 IC50 (nM) vs ATRT Cell Lines[11]



Due to their rarity, pursuit of diseases like ATRT affords special FDA approval pathways including Orphan Drug Designation and access to the Rare Pediatric Disease Priority Review Voucher Program.[12] Additionally, the discovery of the relevance of SMARCB1 to LP-184 may hold significance in other, peripheral cancers. In addition to the brain and CNS, ATRT and RT can materialize in the kidney. SMARCB1 mutations may occur in certain types of lung and ovarian cancer as well. Lantern tested various cell types, with varying SMARCB1 expression for sensitivity to LP-184 and found statistical significance between SMARCB1 expression and LP-184 sensitivity. For experimental insights regarding ATRT and biomarkers SMARCB1 and PTGR1, see our previous report here.

Priority Review Vouchers

One of the incentives to develop therapies in rare pediatric conditions is the FDA's Priority Review Voucher (PRV). Under Section 529 of the Federal Food, Drug and Cosmetic Act, the FDA may award priority review vouchers to sponsors of rare pediatric disease product applications, subject to certain criteria.[13] Qualification for a voucher requires approval for a drug or biologic for a rare pediatric disease. The voucher can be redeemed to receive a priority review of a subsequent approval application for a different product. Priority review can reduce the time for review from 10 months to six.[14] A fee of $2.1 million is required to redeem the voucher and they do not expire.

Due to the pandemic, the Office of Orphan Products Development (OOPD) has relaxed constraints regarding the applications for rare pediatric disease designation, as well as others including orphan drug and humanitarian use device designations. Applicants are now able to submit via email to the OOPD.

The Rare Pediatric Disease Priority Review Voucher Program (RPDRPVP) was recently extended on December 27, 2020. Under sunset provisions, after September 30, 2024, the FDA may only award vouchers for drugs with rare pediatric disease designation granted before the cutoff date. After September 30, 2026, no vouchers may be awarded unless the program is renewed or extended by Congress.

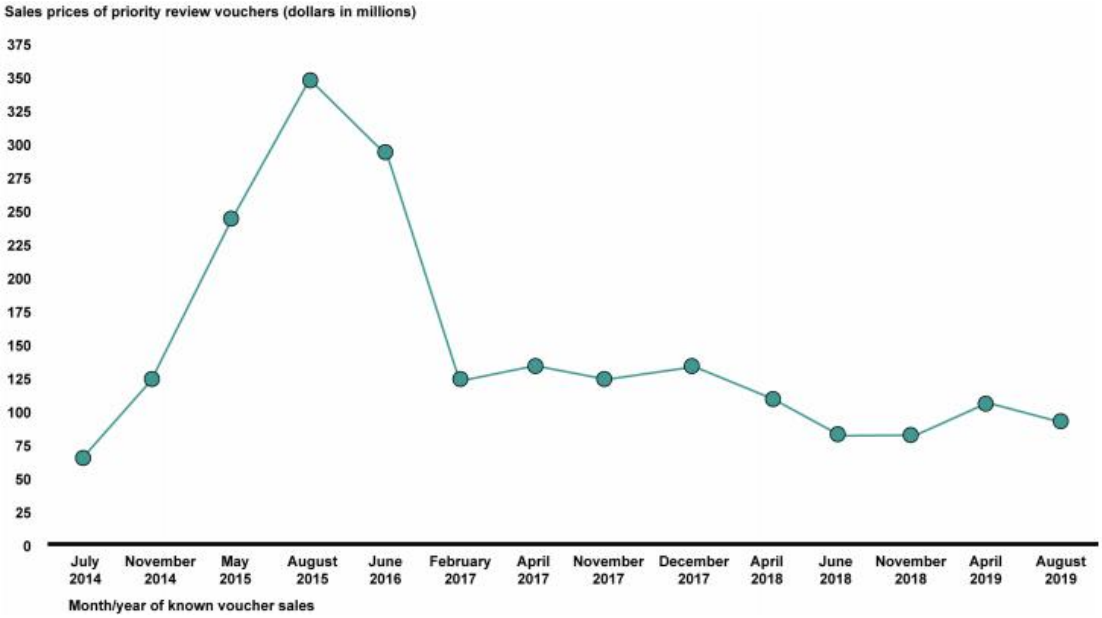
The FDA issued revised draft guidance on the RPDRPVP on July 29, 2019. Draft guidance, in general, allows the FDA to alert the market of potential changes and gives opportunity to receive feedback from industry participants.

[11] Lantern Pharma Company Overview January 11, 2021
[12] Developing Products for Rare Diseases & Conditions | FDA
[13] Rare Pediatric Disease (RPD) Designation and Voucher Programs | FDA
[14] Home - Priority Review Vouchers (duke.edu)

The RPDRPVP guidance concerned the definition of rare pediatric disease as updated in the Advancing Hope Act of 2016, and also revised explanation of voucher eligibility requirements. As it stands, a rare pediatric disease is one that is rare (fewer than 200,000 in the US) and that is serious or life-threatening primarily in individuals 18 and younger, and for which there is no reasonable expectation of cost recovery through US sales of the drug.

