

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## Apollo Endosurgery, Inc.

**Form: 10-K**

**Date Filed: 2016-03-22**

Corporate Issuer CIK: 1251769

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

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**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-35706

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**LPATH, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**16-1630142**  
(I.R.S. Employer  
Identification No.)

**4025 Sorrento Valley Blvd., San Diego, California**  
(Address of principal executive offices)

**92121**  
(Zip Code)

Registrant's telephone number (858) 678-0800

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Name of Exchange on which registered

Common Stock, \$0.001 par value per share

The NASDAQ Stock Market LLC (NASDAQ Capital Market)

Securities registered pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant computed based on the last sale price of \$ 0.28 as reported on the NASDAQ Stock Market on June 30, 2015 is \$7,002,000. For purposes of this calculation, shares of common stock held by each officer and director and by each person or group who owns 10% or more of the outstanding common stock have been excluded from the calculation of aggregate market value as such persons or groups may be deemed to be affiliates.

As of February 12, 2016, there were 33,138,598 shares of the issuer's \$.001 par value common stock issued and outstanding.

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**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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**LPATH, INC.**  
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## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report includes statements of our expectations, intentions, plans, and beliefs that constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and are intended to come within the safe harbor protection provided by those sections. These forward-looking statements are principally, but not solely, contained in the section captioned “Business” below and the section captioned “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance or achievements, and may contain the words “estimate,” “project,” “intend,” “forecast,” “anticipate,” “plan,” “planning,” “expect,” “believe,” “will,” “will likely,” “should,” “could,” “would,” “may” or words or expressions of similar meaning. All such forward-looking statements involve risks and uncertainties, including, but not limited to:

- Our ability to negotiate and consummate a strategic transaction on a timely basis and on terms acceptable to our stockholders.
- Our ability to continue as a going concern beyond the third quarter of 2016.
- The amount and timing of our future operating expenses, including costs to wind-down our operations.
- Our interpretation of the results of the pre-clinical and clinical trials for our product candidates.
- Our ability to successfully complete additional clinical trials on a timely basis and obtain regulatory approvals for one or more of our product candidates.
- The potential biological effects and indications for our product candidates.
- The market opportunity for our product candidates.
- Our ability to complete additional discovery and development activities for drug candidates utilizing our proprietary ImmuneY2 drug discovery process.

In addition to the items described in this report under the heading “Risk Factors,” many important factors affect our ability to achieve our stated objectives and to successfully develop and commercialize any product candidates, including, among other things:

- We may not be able to successfully completing a strategic transaction or otherwise secure additional capital in order to carry out our planned activities beyond the third quarter of 2016.
- Any strategic transaction we complete may not be acceptable to our stockholders and may not enhance stockholder value or provide the expected benefits.
- Our current product candidate portfolio is limited and in the early stages of clinical development , which could limit our ability to raise the funds required to support our operations and the future development of these drug candidates.
- We have a history of net losses and we may never achieve or maintain profitability.
- We may not be successful in maintaining our listing on the Nasdaq Stock Market, which could seriously harm the liquidity of our stock and our ability to raise capital or complete a strategic transaction.
- The results of our pre-clinical testing and our clinical trials may not support either further clinical development or the commercialization of our drug candidates.

- We may not successfully complete additional clinical trials for our product candidates on a timely basis, or at all.
- None of our drug candidates has received regulatory approval at this time, and we may fail to obtain required governmental approvals for our drug candidates.
- Our products could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.

Therefore, investors are cautioned that the forward-looking statements included in this report may prove to be inaccurate and our actual results or performance may differ materially from any future results or performance expressed or implied by the forward-looking statements. In light of the significant uncertainties inherent to the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by us or any other person that our objectives and plans will be achieved in any specified time frame, if at all. These forward-looking statements represent beliefs and assumptions only as of the date of this report. Except to the extent required by applicable laws or rules, we do not intend to update any forward-looking statements contained herein or to announce revisions to any of such forward-looking statements to reflect new information or future events or developments.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a biotechnology company focused on the discovery and development of lipidomic-based therapeutic antibodies, an emerging field of medical science that targets bioactive signaling lipids to treat a wide range of human diseases. We have developed three drug candidates, advancing each of them into clinical trials, and built evidence to support our approach of targeting bioactive lipids to treat a wide range of diseases. In January 2016, we completed the dosing of all subjects in our Phase 1 clinical trial of Lpathomab.

As of December 31, 2015, we had cash and cash equivalents totaling \$8.9 million. We have incurred significant net losses since our inception. To conserve our cash resources, we have reduced our headcount and limited our research and product development activities. As a result of these actions, we believe our current resources should be sufficient to fund our operations through the third quarter of 2016.

Our Board of Directors has engaged a financial advisory firm to explore our available strategic alternatives, including possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. We believe it is in our stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives we may identify in the near term. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Further, our expenses may exceed our current plans and expectations, which could require us to complete a transaction or wind-down our operations sooner than anticipated. Additionally, any transaction we consummate may offer limited value for our existing drug candidates and proprietary technology and may not enhance stockholder value or provide the expected benefits. If we are unable to successfully complete a strategic transaction or otherwise secure additional capital on a timely basis and on terms that are acceptable to our stockholders, we may be required to cease our operations altogether.

#### Lpathomab

Lpathomab is a humanized monoclonal antibody ("mAb") against lysophosphatidic acid ("LPA"), a bioactive lipid that has been characterized in scientific literature as playing a key role in nerve injury and neuropathic pain. Published research has also demonstrated that LPA is a significant promoter of cancer-cell growth and metastasis in a broad range of tumor types, and plays a key role in pulmonary fibrosis. Our preclinical studies showed strong in vivo results with Lpathomab in several different pain models, which suggest that LPA may be an attractive target across a variety of chronic pain conditions, including diabetic peripheral neuropathy, post-herpetic neuralgia, chemotherapy-induced neuropathic pain and pain associated with lumbosacral radiculopathy.

In January 2016, we completed the dosing of all subjects in our Phase 1a clinical trial of Lpathomab. The double-blind, placebo-controlled, single ascending dose trial was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of Lpathomab in healthy volunteers. The trial also aimed to establish a maximum tolerated dose for future clinical studies in patients with neuropathic pain or other potential indications. The trial included a total of five cohorts at increasing doses. Lpathomab was well tolerated at all doses tested, and no serious adverse events or dose limiting toxicities were observed during the trial. The follow-up period for patients participating in this Phase 1a trial will be completed in March 2016, and we expect the final study results, including pharmacokinetic, pharmacodynamic, and safety data, to be available in the second quarter of 2016.

#### iSONEP

iSONEP™ is the ocular formulation of sonepcizumab, a mAb against sphingosine-1-phosphate ("S1P"). Sphingomab™ is the original mouse version of this monoclonal antibody. iSONEP is administered by intravitreal (inside the eye) injection, and has demonstrated multiple mechanisms of action in ocular models of disease, including anti-angiogenesis, anti-inflammatory, anti-fibrotic and anti-vascular permeability. This combination of mechanisms suggested that: (i) iSONEP might have a comparative advantage over currently marketed products for "wet" age-related

macular degeneration (“wet AMD”) and (ii) iSONEP might demonstrate clinical efficacy in a broad range of retinal diseases where there is currently a significant unmet medical need, including diabetic retinopathy (a complication of diabetes affecting the retina), dry AMD, and glaucoma-related surgery.

In 2010, we entered into an agreement with Pfizer Inc., which was amended in 2012 (collectively, the “Pfizer Agreement”), that provided Pfizer with an exclusive option for a worldwide license to develop and commercialize iSONEP. From 2011 to 2015 in collaboration with Pfizer, we conducted a multicenter, Phase 2 clinical trial evaluating iSONEP in patients with wet age-related macular degeneration (wet AMD) (the “Nexus trial”). During the second quarter of 2015, we announced that our Nexus trial did not meet its primary or key secondary endpoints. Based on the failure of iSONEP to meet these endpoints, Pfizer elected to allow its option to develop and commercialize iSONEP to expire unexercised on August 9, 2015. As a result, the Pfizer Agreement terminated by its terms, and all rights that Pfizer held in the iSONEP program have reverted to Lpath.

Following completion of the Nexus trial, we conducted further analyses of the clinical trial data, including additional anatomical endpoints, to better understand the results. While iSONEP did not meet the primary endpoint of the Nexus trial by showing statistically significant improvement in visual acuity at day 120 of the trial, analyses of the follow-up data from the completed trial did provide interesting signals of possible therapeutic benefit from iSONEP. Long-term follow-up data suggests that treatment of wet AMD patients with iSONEP, in combination with anti-VEGF treatments, may result in reductions in total wet AMD lesion area and may allow patients to maintain their visual acuity gains for longer periods of time than would be expected from anti-VEGF treatment alone. We believe that these signals of activity in the Nexus trial are appropriate for further clinical investigation. We are seeking a partner for future studies of iSONEP in order to obtain the funding and additional expertise required to advance this program.

## **ASONEP**

ASONEP™ is the systemic formulation of sonopocizumab. In the first quarter of 2010, we completed a Phase 1 clinical trial in which ASONEP was evaluated in very late-stage cancer patients. In that trial, ASONEP was well tolerated at all dose-levels ranging from 1 mg/kg to 24 mg/kg, other than minor infusion-related reactions observed at the highest dose. More than half the patients that completed the initial four-treatment evaluation period showed stable disease, and durable stable disease was observed in several patients. Based on these results, in 2013 we commenced a Phase 2a single-agent, open-label study of ASONEP trial in patients with advanced renal cell carcinoma (RCC).

In March 2015, we announced that our Phase 2a clinical trial of ASONEP™ did not meet the primary endpoint of statistically significant progression-free survival. ASONEP™ is the systemic formulation of sonopocizumab. To successfully meet the primary endpoint of progression-free survival, at least 20 out of 39 patients needed to be progression-free at four months of treatment. Fourteen out of 40 patients (over enrolled by one patient) were progression-free at four months. Eight of the fourteen patients were progression-free for at least six months, of which three patients remained progression-free for over 20 months. Overall, ASONEP was well-tolerated. The ASONEP study follow-up period concluded during the third quarter of 2015, and there are no longer any patients being treated with ASONEP. We are now exploring other indications where ASONEP may have a greater chance of success.

As part of the Pfizer Agreement, Lpath granted to Pfizer a right of first refusal for ASONEP. That right of first refusal expired on August 9, 2015, concurrent with the expiration of Pfizer’s option to acquire the license to iSONEP.

## **ImmuneY2™ Technology**

We believe we are the only company to have developed functional therapeutic monoclonal antibodies against any bioactive lipid, of which there are estimated to be 1,000 or more. We produced these unique antibodies using our ImmuneY2™ technology, a series of proprietary processes we have developed. We continue to apply the ImmuneY2 process to other bioactive lipids that are validated targets for disease treatment, thereby expanding our potential pipeline of novel monoclonal antibody-based drug candidates.

We have a strong intellectual-property position in the bioactive-lipid area, with 70 issued patents, including 35 foreign patents, and 79 pending patents, including 61 foreign patent applications. Most of these patents were developed in-house based on our pioneering research on bioactive lipid signaling. Our research partners to date have included the

M.D. Anderson Cancer Center, the UCLA Brain Injury Research Center, Johns Hopkins University, the Harvard Medical School, the University of Florida College of Medicine, the University of California — San Diego, the French National Centre for Scientific Research, the Center for Eye Research Australia, the University of Melbourne, Australia, the Beth Israel Deaconess Medical Center, the Walter Reed Army Institute for Research, the Medical University of South Carolina, the Virginia Commonwealth University, and the University of Kentucky.

## The Emergence of Lipidomics

For many years the drug-development industry has been fundamentally protein-centric, and most drugs on the market (and most drug candidates in clinical trials) target proteins. The recognition among medical researchers that bioactive lipids play key roles in disease is a relatively recent development. "Although the concept of 'bioactive lipids' has been decades in the making, it has only started to gain traction in the past 20 years, and promises to occupy centre-stage in cell biology research in the twenty-first century." (*Nature Reviews*, February 2008)

In an article published in 2006, the *British Journal of Cancer* described the emergence of lipidomics in drug discovery:

*The focus on proteins was a natural consequence of the science community's evolving understanding of biochemistry, which allowed researchers to identify potential protein targets involved in key metabolic and signaling pathways. Some of the first drugs developed by the rational-drug-design approach to the scientific method came after the discovery of key enzymes, receptors, and ion channels [all proteins] as they emerged in the basic science literature. One can argue that target identification now is driven by the technological developments of proteomics and genomics, both of which reflect the persistent 'protein-centric' view of drug discovery.*

*Now, the field of lipidomics (a subset of 'metabolomics') has emerged...and provides new opportunities for drug discovery. As was the case for proteomics and genomics, tools of measurement led the way. For lipidomics, the development of electrospray tandem mass spectrometry and other tools has facilitated our understanding of the cellular lipidome, and we now believe that there are over 1,000 members of the lipidome, opening up an entire array of new potential targets for therapeutic interventions.*

*It has been recognized that alterations in lipid metabolism can lead to cancer, cardiovascular disease, diabetes, neurodegenerative disorders, immune function, pain, mental disorders, and inflammation. (British Journal of Cancer, October 2006).*

We believe that we are the leader in developing lipidomic-based therapeutics and humanizing related mAbs. This emerging field of medical science involves two areas of expertise:

1. *An understanding of the role of bioactive lipids in their respective signaling systems so that potentially important targets can be identified:* The study of lipidomics is complex, as bioactive lipids have a molecular weight significantly lower than proteins and, unlike proteins, are not water-soluble. As such, many of the measurement and analytical tools that exist in the protein-centric pharmaceutical industry are not effective when dealing with bioactive lipids. Because of our long-standing focus on bioactive lipids as targets for human disease, we are one of the few companies that have developed the expertise and assays to address the unique challenges of lipidomics.
2. *The ability to inhibit the identified bioactive-lipid targets:* Bioactive lipids are difficult to inhibit for the same reasons that make them difficult to study—they are extremely small and they are not water-soluble. As such, many companies have tried to generate monoclonal antibodies that inhibit the functional activity of bioactive lipids, only to have failed. We believe we are the only company to have developed functional monoclonal antibodies against bioactive lipids such as S1P or LPA. This capability is based on our proprietary ImmuneY2 technology.



## Product Opportunities

Our key product-development programs are summarized in Table 1:

**Table 1. Primary Product-Development Programs**

<b>PRODUCT</b>	<b>Description</b>	<b>Indication</b>	<b>Status</b>
<b>Lpathomab</b>	mAb against LPA, a tumorigenic and metastatic agent and a validated contributor to neuropathic pain and traumatic brain injury.	Neuropathic pain, chemo-induced pain, traumatic brain injury, and fibrosis	Dosing completed in Phase 1a clinical trial in healthy volunteers. Study results expected in the second quarter of 2016. Demonstrated in vivo mechanisms that contribute to progression of diabetic retinopathy and wet AMD.
<b>iSONEP</b>	mAb against S1P, a validated angiogenic growth factor & contributor to inflammation	Age-related macular degeneration, RPE detachment, and other retinal diseases	Phase 2 clinical trial of iSONEP in patients with Wet-AMD did not meet primary end point or key secondary end points. Long-term follow-up data suggests that iSONEP, when used in combination with anti-VEGF treatments, may result in reductions in total wet AMD lesion area and may allow patients to maintain their visual acuity gains for longer periods of time than anti-VEGF treatments alone. We are pursuing licensing, partnering and other strategic alternatives to help fund further clinical investigation.
<b>ASONEP</b>	mAb against S1P, a validated angiogenic factor and validated mediator of lymphocyte trafficking	Cancer—various tumor types	Phase 2a single-agent, open-label study of ASONEP did not meet the primary end-point of statistically significant progression-free survival in patients with advanced renal cell carcinoma (RCC). We are exploring other indications where ASONEP may have a greater chance of success.

## **Lpathomab**

Our drug discovery team, using our proprietary ImmuneY2 technology, was the first, we believe, to generate functional mAbs against lysophosphatidic acid (“LPA”). LPA is a key bioactive lipid and has long been recognized in the literature as a significant promoter of cancer-cell growth and metastasis in a broad range of tumor types. Published research has demonstrated that LPA is also a significant contributor to neuropathic pain and traumatic brain injury, and plays a key role in pulmonary fibrosis. Because of its potentially significant role in a number of diseases, including pain, fibrosis, and cancer, other companies have tried, unsuccessfully, to create an antibody against LPA.

In July 2015, we announced that the FDA had authorized us to initiate our Phase 1a clinical trial. We commenced the Phase 1a clinical trial in September 2015, and completed the dosing phase of the clinical trial in January 2016. The double-blind, placebo-controlled, single ascending dose trial was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of Lpathomab in healthy volunteers. The trial also aimed to establish a maximum tolerated dose for future clinical studies in patients with neuropathic pain or other potential indications. The trial included a total of five cohorts at increasing doses. Lpathomab was well tolerated at all doses tested, and no serious adverse events or dose limiting toxicities were observed during the trial. The follow-up period for patients in this Phase 1a trial will be completed in March 2016, and we expect the final study results, including pharmacokinetic, pharmacodynamic, and safety data, to be available in the second quarter of 2016.

## **iSONEP**

iSONEP is the ocular formulation of sonepcizumab, a mAb against S1P, a bioactive lipid implicated in the progression of many diseases including various angiogenic-related diseases and inflammatory-oriented indications, multiple sclerosis, and many types of cancer. iSONEP—and ASONEP as well (see below)—acts as a molecular sponge to selectively absorb S1P from blood and from certain tissues.

### *Pre-Clinical and Phase 1 Clinical Trial Results*

iSONEP demonstrated promising anti-angiogenic results in various eye models of wet AMD, as performed by Dr. Maria Grant (University of Florida) and Dr. Peter Campochiaro (Johns Hopkins University). Moreover, Dr. Campochiaro’s studies also demonstrated that iSONEP has strong anti-vascular permeability effects in the eye, as well as promising anti-inflammatory properties. Studies that we performed in-house suggest iSONEP also may have anti-fibrotic effects.

In 2009, we completed a Phase 1 clinical trial in which iSONEP was evaluated in patients with wet AMD. In that trial, iSONEP met its primary endpoint of being well tolerated in all 15 patients at dose levels ranging from 0.2 mg to 1.8 mg per intravitreal injection. No drug-related serious adverse events were reported in any of the patients. Positive biological effects were also observed in some patients in this clinical study, the most common being regression in Choroidal neovascularization (CNV), which is the underlying cause of the disease that eventually leads to degeneration of the macula. Most of these positive effects appear to be largely independent of the effects seen when patients undergo treatment with the drugs that are the current market leaders for the treatment of wet AMD.

iSONEP’s non-overlapping effects relative to anti-VEGF therapeutics was predicted. As Campochiaro *et al.* state in *Journal of Cellular Physiology*, “Since S1P may have both independent and overlapping effects with VEGF, it is a particularly appealing target. There may be advantages to combined blockade of VEGF [Lucentis] and blockade of S1P [iSONEP].”

The most significant benefit observed in the Phase 1 trial was a regression in choroidal neovascularization (CNV), which is the underlying cause of the disease that eventually leads to degeneration of the macula, the area of the retina responsible for central vision. Of the seven patients that had a baseline lesion that was considered by experienced ophthalmologists to be “large,” four experienced a reduction exceeding 5 mm<sup>2</sup> and three experienced a reduction of greater than 75%—all with a single dose of iSONEP. This type of clinical benefit is not typical with other treatments, as the published data (Heier JS *et al.* *Ophthalmology*.2006; 113:642e1-642.e4) suggest that, even with repeated Lucentis® dosing, the total physical size of CNV lesion does not show much reduction.

Due to the small sample size, all biological effects described above can only be characterized as possibly correlative; no causal relationship has yet been established, statistically or otherwise.

The fact that these biological effects appear to be non-overlapping vis-à-vis those of the predominant market leaders, Lucentis®, Avastin®, and Eylea® may be important. Wet AMD is characterized by the pathologic disruption of the retina, which is caused collectively by (i) new-blood-vessel growth in the choroid layer under the retina, (ii) sub-retinal fibrosis, (iii) general inflammation in the retinal area, and (iv) edema caused by new blood vessels that do not form perfectly and are thereby permeable (or leaky).

Lucentis, Avastin, Eylea target the protein VEGF, a validated promoter of permeable and leaky blood vessels, and appear to exert most of their beneficial effect via an anti-permeability action that results in resolution of intra and sub-retinal edema. However, the actual CNV lesion does not typically regress.

In contrast, iSONEP has been shown in various animal models of disease not only to reduce blood-vessel growth and leakiness, but to significantly mitigate ocular fibrosis (Grant et al, *Experimental Eye Research*, August 2008) and to substantially reduce inflammation in the eye (Campochiaro et al., *Journal of Cellular Physiology*, October 2008). As such, iSONEP has the potential to be an effective wet AMD treatment since it may act synergistically with anti-VEGF approaches as a combination therapy to address the complex processes and multiple steps that ultimately lead to vision loss for wet AMD patients.

The promising results of the Phase 1 clinical trial together with the preclinical studies suggest the following:

- (i) iSONEP may have comparative advantages over currently available treatments like Lucentis, Avastin or Eylea. The loss of visual acuity associated with AMD is caused by a combination of all the factors mentioned above, yet Lucentis, Avastin, and Eylea apparently fail to address inflammation and sub-retinal fibrosis. Thus, iSONEP may improve vision on a more-consistent basis across the patient population and may treat the multiple mechanisms that cause exudative-AMD-related vision loss. Such an agent might act as an adjunct therapy to an anti-VEGF agent.
- (ii) iSONEP may be able to inhibit the vascular and extravascular components of ischemic retinopathies such as diabetic retinopathy and the dry form of AMD, both of which represent significant unmet medical needs.
- (iii) iSONEP might be efficacious in treating fibrotic-related disorders of the eye, including proliferative retinopathy, post glaucoma filtration surgery (trabeculectomy or valve implantation), and various anterior-segment diseases.

#### *Pfizer Agreement and Phase 2 Clinical Trial*

In 2010, we entered into an agreement with Pfizer Inc., which was amended in 2012 (collectively, the "Pfizer Agreement"), that provided Pfizer with an exclusive option for a worldwide license to develop and commercialize iSONEP. From 2011 to 2015 in collaboration with Pfizer, we conducted a multicenter, Phase 2 clinical trial evaluating iSONEP in patients with wet AMD (the "Nexus trial"). During the second quarter of 2015, we announced that our Nexus trial did not meet its primary or key secondary endpoints. The wet AMD patients in the Nexus trial did not show statistically significant improvement in visual acuity at day 120 of the trial, the primary endpoint, when treated with iSONEP as an adjunctive or monotherapy. As we have previously disclosed, based on the failure of iSONEP to meet these primary endpoints of the Nexus trial, Pfizer elected to allow its option to develop and commercialize iSONEP to expire unexercised on August 9, 2015. As a result, the Pfizer Agreement terminated by its terms, and all rights that Pfizer held in the iSONEP program have reverted to Lpath.

Following completion of the Nexus clinical trial, we conducted further analyses of the clinical trial data, including additional anatomical endpoints, to better understand the results. While iSONEP did not meet the primary endpoint of the Nexus trial by showing statistically significant improvement in visual acuity at day 120 of the trial, analyses of the follow-up data from the completed trial did provide interesting signals of possible therapeutic benefit from iSONEP. Long-term follow-up data through the conclusion of the trial after nine months suggests that treatment of wet AMD patients with iSONEP, in combination with anti-VEGF treatments, may result in reductions in total wet AMD lesion area and may allow patients to maintain their visual acuity gains for longer periods of time than would be expected from anti-VEGF treatment alone. We believe that these signals of activity in the Nexus trial are appropriate for further clinical investigation. We are seeking a partner for future studies of iSONEP in order to obtain the funding and additional expertise required to advance this program.

## **ASONEP**

ASONEP is the systemic formulation of sonepcizumab; as such, it is also a mAb against the bioactive lipid S1P which has been implicated in the progression of various types of cancer and other angiogenic-related and inflammatory-oriented indications. It is well documented in scientific literature that S1P is a key protector of cancer cells when tumors are stressed by radiation or chemotherapy. Many studies have been conducted that demonstrate a strong link between S1P and several prevalent tumor types, including renal cell carcinoma (kidney cancer), leukemia, prostate cancer, neuroblastoma, (a brain tumor), lung cancer, pancreatic cancer, and melanoma (skin cancer).

### *Preclinical and Phase 1 Clinical Trial Results*

ASONEP has demonstrated efficacy in preclinical models of several types of human cancers. In addition, the safety profile of ASONEP was extremely favorable throughout a Phase 1 clinical trial as well as in a wide variety of preclinical studies at multiples of anticipated human exposure.

