U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

Mark One

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

For the fiscal year ended **December 31, 2017**

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

Commission File No. **000-52542**

Spotlight Innovation Inc.

(Name of small business issuer in its charter)

Nevada	**98-0518266**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

11147 Aurora Avenue
Aurora Business Park, Building 3
Urbandale, Iowa 50322
(Address of principal executive offices)

(515) 274-9087
(Issuer's telephone number)

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

COMMON STOCK, $0.001
(Title of Class)

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 Section 15(d) of the Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant has (i) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (ii) 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 Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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 is not contained in this form, 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 file, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filed	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
(Do not check if a smaller reporting company.)		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by checkmark 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 computed by reference to the average bid and asked price of the common equity, as of the last business of the registrants most recently completed second fiscal quarter was $3,230,395.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: As of April 17, 2018, there were 34,365,907 shares of the Company's common stock outstanding.

SPOTLIGHT INNOVATION INC.
FORM 10-K
INDEX

PART I

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Securities Exchange Act of 1934 and the Securities Act of 1933 that involve risks and uncertainties. Forward-looking statements convey our current expectations or forecasts of future events. All statements contained in this Annual Report other than statements of historical fact are forward-looking statements. Forward-looking statements include statements regarding our future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations. The words "may," "continue," "estimate," "intend," "plan," "will," "believe," "project," "expect," "seek," "anticipate," "should," "could," "would," "potential," or the negative of those terms and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this report. All of these forward-looking statements are based on information available to us at this time, and we assume no obligation to update any of these statements. Actual results could differ from those projected in these forward-looking statements as a result of many factors, including those identified in "Business," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere. We urge you to review and consider the various disclosures made by us in this report, and those detailed from time to time in our filings with the Securities and Exchange Commission, that attempt to advise you of the risks and factors that may affect our future results. Factors that could cause actual results to differ materially include, among others, our ability to make good decisions about the deployment of capital, our substantial capital requirements and absence of liquidity, competition, our inability to obtain maximum value for our holdings, our ability to attract and retain qualified employees, our ability to execute our strategy, market valuations in sectors in which we operate, our need to manage our assets, and risks associated with our assets and their performance, including the fact that most have a limited history and a history of operating losses, face intense competition and may never be profitable, the effect of economic conditions in the business sectors in which our partner companies operate, compliance with government regulation and legal liabilities, all of which are discussed in Item 1A. Risk Factors." Many of these factors are beyond our ability to predict or control. In addition, as a result of these and other factors, our past financial performance should not be relied on as an indication of future performance. All forward-looking statements attributable to us, or to persons acting on our behalf, are expressly qualified in their entirety by this cautionary statement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report might not occur.

ITEM 1. BUSINESS.

Overview

Spotlight Innovation Inc. (the "Company") is a pharmaceutical company focused on acquiring the intellectual property rights to innovative and proprietary therapeutics designed to address unmet medical needs with an emphasis on rare, emerging, or neglected diseases. In late summer/early fall of 2016 the Company changed its disease focus and has revised its product offerings including the addition of new indications and the elimination of previous programs.

The Company works to maintain a balanced portfolio of early- and late-stage product candidates. We conserve capital and streamline operations through cost-effective collaborations with:

- Contract research organizations (CROs)
- Contract manufacturing organizations (CMOs)
- Academic laboratories

As of December 31, 2017, the Company had four subsidiaries: Celtic Biotech Iowa, Inc., Caretta Therapeutics, LLC, SMA Therapeutics, LLC, and Zika Therapeutics, LLC. The Company's focus areas include, cancer, pain management, Zika virus infection, and spinal muscular atrophy.

Cancer

On June 4, 2014, our subsidiary, Celtic Biotech Iowa, Inc. (hereinafter "Celtic Iowa") acquired Celtic Biotech Limited (hereinafter "Celtic Limited"). Celtic Limited was founded in 2003 in Dublin, Ireland to develop novel therapies derived from snake venom for the treatment of solid cancers and pain in humans.

Celtic Iowa's main focus has been the development of the specific snake venom toxin crotoxin, as a pain and cancer therapeutic. Derived from naturally specialized receptor-binding proteins, these products may have the potential to reduce treatment costs, improve quality-of-life and increase survival.