Because the vouchers are used toward the marketing approval of another (non-rare pediatric disease) drug, PRVs have been bought and sold in the market. PRV sales have ranged between $67.5 million to $350 million.[15] Recent transactions include Rhythm Pharmaceuticals' sale of its PRV for $100 million, announced January 5, 2021.

Exhibit IV - PRV Sale Price vs Time[16]



LP-184 Collaborations

On September 27, Lantern announced a collaboration and research agreement with Fox Chase Cancer Center in Philadelphia, Pennsylvania. The cooperation will advance efforts with Lantern's LP-184 in pancreatic cancer to develop a more biologically relevant and robust gene signature for future clinical trials and improve the precision of cancer treatment. The work on LP-184 at Fox Chase, led by Igor Astsaturov, M.D., Ph.D., will identify the opportunities for the candidate in pancreatic cancers. The effort will employ 3D organoids and patient derived xenograft (PDx) models to identify the biomarker signatures necessary to characterize the mechanisms behind LP-184. Lantern had previously announced that it was engaged in discussions with Fox Chase to advance LP-184 related to evaluating the correlation of sensitivity of PTGR1 status using cell lines and PDx models in various cancer types.

Georgetown University and Lantern announced a continuation in their agreement on October 5th related to advancing LP-184 in genomically defined solid tumors, including prostate and pancreatic cancers. Lantern has been collaborating with Georgetown since 2019 to determine the efficacy of LP-184 in a panel of prostate cancer organoid models and engineered pancreatic cancer cell lines. The studies will gather data on LP-184 responses and drug sensitivity in prostate and pancreatic cancers. This first stage of work demonstrated that LP-184 had nanomolar potency across a wide variety of prostate cancer cell lines, had the ability to kill PTGR1 expressing cancer cells and exhibited dose dependent cancer cell death in 3D organoid cultures. The efforts are generating genomic, transcriptomic and drug sensitivity data that will refine the response signature and identify the DNA repair deficiencies that are most likely to respond to LP-184. So far the studies have suggested that LP-184's mechanism of action damages and blocks a critical pathway for cancer cell proliferation and is particularly amenable to combination therapies in a number of tumor types. The next stage of the Georgetown collaboration will focus on a larger set of PDx models and attempt to confirm the role of PTGR1 and the genetic mutations driving the DNA damage repair pathways that make the drug potent in the identified cancers. In preparation for clinical trials, these efforts will develop a more biologically relevant and robust gene signature that is more personalized and effective for specific patients with prostate cancer.

[15] GAO January 2020 FDA's Priority Review Voucher Programs, Accessed March 11, 2021
[16] GAO January 2020 FDA's Priority Review Voucher Programs, Accessed March 11, 2021

RADR: 1.2 Billion Data Points

When Lantern went public with its IPO in 2020, RADR began with a dataset of 275 million datapoints. As publicized on March 10, 2021, RADR now features over 1.2 billion data points and expects to reach over 3 billion data points before year end. Some of the growth in datapoints related to Lantern's new indication in ATRT, as RADR was enriched with CNS cancer data once it was found that LP-184 could cross the blood-brain barrier.