We believe ASONEP may be effective in reducing the four major processes of cancer progression: tumor proliferation, tumor metastasis, tumor-associated angiogenesis, and protection from cell death. The other mAbs on the market or in clinical trials of which we are aware generally inhibit only one or two tumor-promoting effects in a broad range of cancers. As such, we believe that ASONEP may have a comparative advantage over other therapeutic antibody approaches for cancer.

Other potential advantages of ASONEP, which are generally related to our unique approach of targeting bioactive lipids (whereas most therapeutic mAbs on the market and in clinical trials are directed against protein targets), include the following:

- a) *ASONEP's preclinical data may translate into humans more predictably than typical protein-targeted drug candidates.* Unlike protein targets, S1P has a single molecular structure that is conserved among species (i.e., S1P in a mouse is the same as in monkeys and humans), which is not the case for protein targets. This possibly provides for a greater translation (i.e., higher predictive value) between animal efficacy studies and possible human clinical significance.
- b) *Cancer cells (and other pathogenic cell types) may not as easily "escape therapy" by mutating around the therapy.* When the target is a protein, cancerous cells can "escape therapy" by mutating around the therapy; they do this either (i) through a form of natural selection, by "selecting" the isoform of the protein that the drug has least efficacy against, or (ii) by making a new version of the protein that the drug is less effective against (and cancer cells have already proven to be highly likely to mutate). S1P, on the other hand, has no isoforms (or splice variants) so the natural selection process described above cannot occur. In addition, the second approach described above is highly unlikely to occur because cells are programmed to produce proteins and not lipids.

- c) *Antibodies that bind to lipids may be able to attain certain efficiencies and potencies that protein-targeted antibodies cannot attain.* A typical antibody usually binds and inhibits one (in some cases, two) protein targets. Lipids are so small, by contrast, that each antibody can bind and inhibit two or more such lipid molecules, providing certain efficacies and potencies that typical antibodies cannot attain.
- d) *ASONEP has greater binding affinity than other antibodies.* The affinity of ASONEP (i.e., the “strength” of binding to its target, S1P) is higher than antibody therapeutics that are currently used in the clinic as molecular sponges.

ASONEP has demonstrated favorable results in disease models for clinical indications other than cancer. In a preclinical study conducted at Harvard Medical School using ASONEP in an Experimental Autoimmune Encephalomyelitis (EAE) model of Multiple Sclerosis, ASONEP performed favorably compared against FTY720, a Novartis compound that was recently approved by the FDA as a treatment for Multiple Sclerosis.

In the first quarter of 2010, we completed a Phase 1 clinical trial in which ASONEP was tested in patients having cancer. The trial met its primary endpoint of identifying safe dose levels for investigation in the Phase 2 setting. ASONEP was well tolerated at all dose-levels, ranging from 1 mg/kg to 24 mg/kg. In the dose-escalation phase of the study, three evaluable patients were treated per dose level, with each one receiving four intravenous treatments during the initial evaluation period. Patients could continue ASONEP treatment after this initial evaluation period as long as the patient’s disease did not progress. The study also included an extension phase, where six additional patients were dosed at the highest dose (24 mg/kg) using the same dosing guidelines described above.

More than half the patients that completed the initial four-treatment evaluation period showed stable disease. Durable stable disease was observed in several patients. The test results offer considerable flexibility with dose level in future studies because ASONEP was equally well tolerated across all doses that were tested, other than minor infusion-related reactions observed at the highest dose of 24 mg/kg.

#### *Phase 2 Clinical Trial*

In March 2015, we announced that our Phase 2a single-agent, open-label study of ASONEP™ did not meet the primary endpoint of statistically significant progression-free survival in patients with advanced renal cell carcinoma (RCC). To successfully meet the primary endpoint of progression-free survival, at least 20 out of 39 patients needed to be progression-free at four months of treatment. Fourteen out of 40 patients (over enrolled by one patient) were progression-free at four months. Eight of the fourteen patients were progression-free for at least six months, of which three patients remained progression-free for over 20 months. Overall, ASONEP was well-tolerated. The ASONEP study follow-up period concluded during the third quarter of 2015, and there are no longer any patients being treated with ASONEP. We are now exploring other indications where ASONEP may have a greater chance of success.

As part of the Pfizer Agreement, Lpath granted to Pfizer (or a third party who may acquire Pfizer’s rights) a right of first refusal for ASONEP. That right of first refusal expired on August 9, 2015, concurrent with the expiration of Pfizer’s option to acquire the license to iSONEP.

#### **Business Strategy**

With our long-standing focus on bioactive lipids as targets for human disease, we have developed an expertise involving various tools and technologies that positions us as a leader in the emerging category of lipidomic-based therapeutics. We have an opportunity to leverage this expertise by using our proprietary ImmuneY2 drug-discovery engine to add novel bioactive-lipid-oriented product candidates to our therapeutic pipeline. In addition, we can continue to explore opportunities to licensing in technologies and compounds that further leverage our unique expertise and related intellectual property.

## **Manufacturing, Development, and Commercialization Strategy**

We have outsourced current Good Laboratory Practices (“cGLP”) preclinical development activities (e.g., toxicology) and cGMP manufacturing and clinical development activities to contract research organizations (“CROs”) and contract manufacturing organizations (“CMOs”). CROs and CMOs are third-parties that specialize in executing processes relating to project-oriented research activities on behalf of their clients and are commonly engaged in the industry. We outsource manufacturing to organizations with approved facilities and manufacturing practices. Marketing, sales, and distribution will likely be through strategic partners that license the right to market, sell, and distribute our compounds in exchange for some combination of up-front payments, royalty payments, and milestone payments. Our research and development expenses were \$8.6 million and \$18.1 million in fiscal years 2015 and 2014, respectively.

In 2013, we entered into a Development and Manufacturing Services agreement with Gallus to conduct the manufacturing process development and scale-up activities followed by the cGMP manufacture of Lpathomab. Pursuant to the terms of that agreement, Gallus performed the upstream and downstream process development, and cGMP manufacture for the Lpathomab clinical material used in our recent Phase 1 clinical trial. In addition, to ensure that we had adequate supplies of clinical material to complete the Phase 2 clinical trials of iSONEP and ASONEP, we contracted with Gallus for the production of cGMP material for both of those clinical trials. Production of that material was completed in the fourth quarter of 2014. In 2014, DPx Holdings B.V. acquired Gallus and merged it into Patheon, Inc. (“Patheon”). We believe we have a good relationship with Patheon (formerly Gallus) and that, if we need to manufacture additional clinical material in the future, we will be able to do so pursuant to the terms of the 2013 Development and Manufacturing Services agreement, which does not expire until 2018. Patheon is currently our single manufacturer for ASONEP, iSONEP, and Lpathomab and may not be replaced without significant effort and delay in production. Further, we believe we have adequate supplies of cGMP clinical material to begin the Phase 1b/2a clinical trial for Lpathomab. However, we may need to manufacture additional clinical material to complete that clinical trial, depending on various factors, including the stability of the drug product and the length of time that patients remain on the clinical trials. A supply interruption or an increase in demand beyond our current manufacturer’s capabilities could harm our ability to manufacture such products until new manufacturers are identified and qualified, which would have a significant adverse effect on our business and results.

### **Competition**

The pharmaceutical, biopharmaceutical and biotechnology industries are very competitive, fast moving and intense, and expected to be increasingly so in the future. Other larger and better funded companies have developed and are developing drugs that, if not similar in type to our drugs, are designed to address the same signaling pathways, or patient or subject population. For example, there are a number of approved drugs that are currently being used in the treatment of wet AMD as well as a number of companies currently developing drugs to treat wet AMD, which is the target market for iSONEP. The current market leaders for the treatment of wet AMD are the VEGF inhibitors, including Lucentis® (a product of Genentech, a member of the Roche Group), Eylea® (a product of Regeneron Pharmaceuticals) and (off-label) Avastin® (a product of Genentech, a member of the Roche Group). Therefore, our lead products, other products we may develop, or any other products we may acquire or in-license may not be, or may not be perceived to be, the most efficacious (at all or for a majority of patients), the safest, the first to market, or the most economical to make or use. If a competitor’s product is, or is perceived to be, more advantageous than ours, for whatever reason, then we could make less money from sales, if we are able to generate sales at all.

### **In-licensed Technology**

#### *Medical Research Council Technology*

In August 2005, Lpath entered into a collaboration agreement (the “AERES Agreement”) with AERES Biomedical Limited (“AERES”) to “humanize” the company’s *Sphingomab* monoclonal antibody. Humanization under this agreement with AERES involves utilizing proprietary processes owned by AERES for the purpose of modifying Sphingomab antibodies originally contained in mice for potential human acceptance in a clinical trial. The humanized version of Sphingomab that was produced from the collaboration with AERES is called Sonepcizumab. In 2014,

AERES' rights and obligations pursuant to the AERES Agreement with Lpath were transferred to Medical Research Council Technology ("MRCT") by means of a Deed of Novation, which obligates MRCT to perform and be bound by the terms of the AERES Agreement. No amounts were paid to AERES or MRCT during 2015 and 2014. Lpath could owe MRCT certain additional contingent amounts when drug candidates based on Sonepcizumab pass through the levels of the FDA drug review and approval process. MRCT will be entitled to a royalty, not to exceed 4%, on any revenues generated by the ultimate commercialization of any drug candidate based on Sonepcizumab.

### **Patents and Proprietary Rights**

Our success will depend, in part, on our ability to obtain patent protection for our products in the United States and other countries. We have created a broad intellectual-property position in the bioactive lipid arena. Our patent portfolio now includes 70 issued patents, including 35 foreign patents, and 79 pending patents, including 61 foreign patent applications. These patents primarily concern the use of reagents and methods designed to interfere with the actions of bioactive lipids involved in human disease. Our intellectual-property portfolio includes compositions of matter that specifically bind to sphingolipids and sphingolipid metabolites. These agents, including antibodies, could be used in the diagnosis and treatment of various diseases and disorders, including cardiovascular and cerebrovascular disease, cancer, inflammation, autoimmune disorders, ocular disease, and angiogenesis. We have also obtained issued claims on sphingolipid targets (e.g., receptors and signaling sphingolipids) and methods for using such targets in drug-discovery screening efforts. We believe that our patent portfolio provides broad, commercially significant coverage of antibodies, receptors, enzymes, or other moieties that bind to a lysolipid (or a sphingolipid metabolite) for diagnostic, therapeutic, or screening purposes. Our issued patents begin to expire in 2017. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position.

### **Government Regulation**

The FDA and comparable regulatory agencies in foreign countries, as well as drug regulators in state and local jurisdictions, impose substantial requirements upon the clinical development, manufacturing, and marketing of pharmaceutical products. These agencies and other federal, state and local entities also regulate research and development activities and the human testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising, and promotion of our product candidates (and any other products we may develop, acquire, or in-license).

The process required by the FDA under the drug provisions of the United States Food, Drug, and Cosmetic Act before our initial products may be marketed in the U.S. generally involves the following:

- Preclinical laboratory and animal tests;
- Submission of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for its intended use;
- Submission to the FDA of a New Drug Application ("NDA"); and
- FDA review and approval, or otherwise, of an NDA.

The testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approval will be granted on an expeditious basis, if at all. Preclinical tests include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. Certain preclinical tests must be conducted in compliance with cGMP regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be replicated. In some cases, long-term preclinical studies are conducted while clinical studies are ongoing.

We are required to submit the results of our preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Our submission of an IND may not result in FDA authorization to commence clinical trials. All clinical trials must be conducted under the supervision of a qualified investigator in accordance with good clinical practice regulations. Among other things, these regulations include the requirement that all subjects provide informed consent. Further, an independent Institutional Review Board ("IRB") at each medical center proposing to conduct the clinical trials must review and approve any clinical study. Each IRB also continues to monitor the study and must be kept aware of the study's progress, particularly as to adverse events and changes in the research. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events occur.

Human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase 1: The drug is initially introduced into human subjects or patients and tested for safety, dosage tolerance, absorption, distribution, metabolism, and excretion ("ADME").
- Phase 2: The drug is studied in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: When Phase 2 evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase 3 trials are undertaken to further evaluate dosage and clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites.

We cannot be certain that we will successfully initiate or complete Phase 1, Phase 2, or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Concurrent with clinical trials and pre-clinical studies, we also must develop information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product, and we must develop methods for testing the quality, purity, and potency of the final products. Additionally, appropriate packaging must be selected and tested and chemistry stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf-life.

The results of product development, pre-clinical studies, and clinical studies are submitted to the FDA as part of an NDA for approval of the marketing and commercial shipment of the product. The FDA reviews each NDA submitted and may request additional information, rather than accepting the NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the FDA accepts the NDA for filing, the agency begins an in-depth review of the NDA. The FDA has substantial discretion in the approval process and may disagree with our interpretation of the data submitted in the NDA.

The review process may be significantly extended by FDA requests for additional information or clarification regarding information already provided. Also, as part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation. The FDA is not bound by the recommendation of an advisory committee. Manufacturing establishments often also are subject to inspections prior to NDA approval to assure compliance with cGMPs and with manufacturing commitments made in the relevant marketing application.



Under the Prescription Drug User Fee Act ("PDUFA"), submission of an NDA with clinical data requires payment of a fee to the FDA, which is adjusted annually. In return, the FDA assigns a goal of ten months for standard NDA reviews from acceptance of the application to the time the agency issues its "complete response," in which the FDA may approve the NDA, deny the NDA if the applicable regulatory criteria are not satisfied, or require additional clinical data. Even if the requested data is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. If the FDA approves the NDA, the product becomes available for physicians to prescribe. Even if the FDA approves the NDA, the agency may decide later to withdraw product approval if compliance with regulatory standards is not maintained or if safety problems occur after the product reaches the market. The FDA may also require post-marketing studies, sometimes known as Phase 4 studies, as a condition of approval to develop additional information regarding the safety of a product. In addition, the FDA requires surveillance programs to monitor approved products that have been commercialized, and the agency has the power to establish and require changes in labeling and to prevent further marketing of a product based on the results of these post-marketing programs.

Satisfaction of the above FDA requirements or requirements of state, local and foreign regulatory agencies typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the pharmaceutical product or medical device. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for our lead products (or any other products we may develop, acquire, or in-license) on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from preclinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain regulatory approvals would have a material adverse effect on our business.

Any products manufactured or distributed by us pursuant to the FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the drug, submitting other periodic reports, drug sampling and distribution requirements, notifying the FDA and gaining its approval of certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, and complying with the FDA promotion and advertising requirements. Drug manufacturers and their subcontractors are required to register their facilities with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with good manufacturing practices, which impose procedural and documentation requirements upon our third-party manufacturers. Failure to comply with these regulations could result, among other things, in suspension of regulatory approval, recalls, suspension of production or injunctions, seizures, or civil or criminal sanctions. We cannot be certain that our present or future subcontractors will be able to comply with these regulations and other FDA regulatory requirements.

The FDA regulates drug labeling and promotion activities. The FDA has actively enforced regulations prohibiting the marketing of products for unapproved uses. Under the FDA Modernization Act of 1997, the FDA will permit the promotion of a drug for an unapproved use in certain circumstances, but subject to very stringent requirements.

Our product candidates are also subject to a variety of state laws and regulations in those states or localities where our lead products (and any other products we may develop, acquire, or in-license) are manufactured or marketed. Any applicable state or local regulations may hinder our ability to market our lead products (and any other products we may develop, acquire, or in-license) in those states or localities. In addition, whether or not FDA approval has been obtained, approval of a pharmaceutical product by comparable governmental regulatory authorities in foreign countries must be obtained prior to the commencement of clinical trials and subsequent sales and marketing efforts in those countries. The approval procedure varies in complexity from country to country, and the time required may be longer or shorter than that required for FDA approval.

The FDA's policies may change, and additional government regulations may be enacted which could prevent or delay regulatory approval of our potential products. Moreover, increased attention to the containment of health care costs

in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

### **Other Regulatory Requirements**

The U.S. Federal Trade Commission and the Office of the Inspector General of the U.S. Department of Health and Human Services (“HHS”) also regulate certain pharmaceutical marketing practices. Also, reimbursement practices and HHS coverage of medicine or medical services are important to the success of procurement and utilization of our product candidates, if they are ever approved for commercial marketing.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, relationships with treating physicians, data protection, the export of products to certain countries, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations now or in the future. We cannot assure you that any portion of the regulatory framework under which we currently operate will not change and that such change will not have a material adverse effect on our current and anticipated operations.

### **Employees**

As of February 1, 2016, we employed 14 individuals, of whom 7 held advanced degrees. A significant number of our management and professional employees have had prior experience with pharmaceutical, biotechnology, or medical product companies. Collective bargaining agreements do not cover any of our employees, and we consider relations with our employees to be good.

### **SEC Filings; Internet Address; Trademarks**

Our Internet address is [www.lpath.com](http://www.lpath.com). We file our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports with the SEC and make such filings available free of charge on our website, [www.lpath.com](http://www.lpath.com), as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information found on our website shall not be deemed incorporated by reference by any general statement incorporating by reference this report into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934, except to the extent we specifically incorporate the information found on our website by reference, and shall not otherwise be deemed filed under such Acts.

Our filings are also available through the SEC’s website, [www.sec.gov](http://www.sec.gov), and at the SEC Public Reference Room at 100 F Street, NE Washington DC 20549. For more information about the SEC Public Reference Room, you can call the SEC at 1-800-SEC-0330.

iSONEP™, ASONEP™ Lpathomab™, ImmuneY2™ and our logo are our trademarks. This Annual Report on Form 10-K also includes trademarks, trade names and service marks that are the property of other organizations.

## **ITEM 1A. RISK FACTORS**

*Any investment in our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this Annual Report on Form 10-K, before you decide to buy our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our operations. If any of the following risks actually occur, our business would likely suffer and the trading price of our securities could decline, and you may lose all or part of the money you paid to buy our securities.*

**Risks primarily associated with our business:**

***We may not be successful in negotiating and consummating a strategic transaction.***

Our Board of Directors has engaged a financial advisory firm to explore our available strategic alternatives to obtain the capital required to fund our future operations or otherwise enhance stockholder value, including possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. We believe it is in our stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives we may identify in the near term. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Further, our expenses may exceed our current plans and expectations, which could require us to complete a transaction or wind-down our operations sooner than anticipated. Additionally, any transaction we consummate may offer limited value for our existing drug candidates and proprietary technology and may not enhance stockholder value or provide the expected benefits. If we are unable to successfully complete a strategic transaction or otherwise secure additional capital on a timely basis and on terms that are acceptable to our stockholders, we may be required to cease our operations altogether.

***We will require, and may not be able to obtain, substantial additional financial resources in order to carry out our planned activities and to continue as a going concern beyond the third quarter of 2016.***

As of December 31, 2015, we had cash and cash equivalents totaling \$8.9 million. Although we may receive limited additional funding under our existing NIH grants, our existing cash resources are not sufficient to meet our operating plan for the full 12 month period after the date of this filing, and we may not be able to continue as a going concern. Accordingly, the report from our independent registered public accounting firm accompanying the financial statements included in this Annual Report on Form 10-K contains an emphasis of a matter regarding our ability to continue as a going concern. To help extend our operating window, we have reduced our headcount and limited our research and product development activities. Based on our current plans and available resources, we believe we can maintain our current operations through the end of the third quarter of 2016. We estimate that the costs to wind-down our operations in an orderly manner will cost approximately \$2.5 million. As a result, we need to secure significant additional capital to continue to fund our operations and our drug discovery and development projects beyond the third quarter of 2016. Moreover, our expenses may exceed our current plans and expectations, which would require us to secure additional capital or wind-down our operations sooner than anticipated. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us or to our stockholders. If we are unable complete a strategic transaction or otherwise raise funds to satisfy our capital needs on a timely basis and control our operating costs, there can be no assurance that we will be able to continue to operate our business beyond the third quarter of 2016.

***Our current product candidate portfolio is limited and in the early stages of development.***

In May 2015, we announced that our multicenter, Phase 2 "Nexus" clinical trial evaluating iSONEP in patients with wet AMD did not meet its primary or key secondary endpoints. Based on long-term follow-up data suggesting that iSONEP, when used in combination with anti-VEGF treatments, may result in reductions in total wet AMD lesion area and may allow patients to maintain their visual acuity gains for longer periods of time than anti-VEGF treatments alone, we are pursuing licensing, partnering and other strategic alternatives to help fund further clinical investigation of iSONEP, but there is no assurance that we will be able to do so. Additionally, in March 2015, we announced that our Phase 2a single-agent, open-label study of ASONEP did not meet the primary endpoint of statistically significant progression-free survival in patients with advanced renal cell carcinoma (RCC). We are exploring other indications where ASONEP may have a greater chance of success, but there is no assurance that we will be able to do so. In addition, although we recently completed the dosing phase of a Phase 1 clinical trial for our third product candidate, Lpathomab we do not have sufficient funds at this point to pursue additional clinical work on Lpathomab. Moreover, even if we can raise additional funds, there is no assurance that we can successfully develop Lpathomab, prove it to be safe and efficacious in clinical trials, or meet applicable regulatory standards. In addition, our ImmuneY2™ process of generating monoclonal antibodies against lipid mediators may not be successful against future targets. As such, there

can be no assurance that we will be able to develop a monoclonal antibody against our future targets, and thus, we may fail to generate additional clinical candidates for our pipeline. Moreover, given the early stage of development of our current clinical and preclinical drug candidates, we may not be successful in entering into collaboration or license agreements for these drug candidates, which could limit our ability to raise the funds required to support our operations and the future development of these drug candidates.

***We are in the early stages of drug development, and we may be unable to generate significant revenues and may never become profitable.***

We are in the early stages of drug development, and have not received FDA approval for marketing any of our drug candidates. We have generated approximately \$55.0 million in revenues from inception through December 31, 2015 and, as of December 31, 2015, we had an accumulated deficit of approximately \$76.1 million. We expect to incur significant operating losses for the foreseeable future as we continue to develop and seek regulatory approval for our drug candidates. We cannot provide any assurance that any of our drug candidates will prove to be clinically significant or will receive regulatory approval. For example, we reported that two of our drug candidates, iSONEP and ASONEP, failed to meet the endpoints of the Phase 2 clinical trials we conducted for these drug candidates. Even if the drug candidates were to receive any regulatory approval, there can be no assurance that we could provide for their effective marketing and sales, either by ourselves or in partnership with others. Consequently there can be no assurance that we will ever achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Accordingly, our prospects must be considered in light of the risks, expenses, and difficulties frequently encountered by companies in an early stage of drug development.

***The results of our clinical trials may not support either further clinical development or the commercialization of our product candidates.***

Even if we complete clinical trials for our drug candidates as planned, the results from these clinical trials may not support either the further clinical development or the commercialization of our product-candidates. For example, on May 20, 2015, we announced that our multicenter, Phase 2 "Nexus" clinical trial evaluating iSONEP in patients with wet AMD did not meet its primary or key secondary endpoints. Wet AMD patients who participated in our Nexus trial did not show statistically significant improvement in visual acuity when treated with iSONEP as an adjunctive or monotherapy. Based on these results, Pfizer Inc. did not elect to exercise its contractual option to obtain worldwide rights to iSONEP, and its contractual option expired, unexercised. Based on long-term follow-up data suggesting that iSONEP, when used in combination with anti-VEGF treatments, may result in reductions in total wet AMD lesion area and may allow patients to maintain their visual acuity gains for longer periods of time than anti-VEGF treatments alone, we are pursuing licensing, partnering and other strategic alternatives to help fund further clinical investigation of iSONEP, but there is no assurance that we will be able to do so. Additionally, on March 24, 2015, we announced that our Phase 2a single-agent, open-label study of ASONEP™ did not meet the primary endpoint of statistically significant progression-free survival in patients with advanced renal cell carcinoma (RCC). We are exploring other indications where ASONEP may have a greater chance of success, but there is no assurance that we will be able to do so.

Moreover, based on the results of our preclinical studies with Lpathomab, we elected to submit an Investigational New Drug Application (IND) for Lpathomab with the FDA, and completed the dosing phase in the Phase 1a clinical trial of Lpathomab. The follow-up period for patients in the Phase 1a trial will be completed in March 2016, and we expect the final study results, including pharmacokinetic, pharmacodynamic, and safety data, to be available in the second quarter of 2016. The results from this Phase 1 clinical trial on Lpathomab may be different from our preclinical studies and may not support further clinical development and/or the commercialization of Lpathomab. The same is true for any of our existing and future drug candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results from any later clinical trials may not replicate the results of prior clinical trials and pre-clinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans, effective for indicated uses, or commercially viable given the competitive environment and reimbursement issues. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

In addition, we or the FDA may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in any INDs or the conduct of these trials. A number of companies in the biotechnology and drug development industries have suffered significant setbacks in advanced clinical trials despite promising results in earlier trials. In the end, we may be unable to develop marketable products.