In March of 2017, Celtic Iowa commenced Part 2 of its Phase I dose escalation safety study, *Crotoxin in Patients with Advanced Cancer using an Intravenous Route of Administration*. ImmunoClin Ltd., a company specializing in clinical development, is the contract research organization ("CRO") overseeing the study conduct. Part 2 of the Phase I study uses a revised protocol designed to determine whether faster dose escalation can be attained in a shortened time frame without increased risk to patients. The trial is being conducted at the Department of Medical Oncology at Pitié-Salpêtrière Hospital in Paris, France under the direction of Principal Investigator Maria A. Gil-Delgado, MD, PhD. Dr. Gil-Delgado is a member of the American Society of Clinical Oncology ("ASCO"). Noted French oncologist David Khayat, MD, PhD, FASCO, a Board Member of ASCO, is serving as Principal Scientific Advisor.

Pain Management

Our subsidiary Caretta Therapeutics, LLC ("Caretta") develops and commercializes homeopathic, over-the-counter products derived from cobra venom, and intended to treat chronic pain.

Caretta holds a license agreement with Dr. Paul Reid to develop, manufacture and sell certain products derived from cobra venom that may have analgesic properties. In the August 2017, Caretta launched the topical analgesic product Venodol roll-on, a non-addictive alternative to opioid and steroidal analgesics intended to provide relief from chronic pain. Additionally, Caretta has signed a Master Broker Agreement with a premier global distribution brokerage firm to distribute its products into supermarket, drug store, mass merchandise and warehouse chains.

Spinal Muscular Atrophy

In October 2016, the Company entered into an Exclusive License Agreement with Indiana University Research and Technology Corporation to commercialize STL-182, an orally-available small molecule that may have therapeutic potential for treating spinal muscular atrophy. Spinal muscular atrophy is an autosomal recessive disorder that is a leading genetic cause of death in infants and toddlers. Synthesis and early preclinical testing of STL-182 was accomplished through a research collaboration between Professors Elliot Androphy of Indiana University School of Medicine, and Kevin Hodgetts, director of the Laboratory for Drug Discovery in Neurodegeneration at Brigham and Women's Hospital. Their work was supported in part by the National Institute of Neurological Disorders and Stroke and the National Institute of Child Health and Human Development. Professor Androphy and Professor Hodgetts are members of the Company's Scientific Advisory Board.

On June 21, 2017, the Company entered into a Sponsored Research Agreement with The Brigham and Women's Hospital Inc. ("BWH") to support research directed by BWH Professor Kevin Hodgetts aimed at developing safe and effective drugs to treat patients with spinal muscular atrophy.

On August 14, 2017, the Company entered into a Sponsored Research Agreement with The Trustees of Indiana University ("IU") to support research directed by IU Professor Dr. Elliot Androphy aimed at developing safe and effective drugs to treat patients with spinal muscular atrophy.

Spinal muscular atrophy affects between 1 in 6,000 and 1 in 10,000 newborns. Approximately 1 in 40 to 1 in 50 adults have only a single intact spinal motor neuron 1 (SMN1) gene, which encodes a protein (SMN) required for proper neuromuscular function. An infant who inherits no intact SMN1 gene from either parent may develop spinal muscular atrophy and lose the ability to sit, stand, walk, swallow, and/or breathe. In about 60% of cases, patients with spinal muscular atrophy die by age two. Even in spinal muscular atrophy patients, low levels of functional spinal muscular atrophy protein are produced by an SMN1-related gene called SMN2. One therapeutic strategy to treat spinal muscular atrophy is to increase levels of functional SMN protein encoded by SMN2. In mouse models of spinal muscular atrophy, STL-182 may restore neuromuscular function by stabilizing endogenous SMN protein.

The Company has engaged a top-tier contract research organization (CRO) to conduct additional preclinical mouse studies of STL-182. These studies are ongoing and are expected to continue throughout 2018.

Zika Virus Infection

In August 2016, the Company entered into a sponsored research agreement with Florida State University ("FSU") to support research directed by FSU Professor Hengli Tang aimed at developing safe and effective drugs to treat patients infected with the Zika virus (ZIKV). Professor Tang is a member of the Company's Scientific Advisory Board.

In November 2016, the Company obtained from the Florida State University Research Foundation ("FSURF") exclusive, worldwide rights to develop and commercialize certain compounds for the treatment of viral infections, including Zika virus infection. Included among the licensed compounds are those identified in a study co-authored by Professor Tang that was published in *Nature Medicine*.

In January 2017, the Company entered into a second license agreement with FSURF for the development and commercialization of additional anti-Zika virus compounds. As with the initial license agreement, this agreement grants the Company exclusive, worldwide rights to develop and commercialize certain compounds for the treatment of viral infections, including Zika virus infection.