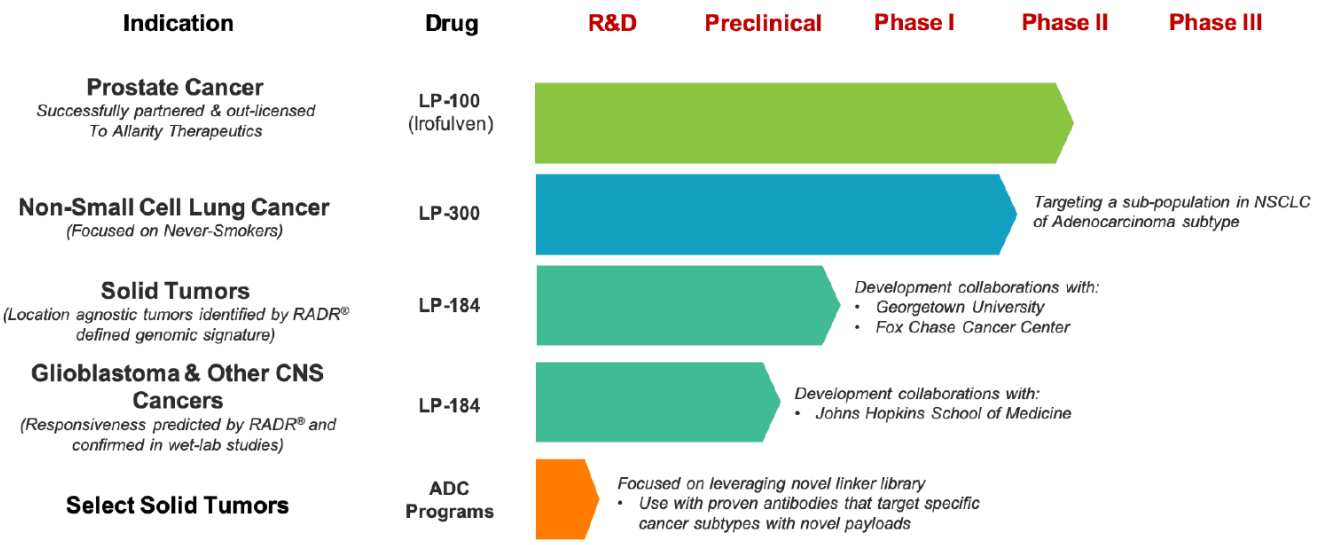
$69 Million Public Offering

On January 20, 2021, Lantern announced the closing of a public offering that yielded $69 million gross and saw the full exercise of underwriter over-allotment option. The offer sold 4,928,571 shares of common stock at $14.00 per share, which included 642,856 in underwriter purchases. Gross proceeds amounted to $69 million and net proceeds were approximately $64 million. Management has guided toward a cash position of over $80 million by the end of first quarter 2021.

With this successful capital raise, Lantern attracted investment from Black River, Corriente, Empery Asset Management, Altium Capital and 5T Capital among others. The raise is expected to allow completion of trials in brain cancers, more specifically ATRT. The raise is also expected to allow Lantern to launch Phase I trials for its ADC program. The additional cash is sufficient for Lantern to fund operations over the next several years and achieve identified milestones, independent of near-term fluctuations in capital markets.

Lantern Clinical Pipeline

Exhibit V - Lantern Pharma Pipeline[17]



[17] Lantern Pharma 2020 Form 10-K

Historical and Forward Looking Milestones

- First patient dosed with LP-100 - 4Q:18
- Announced collaboration with NCI to identify response-predictive gene signatures - October 4Q:19
- IPO and initiation of trading on the NASDAQ – June 10, 2020
- LP-300 cGMP contract – July 2020
- Regulatory interaction for Phase II trial design, LP-300 – 2H:20
- Phase II of LP-100 in mCRPC readout – 1H:21
- Phase II launch of LP-300 – 3Q:21
- Phase I launch of LP-184 – 4Q:21 to 1Q:22

Investment Thesis

- **Proprietary RADR AI-driven algorithm for detecting genetic/biomarker signatures**
- **Opportunities to salvage failed drugs with clinically validated safety history**
- **Declining returns and smaller end markets can benefit from improved drug development approaches that leverage AI**
    - **Build from existing preclinical and clinical work**
    - **Pursue orphan indications and personalized medicine**
    - **Generate pivotal data with less expensive, targeted trials**
    - **Use modeling and complex algorithms to reduce failure risk**
- **Over four years of financial runway**

Summary

Management anticipates 2021 to be a year of transformational growth and progress with an increase to seven targets in the pipeline and a large war chest of cash to fund preclinical and clinical work for years to come. In the third quarter of 2021, we anticipate the initiation of the Phase II LP-300 study in non-small cell lung cancer among non-smokers, IND-enabling studies of LP-184 in multiple solid tumors, continued advancement of the ADC program and continued investment in RADR's growing dataset. Management also expects to disclose additional PTGR1 over-expressing tumors as indications for LP-184.

With the recent $69 million raise, Lantern is now equipped to complete clinical trials in both GBM and ATRT, and Phase I trials in its ADC program. Commencement of Phase I ADC trials are expected as early as 4Q:21. We maintain our recently increased price target of $30.00 per share. For added detail on Lantern's proprietary AI development platform, RADR, and for background on indications and Lantern's clinical candidates, please refer to further discussion in our initiation.

PROJECTED FINANCIALS

Lantern Pharma, Inc. - Income Statement

Lantern Pharma Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 A	2020 A	2021 E	2022 E
Total Revenues ($US)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
General & Administrative	$1,475	$340	$676	$1,101	$1,548	$3,665	$3,400	$3,690
Research & Development	$953	$137	$157	$601	$1,348	$2,243	$8,611	$12,343
Income from operations	($2,428)	($477)	($833)	($1,701)	($2,896)	($5,908)	($12,011)	($16,033)
Pre-Tax Income	($2,428)	($477)	($833)	($1,701)	($2,896)	($5,908)	($12,011)	($16,033)
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	**($2,428)**	**($477)**	**($833)**	**($1,701)**	**($2,896)**	**($5,908)**	**($12,011)**	**($16,033)**
Reported EPS	**($1.23)**	**($0.24)**	**($0.31)**	**($0.27)**	**($0.47)**	**($1.37)**	**($1.11)**	**($1.42)**
Basic Shares Outstanding	1,978	2,021	2,719	6,215	6,217	4,305	10,807	11,264

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

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HISTORICAL STOCK PRICE

Lantern Pharma, Inc. – Share Price Chart[18]



[18] Source: Zacks Research System

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