Further, we have not obtained an agreement with the FDA that the design of our planned studies for any of our drug candidates would be sufficient to lead to product approval even if the results are positive. Moreover, we have not developed or reached an agreement with the FDA on the detailed statistical analysis plan that will be used to analyze the data from these clinical trials. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

***We could be delisted from NASDAQ, which could seriously harm the liquidity of our stock and our ability to raise capital or complete a strategic transaction***

In July 2015, we received a letter (the "Notice") from the Listing Qualifications staff (the "Staff") of The NASDAQ Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the our common stock for the last 30 consecutive business days, we no longer met the requirement to maintain a minimum bid price of \$1 per share, as set forth in Nasdaq Listing Rule 5550(a)(1). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until January 5, 2016, in which to regain compliance. If our common stock is delisted from Nasdaq, we anticipate that our shares of common stock would trade on the OTC bulletin board. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least \$1 per share for a minimum of ten consecutive business days during this 180-day period. Because we did not regain compliance within this 180-day period, we requested and received on January 6, 2016, an additional compliance period of 180 calendar days, or until July 5, 2016. In order to be eligible for this additional compliance period, we had to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement. During this second compliance period, we intend to cure the deficiency, by seeking approval from our stockholders to effect a reverse stock split. However, we cannot provide assurance that our stockholders will approve the reverse stock split, or that we will be able to cure the deficiency in our bid price during this second compliance period. If we fail to satisfy the continued listing requirements on a timely basis, we cannot assure you that our common stock will continue to be listed on Nasdaq beyond July 5, 2016.

A delisting from Nasdaq and commencement of trading on the OTC bulletin board would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of shares of our common stock (and the accompanying valuation of our company);
- our ability to obtain financing or complete a strategic transaction for the continuation of our operations;
- the number of institutional and other investors that will consider investing in shares of our common stock;
- the number of market makers in shares of our common stock;
- the availability of information concerning the trading prices and volume of shares of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

All of these factors could hinder our ability to continue our operations beyond the third quarter of 2016.

***We may have delays in completing our clinical trials and we may not complete them at all.***

We have not completed the clinical trials necessary to obtain FDA approval to market any of our product candidates. The clinical trial process is also time consuming, and we do not know whether planned clinical trials will begin on time or whether we will complete any of our clinical trials on schedule, or at all. In addition, any future clinical trials we pursue may be delayed or terminated in the future as a result of many factors, including the following:

- not have sufficient funding to support the clinical trial;
- difficulty in securing centers to conduct trials;
- slower than expected patient enrollment or lack of a sufficient number of patients that meet the enrollment criteria for our clinical trials and our inability to change our clinical protocols to respond to such delays;
- patients failing to complete clinical trials due to safety issues, treatment protocol requirements, side effects, dissatisfaction with the product candidate, or other reasons;
- unexpected adverse reactions by patients or a temporary suspension or complete ban on trials of our products due to adverse side effects;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- inability to change clinical trial protocols if we experience unexpected delays;
- inability to maintain or manufacture a supply of the investigational drug or the active comparators in sufficient quantities to support the trials;
- disagreements with our collaborators on clinical trial protocols or design;
- delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical testing sites;
- regulators or Institutional Review Boards may not authorize us to commence a clinical trial;
- regulators or Institutional Review Boards may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- the FDA instituting future clinical holds on our clinical trials, and delays or failure of the FDA to remove such clinical holds;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable risks or for other reasons;
- difficulty in maintaining contact with patients after treatment may prevent us from collecting the data required by our study protocols;
- product candidates demonstrating a lack of efficacy during clinical trials;
- governmental or regulatory delays, changes in regulatory requirements, policy and guidelines;
- competition with ongoing clinical trials and scheduling conflicts with participating clinicians; and
- delays in completing data collection and analysis for clinical trials.

In the past, we have experienced significant delays in our clinical trials for one or more of the reasons outlined above. For example, in January 2012, the FDA placed our clinical trials on hold 2012 following a determination by the FDA that our fill-and-finish contractor that had filled the iSONEP clinical trial vials was not in compliance with the FDA's current Good Manufacturing Practice ("cGMP") standards during the time period it provided those services to the Company. Thereafter, we were required to manufacture new drug product, which resulting in our inability to resume dosing patients until September 2012.

In addition, we rely on academic institutions, hospitals and medical centers, physician practices and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol, applicable regulations or good clinical practices. We also rely on clinical research organizations to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner. If the delays or costs are significant, our financial results and ability to commercialize our products will be adversely affected.

***We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls or require us to cease operations sooner than anticipated.***

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the time and resources required to complete a financing, licensing arrangement or strategic transaction;
- the time and resources required to develop our product candidates, conduct pre-clinical and clinical trials, obtain regulatory approvals, and create effective sales and marketing capabilities;
- the costs required to wind-down our operations;
- the time and costs of manufacturing additional supplies of our investigational drug or obtaining the active comparators for our clinical trials;
- the expenses we incur for research and development required to develop our drug candidates and to maintain and improve our technology;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

In addition, our budgeted expense levels are based in part on our expectations concerning future revenues. However, our ability to generate any revenues depends largely on the progress of our drug candidates through clinical trials, and ultimately on receiving marketing approval from the FDA, which is difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected shortfall in revenues. As a result, a significant shortfall in our planned revenues could have an immediate and material adverse effect on our business and financial condition.

***We must obtain governmental approval for each of our products, which is an expensive and complicated process in which any number of problems could arise that would adversely affect our business.***

Our product candidates target lipids, as opposed to proteins, and the FDA has not previously approved any similar product. Thus, we may encounter unexpected safety, efficacy, or manufacturing issues as we seek to obtain

regulatory approval, and we may never receive approval from the FDA or other governmental authorities for our drug candidates.

The development, production and marketing of our products are subject to extensive regulation by government authorities in the United States and most other developed countries. The process of obtaining approval from the FDA in the United States requires conducting extensive pre-clinical and clinical testing. We have limited experience in, and limited resources available for, regulatory and clinical activities. Any of the following events relating to the regulatory approval of our drug candidates can occur and, if any did occur, any one could have a material adverse effect on our business, financial conditions and results of operations:

- inability to successfully complete our clinical trials in accordance with our clinical protocols and FDA regulations;
- results of clinical trials not yielding sufficiently conclusive favorable data for regulatory agencies to approve the use of our products in development, or any other products we may acquire or in-license;
- the FDA or other regulatory authorities may place a clinical trial on clinical hold;
- delays, sometimes long delays, in obtaining approval for our product candidates, including, but not limited, to requests for additional clinical trials;
- changes in the rules and regulations governing the approval process for product candidates such as ours during the testing and review period, which can result in the need to spend time and money for further testing or review;
- the authorized use of any product, if approved, is more limited than required for commercial success, or approval is conditioned on completion of further clinical trials or other activities; and
- any approval being withdrawn, or limited, if previously unknown problems arise with our human-use product or data arising from its use.

Failure to comply with applicable regulations can, among other things, result in non-approval, suspensions of regulatory approvals, fines, product seizures and recalls, operating restrictions, injunctions and criminal prosecution.

***A source of revenue, grant funds from the National Institutes for Health, may not continue to be a source of revenue in the future.***

Although we have applied for and been awarded grants in the past, the National Institutes of Health (“NIH”) may not in the future find our applications worthy of such grants.

In addition, the NIH requires audits of those recipients of grant funds exceeding \$500,000 in any year, a threshold that we have exceeded in 2014. Such audits test the allowability and allocation of expenditures and ultimately compliance with OMB Circular A-133 audit requirements. There can be no assurance that we will pass such an audit, and failure to pass could result in a material adverse effect on our cash flow and our business operations.

***Our drug-development programs depend upon third-party researchers who are outside our control.***

We depend upon independent investigators and collaborators, such as universities, medical institutions, and clinical research organizations to conduct our pre-clinical and clinical trials under agreements with us. Such agreements are often standard-form agreements typically not subject to extensive negotiation. These investigators or collaborators are not our employees, and in general we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA



applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us.

***Our collaborations with outside scientific and clinical advisors may be subject to restriction and change.***

We work with scientific and clinical advisors at academic and other institutions who are experts in the fields of oncology, ophthalmology, pain, traumatic brain injury, and autoimmune disorders (such as multiple sclerosis). They assist us in our research and development efforts and advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. Although our scientific and clinical advisors and collaborators generally agree not to engage in competing work, if a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the clinical development of our drug candidates.

***We are dependent on third-party manufacturers, over whom we have limited control, to manufacture our products.***

The manufacturing process of iSONEP, ASONEP, Lpathomab, and any other therapeutic products we may want to evaluate or commercialize involves a number of steps and requires compliance with stringent quality control specifications imposed by us and by the FDA. Moreover, our proposed products may be manufactured only in a facility that has undergone a satisfactory inspection and certification by the FDA. We do not have any manufacturing facilities ourselves and expect to rely on one or more third-party manufacturers to properly manufacture our products currently in clinical development as well as any other products we may develop or in-license. We may not be able to quickly replace our manufacturing capacity if we were unable to use a third party's manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure or other difficulty, or if such facilities are deemed not in compliance with current Good Manufacturing Practice ("cGMP") requirements, and the noncompliance could not be rapidly rectified. For example, in January 2012, we temporarily suspended dosing patients in our PED and wet AMD trials, because we learned from the FDA that our fill-and-finish contractor, Formatech, Inc., was not in compliance with cGMP requirements during the period in August 2010 that the iSONEP clinical vials were filled. After we suspended dosing, we were notified by the FDA that the iSONEP trials were being placed on clinical hold. Thereafter, we were required to manufacture new drug product, which resulting in our inability to resume dosing patients until September 2012.

In addition, we may not be able to maintain our relationship with any manufacturer we select. A supply interruption or an increase in demand beyond our current manufacturer's capabilities could harm our ability to manufacturer such products until new manufacturers are identified and qualified, which would have a significant adverse effect on our business and results.

Additionally, our inability or reduced capacity to have our products manufactured would prevent us from successfully evaluating or commercializing our proposed products. Our dependence upon third parties for the manufacture of our proposed products may adversely affect our profit margins and our ability to develop and deliver proposed products on a timely and competitive basis. Any delays in formulation and manufacturing objectives may cause a delay in our clinical program, and could have an adverse effect on the price of our shares.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenue.***

We do not currently have an organization for the sales, marketing and distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, we must build a sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In addition, we have no experience in developing, training or managing a sales force and will incur substantial additional expenses in doing so. The cost of establishing and maintaining a sales force may exceed its cost effectiveness. Furthermore, we will compete with many companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete successfully against these companies. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

***Physicians and patients may not accept and use our drugs.***

Even if the FDA approves our initial lead products (or any other product we attempt to commercialize), physicians and patients may not accept and use it. Acceptance and use of any of our future products, if approved, will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- cost-effectiveness of our drugs or diagnostic products relative to competing products;
- availability of reimbursement from government or other healthcare payors for our products; and
- effectiveness of marketing and distribution efforts by us and our third-party collaborators, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance, subsequent to approval, would severely harm our business.

***Our industry is highly competitive, so even if our products ultimately get approved by the FDA, our success depends on our ability to sustain competitive advantages.***

The pharmaceutical, biopharmaceutical and biotechnology industries are very competitive, fast moving and intense, and, are expected to be increasingly so in the future. Other companies have developed and are developing drugs that, if not similar in type to our drugs, are designed to provide comparable clinical significance. Therefore, our lead products, other products we may develop, or any other products we may acquire or in-license may not be, or may not be perceived to be, the most efficacious (at all or for a majority of patients), the safest, the first to market, or the most economical to make or use. If a competitor's product is, or is perceived to be, more advantageous than ours, for whatever reason, then we could make less money from sales, if we are able to generate sales at all.

There are many reasons why a competitor might be more successful than we are, including:

- Many competitors have greater financial resources and can afford more technical and development setbacks than we can.
- Many competitors have been in the drug-discovery and drug-development business longer than we have. They have greater experience than we have in critical areas like clinical testing, obtaining regulatory approval, and sales and marketing. This experience and their name recognition give them a competitive advantage over us.
- Some competitors may have a better patent position protecting their technology than we have or will have to protect our technology. If we cannot use our proprietary rights to prevent others from copying our technology or developing similar technology, then our competitive position will be harmed.
- Some companies with competitive technologies may move through stages of development, approval, and marketing faster than we do. If a competitor receives FDA approval before we do, then it will be authorized to sell its products before we can sell ours. Because the first company "to market" often has a significant advantage over latecomers, a second-place position could result in less-than-anticipated sales.

The United States Food, Drug, and Cosmetic Act and FDA regulations and policies provide incentives to manufacturers to challenge patent validity or create modified, non-infringed versions of a drug in order to facilitate the approval of abbreviated new drug application for generic substitutes. These same incentives also encourage manufacturers to submit new drug applications, known as 505(b)(2) applications, that rely on literature and clinical data

not originally obtained by the drug sponsor. In light of these incentives and especially if our lead products (or our other drug candidates in development or any other products we may acquire or in-license) are commercially successful, other manufacturers may submit and gain successful approval for either an abbreviated new drug application or a 505(b)(2) application that will compete directly with our products. Such competition will likely cause a reduction in our revenues.

***If Medicare and other third-party payors, including managed care organizations, do not provide adequate reimbursement for our drugs or our diagnostic products, if commercialized, the commercial success of our product candidates could be compromised.***

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from third party payors, including state and federal government authorities, private health insurers and health maintenance and managed care organizations. These third-party payors are increasingly attempting to limit both the coverage and the level of reimbursement of new drug products to contain costs. Consequently, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Third party payors may not establish adequate levels of reimbursement for the products that we commercialize, which could limit their market acceptance and result in a material adverse effect on our financial condition.

Reimbursement by a third-party payor may depend on a number of factors, including a payor's determination that our product candidates, if commercialized, are: experimental or investigational; not medically necessary; not appropriate for the specific patient or clinical indication; or not cost-effective.

Reimbursement by Medicare may require a review that will be lengthy and that will be performed under the provisions of a National Coverage Decision process with payment limits as the Secretary of Health and Human Services (HHS) determines appropriate. We cannot guarantee that the Secretary of HHS will act to approve any of our products, if commercialized, on a timely basis, or at all. In addition, there have been and will most likely continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. Any future changes in Medicare reimbursement that may come about as a result of enactment of healthcare reform or of deficit-reduction legislation will likely continue the downward pressure on reimbursement rates. In addition, emphasis on managed care in the United States may continue to pressure the pricing of healthcare services. In certain countries outside the United States, pricing and profitability of prescription pharmaceuticals are subject to government control. Third party payors, including Medicare, are challenging the prices charged for medical products and services. In addition, government and other third-party payors increasingly are limiting both coverage and the level of reimbursement for many drugs and diagnostic products. If government and other third-party payors do not provide adequate coverage and reimbursement for our products, it may adversely affect our business. Since policy-level reimbursement approval is required from each private payor individually, seeking such approvals is a time-consuming and costly process. If we are unable to obtain adequate reimbursement approval from Medicare and private payors for any of our products, or if the amount reimbursed is inadequate, our ability to generate revenue will be limited.

***We may incur significant or currently undeterminable costs in complying with environmental laws and regulations.***

We use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. As appropriate, we will store these materials and wastes resulting from their use at our or our outsourced laboratory facility pending their ultimate use or disposal. We will contract with a third party to properly dispose of these materials and wastes. We will be subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We may also incur significant costs complying with environmental laws and regulations adopted in the future.

***We may be subject to product liability claims.***

The development, manufacture, and sale of pharmaceutical products expose us to the risk of significant losses resulting from product liability claims. Although we intend to obtain and maintain product liability insurance to offset some of this risk, we may be unable to secure such insurance or it may not cover certain proven claims against us.

We may not be able to afford to obtain insurance due to rising costs in insurance premiums in recent years. If we are able to secure insurance coverage, we may be faced with a successful claim against us in excess of our product liability coverage that could result in a material adverse impact on our business. If insurance coverage is too expensive or is unavailable to us, we may be forced to self-insure against product-related claims. Without insurance coverage, a successful claim against us and any defense costs incurred in defending ourselves may have a material adverse impact on our operations.

***If we lose the services of key management personnel, we may not be able to execute our business strategy effectively.***

Our future success depends in a large part upon the continued service of key members of our senior management team. In particular, our Interim Chief Executive Officer and Chief Financial Officer, Gary Atkinson, our Senior Vice President and Chief Development Officer, Dario Paggiarino, M.D., and our Senior Vice President and Chief Scientific Officer, Gary Woodnutt, Ph.D. are critical to our overall management as well as the development of our technology, our culture and our direction. Our business and prospects depends in part on our ability to identify and retain a permanent Chief Executive Officer who can assist us in executing on our business plan.

None of our executive officers and key employees has long-term employment contracts with us, and we do not maintain any key-person life insurance policies. The failure to identify and retain a permanent Chief Executive Officer or the loss of any of our management or key personnel could materially harm our business.

***We rely on highly skilled personnel and, if we are unable to retain or motivate key personnel or hire additional qualified personnel, we may not be able to grow effectively.***

Our performance is largely dependent on the talents and efforts of highly skilled individuals. Our future success depends on our continuing ability to identify, hire, develop, motivate, and retain highly skilled personnel for all areas of our organization. Competition in our industry for qualified employees is intense. We expect that as more companies in the biotechnology and pharmaceutical industries establish programs to discover drugs that target bioactive lipids, the demand for scientists with experience working with bioactive lipids will increase. As that demand increases, it is likely that certain of our competitors will directly target certain of our employees. Our continued ability to compete effectively depends on our ability to retain and motivate our existing employees.

We may also need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing, and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies and other emerging entrepreneurial companies, as well as universities and research institutions. Competition for such individuals, particularly in the Southern California area, is intense. Even though the current economic conditions have somewhat softened demand for qualified personnel, we expect that over the longer term we will continue to face stiff competition and may not be able to successfully recruit or retain such personnel. Attracting and retaining qualified personnel will be critical to our success.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate

coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our ability to use net operating loss carry forwards and research and development tax credits to offset future taxable income or future tax will be limited and may be limited further in the future due to changes in ownership (within the meaning of IRC Section 382) that have occurred and may occur in the future.***

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three year period. Ownership changes may occur in the future, which could eliminate or restrict our ability to use NOL carry forwards and research and development tax credits. In addition, the California state government suspended the use of existing California NOL carryforwards in some years, such as 2010 and 2011. In those years companies have not been permitted to utilize NOL carryforwards to reduce the amount of taxes payable to the state. If that fiscal policy were to continue then the California benefits could be deferred, modified, or lost.

Limitations on our ability to use NOL carry forwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal and state income taxes earlier than would be required if such limitations were not in effect.

**Risks associated with our intellectual property:**

***Our intellectual property rights are valuable, and our inability to protect them could reduce the value of our products, services and brand.***

Our patents, trademarks, trade secrets, copyrights and other intellectual property rights are critically important assets to us. Events outside of our control could jeopardize our ability to protect our intellectual property rights. For example, effective intellectual property protection may not be available in every country in which our products and services are distributed. In addition, the efforts we have taken to protect our intellectual property rights may not be sufficient or effective. Any significant impairment of our intellectual property rights could harm our business or our ability to compete. Protecting our intellectual property rights is costly and time consuming, and the unauthorized use of our intellectual property could cause these costs to rise significantly and materially affect our operating results.

While our goal is to obtain patent protection for our innovations, they may not be patentable or we may choose not to protect certain innovations that later turn out to be important for our business. Even if we do obtain protection for our innovations, the scope of protection gained may be insufficient or a patent issued may be deemed invalid or unenforceable, as the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. The patenting process, enforcement of issued patents, and defense against claims of infringement are inherently costly and risky. We may not have the financial resources to defend our patents, thereby reducing our competitive position and our business prospects. Specific risks associated with the patent process include the following:

- The United States or foreign patent offices may not grant patents of meaningful scope based on the applications we have already filed and those we intend to file. If our current patents do not adequately protect our drug molecules and the indications for their use, then we will not be able to prevent imitation and any product may not be commercially viable.
- Some of the issued patents we now license may be determined to be invalid. If we have to defend the validity of the patents that we have in-licensed, the costs of such defense could be substantial, and there is

no guarantee of a successful outcome. In the event any of the patents we have in-licensed is found to be invalid, we may lose competitive position and may not be able to receive royalties for products covered in part or whole by that patent under license agreements.

- In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our drug candidates.
- Although we try to avoid infringement, there is the risk that we will use a patented technology owned by another person or entity and/or be sued for infringement. For example, U.S. patent applications are confidential while pending in the Patent and Trademark Office, and patent offices in foreign countries often publish patent applications for the first time six months or more after filing. Further, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. In addition, defending or indemnifying a third party against a claim of infringement can involve lengthy and costly legal actions, and there can be no guarantee of a successful outcome.

Specifically, we have filed patents to protect our compositions of matter and methods to treat several disease states, including cancer, cardiovascular disease, cerebrovascular disease, hyperproliferative diseases, and angiogenesis. We do not know whether our claims will be granted. Even if we do obtain protection for our innovations, the scope of protection gained may be insufficient or a patent issued may be deemed invalid or unenforceable.

We also seek to maintain certain intellectual property as trade secrets. The secrecy of this information could be compromised by third parties, or intentionally or accidentally disclosed to others by our employees, which may cause us to lose any competitive advantage we enjoy from maintaining these trade secrets.

***We may in the future be subject to intellectual property rights claims, which are costly to defend, which could require us to pay damages, and which could limit our ability to use certain technologies in the future.***

Companies in the pharmaceutical, biopharmaceutical and biotechnology industries own large numbers of patents, copyrights, trademarks, and trade secrets and frequently enter into litigation based on allegations of infringement or other violations by others of intellectual property rights. As our products get closer to commercialization, there is greater possibility that we may become subject to an infringement claim based on use of our technology such that we would be unable to continue using the technology without obtaining a license or settlement from third parties. We may not be able to obtain these licenses on acceptable terms, or at all. If we fail to obtain a required license or are unable to alter the design of our technology to fall outside the scope of a third party patent, we may be unable to market some of our products, which would limit our prospects for profitability.

Any intellectual property claims, whether merited or not, could be time-consuming and expensive to litigate and could cause us to divert critical management and financial resources to the resolution of such claims. We may not be able to afford the costs of litigation. Any legal action against us or our collaborators or us could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize and sell products; or

- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

As a result, an adverse determination also could prevent us from offering our products to the marketplace.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property.***

Because we operate in the highly technical field of drug discovery and development, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

**Risks primarily associated with our stock:**

***The price of our common stock may be volatile .***

Our common stock is traded on the Nasdaq Capital Market, or NASDAQ. The trading price of our common stock may fluctuate substantially. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- our limited resources and ability to continue as a going concern;
- the terms of any financing, licensing arrangement or strategic transaction we announce, if any;
- price and volume fluctuations in the overall stock market from time to time;
- fluctuations in stock market prices and trading volumes of similar companies;
- actions of investors that affect the market price;
- actual or anticipated changes in our operating expenses or fluctuations in our operating results or in the expectations of securities analysts;
- general economic conditions and trends;
- the announcement of collaboration agreements to pursue further clinical development of our drug candidates;

- sales of large blocks of our stock;
- departures of key personnel;
- changes in the regulatory status of our product candidate or clinical trials;
- announcements of new products or technologies by competitors;
- regulatory developments in the United States and other countries.

***If shares of our common or preferred stock available for issuance or shares eligible for future sale were introduced into the market, it could hurt our stock price.***

We are authorized to issue 100,000,000 shares of common stock. As of February 16, 2016, there were an aggregate of 39,655,016 shares of our common stock issued and outstanding on a fully-diluted basis. That total includes 1,930,774 shares of our common stock that may be issued upon the exercise of outstanding stock options and the vesting of outstanding restricted stock units, and 4,585,644 shares of common stock that may be issued upon the exercise of outstanding warrants. That total does not include 904,128 shares of common stock that have been reserved for future issuance under our Amended and Restated 2005 Equity Incentive Plan. The exercise of outstanding options and/or warrants or the future issuance of equity awards may cause substantial dilution to those who hold shares of common stock prior to such exercises or issuances.