Refractory Glaucoma

The Company had made a strategic, external investment in Solx, Inc., a Massachusetts-based, privately-held medical device company that develops innovative surgical technologies to treat refractory glaucoma and preserve vision. In September 2017, the FDA denied the application of SOLX, and the Company wrote off its investment during the period ending September 30, 2017.

Intellectual Property

The Company's goal is to protect the proprietary technologies that we believe to be key to our strategy. We seek to maintain patent protection to cover our product candidates, their methods of use, related technology and other inventions that we consider important to our business. We also rely on trade secrets and monitoring of our proprietary information to protect the aspects of our business that are necessarily appropriate for patent protection. A third party may hold intellectual property, including patent rights, which are important or necessary to the development of our technologies. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license, or were not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially. The scope of coverage claimed in a patent application can be significantly reduced and or modified before and after the patent is issued. Consequently, we do not know whether any of our technology candidates will be protectable or remain protected by enforceable patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

The table below reflects the Intellectual Property of the Company:

	PATENT NO.	ISSUE DATE	TITLE
Celtic Biotech	U.S. Patent 8,921,305	Dec 2014	*Crotoxin Administration for Cancer Treatment and Pain Relief*
Celtic Biotech	U.S. Patent 8,278,265	Oct 2012	*Methods, Kits and Compositions with Crotamine*
Celtic Biotech	U.S. Patent 9,345,751	May 2016	*Crotalus Durissus Terrificus Venom Administration for Cancer Treatment and Pain Relief*

Research and Development

The Company's business is dependent on conducting research and development. We have spent and continue to spend significant time and capital on conducting research and development. Research and development expenses were $742,118 and $232,798 for 2017 and 2016, respectively. The Company anticipates that research and development expenses will continue to be substantial and to significantly increase as we continue the development of our existing technologies.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from different sources, including large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, and medical technology companies. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are a large number of companies developing or marketing therapies for the indications that we are pursuing. Many of our competitors have substantially greater financial, technical and human resources and significantly greater experience in the development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Small or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We also compete with these companies in recruiting and retaining qualified scientific personnel and establishing clinical trial sites and patient registration for clinical trials.

FDA 2018 Policy Priority

The FDA implemented an aggressive stance to address serious threats to public health including the opioid addiction crisis. This includes fostering innovation, and the creation of new drug development pathways for non-opioid drugs that are averse to manipulation and addiction.

Homeopathic Drugs

The FDA has proposed policies that would enhance enforcement action against homeopathic drugs that may be unsafe to the consumer. The finalization of a draft guidance document focused on homeopathic drugs (released December, 2017) will subject these products to further scrutiny with safety and effectiveness claims. Although, the prioritization is toward drugs targeting high-risk disease conditions, the expectation is that eventually all homeopathic drugs will be impacted.

Rare, Emerging Diseases, and Diseases with unmet medical needs

The FDA has implemented several incentivized programs to encourage private sector innovation and development of drugs for rare, emerging diseases, and diseases with unmet medical needs. These incentives include, but are not limited to federal funding awards, and strategies to accelerate the approval process to enable faster access for public health.

FDA Approval Process

(Source: fda.gov)

(a) **Investigational New Drug Application ("IND") -** At IND, the FDA decides whether it is reasonably safe for the company to move forward with testing the drug in humans after evaluating the results of preclinical testing in laboratory animals and what they propose to do for human testing.

(b) **Clinical Trials -** Drug studies in humans can begin only after an IND is reviewed by the FDA and a local institutional review board. At the commencement of clinical trials, they approve the clinical trial protocols, which describe the type of people who may participate in the clinical trial, the schedule of tests and procedures, the medications and dosages to be studied, the length of the study, the study's objectives, and other details.

(c) **Phase 1 -** Phase 1 studies are usually conducted in healthy volunteers. The goal is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted. Phase 1 focuses on safety.

(d) **Phase 2 -** Phase 2 studies begin if Phase 1 studies do not reveal unacceptable toxicity. Phase 2 focuses on effectiveness. This phase aims to obtain preliminary data on whether the drug works in people who have a certain disease or condition. For controlled trials, patients receiving the drug are compared with similar patients receiving a different treatment--usually an inactive substance (placebo).

(e) **Phase 3 -** Phase 3 studies begin if evidence of effectiveness is shown in Phase 2. These studies gather more information about safety and effectiveness, studying different populations in a larger group and different dosages and using the drug in combination with other drugs.