We may sell our authorized, but unissued, common stock to satisfy our funding requirements. We are also authorized to issue 15,000,000 shares of preferred stock, without stockholder approval. The preferred stock may have rights that are superior to the rights of the holders of our common stock, at a purchase price then approved by our Board of Directors. The sale or the proposed sale of substantial amounts of our common or preferred stock in the public markets may adversely affect the market price of our common stock and our stock price. Our stockholders may also experience substantial dilution.

***We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.***

We currently intend to invest our future earnings, if any, to fund the development and growth of our business. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in any debt agreements we may enter into and other factors our board of directors may deem relevant. If we do not pay dividends, your ability to achieve a return on your investment in our company will depend on any future appreciation in the market price of our common stock. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our holders have purchased their common stock.

***As a public company, we may have to implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements, which will increase our costs and require additional management resources.***

We have limited resources and we intend to continue to spend most of our resources on research, development and other operational expenses. We are currently classified as a Smaller Reporting Company under Exchange Act regulations. Until we are classified as an Accelerated Filer (based upon our market capitalization reaching \$75 million as of the applicable measuring date, among other requirements), we are exempt from compliance with Section 404(b) of the Sarbanes-Oxley Act of 2002, relating to the attestation and reporting by our external auditing firm on our internal controls. However, if we were no longer exempt from compliance with certain provisions of the Sarbanes-Oxley Act of 2002, we would incur significant additional costs, which would be material to us and would affect our results of operations. In order to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, we may be required to expand disclosures and accelerate our financial reporting requirements. If we are unable to complete the required Section 404(b) assessment as to the adequacy of our internal control over financial reporting, if we fail to maintain or implement adequate controls, or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting as of the date of our first



Form 10-K for which compliance is required (compliance will not be required with respect to our Form 10-K for the year ended December 31, 2015, but could be required with respect to our Form 10-K for the year ended December 31, 2016 depending on the value of our public float as of June 30, 2016), our ability to obtain additional financing could be impaired. In addition, investors could lose confidence in the reliability of our internal control over financial reporting and in the accuracy of our periodic reports filed under the Exchange Act. A lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline. In addition, we could be delisted from the NASDAQ Capital Market.

***Our governing documents provide indemnification for officers, directors and employees.***

Our governing instruments provide that officers, directors, employees and other agents shall only be liable to us for losses, judgments, liabilities and expenses for actions arising from actions not taken in good faith or of which indemnification would be otherwise unlawful in the performance of his or her obligations. Thus certain alleged errors or omissions might not be actionable by us. The governing instruments also provide that, under the broadest circumstances allowed under law, we must indemnify our officers, directors, employees and other agents for losses, judgments, liabilities, expenses, attorney's fees, and amounts paid in settlement of any claims sustained by them in connection with our Company, including liabilities under applicable securities laws.

***Anti-takeover provisions in our charter and bylaws could make a third party acquisition of the Company difficult.***

Our board of directors is authorized to provide for the issuance of shares of preferred stock in series and, by filing a certificate pursuant to the applicable law of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences, and rights of the shares of each such series and the qualifications, limitations, or restrictions thereof without any further vote or action by the stockholders. The issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could be used to discourage an unsolicited acquisition proposal. For instance, the issuance of a series of preferred stock might impede a business combination by including class voting rights that would enable the holder to block such a transaction, or facilitate a business combination by including voting rights that would provide a required percentage vote of the stockholders. In addition, under certain circumstances, the issuance of preferred stock could adversely affect the voting power of the holders of the common stock. Although our board of directors is required to make any determination to issue such stock based on its judgment as to the best interests of our stockholders, our board of directors could act in a manner that would discourage an acquisition attempt or other transaction that some, or a majority, of the stockholders might believe to be in their best interests or in which stockholders might receive a premium for their stock over the then market price of such stock. Our board of directors does not at present intend to seek stockholder approval prior to any issuance of currently authorized stock, unless otherwise required by law or otherwise. We have no present plans to issue any preferred stock.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***You may experience future dilution as a result of future equity offerings.***

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share as the shares you hold. We cannot assure you that we will be able to sell shares or other securities in any offering at a price per share that is equal to or greater than the price per share of the shares you hold, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or securities convertible into common stock in future transactions may be higher or lower than the price per share as the shares you hold.

***If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our administrative offices and research facilities are located at 4025 Sorrento Valley Blvd. San Diego, California 92121, and we consider them to be in good condition and adequately utilized. We lease approximately 12,000 square feet of laboratory and office space at this location. The lease term runs through November 10, 2016. The Company has one five-year renewal option under the lease. Approximately 200 square feet of the facility is subleased to a company that is owned by one of our directors and significant stockholders. The terms of this sublease, in general, are identical to the terms of our direct lease in all material respects. If we do not renew our existing lease, we believe that alternative space would be available to us at commercially reasonable terms.

**ITEM 3. LEGAL PROCEEDINGS**

We are not currently a party in any material legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock is traded on the NASDAQ Capital Market under the symbol “LPTN”. The closing price of our common stock on March 7, 2016 was \$0.18 per share.

The following table sets forth the high and low prices for our common stock for the periods indicated, as reported by NASDAQ:

	2015		2014	
	High	Low	High	Low
First quarter	\$ 3.71	\$ 2.47	\$ 5.11	\$ 4.26
Second quarter	\$ 2.49	\$ 0.26	\$ 4.76	\$ 3.72
Third quarter	\$ 0.34	\$ 0.19	\$ 4.03	\$ 3.05
Fourth quarter	\$ 0.28	\$ 0.18	\$ 3.69	\$ 2.40

As of February 1, 2016, we had approximately 75 stockholders of record (excluding an indeterminable number of stockholders whose shares are held in street or “nominee” name). We have not paid any dividends on our common stock since our inception and do not expect to pay dividends on our common stock in the foreseeable future.

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2015:

**EQUITY COMPENSATION PLAN INFORMATION**

	Number of Shares to be Issued Upon Exercise of Outstanding Stock Options and Restricted Stock Units	Weighted-Average Exercise Price of Outstanding Stock Options	Number of Shares Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders	1,930,774 (1)	\$ 4.35 (2)	1,429,128
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>1,930,774</b>	<b>\$ 4.35</b>	<b>1,429,128</b>

(1) Includes 641,834 restricted stock units.

(2) Excludes 641,834 restricted stock units.

**ITEM 6. SELECTED FINANCIAL DATA**

This item has been omitted as the Company qualifies as a smaller reporting company.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis in conjunction with our consolidated financial statements and related notes contained elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of a variety of factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K and those discussed in other documents we file with the SEC. In light of these risks, uncertainties, and assumptions, readers are cautioned not to place undue reliance on such forward-looking statements. These forward-looking statements represent beliefs and assumptions only as of the date of this Annual Report on Form 10-K. Except as required by applicable law, we do not intend to update or revise forward-looking statements contained in this Annual Report on Form 10-K to reflect future events or circumstances.*

### Overview

We are a biotechnology company focused on the discovery and development of lipidomic-based therapeutic antibodies, an emerging field of medical science that targets bioactive signaling lipids to treat a wide range of human diseases. We have developed three drug candidates, advancing each of them into clinical trials, and built evidence to support our approach of targeting bioactive lipids to treat a wide range of diseases. In January 2016, we completed the dosing of all subjects in our Phase 1 clinical trial of Lpathomab.

As of December 31, 2015, we had cash and cash equivalents totaling \$8.9 million. We have incurred significant net losses since our inception. To conserve our cash resources, we have reduced our headcount and limited our research and product development activities. As a result of these actions, we believe our current resources should be sufficient to fund our operations through the third quarter of 2016.

Our Board of Directors has engaged a financial advisory firm to explore our available strategic alternatives, including possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. We believe it is in our stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives we may identify in the near term. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Further, our expenses may exceed our current plans and expectations, which could require us to complete a transaction or wind-down our operations sooner than anticipated. Additionally, any transaction we consummate may offer limited value for our existing drug candidates and proprietary technology and may not enhance stockholder value or provide the expected benefits. If we are unable to successfully complete a strategic transaction or otherwise secure additional capital on a timely basis and on terms that are acceptable to our stockholders, we may be required to cease our operations altogether.

### Lpathomab

Lpathomab is a humanized monoclonal antibody ("mAb") against lysophosphatidic acid ("LPA"), a bioactive lipid that has been characterized in scientific literature as playing a key role in nerve injury and neuropathic pain. Published research has also demonstrated that LPA is a significant promoter of cancer-cell growth and metastasis in a broad range of tumor types, and plays a key role in pulmonary fibrosis. Our preclinical studies showed strong in vivo results with Lpathomab in several different pain models, which suggest that LPA may be an attractive target across a variety of chronic pain conditions, including diabetic peripheral neuropathy, post-herpetic neuralgia, chemotherapy-induced neuropathic pain and pain associated with lumbosacral radiculopathy.

In January 2016, we completed the dosing of all subjects in our Phase 1a clinical trial of Lpathomab. The double-blind, placebo-controlled, single ascending dose trial was designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of Lpathomab in healthy volunteers. The trial also aimed to establish a maximum tolerated dose for future clinical studies in patients with neuropathic pain or other potential indications. The

trial included a total of five cohorts at increasing doses. Lpathomab was well tolerated at all doses tested, and no serious adverse events or dose limiting toxicities were observed during the trial. The follow-up period for patients participating in this Phase 1a trial will be completed in March 2016, and we expect the final study results, including pharmacokinetic, pharmacodynamic, and safety data, to be available in the second quarter of 2016.

## **iSONEP**

In 2010, we entered into an agreement with Pfizer Inc., which was amended in 2012 (collectively, the “Pfizer Agreement”), that provided Pfizer with an exclusive option for a worldwide license to develop and commercialize iSONEP. From 2011 to 2015 in collaboration with Pfizer, we conducted a multicenter, Phase 2 clinical trial evaluating iSONEP in patients with wet age-related macular degeneration (wet AMD) (the “Nexus trial”). During the second quarter of 2015, we announced that our Nexus trial did not meet its primary or key secondary endpoints. Based on the failure of iSONEP to meet these endpoints, Pfizer elected to allow its option to develop and commercialize iSONEP to expire unexercised on August 9, 2015. As a result, the Pfizer Agreement terminated by its terms, and all rights that Pfizer held in the iSONEP program have reverted to Lpath.

Following completion of the Nexus trial, we conducted further analyses of the data including additional anatomical endpoints to better understand the results. While iSONEP did not meet the primary endpoint of the Nexus trial at day 120 of the trial, analyses of the data from the completed trial did provide interesting signals of possible therapeutic benefit from iSONEP. Long-term follow-up data through the conclusion of the trial after nine months suggests that treatment of wet AMD patients with iSONEP, in combination with anti-VEGF treatments, may result in reductions in total wet AMD lesion area and may maintain visual acuity gains for longer periods of time than would be expected from anti-VEGF treatment alone. We believe that these signals of activity in the Nexus trial are appropriate for further clinical investigation. We are seeking a partner for future studies of iSONEP in order to obtain the funding and additional expertise required to advance this program.

## **ASONEP**

In March 2015, we announced that our Phase 2a single-agent, open-label study of ASONEP™ did not meet the primary endpoint of statistically significant progression-free survival in patients with advanced renal cell carcinoma (RCC). ASONEP™ is the systemic formulation of sonepcizumab. To successfully meet the primary endpoint of progression-free survival, at least 20 out of 39 patients needed to be progression-free at four months of treatment. Fourteen out of 40 patients (over enrolled by one patient) were progression-free at four months. Eight of the fourteen patients were progression-free for at least six months, of which three patients remained progression-free for over 20 months. Overall, ASONEP was well-tolerated. The ASONEP study follow-up period concluded during the third quarter of 2015, and there are no longer any patients being treated with ASONEP. We are now exploring other indications where ASONEP may have a better chance of success.

As part of the Pfizer Agreement, Lpath granted to Pfizer (or a third party who may acquire Pfizer’s rights) a right of first refusal for ASONEP. That right of first refusal expired on August 9, 2015, concurrently with the expiration of Pfizer’s option to acquire the license to iSONEP.

We have incurred significant net losses since our inception. As of December 31, 2015, we had an accumulated deficit of approximately \$76.0 million. As they are currently planned, we estimate that our ongoing drug discovery and development efforts, including general and administrative expenses, will require us to use approximately \$6.4 million from January 1, 2016, through the third quarter of 2016. As of December 31, 2015, we had cash and cash equivalents totaling \$8.9 million. We believe these funds should be sufficient to fund our planned operations, and drug discovery and development activities through the third quarter of 2016.

We expect our overall expenditures to decrease in the near term as we conclude the Phase 1a clinical trial for Lpathomab and limit our research and development activities. The lengthy process of completing clinical trials and seeking regulatory approval for one product candidate typically requires expenditures in excess of approximately \$100 million, according to industry data. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, would cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

## **Reincorporation**

On July 17, 2014, we changed our state of incorporation from the State of Nevada to the State of Delaware (the “Reincorporation”) pursuant to a plan of conversion, dated July 17, 2014 (the “Plan of Conversion”). The Reincorporation was accomplished by the filing of (i) articles of conversion with the Secretary of State of the State of Nevada, and (ii) a certificate of conversion and a certificate of incorporation with the Secretary of State of the State of Delaware. Pursuant to the Plan of Conversion, we also adopted new bylaws. The Reincorporation did not affect any of the Company’s material contracts with any third parties, and the Company’s rights and obligations under such material contractual arrangements continue to be rights and obligations of the Company after the Reincorporation. The Reincorporation did not result in any change in headquarters, business, jobs, management, location of any of the offices or facilities, number of employees, assets, liabilities or net worth (other than as a result of the costs incident to the Reincorporation) of Lpath.

## **Revenue**

From 2011 to 2015, in collaboration with Pfizer and pursuant to the terms of the Pfizer Agreement, we conducted the Nexus trial, a Phase 2 study in wet AMD patients. As we have previously disclosed, based on the failure of iSONEP to meet the primary endpoint of the Nexus trial, Pfizer elected to allow its option to expire unexercised on August 9, 2015. As a result, the Pfizer Agreement terminated by its terms, and all rights that Pfizer held in the iSONEP program have reverted to Lpath. As of December 31, 2015, Pfizer had paid the Company \$26.0 million pursuant to the terms of the Pfizer Agreement.

From our inception through December 31, 2015, we have also generated \$10.2 million in revenue from research grants awarded primarily by the National Institutes of Health (NIH), and \$0.4 million in royalty revenue from a licensing agreement with a company that produces novel research assays. We expect to continue to receive small amounts of revenue from research grants and our existing source of royalty revenue.

## **Research and Development Expenses**

Our research and development expenses consist primarily of salaries and related employee benefits; research supplies and materials; external costs associated with our drug discovery research; and external drug development costs, including preclinical testing and regulatory expenses, manufacturing of material for clinical trials, and the costs of conducting clinical trials. Our historical research and development expenses are principally related to the drug discovery and clinical development efforts in creating and developing our lead product candidates, iSONEP, ASONEP, and Lpathomab.

We charge all research and development expenses to operations as incurred. We expect our research and development expenses to increase significantly in the future as our product candidates move through pre-clinical testing and into clinical trials.

Due to the risks inherent in the drug discovery and clinical trial process and given the early stage of our product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Clinical development timelines, the probabilities of success, and development costs vary widely. While we are currently focused on advancing each of our product development programs, we anticipate that we will periodically make determinations as to the scientific and clinical success of each product candidate, as well as ongoing assessments as to each product candidate’s commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates will be subject to future partnering, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. As a result, we cannot be certain when and to what extent we will receive cash inflows from the commercialization of our product candidates.

## **General and Administrative Expenses**

Our general and administrative expenses principally comprise of salaries and benefits and professional fees related to our business development, intellectual property, finance, human resources, legal, and internal systems support functions. In addition, general and administrative expenses include insurance and an allocated portion of facilities and information technology costs.

We anticipate increases in general and administrative expenses as we add personnel, increase our business development activities, become subject to the full Sarbanes-Oxley compliance obligations applicable to larger publicly-held companies, and continue to develop and prepare for the commercialization of our product candidates.

## **Application of Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

### ***Research and Development***

Our sponsored research and development costs related to future products and redesign of present products are expensed as incurred.

### ***Patent Expenses***

Legal and filing costs directly associated with obtaining patents are capitalized. Upon issuance of a patent, amortization is computed using the straight-line method over the estimated remaining useful life of the patent. The recoverability of capitalized patent costs is a significant estimate in the company's financial statements.

### ***Revenue Recognition***

*Research and Development Revenue Under Collaborative Agreements.* We have and may in the future enter into collaborations where we receive non-refundable upfront payments. Generally, these payments are made to secure licenses or option rights to our drug candidates. Non-refundable payments are recognized as revenue when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and we have no further performance obligations under the agreement. Multiple-element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables, which often include a license together with performance obligations such as research and development responsibilities and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting. We recognize up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted for as a single unit of accounting and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

If we are involved in a steering committee as part of a multiple-element arrangement that is accounted for as a single unit of accounting, we assess whether our involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

When we receive reimbursement for our research costs under collaborative agreements, such reimbursements are recognized as revenue as the underlying costs are incurred.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we must determine the period over which our performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. We recognize revenue using the relative performance method provided that we can reasonably estimate the level of effort required to complete our performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If we cannot reasonably estimate the level of effort required to complete our performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and we cannot reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period we expect to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If we cannot reasonably estimate when our performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until we can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under a collaboration arrangement and the period over which we are expected to complete our performance obligations under an arrangement.

Collaboration agreements may also contain substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive company effort is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and
- a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone, and therefore the resulting payment would be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above.

*Grant Revenue.* Our primary source of revenue to date has been research grants received from the National Institutes of Health. We recognize grant revenue as the related research expenses are incurred, up to contractual limits.



*Royalty Revenue.* We recognize royalty revenue from licensed products when earned in accordance with the terms of the license agreements. Net sales figures used for calculating royalties include deductions for costs of unsaleable returns, cash discounts, freight, postage, and insurance.

#### ***Stock-Based Compensation***

Issuances of common stock, stock options, warrants, or other equity instruments to employees and non-employees as the consideration for goods or services we receive are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). Generally, the fair value of any options, warrant or similar equity instruments issued, have been estimated based on the Black-Scholes option pricing model.

#### ***Net Operating Losses and Tax Credit Carryforwards***

At December 31, 2015, we had federal and California net operating loss (“NOL”) carryforwards of approximately \$82 million and \$74 million, respectively. Under current law, the federal and California NOL carryforwards may be available to offset taxable income through 2035. In some years the California state government has suspended the use of existing California NOL carryforwards. In those years companies have not been permitted to utilize NOL carryforwards to reduce the amount of taxes payable to the state. If that fiscal policy were to continue, then the California benefits could be deferred, modified, or lost.

As of December 31, 2015, we also had federal and California research and development tax credit carryforwards of \$1.8 million and \$0.8 million, respectively. These tax credits may be available to offset future taxes. The federal credits begin expiring in 2016, and the state credits do not expire.

A valuation allowance has been established to reserve the potential benefits of these carryforwards in our consolidated financial statements to reflect the uncertainty of future taxable income required to utilize available tax loss carryforwards and other deferred tax assets. Under the provisions of Section 382 of the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that we can utilize annually in the future to offset taxable income. If a change in our ownership is deemed to have occurred or occurs in the future, our ability to use our net operating loss and tax credit carryforwards in any fiscal year may be significantly limited.

#### ***Fair Value of Warrant Liability***

We measure fair value in accordance with the applicable accounting standards in the Financial Accounting Standards Board (“FASB”) Codification. Fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, there exists a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1—unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access as of the measurement date.
- Level 2—inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.
- Level 3—unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date.

This hierarchy requires us to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

We determined the fair value of the warrants using a Black-Scholes. The model considered amounts and timing of future possible equity and warrant issuances and historical volatility of our stock price.

## Results of Operations

### Comparison of Years Ended December 31, 2015 and 2014

*Grant and Royalty Revenue.* Grant and royalty revenue for 2015 decreased to \$52,000 from \$632,000 in 2014. The decrease of \$580,000 in 2015 is due principally to the substantial completion active NIH grants in early 2015.

*Research and Development Revenue Under Collaborative Agreements.* As described in Note 3 to the consolidated financial statements, in December 2010 we entered into an agreement with Pfizer, Inc., which agreement was amended in 2012, that provided financial support for our iSONEP and ASONEP development programs. The Agreement terminated on August 9, 2015, after which Pfizer had no further obligation to reimburse us for any costs of the Nexus trial. We recognized revenues under research and development collaborative agreements as follows:

	Year Ended	
	December 31,	
	2015	2014
Cost reimbursements	\$ 1,422,743	\$ 4,075,623
Amortization of license and development fees	125,000	373,000
	<u>\$ 1,547,743</u>	<u>\$ 4,448,623</u>

The decrease in revenues in 2015 is due to the completion of the Nexus in May 2015.

*Research and Development Expenses.* Research and development expenses for 2015 totaled \$8.6 million compared to \$18.1 million for 2014, a decrease of \$9.6 million. This decrease was primarily attributable to the conclusion of our Nexus and ASONEP clinical trials in 2015 and the reduction of our work force following the results of the Nexus trial.

*General and Administrative Expenses.* General and administrative expenses were \$3.9 million for the year ended December 31, 2015 compared to \$4.8 million for 2014, a decrease of \$0.9 million. The decrease in 2015 is due principally to the reduction in our work force.

*Change in Fair Value of Warrants.* Various factors are considered in the Black-Scholes model we use to value outstanding warrants, including our current stock price, the remaining life of the warrants, the volatility of our stock price, and the risk-free interest rate. Future changes in these factors will have a significant impact on the computed fair value of the warrant liability. The most significant factor in the valuation model is our stock price. Our stock has been thinly traded and relatively small transactions can impact our quoted stock price significantly. As such, we expect future changes in the fair value of the warrants to continue to vary significantly from quarter to quarter. We caution that the change in fair value of the warrants should not be given undue importance when considering our financial condition and our results of operations. We do not believe that these adjustments, which are required by current generally accepted accounting principles, reflect economic activities or financial obligations undertaken by us.

## Liquidity and Capital Resources

Since inception, our operations have been financed primarily through the sale of equity and debt securities and funds received from corporate partners pursuant to research and development collaboration agreements. From inception through December 31, 2015, we had received net proceeds of approximately \$86.2 million from the sale of equity securities and the issuance of convertible promissory notes. In addition, we had received a total of \$44.3 million from corporate partners, including a total of \$26.6 million in funding from our research and development arrangement with Pfizer during the years ended December 31, 2011 through 2015.

In March 2014, the company entered into an at-the-market issuance sales agreement (the "Sales Agreement") with MLV & Co. (the "MLV Agreement"). Subject to limitations set by the SEC, the company may from time to time,

at the company's option, issue and, through MLV, sell shares of its common stock having an aggregate offering price of up to \$23 million under the MLV Agreement. Sales of common stock through MLV, if any, will be made by any method that is deemed an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by the Lpath and MLV. Subject to the terms and conditions of the MLV Agreement, MLV will use commercially reasonable efforts to sell the common stock based upon the company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). Lpath is not obligated to make any sales of its common stock under the MLV Agreement. Any shares sold will be sold pursuant to the company's effective shelf registration statement on Form S-3 (the "Shelf Registration Statement"). The company will pay MLV a commission of up to 3.0% of the gross proceeds. The MLV Agreement will terminate upon the earlier of the sale of all common stock subject to the MLV Agreement or termination of the MLV Agreement by the company or MLV.

During 2015, the company sold 13,674,916 shares at sales prices ranging from \$0.34 to \$0.21 per share, resulting in \$3,722,000 in net proceeds. During the year ended December 31, 2014, the company sold 2,161,833 shares at sales prices ranging from \$3.50 to \$5.16 per share, resulting in \$9,730,000 in net proceeds. There have been no sales of shares through the MLV Agreement subsequent to December 31, 2015.

Under the SEC's rules, the company will not be eligible to sell any shares under the Shelf Registration Statement and the accompanying MLV Agreement immediately following the filing of this Annual Report on Form 10-K. Because the market value of the company's common stock held by non-affiliate stockholders is less than \$75 million, the SEC limits the amount of stock the company may offer and sell during any 12 month period to a maximum of one-third of the market value of the common stock held by company's non-affiliate stockholders. The company is required to select a new measurement date for its market value each time it files an Annual Report on Form 10-K. Accordingly, based on the current market value of the company's common stock and its sales under the MLV Agreement within the past 12 months, the company has no current eligibility to make sales under the Shelf Registration Statement and the accompanying MLV Agreement.

In September 2014, Lpath sold 3,605,042 registered shares of common stock and warrants to purchase 3,605,042 unregistered shares of common stock in a direct offering at a purchase price of \$3.475 per share-and-warrant-share combination. The warrants have an exercise price of \$3.36 per underlying share, are immediately exercisable, and terminate on the five-year anniversary of issuance. Each warrant may be exercised using a cashless exercise procedure if the resale of the underlying shares are not covered by an effective registration statement. Net proceeds of this offering totaled \$11,500,000 after deducting placement agent fees and other expenses of the offering. Maxim Group LLC ("Maxim") acted as the exclusive placement agent for the offering. Maxim received a placement agent fee of \$751,651 and an unregistered warrant to purchase 54,076 unregistered shares of common stock (the "Maxim Warrant") as well as the reimbursement of fees and expenses up to \$60,000. The Maxim Warrant has an exercise price of \$3.36 per share, is immediately exercisable, and will terminate on August 23, 2018. As part of the transaction, Lpath agreed not to offer any variable-rate securities until October 23, 2015, provided, however, that the Company can still utilize its existing at-the-market vehicle. In October 2014, pursuant to the terms of a registration rights agreement Lpath entered into in connection with the direct offering discussed above, Lpath registered for resale 3,605,042 shares of common stock issuable upon exercise of the warrants issued in the direct offering discussed above. The shares were registered on Form S-3 and the registration statement was declared effective by the Securities and Exchange Commission on October 23, 2014.

As of December 31, 2015, the company had cash and cash equivalents totaling \$8.9 million. We may also receive limited additional funding from future awards of NIH grants. As they are currently planned, however, we do not believe that our existing cash resources will be sufficient to meet our operating plan for the full 12 month period after the date of this filing. Accordingly, the report from our independent registered public accounting firm accompanying the financial statements included in this Annual Report on Form 10-K contains an emphasis of a matter regarding our ability to continue as a going concern. To help extend our operating window, we have reduced our headcount and limited our research and product development activities. Based on our current plans and available resources, we believe we can maintain our current operations through the end of the third quarter of 2016. We estimate that the costs to wind-down our operations in an orderly manner will cost approximately \$2.5 million. As a result, we need to secure significant additional capital to continue to fund our operations and our drug discovery and development projects beyond the third

quarter of 2016. Moreover, our expenses may exceed our current plans and expectations, which would require us to secure additional capital or wind-down our operations sooner than anticipated.

Our Board of Directors has engaged a financial advisory firm to explore our available strategic alternatives, including possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. We believe it is in our stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives we may identify in the near term. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Further, our expenses may exceed our current plans and expectations, which could require us to complete a transaction or wind-down our operations sooner than anticipated. Additionally, any transaction we consummate may offer limited value for our existing drug candidates and proprietary technology and may not enhance stockholder value or provide the expected benefits. If we are unable to successfully complete a strategic transaction or otherwise secure additional capital on a timely basis and on terms that are acceptable to our stockholders, we may be required to cease our operations altogether.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital for the purpose of funding our operations, while at the same time maximizing the income we receive from our investments without materially increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash, cash equivalents, and short-term investments in a variety of securities, including commercial paper and money market funds. Our cash and investments at December 31, 2015 consisted exclusively of cash in bank accounts, certificates of deposit, and a money market mutual fund that is restricted to invest only in short-term U.S. Treasury securities. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents and short-term investments, we do not believe that an increase or decrease in market rates would have a material impact on the value of our portfolio.

## ITEM 8. FINANCIAL STATEMENTS

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders  
Lpath, Inc.

We have audited the accompanying consolidated balance sheets of Lpath, Inc. and subsidiary (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Lpath, Inc. and subsidiary as of December 31, 2015 and 2014, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company's recurring losses and negative operating cash flows raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Moss Adams LLP

San Diego, California  
March 22, 2016

**LPATH, INC.**  
**Consolidated Balance Sheets**  
**December 31,**

	2015	2014
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 8,889,616	\$ 17,282,325
Accounts receivable	6,988	727,178
Prepaid expenses and other current assets	357,281	413,260
Total current assets	9,253,885	18,422,763
Equipment and leasehold improvements, net	149,271	221,148
Patents, net	2,132,129	2,236,909
Deposits and other assets	77,160	77,350
Total assets	<b>\$ 11,612,445</b>	<b>\$ 20,958,170</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 294,010	\$ 2,865,165
Accrued compensation	546,578	848,583
Accrued expenses	204,237	383,623
Deferred contract revenue	-	125,000
Deferred rent, short-term portion	35,629	33,744
Total current liabilities	1,080,454	4,256,115
Deferred rent, long-term portion	-	35,629
Warrants	-	850,000
Total liabilities	1,080,454	5,141,744
Stockholders' Equity:		
Common stock - \$.001 par value; 100,000,000 shares authorized; 33,138,598 and 19,224,708 issued and outstanding at December 31, 2015 and 2014, respectively	33,139	19,225
Additional paid-in capital	86,542,367	81,830,410
Accumulated deficit	(76,043,515)	(66,033,209)
Total stockholders' equity	10,531,991	15,816,426
Total liabilities and stockholders' equity	<b>\$ 11,612,445</b>	<b>\$ 20,958,170</b>

See accompanying notes to the consolidated financial statements.

**LPATH, INC.**  
**Consolidated Statements of Operations**  
**Years Ended December 31,**

	<u>2015</u>	<u>2014</u>
<b>Revenues:</b>		
Grant and royalty revenue	\$ 52,020	\$ 631,840
Research and development revenue under collaborative agreements	<u>1,547,743</u>	<u>4,448,623</u>
Total revenues	<u>1,599,763</u>	<u>5,080,463</u>
<b>Expenses:</b>		
Research and development	8,513,974	18,126,701
General and administrative	<u>3,946,147</u>	<u>4,758,831</u>
Total expenses	<u>12,460,121</u>	<u>22,885,532</u>
Loss from operations	(10,860,358)	(17,805,069)
Other income, net	52	18
Change in fair value of warrants	<u>850,000</u>	<u>1,250,000</u>
Net loss	<u>\$ (10,010,306)</u>	<u>\$ (16,555,051)</u>
Basic and diluted net loss per share	\$ (0.39)	\$ (1.00)
Weighted-average shares outstanding used in the calculation	25,734,836	16,555,654

See accompanying notes to the consolidated financial statements.

**Lpath, Inc.**  
**Consolidated Statement of Changes in Stockholders' Equity**  
**Years Ended December 31, 2015 and 2014**

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-in Capital		
<b>Balance, January 1, 2014</b>	13,387,914	\$ 13,388	\$ 59,432,943	\$ (49,478,158)	\$ 9,968,173
Common stock issued for cash, net of issuance costs	5,766,875	5,767	21,231,675	—	21,237,442
Stock options exercised	715	1	249	—	250
Stock-based compensation	69,204	69	1,165,543	—	1,165,612
Net loss	—	—	—	(16,555,051)	(16,555,051)
<b>Balance, December 31, 2014</b>	19,224,708	19,225	81,830,410	(66,033,209)	15,816,426
Common stock issued for cash, net of issuance costs	13,669,616	13,670	3,706,815	—	3,720,485
Stock options exercised	82,616	83	47,595	—	47,678
Stock-based compensation	161,658	161	957,547	—	957,708
Net loss	—	—	—	(10,010,306)	(10,010,306)
<b>Balance, December 31, 2015</b>	<u>33,138,598</u>	<u>\$ 33,139</u>	<u>\$ 86,542,367</u>	<u>\$ (76,043,515)</u>	<u>\$ 10,531,991</u>

See accompanying notes to the consolidated financial statements.



**LPATH, INC.**  
**Consolidated Statements of Cash Flows**  
**Years Ended December 31,**

	<u>2015</u>	<u>2014</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (10,010,306)	\$ (16,555,051)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Share-based compensation expense	953,019	1,236,274
Change in fair value of warrants	(850,000)	(1,250,000)
Depreciation and amortization	466,988	216,088
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	720,190	582,859
Prepaid expenses and other current assets	55,979	(120,783)
Accounts payable and accrued expenses	(3,046,676)	1,101,210
Deferred contract revenue	(125,000)	(373,000)
Other	(32,731)	(24,008)
Net cash used in operating activities	<u>(11,868,537)</u>	<u>(15,186,411)</u>
<b>Cash flows from investing activities:</b>		
Equipment and leasehold improvement expenditures	(21,117)	(105,611)
Patent expenditures	(270,035)	(430,304)
Net cash used in investing activities	<u>(291,152)</u>	<u>(535,915)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock and warrants, net	3,720,485	21,237,442
Proceeds from options and warrants exercised	47,678	250
Payment for restricted stock tax liability on net settlement	(1,183)	(84,680)
Net cash provided by financing activities	<u>3,766,980</u>	<u>21,153,012</u>
Net increase (decrease) in cash and cash equivalents	(8,392,709)	5,430,686
Cash and cash equivalents at beginning of period	17,282,325	11,851,639
Cash and cash equivalents at end of period	<u>\$ 8,889,616</u>	<u>\$ 17,282,325</u>
<b>Supplemental disclosure of cash flow information:</b>		
<b>Cash paid during the year for:</b>		
Income taxes	<u>\$ 1,600</u>	<u>\$ 1,600</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Change in fair value of warrant liability	<u>\$ (850,000)</u>	<u>\$ (1,250,000)</u>

See accompanying notes to the consolidated financial statements.

**LPATH, INC.**

**Notes to Consolidated Financial Statements  
Years Ended December 31, 2015 and 2014**

**Note 1—THE COMPANY AND A SUMMARY OF ITS SIGNIFICANT ACCOUNTING POLICIES**

*Organization and Business*

Lpath, Inc. (“Lpath,” “we,” or “the company”) is a biotechnology company focused on the discovery and development of lipidomic-based therapeutic antibodies, an emerging field of medical science that targets bioactive signaling lipids to treat a wide range of human diseases. We have developed three drug candidates, advancing each of them into clinical trials, and built evidence to support our approach of targeting bioactive lipids to treat a wide range of diseases.

On July 17, 2014, Lpath changed its state of incorporation from the State of Nevada to the State of Delaware (the “Reincorporation”) pursuant to a plan of conversion, dated July 17, 2014 (the “Plan of Conversion”). The Reincorporation was accomplished by the filing of (i) articles of conversion with the Secretary of State of the State of Nevada, and (ii) a certificate of conversion and a certificate of incorporation with the Secretary of State of the State of Delaware. Pursuant to the Plan of Conversion, Lpath also adopted new bylaws. The Reincorporation did not affect any of the company’s material contracts with any third parties, and the company’s rights and obligations under such material contractual arrangements continue to be rights and obligations of the company after the Reincorporation. The Reincorporation did not result in any change in headquarters, business, jobs, management, location of any of the offices or facilities, number of employees, assets, liabilities or net worth (other than as a result of the costs incident to the Reincorporation) of Lpath.

*Basis of Presentation*

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The consolidated financial statements include the accounts of Lpath, Inc. and its wholly-owned subsidiary, Lpath Therapeutics Inc. All significant intercompany balances and transactions have been eliminated in consolidation.

*Estimates*

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from those estimates.

*Cash and Cash Equivalents*

Cash and cash equivalents consist of cash deposits, money market deposits, and certificates of deposit.

*Concentration of Credit Risk*

Financial instruments that potentially subject the company to a significant concentration of credit risk consist of cash and cash equivalents. The company maintains its cash balances with one major commercial bank in non-interest bearing accounts. Accounts at FDIC-insured institutions are insured by the FDIC up to \$250,000.

The company invests its excess cash in money market mutual funds and in certificates of deposit of federally insured financial institutions. The company has established guidelines relative to diversification of its cash investments and their maturities that are intended to secure safety and liquidity. To date, the company has not experienced any

impairment losses on its cash equivalents. The company has not experienced any losses on its deposits of cash and cash equivalents, short-term and long-term investments.

The company's accounts receivable are derived from entities located in the United States. The company performs ongoing credit evaluation of its debtors, does not require collateral, and maintains allowances for potential credit losses on customer accounts when deemed necessary. To date, there have been no such losses and the company has not recorded an allowance for doubtful accounts.

#### *Equipment and Leasehold Improvements*

Equipment and leasehold improvements are recorded at cost. Equipment depreciation is computed using the straight-line method over the estimated useful asset lives, which range from three to five years. Leasehold improvements are amortized over the shorter of their estimated useful lives or the remainder of the lease term. Repairs and maintenance are charged to expense as incurred.

#### *Patents*

Legal and filing costs directly associated with obtaining patents are capitalized. Upon issuance of a patent, amortization is computed using the straight-line method over the estimated remaining useful life of the patent.

#### *Long-lived Assets*

The company accounts for the impairment and disposition of long-lived assets for events or changes in circumstances which indicate that their carrying value may not be recoverable. The company recorded charges for impairments of patents totaling \$298,709 and \$61,314 in 2015 and 2014, respectively.

#### *Deferred Rent*

Rent expense is recorded on a straight-line basis over the term of the lease. The difference between rent expense and amounts paid under the lease agreement is recorded as deferred rent. Lease incentives, including tenant improvement allowances, are also recorded as deferred rent and amortized on a straight-line basis over the lease term.

#### *Stock-based Compensation Expense*

Compensation expense is measured based on the fair value of the award at the grant date, including estimated forfeitures, and is adjusted to reflect actual forfeitures and the outcomes of certain conditions. Compensation issued to non-employees is remeasured quarterly and income or expense is recognized during their vesting terms.

#### *Revenue Recognition*

Lpath has and may in the future enter into collaborations where we receive non-refundable up-front payments. Generally, these payments secure licenses to Lpath drug candidates. Non-refundable payments are recognized as revenue when the company has a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and the company has no further performance obligations under the license agreement. Multiple-element arrangements, such as license and development arrangements, are analyzed to determine whether the deliverables, which often include a license together with performance obligations such as research and development responsibilities and steering committee services, can be separated or whether they must be accounted for as a single unit of accounting. The company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and the fair value of the undelivered performance obligations, typically including research and/or steering committee services, can be determined. If the fair value of the undelivered performance obligations can be determined, such obligations would then be accounted for separately as performed. If the license is considered to either (i) not have stand-alone value or (ii) have stand-alone value but the fair value of any of the undelivered performance obligations cannot be determined, the arrangement would then be accounted

for as a single unit of accounting, and the license payments and payments for performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed.

If the company is involved in a steering committee as part of a multiple-element arrangement that is accounted for as a single unit of accounting, the company assesses whether its involvement constitutes a performance obligation or a right to participate. Steering committee services that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the company expects to complete its aggregate performance obligations.

When the company receives reimbursement for research costs under collaborative agreements, such reimbursements are recognized as revenue as the underlying costs are incurred.

Whenever the company determines that an arrangement should be accounted for as a single unit of accounting, it must determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a relative performance or straight-line method. The company recognizes revenue using the relative performance method provided that the company can reasonably estimate the level of effort required to complete its performance obligations under an arrangement and such performance obligations are provided on a best-efforts basis. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the relative performance method, as of each reporting period.

If the company cannot reasonably estimate the level of effort required to complete its performance obligations under an arrangement, the performance obligations are provided on a best-efforts basis and the company can reasonably estimate when the performance obligation ceases or the remaining obligations become inconsequential and perfunctory, then the total payments under the arrangement, excluding royalties and payments contingent upon achievement of substantive milestones, would be recognized as revenue on a straight-line basis over the period the company expects to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line basis, as of the period ending date.

If the company cannot reasonably estimate when its performance obligation either ceases or becomes inconsequential and perfunctory, then revenue is deferred until the company can reasonably estimate when the performance obligation ceases or becomes inconsequential. Revenue is then recognized over the remaining estimated period of performance.

Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the company is expected to complete its performance obligations under an arrangement.

Collaboration agreements may also contain substantive milestone payments. Substantive milestone payments are considered to be performance bonuses that are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive company effort is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and
- a reasonable amount of time passes between the up-front license payment and the first milestone payment as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management's judgment. If any of these conditions are not met, the resulting payment would not be considered a substantive milestone and, therefore, the resulting payment would be considered part of the consideration for the single unit of accounting and would be recognized as revenue, as such performance obligations are performed under either the relative performance or straight-line methods, as applicable, and in accordance with these policies as described above.

*Grant Revenue.* Lpath recognizes grant revenue as the related research expenses are incurred, up to contractual limits.

*Royalty Revenue.* Lpath recognizes royalty revenue from licensed products when earned in accordance with the terms of the license agreements. The licensee's net sales figures used for calculating royalties include deductions for costs of unsaleable returns, cash discounts, freight, postage, and insurance.

#### *Research and Development*

Research and development costs are charged to expense when incurred.

#### *Employee Benefit Plan*

The company has a 401(k) defined contribution plan that provides benefits for most employees. An employee is eligible to participate in this plan after one month of service. The plan provides for full vesting of benefits over five years. Company contributions to the plan are made at the discretion of the Board of Directors and aggregated \$96,182 and \$108,534 in 2015 and 2014, respectively.

#### *Income Taxes*

Deferred taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

A net deferred tax asset related primarily to federal and state net operating loss and research and development credit carryforwards has been fully reserved due to uncertainties regarding Lpath's ability to realize these tax benefits in future periods. Consequently, no income tax benefit has been recorded for the years ended December 31, 2015 and 2014.

Lpath periodically evaluates its tax positions to determine whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities. Lpath has not incurred any interest or penalties as of December 31, 2015 with respect to income tax matters. Lpath does not expect that there will be unrecognized tax benefits of a significant nature that will increase or decrease within 12 months of the reporting date.

#### *Comprehensive Income (Loss)*

Comprehensive income (loss) is comprised of net loss and certain changes in equity that are excluded from net loss. At December 31, 2015 and 2014, Lpath had no reportable differences between net loss and comprehensive loss.

#### *Per Share Data*

Basic net income (loss) per common share is computed by dividing net income (loss) for the period by the weighted-average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted-average number of common and common dilutive equivalent shares, such as stock options, restricted stock units, restricted stock awards, warrants, and convertible securities outstanding during the period.

Anti-dilutive common stock equivalents were excluded from the calculation of diluted income (loss) per share as follows:

	Years Ended	
	December 31,	
	2015	2014
Stock options	1,451,298	740,954
Warrants	4,585,644	4,587,359
Restricted stock units	479,476	641,834
Total	<u>6,516,418</u>	<u>5,970,147</u>

#### *Impact of Recently Issued Accounting Standards*

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes, which eliminates the current requirement to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, entities will be required to classify all deferred tax assets and liabilities as noncurrent. ASU 2015-17 will be effective for fiscal years beginning after December 15, 2017, and early adoption is permitted. The company does not expect the adoption of this ASU will have a significant impact on its financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenues from Contracts with Customers (Topic 606). This guidance applies to any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. The core principle of this guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance supersedes existing revenue recognition guidance, including most industry-specific guidance, as well as certain related guidance on accounting for contract costs. For nonpublic entities, this guidance is effective for annual reporting periods beginning after December 15, 2018. Limited early adoption options are permitted. The company is currently evaluating the impact of this ASU on its financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. ASU 2014-15 defines management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. The guidance in ASU 2014-15 is effective for annual reporting periods beginning after December 15, 2016, with early application permitted. The company is currently evaluating the impact of this ASU on its financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The company is currently evaluating the impact of this ASU on its financial statements.

#### **Note 2 – GOING CONCERN UNCERTAINTY**

The accompanying consolidated financial statements have been prepared assuming that the company will continue as a going concern. Lpath utilized cash in operations of \$11.9 and \$15.2 million during the years ended December 31, 2015 and 2014, respectively. These conditions raise substantial doubt about the company's ability to continue as a going concern. Management's plans with regard to these matters are discussed below. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As of December 31, 2015, the company had cash and cash equivalents totaling \$8.9 million. We may also receive limited additional funding from future awards of NIH grants. As they are currently planned, however, we do not believe that our existing cash resources will be sufficient to meet our operating plan for the full 12 month period after the date of this filing. Accordingly, the report from our independent registered public accounting firm accompanying the financial statements included in this Annual Report on Form 10-K contains an emphasis of a matter regarding our ability to continue as a going concern. To help extend our operating window, we have reduced our headcount and limited our research and product development activities. Based on our current plans and available resources, we believe we can maintain our current operations through the end of the third quarter of 2016. We estimate that the costs to wind-down our operations in an orderly manner will cost approximately \$2.5 million. As a result, we need to secure significant additional capital to continue to fund our operations and our drug discovery and development projects beyond the third quarter of 2016. Moreover, our expenses may exceed our current plans and expectations, which would require us to secure additional capital or wind-down our operations sooner than anticipated.

Our Board of Directors has engaged a financial advisory firm to explore our available strategic alternatives, including possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing arrangements and/or equity and debt financings. This strategic process is both active and ongoing, and includes a range of interactions with potential transaction counterparties. We believe it is in our stockholders' best interests at this time to continue to pursue one or more of these transactions, or other strategic alternatives we may identify in the near term. Although we are actively pursuing our strategic alternatives, there is no assurance that we will be able to successfully negotiate and consummate a transaction on a timely basis, or at all. Further, our expenses may exceed our current plans and expectations, which could require us to complete a transaction or wind-down our operations sooner than anticipated. Additionally, any transaction we consummate may offer limited value for our existing drug candidates and proprietary technology and may not enhance stockholder value or provide the expected benefits. If we are unable to successfully complete a strategic transaction or otherwise secure additional capital on a timely basis and on terms that are acceptable to our stockholders, we may be required to cease our operations altogether.

**Note 3—RESEARCH AND DEVELOPMENT COLLABORATIVE AGREEMENT**

In 2010, Lpath entered into an agreement providing Pfizer Inc. ("Pfizer") with an exclusive option for a worldwide license to develop and commercialize iSONEP™ ("the Pfizer Agreement"), Lpath's lead monoclonal antibody product candidate that is being evaluated for the treatment of wet age-related macular degeneration ("wet AMD") and other ocular disorders.

On May 20, 2015, Lpath announced that its Phase 2 "Nexus" clinical trial evaluating iSONEP™ in patients with wet age-related macular degeneration (wet AMD) did not meet its primary or key secondary endpoints. Wet AMD patients who had not responded adequately to existing anti-vascular endothelial growth factor (VEGF) therapies including Lucentis®, Avastin® and Eylea® did not show any statistically significant improvement in visual acuity when treated with iSONEP as an adjunctive or monotherapy. On August 9, 2015, Pfizer's option to obtain worldwide rights to iSONEP expired, unexercised, which resulted in the termination of the Pfizer Agreement. Consequently, all rights that Pfizer held in the iSONEP program have reverted to Lpath. Lpath has no plans for further development of iSONEP. As part of the Pfizer Agreement, Lpath granted to Pfizer a time-limited right of first refusal for ASONEP™, Lpath's product candidate that is being evaluated for the treatment of cancer. That right of first refusal expired on August 9, 2015, concurrently with the expiration of Pfizer's option to acquire the license to iSONEP. Pfizer has no further obligations to fund clinical trial costs incurred after the expiration date of the Pfizer Agreement.

The company recognized revenue under the Pfizer Agreement as follows:

	Year Ended	
	December 31,	
	2015	2014
Cost reimbursements	\$ 1,422,743	\$ 4,075,623
Amortization of license and development fees	125,000	373,000
	<u>\$ 1,547,743</u>	<u>\$ 4,448,623</u>

**Note 4—COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS**

	2015	2014
<i>Equipment and leasehold improvements:</i>		
Office furniture and fixtures	\$ 9,435	\$ 9,435
Laboratory equipment	612,159	593,027
Computer equipment and software	141,150	142,118
Leasehold improvements	24,902	24,902
	787,646	769,482
Accumulated depreciation	(638,375)	(548,334)
Equipment, net	\$ 149,271	\$ 221,148
<i>Patents:</i>		
Patents	\$ 2,438,875	\$ 2,467,547
Accumulated amortization	(306,746)	(230,638)
Patents, net	\$ 2,132,129	\$ 2,236,909

**Note 5—FAIR VALUE MEASUREMENTS**

The company measures fair value in accordance with the applicable accounting standards in the FASB Codification. Fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, there exists a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1—unadjusted quoted prices in active markets for identical assets or liabilities that the company has the ability to access as of the measurement date.
- Level 2—inputs other than quoted prices included within Level 1 that are directly observable for the asset or liability, or indirectly observable through corroboration with observable market data.
- Level 3—unobservable inputs for the asset or liability are only used when there is little, if any, market activity for the asset or liability at the measurement date.

This hierarchy requires the company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

**Recurring Fair Value Estimates**

Lpath has issued warrants, of which some are classified as equity and some as liabilities. The warrants issued in March 2012 (and expiring in March 2017) provide that in the event of a fundamental transaction, as defined by the warrant agreement, the company may, under certain circumstances, be obligated to settle the March 2012 warrants for cash equal to the value of the warrants determined in accordance with the warrant agreement. The fair value and significant unobservable inputs (level 3) of the March 2012 warrants was zero as of December 31, 2015.