(f) **New Drug Application ("NDA") -** The NDA is the formal step a drug sponsor takes to ask that the FDA consider approving a new drug for marketing in the United States. An NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured.

Employees

We employ four persons on a full-time basis: John M. Krohn, President, COO and Interim CEO; J. William Pim, Chief Financial Officer; Rene Erickson, Vice President of Corporate Communications; and Chitra Edwin, Senior Vice President of Regulatory Affairs. These individuals are primarily responsible for all of our day-to-day operations. Other services are provided by outsourcing and consultant and special purpose contracts.

ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. Before making an investment decision you should carefully consider the risks described below with all of the other information we include in this report and the additional information we include in the other reports we file with the Securities and Exchange Commission (the "SEC" or the "Commission"). These risks may result in material harm to our business and our financial condition and results of operations. In this event, the market price of our common stock may decline and you can lose part or all of your investment.

Risks Related to Our Business and Industry

We are dependent on the success of our product candidates, which may never receive regulatory approval or be successfully commercialized.

All of our product candidates are subject to the risks of failure inherent in developing therapeutics and drug products. With the exception of Venodol, all of our product candidates are in early stages of development and subject to the risks of failure inherent therein.

The ability to successfully commercialize any of our products candidates will depend on, among other things, the ability to:

- receive marketing approvals from the FDA and/or Ex-U.S. regulatory authorities (where required);
- produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;
- establish commercial manufacturing arrangements with third-party manufacturers;
- build and maintain strong sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;
- establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States, and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- secure acceptance of our product candidates from physicians, health care payors, patients and the medical community;
- successfully complete our clinical trials (as applicable); and
- manage our spending as costs and expenses increase due to commercialization and clinical trials.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize any of our product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business. In addition, if we experience unanticipated delays or problems, development costs could substantially increase and our business' financial condition and results of operations will be adversely affected.

We have limited sales and marketing experience and resources, and we may not be able to effectively market and sell our products or product candidates, if approved, in the United States.

We have limited sales and marketing experience. Further, we could face a number of additional risks in establishing internal sales and marketing capabilities, including:

- we may not be able to attract talented and qualified personnel to build an effective marketing or sales force capability;
- the cost of establishing a marketing and sales force capability may not be justifiable in light of the potential revenues generated by any of our products if they were to receive final approval by the FDA; and
- our direct sales and marketing efforts may not be successful.

If we are unable to establish adequate sales and marketing capabilities or are unable to do so in a timely manner, we may not be able to generate product revenues and may never become profitable.

The commercial success of our products and product candidates, if approved, depends upon attaining market acceptance by physicians, patients, third-party payors and the medical community.

Physicians may not prescribe any of our product candidates if approved by the FDA, in which case we would not generate the revenues we anticipate. Market acceptance of any of our products or product candidates by physicians, patients, third-party payors and the medical community depends on, among other things:

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of each product or product candidate as a safe and effective treatment;
- perceived advantages of our products or product candidates over alternative treatments;
- relative convenience and ease of administration of our products or product candidates compared to existing treatments;
- any labeling restrictions placed upon each product or product candidate in connection with its approval;
- the prevalence and severity of the adverse side effects of each of our products or product candidates;
- the clinical indications for which each of our products or product candidates are approved, including any potential additional restrictions placed upon each product or product candidate in connection with its approval;
- prevalence of the disease or condition for which each product or product candidate is approved;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which each product or product candidate is approved for inclusion on formularies of hospitals and managed care organizations;
- any negative publicity related to our or our competitors' products or product candidates, including as a result of any related adverse side effects;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness; and
- the availability of adequate reimbursement by third parties.

If our product candidates do not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenues from these products or product candidates to become or remain profitable on a timely basis, if at all.

Final marketing approval of any of our product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

Our business depends on the successful development and commercialization of our products and product candidates. We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources. We cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any.

The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and effectiveness. The FDA could refuse to file or approve our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and effectiveness. The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA:

- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of any of our product candidates for any indication;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the supply of the active pharmaceutical ingredient, or API, used in our product candidates;
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Our trials may fail to demonstrate acceptable levels of safety, efficacy or any other requirements of our product candidates, which could prevent or significantly delay regulatory approval.

We may be unable to sufficiently demonstrate the safety and efficacy of our product candidates to obtain regulatory approval. We must demonstrate with substantial evidence gathered in well-controlled studies, and to the satisfaction of the FDA with respect to approval in the United States (and to the satisfaction of similar regulatory authorities in other jurisdictions with respect to approval in those jurisdictions), that each product candidate is safe and effective for use in the target indication. The FDA may require us to conduct or perform additional studies or trials to adequately demonstrate safety and efficacy, which could prevent or significantly delay our receipt of regulatory approval and, ultimately, the commercialization of that product candidate.

In addition, the results from the trials that we have completed for our product candidates may not be replicated in future trials, or we may be unable to demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our product candidates. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced development, even after promising results in earlier trials. If our product candidates are not shown to be safe and effective, our clinical development programs could be delayed or might be terminated.

Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Undesirable side effects caused by any of our product (candidates) could cause us or regulatory authorities to interrupt, delay or halt development and could result in the denial of regulatory approval by the FDA or other regulatory authorities, and potential products liability claims. Any undesirable side effects that are caused by any of our product candidates could have a material adverse effect upon that product candidate's development program and our business as a whole.

In addition, if any of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by the product candidate, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of the product candidate or otherwise require us to take the approved product off the market;
- regulatory authorities may require additional warnings, or a narrowing of the indication, on the product label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to modify the product in some way;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of approved products may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining the commercial success of our products and product candidates and could substantially increase commercialization costs.

Delays or failures in the completion of testing of our product candidates would increase our costs and delay or limit our ability to generate revenues.

Delays or failures in the completion of clinical trials for our product candidates could significantly raise our product development costs. We do not know whether current or planned trials will be completed on schedule, if at all. The commencement and completion of clinical development can be delayed or halted for a number of reasons, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- insufficient or inadequate supply or quantity of a product candidate for use in trials;
- difficulties obtaining institutional review board or ethics committee approval to conduct a trial at a prospective site;
- challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other programs for the treatment of similar conditions;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- difficulty retaining patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues; and
- clinical holds imposed by the FDA.

Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, clinical trials may be suspended or terminated by us, an institutional review board or ethics committee overseeing the clinical trial at a trial site (with respect to that site), the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols;
- observations during inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities that ultimately result in the imposition of a clinical hold;
- unforeseen safety issues; or
- lack of adequate funding to continue the trial.

In addition, failure to conduct the clinical trial in accordance with regulatory requirements or the trial protocols may also result in the inability to use the data to support product approval. Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If we experience delays in completion of, or if we terminate any of our clinical trials, our ability to obtain regulatory approval for our product candidates may be materially harmed, and our commercial prospects and ability to generate product revenues will be diminished.

We expect intense competition and, if our competitors develop or market alternatives for treatments of our target indications, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products and product candidates, including large pharmaceutical companies, smaller pharmaceutical companies, biotechnology companies, academic institutions, government agencies and private and public research institutions. The availability of competing products will limit the demand and the price we are able to charge for any of our products or product candidates that are commercialized unless we are able to differentiate them. We anticipate that we will face intense competition when/if our product candidates are approved by regulatory authorities and we begin the commercialization process for our products.

In addition to already marketed competing products, we believe certain companies are developing other products which could compete with our product candidates should they be approved by regulatory authorities. Further, new developments, including the development of other drug technologies, may render our product candidates obsolete or noncompetitive. As a result, our product candidates may become obsolete before we recover expenses incurred in connection with their development or realize revenues from any commercialized product.

Further, many competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and technology;
- drug development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop drugs that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively with the products of our competitors or if such competitors are successful in developing products that compete with any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated at competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment.

Our products and our product candidates, if they receive regulatory approval, may be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Our product candidates would also be, and our approved product and our collaborators' approved products are, subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices (cGMP) regulations. If we, our collaborators or a regulatory authority discovers previously unknown problems with a product, such as side effects of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we or our collaborators, or our or our collaborators' approved products or product candidates, or the manufacturing facilities for our or our collaborators' approved products or product candidates fail to comply with applicable regulatory requirements, a regulatory authority may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing bioequivalence and/or clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements, or suspension of production; or
- seize or detain products or require us to initiate a product recall.

In addition, our product labeling, advertising and promotion of our product candidates upon FDA approval, will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. Physicians may nevertheless prescribe our products and, upon receiving FDA approval, our product candidates to their patients in a manner that is inconsistent with the approved label. The FDA and other authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we are found to have promoted off-label uses, we may be enjoined from such off-label promotion and become subject to significant liability, which would have an adverse effect on our reputation, business and revenues, if any.