*Recurring Level 3 Activity, Reconciliation, and Basis for Valuation*

The table below provides a reconciliation of the beginning and ending balances for the liabilities measured at fair value using significant unobservable inputs (Level 3).



Fair value measurements using significant unobservable inputs (Level 3):

<b>Liabilities:</b>	
Warrant liability as of January 1, 2015	\$ 850,000
Change in fair value of warrants	(850,000)
Warrant liability as of December 31, 2015	<u>\$ -</u>

The company determined the fair value of the warrant liability for certain warrants, as applicable, using a Black-Scholes model. The model considered amounts and timing of future possible equity and warrant issuances and volatility of the company's stock price equal to 100%, as specified in the underlying warrants.

**Note 6—RESEARCH AND LICENSE AGREEMENTS**

In August 2005, Lpath entered into a collaboration agreement (the "AERES Agreement") with AERES Biomedical Limited ("AERES") to "humanize" the company's Sphingomab monoclonal antibody. Humanization under this agreement with AERES involves utilizing proprietary processes owned by AERES for the purpose of modifying Sphingomab antibodies originally contained in mice for potential human acceptance in a clinical trial. The humanized version of Sphingomab that was produced from the collaboration with AERES is called Sonepcizumab. In 2014, AERES' rights and obligations pursuant to the AERES Agreement with Lpath were transferred to Medical Research Council Technology ("MRCT") by means of a Deed of Novation, which obligates MRCT to perform and be bound by the terms of the AERES Agreement. No amounts were paid to AERES or MRCT during 2015 and 2014. Lpath could owe MRCT certain additional contingent amounts when drug candidates based on Sonepcizumab pass through the levels of the FDA drug review and approval process. MRCT will be entitled to a royalty, not to exceed 4%, on any revenues generated by the ultimate commercialization of any drug candidate based on Sonepcizumab.

**Note 7—STOCKHOLDERS' EQUITY**

**Common Stock**

In March 2014, the company entered into an at-the-market issuance sales agreement (the "Sales Agreement") with MLV & Co. (the "MLV Agreement"). Subject to limitations set by the SEC, the company may from time to time, at the company's option, issue and, through MLV, sell shares of its common stock having an aggregate offering price of up to \$23 million under the MLV Agreement. Sales of common stock through MLV, if any, will be made by any method that is deemed an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including by means of ordinary brokers' transactions at market prices, in block transactions or as otherwise agreed by the Lpath and MLV. Subject to the terms and conditions of the MLV Agreement, MLV will use commercially reasonable efforts to sell the common stock based upon the company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose). Lpath is not obligated to make any sales of its common stock under the MLV Agreement. Any shares sold will be sold pursuant to the company's effective shelf registration statement on Form S-3 (the "Shelf Registration Statement"). The company will pay MLV a commission of up to 3.0% of the gross proceeds. The MLV Agreement will terminate upon the earlier of the sale of all common stock subject to the MLV Agreement or termination of the MLV Agreement by the company or MLV.

During 2015, the company sold 13,674,916 shares at sales prices ranging from \$0.34 to \$0.21 per share, resulting in \$3,722,000 in net proceeds. During the year ended December 31, 2014, the company sold 2,161,833 shares at sales prices ranging from \$3.50 to \$5.16 per share, resulting in \$9,730,000 in net proceeds. There have been no sales of shares through the MLV Agreement subsequent to December 31, 2015.

Under the SEC's rules, the company will not be eligible to sell any shares under the Shelf Registration Statement and the accompanying MLV Agreement immediately following the filing of this Annual Report on Form 10-K. Because the market value of the company's common stock held by non-affiliate stockholders is less than \$75 million, the SEC limits the amount of stock the company may only offer and sell during any 12 month period to a maximum of one-third of the market value of the common stock held by company's non-affiliate stockholders. The company is

required to select a new measurement date for its market value each time it files an Annual Report on Form 10-K. Accordingly, based on the current market value of the company's common stock and its sales under the MLV Agreement within the past 12 months, the company has no current eligibility to make sales under the Shelf Registration Statement and the accompanying MLV Agreement.

In September 2014, Lpath sold 3,605,042 registered shares of common stock and warrants to purchase 3,605,042 unregistered shares of common stock in a direct offering at a purchase price of \$3.475 per share-and-warrant-share combination. The warrants have an exercise price of \$3.36 per underlying share, are immediately exercisable, and terminate on the five-year anniversary of issuance. Each warrant may be exercised using a cashless exercise procedure if the resale of the underlying shares are not covered by an effective registration statement. Net proceeds of this offering totaled \$11,500,000 after deducting placement agent fees and other expenses of the offering. Maxim Group LLC ("Maxim") acted as the exclusive placement agent for the offering. Maxim received a placement agent fee of \$751,651 and an unregistered warrant to purchase 54,076 unregistered shares of common stock (the "Maxim Warrant") as well as the reimbursement of fees and expenses up to \$60,000. The Maxim Warrant has an exercise price of \$3.36 per share, is immediately exercisable, and will terminate on August 23, 2018.

In October 2014, pursuant to the terms of a registration rights agreement the company entered into in connection with the direct offering discussed above, the company registered for resale 3,605,042 shares of common stock issuable upon exercise of the warrants issued in the direct offering discussed above. The shares were registered on Form S-3 and the registration statement was declared effective by the Securities and Exchange Commission on October 23, 2014.

### ***Preferred Stock***

Lpath is authorized to issue up to 15,000,000 shares of preferred stock, with a par value of \$0.001 per share. As of December 31, 2015 and 2014, there were no preferred stock shares issued or outstanding.

### ***Equity Incentive Plan***

In November 2005, the company adopted the Lpath, Inc. 2005 Stock Option and Stock Purchase Plan, which permitted stock option grants to employees, outside consultants, and directors. In October 2007, Lpath's stockholders approved the amendment of this plan which was concurrently renamed the Lpath, Inc. Amended and Restated 2005 Equity Incentive Plan (the "Plan"). There are 2,500,000 shares of common stock authorized for grant under the Plan. The Plan allows for grants of incentive stock options with exercise prices of at least 100% of the fair market value of Lpath's common stock, nonqualified options with exercise prices of at least 85% of the fair market value of the company's common stock, restricted stock, and restricted stock units. All stock options granted to date have a ten-year life and vest over zero to five years. Restricted stock units granted have a five-year life and vest over zero to four years, or upon the achievement of specified clinical trial milestones. As of December 31, 2015, a total of 1,429,128 shares of common stock were available for future grant under the Plan.

The following table presents stock-based compensation as included in the company's consolidated statements of operations:

	2015	2014
Stock-based compensation expense by type of award:		
Stock options	\$ 469,080	\$ 507,271
Restricted stock units	<u>483,939</u>	<u>729,003</u>
Total stock-based compensation expense	<u>\$953,019</u>	<u>\$1,236,274</u>
Effect of stock-based compensation expense on		
Research and development	432,083	466,517
General and administrative	<u>520,936</u>	<u>769,757</u>
Total stock-based compensation expense	<u>\$953,019</u>	<u>\$1,236,274</u>

Fair value is determined at the date of grant for employee options and restricted stock units, and at the date at which the grantee's performance is complete for non-employee options and restricted stock units. Compensation cost is recognized over the vesting period based on the fair value of the options and restricted stock units.

Because of the company's net operating losses for tax purposes, it did not realize any tax benefits for the tax deductions from share-based payment arrangements during the years ended December 31, 2015 and 2014.

### **Stock Options**

As of December 31, 2015, there was \$1,221,000 of total unrecognized compensation expense, net of estimated forfeitures, related to unvested options granted under the Plan. That expense is expected to be recognized over a weighted-average period of 5.9 years.

The company uses the Black-Scholes valuation model to estimate the fair value of stock options at the grant date. The Black-Scholes valuation model uses the option exercise price as well as estimates and assumptions related to the expected price volatility of the company's stock, the rate of return on risk-free investments, the expected period during which the options will be outstanding, and the expected dividend yield for the company's stock to estimate the fair value of a stock option on the grant date.

The weighted-average valuation assumptions were determined as follows:

- *Expected stock price volatility:* The estimated expected volatility is based on a weighted-average calculation of a peer group and the company's historical volatility.
- *Risk-free interest rate:* The company bases the risk-free interest rate on the interest rate payable on U.S. Treasury debt securities.
- *Expected term of options:* The expected term of options granted is derived using assumed exercise rates based on historical exercise patterns and represents the period of time that options granted are expected to be outstanding.
- *Expected annual dividends:* The estimate for annual dividends is zero because the company has not historically paid, and does not intend for the foreseeable future to pay, a dividend.

The estimated fair value of stock options granted was determined using a Black-Scholes valuation model with the following weighted average assumptions:

	<b>2015</b>	<b>2014</b>
Risk free interest rate	1.5%	0.9%
Expected life (years)	5.26	3.1
Expected share price volatility	91.9%	64.3%
Expected dividend rate	0%	0%

A summary of the stock option activity under the plan as of December 31, 2015 and 2014, and changes during the years then ended, is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2014	334,981	\$ 4.16		
Granted	474,350	4.45		
Exercised	(715)	0.35		
Expired	(4,287)	0.35		
Forfeited	<u>(63,375)</u>	4.45		
Outstanding at December 31, 2014	740,954	4.35		
Granted	934,000	1.34		
Exercised	(82,616)	0.58		
Expired	(102,533)	4.53		
Forfeited	<u>(38,507)</u>	3.21		
Outstanding at December 31, 2015	<u>1,451,298</u>	<u>2.64</u>	<u>7.69</u>	\$ —
Vested and exercisable at December 31, 2015	<u>535,111</u>	<u>\$ 4.04</u>	<u>5.66</u>	\$ —

The aggregate intrinsic value in the table above represents the total intrinsic value which would have been received by the stock option holders had all option holders exercised their options as of that date. The aggregate intrinsic value is calculated as the difference between the fair market value of the company's common stock on December 31, 2015 of \$0.23 and the exercise price of stock options, multiplied by the number of shares subject to such stock options.

At December 31, 2015, all of the company's outstanding stock options had strike prices above the company's market price of \$0.23. The total intrinsic value of options exercised during the years ended December 31, 2015 and 2014 was \$159,000 and \$3,000, respectively. Cash received from option exercises during the years ended December 31, 2015 and 2014 was approximately \$48,000 and \$250, respectively. Upon stock option exercises, the company issues new shares of common stock.

#### **Restricted Stock Units**

As of December 31, 2015, there was \$387,000 of total unrecognized stock-based compensation expense related to unvested restricted stock units granted under the Plan. The company expects to recognize that expense over a weighted-average period of 1.9 years.

The following table summarizes the restricted stock units activity of the company during 2015 and 2014:

	Total Restricted Stock Units	Weighted- Average Grant Date Fair Value
Outstanding January 1, 2014	721,788	\$ 5.66
Granted	15,000	2.92
Shares issued	(81,829)	6.11
Forfeited	<u>(13,125)</u>	4.97
Outstanding December 31, 2014	641,834	5.55
Granted	19,667	2.87
Shares issued	(166,779)	5.75
Forfeited	<u>(15,246)</u>	4.68
Outstanding December 31, 2015	<u>479,476</u>	\$ 5.40

**Warrants**

Lpath has issued warrants, of which some are classified as equity and some as liabilities. The warrants issued in March 2012 (and expiring in March 2017) provide that in the event of a fundamental transaction, as defined by the warrant agreement, the company may, under certain circumstances, be obligated to settle the March 2012 warrants for cash equal to the value of the warrants determined in accordance with the warrant agreement. The following warrants contained such provisions, and therefore, pursuant to the applicable criteria, they were not indexed to the company's own stock:

<u>Warrant Expiration Dates</u>	<u>Number of Shares</u>	<u>Exercise Price per Share</u>
March 2017	29,750	\$ 5.25
March 2017	882,776	\$ 7.70

The warrant liability reflected on Lpath's balance sheet is a consequence of current generally accepted accounting principles, arising from the implementation of ASC 815. The company believes there is no foreseeable circumstance under which Lpath can be required to make any cash payment to settle any warrant liability that would be carried on the consolidated balance sheet.

The following table summarizes Lpath warrants outstanding as of December 31, 2015:

<u>Warrant Expiration Date</u>	<u>Number of Shares</u>	<u>Exercise Price per Share</u>
January 21, 2017	4,000	\$ 4.00
March 9, 2017	29,750	\$ 5.25
March 9, 2017	882,776	\$ 7.70
May 30, 2017	6,000	\$ 4.00
September 15, 2017	4,000	\$ 4.00
September 25, 2019	3,605,042	\$ 3.36
September 26, 2019	54,076	\$ 3.36
Total:	4,585,644	
Weighted average:		\$ 4.21

The terms of all outstanding warrants permit the company, upon exercise of the warrants, to settle the contract by the delivery of unregistered shares. During 2015, 4,000 warrants were granted, no warrants were exercised, and 5,715 warrants expired. During 2014, 3,669,118 warrants were granted, no warrants were exercised, and 12,858 warrants expired.

**Note 8—INCOME TAXES**

As of December 31, 2015, Lpath had federal and California net operating loss ("NOL") carryforwards of approximately \$82 million and \$74 million, respectively, that will expire beginning in 2016 and continue expiring through 2035. Portions of these NOL carryforwards may be used to offset future taxable income, if any.

As of December 31, 2015, Lpath also has federal and California research and development tax credit carryforwards of \$1.8 million and \$0.8 million, respectively, available to offset future taxes. The federal credits begin expiring in 2016, and the state credits do not expire.

The company's ability to use its net operating loss and research and development credit carryforwards may be substantially limited due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. The company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since the Company became a "loss corporation" under the definition of Section 382. Due to the existence of the valuation allowance, it is not expected that any possible limitation will have an impact on the results of operations or financial position of the company.

Significant components of the company's deferred tax assets and liabilities are as follows:

	2015	2014
<b>Deferred tax assets:</b>		
Federal and state net operating loss carryforwards	\$ 34,568,000	\$ 30,935,000
Research and development credit carryforwards	2,609,000	1,812,000
Stock-based compensation	718,000	1,729,000
Deferred contract revenue	—	54,000
Other, net	63,000	149,000
	<u>37,958,000</u>	<u>34,679,000</u>
<b>Deferred tax liabilities:</b>		
State taxes	(2,540,000)	(2,459,000)
Patent costs	(913,000)	(958,000)
	<u>(3,453,000)</u>	<u>(3,417,000)</u>
Total deferred tax assets	34,505,000	31,262,000
Valuation allowance	(34,505,000)	(31,262,000)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Realization of the deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

As a result of the company's significant operating loss carryforwards and the corresponding valuation allowance, no income tax provision/benefit has been recorded as of December 31, 2015 and 2014. The provision for income taxes using the statutory federal income tax rate of 34% as compared to the company's effective tax rate is summarized as follows:

	2015	2014
Federal tax benefit at statutory rate	\$ 3,404,000	\$ 5,629,000
State tax benefit, net	721,000	1,028,000
Change in fair value of warrants	289,000	425,000
Research and development credits	596,000	—
Employee stock-based compensation	(1,764,000)	(56,000)
Other permanent differences	(3,000)	9,000
Decrease in valuation allowance	<u>(3,243,000)</u>	<u>(7,035,000)</u>
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

#### **Note 9—OPERATING LEASE**

Lpath leases an 11,960 square foot laboratory and office facility in San Diego, California. The lease expires in November 2016. Monthly lease payments are \$28,268, with annual escalations of 3%. The lease grants the Company the right to extend the lease for an additional five-year term.

Lpath's rent expense totaled \$390,000 and \$385,000 for the years ended December 31, 2015 and 2014, respectively. Lpath's sublease income amounted to \$12,000 for the years ended December 31, 2015 and 2014.

#### **Note 10—RELATED-PARTY TRANSACTIONS**

Lpath subleases a portion of its facility to Western States Investment Corporation ("WSIC"), owned by one of Lpath's largest stockholders. The terms of the sublease, in general, are the same as the terms of the company's direct lease. In addition, certain Lpath employees provide investment oversight, accounting, and other administrative services to WSIC. Certain WSIC employees also provide services to Lpath. Lpath and WSIC reimburse each other for costs incurred on behalf of the other entity. Lpath's sublease income amounted to \$11,652 for the years ended December 31, 2015 and 2014.

During 2015 and 2014, WSIC billed Lpath \$12,008 and \$39,300, respectively, for administrative expenses.

As of December 31, 2015, Lpath owed WSIC \$948 for services provided to Lpath. As of December 31, 2014, WSIC owed Lpath \$2,900 for facility expenses and Lpath owed WSIC \$7,100 for services provided to Lpath.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

**(1) Evaluation of Disclosure Controls and Procedures.** Our interim chief executive officer and chief financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective as of the end of such period.

**(2) Management's Annual Report on Internal Control over Financial Reporting.** Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting (as defined in Rule 13a-15(f) and Rule 15d-15(f) of the Securities Exchange Act of 1934, as amended) is a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision of our interim chief executive officer and chief financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, we used the criteria set forth in the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in 2013. Based on this assessment, our management has concluded that, as of December 31, 2015, our internal control over financial reporting was effective based on those criteria.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Our report was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

**(3) Changes in Internal Control over Financial Reporting.** During the quarter ended December 31, 2015, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**(4) Inherent Limitations on Effectiveness of Controls.** Our management, including our interim chief executive officer and chief financial officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The following persons are our directors and executive officers and hold the positions set forth opposite their names as of February 1, 2016:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Daniel H. Petree (1)(2)(3)(4)	60	Chairman of the Board
Jeffrey A. Ferrell (1)(2)	41	Director
Daniel L. Kisner, M.D. (1)(4)	69	Director
Charles A. Mathews (1)(2)(3)	78	Director
Donald R. Swortwood (1)(3)	75	Director
Gary J. G. Atkinson	63	Interim Chief Executive Officer and Chief Financial Officer
Dario A. Paggiarino, M.D.	59	Senior Vice President and Chief Development Officer
Gary Woodnutt, Ph.D.	59	Senior Vice President and Chief Scientific Officer

- (1) Member of the Compensation Committee
- (2) Member of the Audit Committee
- (3) Member of the Nominating and Corporate Governance Committee
- (4) Member of the R&D Advisory Committee

The following sets forth information regarding the business experience of our directors and executive officers as of February 1, 2016:

**Daniel H. Petree**

*Chairman of the Board of Directors*

Mr. Petree has served as a director of Lpath since November 2008, and was appointed as Chairman of the Board in September 2010. Mr. Petree has over 20 years of experience in the biotechnology industry, serving in a variety of roles including investment banker, senior operating manager and corporate and securities lawyer. Mr. Petree is a member and co-founder of P2 Partners, LLC formed in 2000, and a member and co-founder of Four Oaks Partners Consulting, LLC, founded in April 2012, both of which provide transaction advisory services to small and medium-sized science companies. Mr. Petree served as a director of Cypress Biosciences, Inc., a company that provides products for the treatment of patients with Functional Somatic Syndromes and other central nervous system disorders from 2004 to 2011. Before co-founding P2 Partners in 2000, Mr. Petree was President and Chief Operating Officer of Axys Pharmaceuticals, a structure-based drug design company in South San Francisco. Mr. Petree's qualifications to sit on our Board include his experience as an executive and an investment banker in the biotechnology industry, his experience with structuring and negotiating pharmaceutical partnering arrangements and strategic transactions, and his experience serving on public company boards and board committees.

**Jeffrey A. Ferrell**

*Director*

Mr. Ferrell has served as a director of Lpath since April 2007. Mr. Ferrell has served as the Managing Partner of Athyrium Capital Management, LP, a life sciences focused investment and advisory company with offices in New York City, since 2008. From 2001 to 2008, Mr. Ferrell served in a number of capacities at Lehman Brothers. He oversaw public and private life sciences investments for Global Trading Strategies, a principal investment group within Lehman, as a Senior Vice President from 2005 to 2008. Prior to that he was a Vice President in Lehman Brothers' Private Equity division. Prior to joining Lehman in 2001, he was a principal at Schroder Ventures Life Sciences in Boston. Mr. Ferrell holds an A.B. in Biochemical Sciences from Harvard University. Mr. Ferrell's qualifications to sit on our Board include



his experience in providing fund raising and advisory services to life sciences companies, his knowledge of the life sciences industry and his knowledge of the capital markets.

**Daniel L. Kisner, M.D.**

*Director*

Dr. Kisner has been a member of our Board since July 2012. Since July 2010, Dr. Kisner has been a director of Dynavax Technologies Corporation, a clinical stage biopharmaceutical company, and has also served as Chairman of the Board for Tekmira Pharmaceuticals, a biopharmaceutical company since January 2010. From 2003 to 2010, Dr. Kisner was a partner at Aberdare Ventures. Prior to that, Dr. Kisner was President and CEO of Caliper Technologies, leading its evolution from a start-up focused on microfluidic lab-on-chip technology to a publicly traded, commercial organization. Prior to Caliper, he was the President and Chief Operating Officer of Isis Pharmaceuticals, Inc., a biomedical pharmaceutical company. Previously, Dr. Kisner was Division Vice President of Pharmaceutical Development for Abbott Laboratories and Vice President of Clinical Research and Development at SmithKline Beckman Pharmaceuticals. In addition, he held a tenured position in the Division of Oncology at the University of Texas, San Antonio School of Medicine and is certified by the American Board of Internal Medicine in Internal Medicine and Medical Oncology. Our Board believes that Dr. Kisner's background with larger, complex technology-based organizations as well as his significant experience with corporate transactions, including investing in venture-backed life science companies provides the Board with insights for setting strategy and reviewing the operations of the Company. He holds a B.A. from Rutgers University and an M.D. from Georgetown University.

**Charles A. Mathews**

*Director*

Mr. Mathews has served as a director of Lpath since March 2006. Mr. Mathews is an active private investor and has served as an independent director on the boards of a number of public and private companies. From March 2005 to November 2006, Mr. Mathews was Chairman of Avanir Pharmaceuticals (AVNR), a drug development and marketing company and from May to September 2005 he acted as its Chief Executive Officer. Mr. Mathews is a past president of the San Diego Tech Coast Angels, part of an affiliation of over 200 accredited "angel" investors active in the life science and technology industries. From April 2002 until January 2004, Mr. Mathews served as the President and Chief Executive Officer of DermTech International, a privately held contract research organization focused on dermal and transdermal drugs. Mr. Mathews' qualifications to sit on our Board include his leadership experience as an executive in the life sciences industry, his expertise in operations and corporate governance, and his experience serving on public and private company boards and board committees.

**Donald R. Swortwood**

*Director*

Mr. Swortwood participated in the original funding of Lpath, and has served as a director of Lpath since July 2006. He has served as Chairman and Chief Executive Officer of Western States Investment Corporation since the founding of its predecessor in 1975, and has been an active investor and venture capitalist for over thirty-five years. His investing career began in basic industrial areas, such as industrial salt and transportation, and has evolved into technology and science related fields, ranging from a business that developed novel technologies for the detection and treatment of gastro-esophageal reflux disease, which was sold to Medtronic; to a leader in storage area network management software solutions, which was sold to EMC; to a business that developed the first "ear thermometer," which was sold to Wyeth. Currently, the Western States portfolio of holdings includes a number of biotech and life science companies. Mr. Swortwood is a graduate of Stanford University. Mr. Swortwood's qualifications to sit on our Board include his experience as a business leader and venture capitalist and his experience in advising emerging growth life science and technology companies.

**Gary J.G. Atkinson**

*Interim Chief Executive Officer and Chief Financial Officer*

On September 23, 2015, the Board appointed Mr. Atkinson Interim Chief Executive Officer. Mr. Atkinson joined Lpath as Vice President, Chief Financial Officer in 2005. He has more than 20 years of financial management experience in the life science industry. Prior to joining Lpath, Mr. Atkinson served, from 2001 to 2005 as Senior Vice President and Chief Financial Officer at Quorex Pharmaceuticals, Inc., a drug discovery company. From 1995 to 2000, Mr. Atkinson served as Vice President of Finance at Isis Pharmaceuticals, a publicly held pharmaceutical research and development company. He began his career with Ernst & Young, where he earned his CPA certification. Mr. Atkinson is a graduate of Brigham Young University.

**Dario A. Paggiarino, M.D.**

*Senior Vice President and Chief Development Officer*

Dr. Paggiarino joined Lpath in April 2013. He has more than 25 years of experience in the pharmaceutical industry, having directed global development programs in a number of therapeutic areas including ophthalmology, pain, inflammatory conditions, and oncology. Most recently, Dr. Paggiarino served as Vice President and Therapeutic Unit Head for retina diseases at Alcon, a division of Novartis from 2011 to 2013. He also served as Executive Director of Clinical Development and Medical Affairs at Pfizer Global R&D with focus on global clinical development in glaucoma, diabetic and degenerative retinal diseases, and medical responsibilities for Macugen® from 2001 to 2011. Earlier in his career, he held R&D positions of increasing responsibility at Angelini Pharmaceuticals, a privately owned company, ultimately serving as president. Later he joined Pharmacia Global R&D where he was clinical program director of ophthalmology with responsibilities for Xalatan(R), the leading glaucoma therapy in the world, and ocular devices such as viscoelastics (Healon®) and intraocular lenses (CeeOn®, Tecnis®). Dr. Paggiarino earned his degree in Medicine and General Surgery at the University of Rome La Sapienza and has authored numerous scientific articles.

**Gary Woodnutt Ph.D.**

*Senior Vice President and Chief Scientific Officer*

Dr. Woodnutt joined Lpath in April 2013. Prior to joining Lpath, Dr. Woodnutt served as the Vice President, Open Innovation at CovX, a division of Pfizer acquired in 2007, from 2012 to 2013, and as Vice President of Biology Research from 2006 to 2012. From 2002 to 2006, Dr. Woodnutt was the Senior Vice President of Pharmaceutical Research and Development for Diversa Corporation. He began his career in the pharmaceutical industry with Glaxo SmithKline Pharmaceuticals, where he was employed for more than 20 years and rose to the position of Vice President and Head of Biology in the Antimicrobial and Host Defense Group. Dr. Woodnutt received his Ph.D. in biochemistry/physiology from the University of Reading, and he has authored numerous scientific articles.

**Family Relationships**

There are no family relationships between any of our officers and directors.

**GOVERNANCE OF OUR COMPANY**

**Overview**

We are committed to maintaining the highest standards of business conduct and corporate governance, which we believe are fundamental to the overall success of our business, serving our stockholders well and maintaining our integrity in the marketplace. Our Corporate Governance Guidelines and Code of Business Conduct and Ethics, together with our Certificate of Incorporation, Bylaws and the charters of our Board Committees, form the basis for our corporate governance framework. As discussed below, our Board of Directors has established four standing committees to assist it

in fulfilling its responsibilities to the Company and its stockholders: the Audit Committee, the Compensation Committee, the Nominating and Corporate Governance Committee and the R&D Advisory Committee.

### **Corporate Governance Guidelines**

Our Corporate Governance Guidelines are designed to ensure effective corporate governance of our Company. Our Corporate Governance Guidelines cover topics including, but not limited to, director qualification criteria, director responsibilities, director compensation, director orientation and continuing education, communications from stockholders to the Board, succession planning and the annual evaluations of the Board and its Committees. Our Corporate Governance Guidelines are reviewed regularly by the Nominating and Corporate Governance Committee of our Board and revised when appropriate. The full text of our Corporate Governance Guidelines can be found in the “Investors” section of our website accessible at [www.lpath.com](http://www.lpath.com), by clicking the “Corporate Governance” link. A printed copy may also be obtained by any stockholder upon request to our Corporate Secretary.

### **Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers and directors. This Code constitutes a “code of ethics” as defined by the rules of the SEC. This Code also contains “whistle blower” procedures adopted by our Audit Committee regarding the receipt, retention and treatment of complaints related to accounting, internal accounting controls or auditing matters and procedures for confidential anonymous employee complaints related to questionable accounting or auditing matters. Copies of the Code may be obtained free of charge from our website, [www.lpath.com](http://www.lpath.com). Any amendments to, or waivers from, a provision of our Code that applies to any of our executive officers will be posted on our website in accordance with the rules of the SEC. Other than as specifically referenced herein, the information contained on, or that can be accessed through, our website is not a part of this Annual Report.

### **Director Independence**

The Board assesses on a regular basis, and at least annually, the independence of our directors and makes a determination as to which directors are independent. Our Board of Directors has determined that each of our directors is “independent”. In assessing director independence, our Board has adopted the definition of “independent director” under the listing standards of the Nasdaq Stock Market. Our current independent directors are Jeffrey Ferrell, Daniel Kisner, Charles Mathews, Daniel Petree and Donald Swortwood.

### **Board and Committee Attendance**

During the year ended December 31, 2015, the Board of Directors met eleven times and it took action by unanimous written consent one time. Our Board of Directors has established four standing committees to assist it in fulfilling its responsibilities to the Company and its stockholders: the Audit Committee, the Compensation Committee, the Nominating and Corporate Governance Committee and the R&D Advisory Committee. During the last fiscal year, each of our directors attended at least 75% of the total number of meetings of the Board and all Board Committees on which such director served during that period.

### **Director Attendance at Annual Meeting**

We believe the annual meeting provides a good opportunity for our directors to hear any feedback the stockholders may share with the Company at the Meeting. As a result, we encourage our directors to attend each of our annual meetings. We reimburse our directors for the reasonable expenses incurred by them in attending the annual meeting. All of our directors attended the 2015 Annual Meeting.

### **Executive Sessions**

Executive sessions of our independent directors are held at each regularly scheduled meeting of our Board and at other times as necessary and are chaired by the Chairman of the Board. The Board’s policy is to hold executive

sessions without the presence of management, including our former President and Chief Executive Officer until his resignation in November 2014, who was the only non-independent director on the Board. Our Board Committees also generally meet in executive session at the end of each Committee meeting.

## **Board Committees**

Our Board of Directors has established four standing committees to assist it in fulfilling its responsibilities to the Company and its stockholders: the Audit Committee, the Compensation Committee, the Nominating and Corporate Governance Committee and the R&D Advisory Committee. Each Committee acts pursuant to a written charter, each of which has been posted in the “Investors” section of our website accessible at [www.lpath.com](http://www.lpath.com). Each Committee reviews its charter on an annual basis. In addition to the three standing Committees, the Board may approve from time to time the creation of special committees to assist the Board in carrying out its duties.

**The Compensation Committee.** The Compensation Committee of the Board of Directors, currently consists of Messrs. Daniel Kisner (Chair), Jeffrey Ferrell, Daniel Petree, Charles Mathews, and Donald Swortwood. The functions of the Compensation Committee include the approval of the compensation offered to our executive officers and recommending to the full Board of Directors the compensation to be offered to our directors. The Board has determined that Messrs. Mathews, Kisner, Ferrell, Petree and Swortwood are each an “independent director” under the listing standards of the Nasdaq Stock Market. In making such determination the Board considered the source of compensation of each member of the Compensation Committee, including factors relevant to determining whether the member has a relationship to the Company which is material to the member’s ability to be independent from management in connection with the duties of a compensation committee member. In addition, the members of the Compensation Committee qualify as “non-employee directors” for purposes of Rule 16b-3 under the Exchange Act and as “outside directors” for purposes of Section 162(m) of the Internal Revenue Code of 1986, as amended. The Compensation Committee met two times in 2015.

**The Audit Committee.** The Audit Committee of the Board of Directors, currently consists of Messrs. Mathews (Chair), Ferrell, and Petree. The functions of the Audit Committee include the retention of our independent registered public accounting firm, reviewing and approving the planned scope, proposed fee arrangements and results of the Company’s annual audit, reviewing the adequacy of the Company’s accounting and financial controls and reviewing the independence of the Company’s independent registered public accounting firm. The Board has determined that each current member of the Audit Committee is an “independent director” under the listing standards of the Nasdaq Stock Market and Section 10A(m)(3) of the Securities Exchange Act. As required by the listing standards of the Nasdaq Stock Market, each member of the Audit Committee can read and understand fundamental financial statements, including a balance sheet, income statement and cash flow statement. The Board of Directors has also determined that Mr. Mathews is an “audit committee financial expert” within the applicable definition of the SEC. The Audit Committee met four times in 2015.

**The Nominating and Corporate Governance Committee.** The Nominating and Corporate Governance Committee consists of Messrs. Mathews (Chair), Petree, and Swortwood. The Nominating and Corporate Governance Committee evaluates and recommends to the Board nominees for each election of directors and helps oversee the Company’s regulatory and compliance matters. The Board has determined that Messrs. Mathews, Petree and Swortwood are each an “independent director” under the listing standards of the Nasdaq Stock Market. The Nominating and Corporate Governance Committee met two times in 2015.

**The R&D Advisory Committee.** The R&D Advisory Committee consists of Messrs. Kisner (Chair), and Petree. The R&D Advisory Committee evaluates and helps oversee the Company’s research and development initiatives. The Board has determined that Messrs. Kisner and Petree are each an “independent director” under the listing standards of the Nasdaq Stock Market. The R&D Advisory Committee met three times in 2015.

## **Board and Committee Effectiveness**

The Board and each of its Committees performs an annual self-assessment to evaluate their effectiveness in fulfilling their obligations. The Board and Committee evaluations cover a wide range of topics, including, among others,

the fulfillment of the Board and Committee responsibilities identified in the Corporate Governance Guidelines and charters for each Committee.

### **Board Leadership Structure**

Daniel H. Petree serves as Chairman of our Board of Directors. Our Board has determined that separating the positions of Chief Executive Officer and Chairman of the Board is in the best interests of the Company and its stockholders at this time. Our Board believes our leadership structure enhances the accountability of our Chief Executive Officer to the Board and encourages balanced decision making. In addition, the Board believes that this structure provides an environment in which its independent directors are fully informed, have significant input into the content of Board meetings and are able to provide objective and thoughtful oversight of management. Our Board also separated the roles in recognition of the differences in responsibilities. While our Chief Executive Officer is responsible for the day-to-day leadership of the Company, the Chairman of the Board provides guidance to the Board, sets the agenda for Board meetings and presides over the meetings of the full Board and the meetings of the Board's non-management directors. The Board Chairman also provides performance feedback on behalf of the Board to our Chief Executive Officer. The Board intends to carefully evaluate from time to time whether our Chief Executive Officer and Chairman positions should remain separate based on what the Board believes is best for the Company and its stockholders.

### **Board Oversight of Risk**

The Board is actively involved in the oversight of risks that could affect the Company. The Board as a whole has responsibility for risk oversight of the Company's risk management policies and procedures, with reviews of certain areas being conducted by the relevant Board committee. The Board satisfies this responsibility through reports by each Committee Chair regarding the Committee's considerations and actions, as well as through regular reports directly from management responsible for oversight of particular risks within the Company. Specifically, the Board committees address the following risk areas:

- The Compensation Committee is responsible for overseeing the management of risks related to the Company's executive compensation plans and arrangements.
- The Audit Committee discusses with management the Company's major financial risk exposures and the steps management has taken to monitor and control such exposures.
- The Nominating and Corporate Governance Committee considers risks related to regulatory and compliance matters.
- The R&D Advisory Committee considers risks related to the Company's research and development initiatives.

The Board encourages management to promote a corporate culture that incorporates risk management into the Company's day-to-day business operations.

### **Stockholder Recommendations for Director Nominees**

In nominating candidates for election as a director, the Nominating and Corporate Governance Committee will consider a reasonable number of candidates recommended by a single stockholder who has held over 2% of Lpath Common Stock for over one year and who satisfies the notice, information and consent provisions set forth in our Bylaws and Corporate Governance Guidelines. Stockholders who wish to recommend a candidate may do so by writing to the Nominating and Corporate Governance Committee in care of the Corporate Secretary, Lpath, Inc., 4025 Sorrento Valley Blvd., San Diego, California 92121. The Nominating and Corporate Governance Committee will use the same evaluation process for director nominees recommended by stockholders as it uses for other director nominees. A printed copy of our Bylaws may be obtained by any stockholder upon request to our Corporate Secretary.

## Identification and Evaluation of Director Nominees

Our Nominating and Corporate Governance Committee uses a variety of methods for identifying and evaluating director nominees. Our Nominating and Corporate Governance Committee regularly assesses the appropriate size and composition of the Board, the needs of the Board and the respective Board Committees, and the qualifications of candidates in light of these needs. Candidates may come to the attention of the Nominating and Corporate Governance Committee through stockholders, management, current members of the Board, or search firms. The evaluation of these candidates may be based solely upon information provided to the Nominating and Corporate Governance Committee or may also include discussions with persons familiar with the candidate, an interview of the candidate or other actions the Nominating and Corporate Governance Committee deems appropriate, including the use of third parties to review candidates.

While we do not have a stand-alone diversity policy, in considering whether to recommend any director nominee, including candidates recommended by stockholders, we believe that the backgrounds and qualifications of our directors, considered as a group, should provide a significant mix of experience, knowledge and abilities that will allow our Board and its Committees to fulfill their respective responsibilities. As set forth in our Corporate Governance Guidelines, these criteria generally include, among other things, an individual's business experience and skills, as well as independence, judgment, knowledge of our business and industry, professional reputation, leadership, integrity and ability to represent the best interests of the Company's stockholders. In addition, the Nominating and Corporate Governance Committee will also consider the ability to commit sufficient time and attention to the activities of the Board, as well as the absence of any potential conflicts with the Company's interests. The Nominating and Corporate Governance Committee does not assign specific weights to particular criteria and no particular criterion is necessarily applicable to all prospective director nominees. Our Board will be responsible for selecting candidates for election as directors based on the recommendation of the Nominating and Corporate Governance Committee.

We believe that our current Board includes individuals with a strong background in executive leadership and management, accounting and finance, and Company and industry knowledge. In addition, each of our directors has a strong professional reputation and has shown a dedication to his or her profession and community. We also believe that our directors' diversity of backgrounds and experiences, which include medicine, academia, business and finance, results in different perspectives, ideas, and viewpoints, which make our Board more effective in carrying out its duties. We believe that our directors hold themselves to the highest standards of integrity and that they are committed to representing the long-term interests of our stockholders.

## Communications with the Board of Directors

The Board desires that the views of stockholders will be heard by the Board, its Committees or individual directors, as applicable, and that appropriate responses will be provided to stockholders on a timely basis. Stockholders wishing to formally communicate with the Board, any Board Committee, the independent directors as a group or any individual director may send communications directly to the Company at 4025 Sorrento Valley Blvd., San Diego, California 92121, Attention: Corporate Secretary. All clearly marked written communications, other than unsolicited advertising or promotional materials, are logged and copied, and forwarded to the director(s) to whom the communication was addressed. Please note that the foregoing communication procedure does not apply to (i) stockholder proposals pursuant to Exchange Act Rule 14a-8 and communications made in connection with such proposals or (ii) service of process or any other notice in a legal proceeding.

## ITEM 11. EXECUTIVE COMPENSATION

### EXECUTIVE COMPENSATION

The following table summarizes the compensation that we paid to our named executive officers (collectively, the "Named Executives"), during the years ended December 31, 2015 and 2014.

**Summary Compensation Table**

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u>	<u>Bonus</u>	<u>Option Awards</u>	<u>Stock Awards</u>	<u>All Other Compensation</u>	<u>Total</u>
Gary J. G. Atkinson (1)	2015	\$345,769	\$56,000	\$78,657	\$ 47,666	\$ 10,600	\$538,692
Interim Chief Executive Officer, Chief Financial Officer	2014	\$321,404	\$58,200	\$48,205	\$ 66,996	\$ 10,400	\$505,205
Michael Lack (2)	2015	\$232,500	\$ —	\$ —	\$ 22,423 (5)	\$ —	\$254,923
Interim Chief Executive Officer	2014	75,000	\$ —	\$ —	\$ 21,357 (5)	\$ —	96,357
Dario A. Paggiarino, M.D.	2015	\$350,962 (3)	\$51,700	\$56,959 (5)	\$123,331 (5)	\$ 10,600 (7)	\$593,552
Senior Vice President and Chief Development Officer	2014	\$327,885 (3)	\$46,300	\$28,923 (5)	\$123,331 (5)	\$ 10,400 (7)	\$536,839
Gary Woodnutt Ph.D.	2015	\$354,289 (4)	\$76,200	\$56,959 (5)	\$123,331 (5)	\$ 10,600 (7)	\$621,379
Senior Vice President, Development	2014	\$327,885 (4)	\$60,000	\$28,923 (5)	\$123,331 (5)	\$ 10,400 (7)	\$550,539

- (1) Gary Atkinson was appointed as the Company's Interim Chief Executive Officer on September 23, 2015. Mr. Atkinson was paid a base salary of \$325,000 per annum, effective as of March 1, 2014, which was increased to \$335,000 effective March 1, 2015. Mr. Atkinson may be granted annual bonuses and equity awards at the discretion of the Compensation Committee.
- (2) On November 3, 2014, the company entered into a consulting agreement (the "Consulting Agreement") with Mr. Lack in connection with his appointment as Interim Chief Executive Officer. Under the Consulting Agreement, Mr. Lack received a monthly salary of \$37,500, with a guarantee of such salary level for a period of four months, subject to certain exceptions. In addition, the Board granted Mr. Lack restricted stock units for 15,000 shares of Common Stock that vested in full on the date on which he no longer provided services to the Company. The company concluded its contract with Mr. Lack effective September 30, 2015.
- (3) Dario A. Paggiarino, M.D., our Senior Vice President and Chief Development Officer, was paid a base salary of \$330,000 per annum, effective as March 1, 2014, which was increased to \$340,000 effective March 1, 2015. Dr. Paggiarino may be granted annual bonuses and equity awards at the discretion of the Compensation Committee.
- (4) Gary Woodnutt, Ph.D., our Senior Vice President, Research, was paid a base salary of \$330,000 per annum, effective as March 1, 2014, which was increased to \$344,000 effective March 1, 2015. Mr. Woodnutt may be granted annual bonuses and equity awards at the discretion of the Compensation Committee.
- (5) Option and Restricted Stock Units ("RSU") award compensation represents the aggregate annual stock compensation expense of the officer's outstanding stock option grants and RSUs. Compensation for employees is measured at the grant date based on the fair value of the award and is recognized as compensation expense over the service period, which generally represents the vesting period. The grant date fair values of the options and RSUs were computed based on the closing price of the company's common stock on the grant date in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718. Material terms of the outstanding equity awards for each of the named executive officers are set forth in the following table entitled "Outstanding Equity Awards at Fiscal Year-End 2015".
- (6) Amounts represent company matching 401(k) contributions.

The following table details unexercised stock options and RSUs for each of our Named Executives as of December 31, 2015.

Name	OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END								
	OPTION AWARDS				STOCK AWARDS				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Exercise Price (\$)	Expiration Date(1)	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Unearned Shares or Units of Stock That Have Not Vested (#)	Equity Incentive Plan Awards: Market Value of Unearned Shares or Units of Stock That Have Not Vested (\$)	
	Gary J. G. Atkinson	34,375	40,625 (2)	\$ 4.45	2/10/2024	8,482	\$ 1,951	—	\$ —
		—	50,000 (2)	2.86	2/10/2025				
		18,750	131,250 (2)	0.28	6/16/2015				
Michael Lack (3)	—	—	—	—	—	\$ —	—	\$ —	
Dario A. Paggiarino, M.D.	20,625	24,375 (2)	\$ 4.45	2/10/2024	37,500	\$ 8,625	—	\$ —	
	—	50,000 (2)	2.86	2/10/2025					
	18,750	131,250 (2)	0.28	6/16/2015					
Gary Woodnutt Ph.D.	20,625	24,375 (2)	\$ 4.45	2/10/2024	37,500	\$ 8,625	—	\$ —	

- (1) For each option shown, the expiration date is the 10th anniversary of the date the option was granted.
- (2) One quarter of the shares vest one year from the date of grant, the remaining shares vest monthly over the following three years.
- (3) On November 3, 2014, the company entered into a consulting agreement (the "Consulting Agreement") with Mr. Lack in connection with his appointment as Interim Chief Executive Officer. Under the Consulting Agreement, the Board granted Mr. Lack restricted stock units for 15,000 shares of Common Stock that vested in full on September 30, 2015, when we concluded our contract with Mr. Lack.

**Narrative to Summary Compensation Table and Outstanding Equity Awards Table**

The Compensation Committee of the Board of Directors, which is comprised solely of independent directors, has the responsibility for evaluating and authorizing the compensation payable to our executive officers. In setting executive compensation in 2014, the Compensation Committee retained Compensia, Inc., a national compensation consulting firm ("Compensia"), to provide it with competitive market data and analysis regarding the compensation elements offered to the Company's executive officers, including base salary, cash incentives and equity incentives. Compensia provided the analysis based on a peer group of life science companies approved by the Compensation Committee. In setting compensation in 2015, the Compensation Committee considered the data and analysis received from Compensia in 2014, updated compensation data for the Company's peer group and available market information for life science companies, adopted and approved the compensation program for the Company's executive officers described below.

**Salary.** The Compensation Committee sets the base salaries for the Company's executive officer. The amounts included in the Salary column of the Summary Compensation Table reflects an annual salary review by the Compensation Committee and any salary increases are pro-rated based on the effective date of any salary increase.

On November 3, 2014, the company entered into a consulting agreement (the "Consulting Agreement") with Mr. Lack in connection with his appointment as Interim Chief Executive Officer. Under the Consulting Agreement, Mr. Lack will receive a monthly salary of \$37,500, with a guarantee of such salary level for a period of four months, subject to certain exceptions. Effective September 30, 2015, Mr. Lack's consulting agreement concluded.



In February 2015, the Compensation Committee approved an approximate three percent increase in the base salaries for the Company's executive officers to account for cost of living increases. Accordingly, effective March 1, 2015, Mr. Atkinson's base salary was increased from \$325,000 to \$335,000, Dr. Paggiarino's base salary was increased from \$330,000 to \$340,000 and Dr. Woodnutt's base salary was increased from \$330,000 to \$344,000.

**Bonus.** As part of the Company's executive compensation program, the Compensation Committee provides annual performance-based cash incentive awards to our executive officers and other key employees. The annual incentive awards are based on the achievement of Company and individual performance metrics established at the beginning of each fiscal year by the Compensation Committee. Following the end of each fiscal year, the Compensation Committee is responsible for determining the bonus amount payable to the executive officer based on the Company's and the executive officer's performance against the performance metrics established by the Compensation Committee for the recently completed fiscal year. The bonus amounts reflected in the Summary Compensation Table for 2014, reflect the Company's and the executive officer's performance during fiscal 2013; and the bonus amounts reflected in the Summary Compensation Table for 2015, reflect the Company's and the executive officer's performance during fiscal 2014.

Based on its evaluation, the Compensation Committee awarded the named executive officers an average of 57% of their full target bonus amounts over the past two fiscal years.

**Equity Awards.** Our Compensation Committee believes that equity ownership by our executive officers and key employees encourages them to focus on increasing the long-term value of the Company, aligns their interests with those of our stockholders and provides a retention tool as the executives are required to vest in the equity awards over a period of time. From 2007 through 2013, the Compensation Committee granted RSUs to our executive officers and our other key employees pursuant to our Amended and Restated 2005 Equity Incentive Plan ("the Plan"). The RSUs vest over a four-year period, with 25% of the RSUs vesting on the one-year anniversary of the vesting commencement date, and 1/12 of the RSUs vesting over each of the next 12 quarters. In 2014, the Compensation Committee, based on the recommendation of Compensia, determined that it would be in the best interests of the Company and its stockholders to grant stock options to our executive officers and other key employees pursuant to the Plan. The Compensation Committee continued to utilize stock options for the Company's executive officers in 2015. Similar to the RSU grants, the stock options vest over a four-year period, with 25% of the stock options vesting on the one-year anniversary of the vesting commencement date, and 1/36th of the stock options vesting over each of the next 36 months. In June 2015, options were granted to executives that vest over a four-year period with 1/48<sup>th</sup> of the stock options vesting monthly over the 48 month term from the vesting commencement date.

In February 2015, Mr. Atkinson, Dr. Paggiarino, and Dr. Woodnutt were each awarded annual grants of 50,000 options. In 2014, Mr. Atkinson was awarded an annual grant of 75,000 options, and Dr. Paggiarino and Dr. Woodnutt were each awarded annual grants of 45,000 options. Mr. Lack was granted 15,000 RSUs in 2014. In June 2015, Mr. Atkinson, Dr. Paggiarino, and Dr. Woodnutt were each awarded retention grants of 150,000 options.

**All Other Compensation.** We do not provide pension arrangements or post-retirement health coverage for our executives or employees. Our executive officers are eligible to participate in our 401(k) contributory defined contribution plan. In any plan year, we contribute to each participant a matching contribution up to a maximum of 4% of the participant's compensation, subject to statutory limitations. We do not provide any nonqualified defined contribution or other deferred compensation plans.

**Severance.** If Mr. Atkinson's, Dr. Paggiarino's or Dr. Woodnutt's employment is terminated by the Company without cause, each is entitled to receive his base salary and benefits for a period of 12 months following such termination. If any of their employment is terminated in within 24 months after a change of control of the Company, then they will be paid their base salary and benefits for a period of 12 months following such termination, and the portion of their stock options and RSUs that would have vested during the 24 months following the termination will immediately vest.

**Director Compensation**

Our directors play a critical role in guiding our strategic direction and overseeing the management of the Company. Ongoing developments in corporate governance and financial reporting have resulted in an increased demand for such highly qualified and productive public company directors. The many responsibilities and risks and the substantial time commitment of being a director of a public company require that we provide adequate incentives for our directors' continued performance by paying compensation commensurate with our directors' workload. Our non-employee directors are compensated based upon their respective levels of Board participation and responsibilities, including service on Board Committees.

The following table sets forth compensation earned and paid to each non-employee director for service as a director during 2015:

**Director Compensation Fiscal Year 2015**

<b>Name</b>	<b>Fees Paid in Cash</b>	<b>Option Awards</b>	<b>Stock Awards</b>	<b>Total</b>
Jeffrey A. Ferrell	\$41,000	\$51,880 (1)	\$ 2,369 (1)	\$ 95,249
Daniel L. Kisner, M.D.	\$49,000	\$51,880 (2)	\$10,036 (2)	\$110,916
Charles A. Mathews	\$56,000	\$51,880 (3)	\$ 2,369 (3)	\$110,249
Daniel H. Petree	\$58,000	\$51,880 (4)	\$ 3,158 (4)	\$113,038
Donald R. Swortwood	\$37,000	\$51,880 (5)	\$ 2,369 (5)	\$ 91,249

- (1) Mr. Ferrell was appointed to the Board in April 2007 and first elected in October 2007. As of December 31, 2015, Mr. Ferrell held 40,000 stock options, all of which are vested and 11,727 RSUs, all of which are vested.
- (2) Dr. Kisner was appointed to the Board in July 2012. As of December 31, 2015, Dr. Kisner held 40,000 options, all of which are vested and 16,098 RSUs, of which 15,467 are vested.
- (3) As of December 31, 2015, Mr. Mathews held 22,143 stock options, all of which were vested, and 22,143 RSUs, all of which are vested. Mr. Mathews was first elected to the Board in March 2006.
- (4) Mr. Petree was appointed to the Board of Directors in November 2008 and first elected in June 2009. In September 2010, Mr. Petree was elected Chairman of the Board. As of December 31, 2015, Mr. Petree held 40,000 options, all of which are vested, and 20,281 RSUs, all of which are vested.
- (5) As of December 31, 2015, Mr. Donald R. Swortwood held 47,143 stock options, all of which are vested, and 15,212 RSUs, all of which are vested. Mr. Swortwood was first elected to the Board in July 2006.
- (6) The grant date fair values of the options and RSUs were computed based on the closing price of the company's common stock on the grant date in accordance with the Financial Accounting Standards Board's Accounting Standards Codification Topic 718.

***Narrative Discussion of the Director Compensation Table.***

Our director compensation program is overseen and authorized by the Board of Directors, based on the recommendation of the Compensation Committee. The Compensation Committee periodically receives advice and recommendations from Compensia, its compensation consultant, with respect to director compensation matters. During 2015, the terms of the compensation arrangements for our non-management directors were as follows:

- Non-management directors received an annual retainer of \$30,000, which was paid in equal quarterly payments. The Chairman of the Board received an annual retainer of \$50,000, which was paid in equal quarterly payments.

- Members of the Audit Committee received an annual retainer of \$7,000, which was paid in quarterly installments. The Chair of the Audit Committee received an annual retainer of \$16,000, which was paid in quarterly installments.
- Members of the Compensation Committee received an annual retainer of \$4,000, which was paid in quarterly installments. The Chair of the Compensation Committee received an annual retainer of \$9,000, which was paid in quarterly installments.
- Members of the Nominating and Corporate Governance Committee received an annual retainer of \$3,000, which was paid in quarterly installments. The Chair of the Nominating and Corporate Governance Committee received an annual retainer of \$6,000, which was paid in quarterly installments.
- Members of the R&D Advisory Committee received an annual retainer of \$4,000, which was paid in quarterly installments. The Chair of the R&D Advisory Committee received an annual retainer of \$10,000, which was paid in quarterly installments.

Each non-management director was awarded either a stock option grant for 25,000 shares or a grant of restricted stock units (“RSUs”) for 16,667 shares of Lpath Common Stock, at the election of the non-management director. The Stock Options and RSUs will vest over a one-year period.

Our directors did not receive any other meeting fees. We do reimburse our directors for their reasonable expenses in attending Board and Board Committee meetings in accordance with the Company’s reimbursement policy.

For 2016, the Board of Directors, based on the recommendation of the Compensation Committee, determined to maintain the existing director compensation program outlined above, with the following changes:

- Each non-management director was awarded a stock option grant for 25,000 shares of Lpath Common Stock . The Stock Options and RSUs will vest over a one-year period.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth information on the beneficial ownership of our Common Stock as of February 1, 2016 by (i) each stockholder who we believe owns beneficially more than 5% of our Common Stock, (ii) each of our named executive officers and directors and (iii) all of our directors and executive officers as a group. Except as listed below, the address of all owners listed is c/o Lpath, Inc., 4025 Sorrento Valley Blvd., San Diego, CA 92121.

<u>Name of Beneficial Owner</u>	<u>Number of Shares and Nature of Beneficial Ownership(1)</u>	<u>Percent of Common Stock Outstanding(2)</u>
HBM Healthcare Investments (Cayman) Ltd. 23 Lome Tree Bay Avenue West Bay, Grand Cayman, Cayman Islands	4,110,338 (3)	11.9 %
Sabby Management LLC 10 Mountain View Road, Suite 205 Upper Saddle River, NJ 07458	4,697,238 (4)	13.5 %
Donald R. Swortwood Director Chairman & Chief Executive Officer Western States Investment Group 4025 Sorrento Valley Blvd. San Diego, CA 92121 Director	833,407 (5)	2.5 %
Gary J.G. Atkinson Interim Chief Executive Officer, Chief Financial Officer, and Secretary	161,737 (6)	*
Michael Lack Former Interim Chief Executive Officer	15,000 (7)	*
Dario A. Paggiarino, M.D. Senior Vice President and Chief Development Officer	144,272 (8)	*
Gary Woodnutt Ph.D. Senior Vice President, Development	144,272 (8)	*
Charles A. Mathews Director	74,620 (9)	*
Jeffrey A. Ferrell Director	85,728 (10)	*
Daniel L. Kisner, M.D. Director	80,782 (11)	*
Daniel H. Petree Director	104,282 (12)	*
All directors and executive officers as a group (eight persons)	1,644,100 (13)	4.5 %

From time to time, the number of our shares held in the "street name" accounts of various securities dealers for the benefit of their clients or in centralized securities depositories may exceed 5% of the total shares of our Common Stock outstanding.

\* Less than one percent.

- (1) We determined beneficial ownership under rules promulgated by the SEC, based on information obtained from questionnaires, Company records and filings with the SEC. The information is not necessarily indicative of beneficial ownership for any other purpose. Under the rules of the SEC, a person is considered to beneficially own any shares: (i) over which the person, directly or indirectly, exercises sole or shared voting or investment power, or (ii) of which the person has the right to acquire beneficial ownership at any time within 60 days of March 1, 2015 (such as through exercise of stock options). Except as otherwise indicated, the persons named in this table have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them, subject to community property laws where applicable and to the information contained in the footnotes to this table.
- (2) Percentage information is calculated based on 19,321,256 shares of Common Stock outstanding as of March 1, 2016, plus each person's warrants, options, and restricted stock units (RSUs) that are currently exercisable or vested (in the case of (RSUs) or that will become exercisable or vested within 60 days of March 1, 2016). Percentage information for each person assumes that no other individual will exercise any warrants or options.
- (3) According to Schedule 13-G filed with the SEC, includes 2,780,836 shares of Common Stock and 1,329,502 shares of Common Stock issuable upon exercise of warrants.
- (4) According to Schedule 13-G filed with the SEC, includes 2,902,000 shares of Common Stock and 3,700,280 shares of Common Stock issuable upon exercise of warrants.
- (5) Includes 47,143 shares of Common Stock issuable upon the exercise of outstanding options and 15,212 shares of Common Stock that are issuable pursuant to the terms of RSUs.
- (6) Includes 90,625 shares of Common Stock issuable upon the exercise of outstanding options and 40,528 shares of Common Stock that are issuable pursuant to the terms of RSUs.
- (7) Includes 15,000 shares of Common Stock. Mr. Lack served as our interim Chief Executive Officer until his consulting agreement concluded effective September 2015.
- (8) Includes 69,272 shares of Common Stock issuable upon the exercise of outstanding options and 75,000 shares of Common Stock issuable pursuant to the terms of RSUs.
- (9) Includes 26,310 shares of Common Stock issuable upon the exercise of outstanding options and 31,879 shares of Common Stock issuable pursuant to the terms of RSUs.
- (10) Includes 65,000 shares of Common Stock issuable upon the exercise of outstanding options and 11,727 shares of Common Stock issuable pursuant to the terms of RSUs.
- (11) Includes 65,000 shares of Common Stock issuable upon the exercise of outstanding options and 15,782 shares of Common Stock issuable pursuant to the terms of RSUs.
- (12) Includes 65,000 shares of Common Stock issuable upon the exercise of outstanding options and 20,281 shares of Common Stock issuable pursuant to the terms of RSUs.
- (13) Includes shares held by all of the directors and executive officers, including Donald R. Swortwood, Gary J.G. Atkinson, Michael Lack, Dario A. Paggiarino, M.D., Gary Woodnutt Ph.D., Charles A. Mathews, Daniel L. Kisner M.D., Daniel H. Petree, and Jeffrey A. Ferrell.

#### **Section 16(a) Beneficial Ownership Reporting Compliance.**

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Act"), requires our executive officers and directors and persons who beneficially own more than 10% of our Common Stock to file initial reports of beneficial ownership and reports of changes in beneficial ownership with the SEC. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms filed by such persons.

To the Company's knowledge, no person who, during the fiscal year ended December 31, 2014, was a director or officer of the Company, or beneficial owner of more than ten percent of the Company's Common Stock (which is the only class of securities of the Company registered under Section 12 of the Act), failed to file on a timely basis reports required by Section 16 of the Act during such fiscal year. The foregoing is based solely upon a review by the Company of Forms 3 and 4 relating to the most recent fiscal year as furnished to the Company under Rule 16a-3(d) under the Act, and Forms 5 and amendments thereto furnished to the Company with respect to its most recent fiscal year, and any representation received by the Company from any reporting person that no Form 5 is required.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

We have not engaged in any transaction since January 1, 2014 in which the amount involved exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end for fiscal 2015 and 2014 and in which any of our directors, named executive officers or any holder of more than 5% of our Common Stock, or any member of the immediate family of any of these persons or entities controlled by any of them, had or will have a direct or indirect material interest.

For disclosure purposes, we sublease a portion of our facility to Western States Investment Corporation ("WSIC"). Mr. Donald Swortwood, one of our directors, has a 100% ownership interest in WSIC. The terms of the sublease are the same as the financial terms of our direct lease. In addition, certain of our employees provide investment oversight, accounting, and other administrative services to WSIC. Certain WSIC employees also provide services to us. We and WSIC reimburse each other for the cost of the services provided to the other entity.

Our rent expense totaled approximately \$390,000 and \$385,000 for the years ended December 31, 2015 and 2014, respectively. Lpath's sublease income amounted to \$11,652 for the years ended December 31, 2015 and 2014.

During 2015 and 2014, WSIC billed Lpath \$12,008 and \$39,300, respectively, for administrative expenses.

We believe that each of the transactions set forth above: (i) were entered into on terms as fair as those that could be obtained from independent third parties, and (ii) were ratified by our Audit Committee pursuant to our related party transaction policy discussed below.

#### **Related Party Transaction Policy**

Pursuant to our Code of Business Conduct and Ethics, our executive officers, directors, and principal stockholders, including their immediate family members and affiliates, are prohibited from entering into a related party transaction with us without the prior consent of our Audit Committee or our independent directors. Any request for us to enter into a transaction with an executive officer, director, principal stockholder, or any of such persons' immediate family members or affiliates, in which the amount involved exceeds \$120,000 must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting the proposed agreement, our Audit Committee will consider the relevant facts and circumstances available and deemed relevant, including, but not limited, to the risks, costs and benefits to us, the terms of the transaction, the availability of other sources for comparable services or products, and, if applicable, the impact on a director's independence. Our Audit Committee shall approve only those agreements that, in light of known circumstances, are in, or are not inconsistent with, our best interests, as our Audit Committee determines in the good faith exercise of its discretion.

#### ***Compensation Committee Interlocks and Insider Participation.***

None of the members of our Compensation Committee are or have been an officer or employee of us. During fiscal 2015, no member of our Compensation Committee had any relationship with us requiring disclosure under Item 404 of Regulation S K. During fiscal 2015, none of our executive officers served on the Compensation Committee (or its equivalent) or board of directors of another entity any of whose executive officers served on our Compensation Committee or board of directors.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES****Fees Billed to the Company by its independent auditors during Fiscal Years 2015 and 2014.**

Set forth below is certain information concerning fees billed to us by Moss Adams in respect of services provided in 2015 and 2014.

	<u>2015</u>	<u>2014</u>
Audit fees	\$122,000	\$122,000
Audit-related fees	35,000	42,250
Tax Fees	8,500	8,500
All other fees	—	—
Total	<u>\$165,500</u>	<u>\$172,750</u>

*Audit Fees:* For the years ended December 31, 2015 and 2014, the aggregate audit fees billed by Moss Adams were for professional services rendered for audits and quarterly reviews of our consolidated financial statements.

*Audit-Related Fees:* For the years ended December 31, 2015 and 2014, audit-related fees billed by Moss Adams pertained to services rendered in connection with (i) the audit of our Schedule of Expenditures for the National Institutes of Health Research and Development Program, and (ii) procedures required for filings with the SEC in conjunction with financing transactions.

*Tax Fees:* For the years ended December 31, 2015 and 2014, fees billed by Moss Adams related to tax return preparation and tax planning services.

*All Other Fees:* For the years ended December 31, 2015 and 2014, there were no fees billed by Moss Adams for other services, other than the fees described above.

**Policy on Audit Committee pre-approval of audit and permitted non-audit services of independent auditors**

The Audit Committee has determined that all services provided by Moss Adams were compatible with maintaining the independence of such audit firm. The charter of the Audit Committee requires advance approval of all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for the company by our independent registered public accounting firm, subject to any exception permitted by law or regulation. The Audit Committee has delegated to the Chair of the Audit Committee authority to approve permitted services, provided that the Chair reports any decisions to the Audit Committee at its next scheduled meeting. During 2015 and 2014, the Chair of the Audit Committee, subsequently advising the Audit Committee, or the Audit Committee itself pre-approved all audit related and the tax services provided by our independent auditors. During 2015 and 2014, no non-permitted or non-authorized services were performed by our independent registered public accounting firm.

**ITEM 15. EXHIBITS**

(a) The following documents are filed as part of this report:

(1) The following financial statements of Lpath, Inc. are included in Item 8:

<a href="#">Report of Independent Registered Public Accounting Firm</a>	44
<a href="#">Consolidated Balance Sheets</a>	45
<a href="#">Consolidated Statements of Operations</a>	46
<a href="#">Consolidated Statements of Changes in Stockholders' Equity</a>	47
<a href="#">Consolidated Statements of Cash Flows</a>	48
<a href="#">Notes to Consolidated Financial Statements</a>	49

(2) All financial statement schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or other notes thereto.

(3) See the Exhibits under Item 15(b) below for all Exhibits being filed or incorporated by reference herein.

(a) Exhibits:

The following exhibit index shows those exhibits filed with this report and those incorporated herein by reference:

- 2.1 Agreement and Plan of Reorganization, by and between Neighborhood Connections, Inc., Neighborhood Connections Acquisition Corporation, and Lpath Therapeutics Inc. dated July 15, 2005 (filed as an exhibit to the Current Report on Form 8-K filed with the SEC on December 6, 2005 and incorporated herein by reference).
- 2.2 Acquisition Agreement and Plan of Merger, dated as of March 19, 2004, between Neighborhood Connections, Inc. and JCG, Inc. (filed as Exhibit 2.1 to the Current Report on Form 8-K filed on March 22, 2004 and incorporated herein by reference).
- 2.3 Plan of Conversion, dated July 17, 2014, of Lpath, Inc. (filed as Exhibit 2.1 to the Current Report on Form 8-K filed with the SEC on July 21, 2014 and incorporated herein by reference).
- 3.1 Articles of Conversion, as filed with the Secretary of State of the State of Nevada on July 17, 2014 (filed as Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on July 21, 2014 and incorporated herein by reference).
- 3.2 Certificate of Conversion, as filed with the Secretary of State of the State of Delaware on July 17, 2014 (filed as Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on July 21, 2014 and incorporated herein by reference).
- 3.3 Certificate of Incorporation (filed as Exhibit 3.3 to the Current Report on Form 8-K filed with the SEC on July 21, 2014 and incorporated herein by reference).
- 3.4 Bylaws (filed as Exhibit 3.4 to the Current Report on Form 8-K filed with the SEC on July 21, 2014 and incorporated herein by reference).
- 4.1 Form of Common Stock Purchase Warrant for Investors in the Units. (filed as an exhibit to Current Report on Form 8-K filed with the SEC on March 6, 2012 and incorporated herein by reference.)



- 4.2 Form of Common Stock Purchase Warrant for Placement Agents of the Units. (filed as an exhibit to the Current Report on Form 8-K filed with the SEC on March 6, 2012 and incorporated herein by reference.)
- 4.3 Form of Warrant for Griffin Securities, Inc. (filed as an exhibit to the Current Report on Form 8-K filed with the SEC on March 6, 2012 and incorporated herein by reference.)
- 4.4 Form of Warrant Issued to Investors in the September 2014 Offering (filed as Exhibit 4.1 to the Current Report on Form 8-K filed with the SEC on September 22, 2014 and incorporated herein by reference).
- 4.5 Form of Warrant issued to Maxim Group LLC in the September 2014 Offering (filed as Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on September 22, 2014 and incorporated herein by reference).
- 10.1 Lease dated May 31, 2011 between Sorrento Science Park, LLC and Lpath, Inc. for 4025 Sorrento Valley Blvd. San Diego, California 92121 (filed as an exhibit to the Current Report on the Current Report on Form 8-K filed with the SEC on June 3, 2011 and incorporated herein by reference).
- 10.2 Research Collaboration Agreement dated August 2, 2005 between Lpath Therapeutics Inc. and AERES Biomedical Limited (filed as Exhibit 10.4 to the Current Report on Form 8-K/A filed on January 9, 2006 and incorporated herein by reference) (portions of this exhibit have been omitted pursuant to a request for confidential treatment).
- 10.3 Lpath, Inc. Amended and Restated 2005 Equity Incentive Plan (filed as Appendix A to the company's Schedule 14-A Proxy Statement filed on August 28, 2007 and incorporated herein by reference).+
- 10.4 Assignment and Assumption Agreement dated December 1, 2005 by and between Lpath, Inc. and Lpath Therapeutics, Inc. (filed as an exhibit to the Annual Report on Form 10-KSB for the year ended December 31, 2005 filed with the SEC on March 16, 2006 and incorporated herein by reference).
- 10.5 Form of Employment Agreement between Lpath, Inc. and Gary Atkinson dated as of February 6, 2006 (filed as an exhibit to the Current Report on Form 8-K filed with the SEC on March 29, 2006 and incorporated herein by reference).+
- 10.6 Form of Indemnification Agreement for directors and officers. (filed as exhibit 10.1 to Current Report on Form 8-K filed with the SEC on July 21, 2014 and incorporated herein by reference.)
- 10.7 At-The-Market Issuance Sales Agreement, dated as of March 18, 2014 by and between MLV & Co. LLC and Lpath, Inc. (filed as Exhibit 10.25 to the Annual Report on Form 10-K filed with the SEC on March 18, 2014 and incorporated herein by reference).
- 10.8 First Amendment to Employment Agreement, between Lpath, Inc. and Gary Atkinson, entered into as of March 17, 2014. (filed as Exhibit 10.26 to the Annual Report on Form 10-K filed with the SEC on March 18, 2014 and incorporated herein by reference).+
- 10.9 Form of Option Agreement, between the Lpath, Inc. and its officers and directors. (filed as Exhibit 10.27 to the Annual Report on Form 10-K filed with the SEC on March 18, 2014 and incorporated herein by reference).+

10.10	Employment Agreement, dated as of April 15, 2013 by and between Lpath, Inc. and Dario A. Paggiarino, M.D. (filed as Exhibit 10.28 to the Annual Report on Form 10-K filed with the SEC on March 18, 2014 and incorporated herein by reference).+
10.11	Employment Agreement, dated as of April 15, 2013 by and between Lpath, Inc. and Gary Woodnutt Ph.D. (filed as Exhibit 10.29 to the Annual Report on Form 10-K filed with the SEC on March 18, 2014 and incorporated herein by reference).+
10.12	Securities Purchase Agreement, dated September 19, 2014, between Lpath, Inc. and investors in the September 2014 Offering (filed as Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on September 22, 2014 and incorporated herein by reference).
10.13	Form of Registration Rights Agreement between Lpath, Inc. and investors in the September 2014 Offering (filed as Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on September 22, 2014 and incorporated herein by reference).
23.1	Consent of Moss Adams LLP.*
31.1	Section 302 Certification by Interim Chief Executive Officer of Lpath, Inc.*
31.2	Section 302 Certification by Chief Financial Officer of Lpath, Inc.*
32.1	Section 906 Certification by Interim Chief Executive Officer and Chief Financial Officer of Lpath, Inc.*
101.INS# XBRL	Instance Document*
101.SCH# XBRL	Taxonomy Extension Schema Document*
101.CAL# XBRL	Taxonomy Extension Calculation Linkbase Document*
101.DEF# XBRL	Taxonomy Extension Definition Linkbase Document*
101.LAB# XBRL	Taxonomy Extension Label Linkbase Document*
101.PRE# XBRL	Taxonomy Extension Presentation Linkbase Document*

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+ Management contract or compensation plan or arrangement

\* Provided herewith.

(b) Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or other notes hereto.

**SIGNATURES**

In accordance with the requirements of Section 13 on 15(k) of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf on March 22, 2016 by the undersigned thereto.

LPATH, INC.

/s/ GARY J. G. ATKINSON

Gary J. G. Atkinson ,  
*Interim Chief Executive Officer and Chief Financial Officer*  
*(Principal Executive, Financial, and Accounting Officer)*

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Gary J. G. Atkinson and Dario Paggiarino, M.D., jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes may do or cause to be done by virtue hereof.

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 22, 2016.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ GARY J. G. ATKINSON</u> Gary J. G. Atkinson	Interim Chief Executive Officer and Chief Financial Officer (Principal Executive, Financial, and Accounting Officer)	March 22, 2016
<u>/s/ CHARLES A. MATHEWS</u> Charles A. Mathews	Director	March 22, 2016
<u>/s/ DONALD R. SWORTWOOD</u> Donald R. Swortwood	Director	March 22, 2016
<u>/s/ DANIEL L. KISNER, M.D.</u> Daniel L. Kisner, M.D.	Director	March 22, 2016
<u>/s/ JEFFREY FERRELL</u> Jeffrey Ferrell	Director	March 22, 2016
<u>/s/ DANIEL PETREE</u> Daniel Petree	Director	March 22, 2016

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements Nos. 333-149827 and 333-137318 on Form S-8 and Registration Statement No. 333-190651 on Form S-3 of our report dated March 22, 2016, relating to the consolidated financial statements appearing in this Annual Report on Form 10-K of Lpath, Inc. for the year ended December 31, 2015.

/s/ Moss Adams LLP  
San Diego, California  
March 22, 2016

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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Gary J.G. Atkinson, Interim Chief Executive Officer and Chief Financial Officer of Lpath, Inc. (the "Company"), hereby certifies that:

- (1) The Company's Annual Report on Form 10-K for the period ended December 31, 2015, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 22, 2016

/s/ GARY J.G. ATKINSON

Gary J.G. Atkinson, *Interim Chief Executive Officer and Chief  
Financial Officer*  
*(Principal Executive, Financial, and Accounting Officer)*

A signed original of this written statement required by Section 906 has been provided to Lpath, Inc. and will be retained by Lpath, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of Lpath, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

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