If we fail to produce our products and product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our products and product candidates.

We do not currently own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations for clinical materials or commercial products in the foreseeable future. We currently depend on third-party contract manufacturers for the supply of our product candidates, including drug substance for our preclinical research and clinical trials. Any future curtailment in the availability of raw materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Pharmaceutical companies often encounter difficulties in manufacturing, particularly in scaling up production of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our products and product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our bioequivalence and/or clinical trials, increase the costs associated with conducting our bioequivalence and/or clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial.

Manufacturers of pharmaceutical products need to comply with cGMP requirements enforced by the FDA through their facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products and product candidates may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for such product candidate or successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical developments, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our product candidates.

We intend to rely on third-party collaborators to market and commercialize our product candidates, who may fail to effectively commercialize our product candidates.

We currently plan to utilize strategic partners or contract sales forces, where appropriate, to assist in the commercialization of our product candidates, if approved. We currently possess limited resources and may not be successful in establishing collaborations or co-promotion arrangements on acceptable terms, if at all. We also face competition in our search for collaborators and co-promoters. By entering into strategic collaborations or similar arrangements, we will rely on third parties for financial resources and for development, commercialization, sales and marketing and regulatory expertise. Our collaborators may fail to develop or effectively commercialize our product candidates because they cannot obtain the necessary regulatory approvals, they lack adequate financial or other resources, or they decide to focus on other initiatives. Any failure of our third-party collaborators to successfully market and commercialize our product candidates outside of the United States would diminish our revenues and harm our results of operations.

Limitations on our patent rights relating to our product candidates may limit our ability to prevent third parties from competing against us.

Our success will depend on our ability to obtain and maintain patent protection for our proprietary technologies and our product candidates, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. To that end, we seek patent protection in the United States and internationally for our product candidates. Our policy is to actively seek to protect our proprietary position by, among other things, filing patent applications in the United States and abroad (including Europe, Canada and certain other countries when appropriate) relating to proprietary technologies that are important to the development of our business.

The strength of patents in the pharmaceutical industry involves complex legal and scientific questions and can be uncertain. Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we were the first to conceive inventions covered by our patents and pending patent applications or that we were the first to file patent applications for such inventions. In addition, we cannot be certain that our patent applications will be granted, that any issued patents will adequately protect our intellectual property or that such patents will not be challenged, narrowed, invalidated or circumvented.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. Any failure to adequately prevent disclosure of our trade secrets and other proprietary information could have a material adverse impact on our business.

In addition, the laws of certain foreign countries do not protect proprietary rights to the same extent or in the same manner as the United States, and therefore, we may encounter problems in protecting and defending our intellectual property in certain foreign jurisdictions.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell their approved products and our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the pharmaceutical industry expands and more patents are issued, the risk increases that our collaborators' approved products and our product candidates may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware, that may be infringed by our product candidates, which could prevent us from being able to commercialize any of our product candidates. Because patent applications can take many years to issue, there may be currently pending applications which may later result in issued patents that our collaborators' approved products or our product candidates may infringe.

We may be exposed to, or threatened with, future litigation by third parties alleging that our collaborators' approved products or our products or product candidates infringe their intellectual property rights. If one of our collaborators' approved products or our products or product candidates is found to infringe the intellectual property rights of a third party, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize the applicable approved products and product candidates unless we obtain a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our approved products, pending a trial on the merits, which may not occur for several years.

There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. If a third-party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling any product candidate approved in the future, if any;
- if a license is available from a third party, we may have to pay substantial royalties, fees or grant cross-licenses to our intellectual property rights; and
- redesigning any of our product candidates so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent application at risk of not issuing.

Interference proceedings brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceeding or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. There can be no assurance that our product candidate will not be subject to same risks.

We rely and will continue to rely on outsourcing arrangements for certain of our activities, including clinical research of our product candidates and manufacturing of our compounds and product candidates.

We rely on outsourcing arrangements for some of our activities, including manufacturing, preclinical and clinical research, data collection and analysis. We may have limited control over these third parties and we cannot guarantee that they will perform their obligations in an effective and timely manner. Our reliance on third parties, including third-party CROs and CMOs entails risks including, but not limited to:

- non-compliance by third parties with regulatory and quality control standards;
- sanctions imposed by regulatory authorities if compounds supplied or manufactured by a third-party supplier or manufacturer fail to comply with applicable regulatory standards;
- the possible breach of the agreements by the CROs or CMOs because of factors beyond our control or the insolvency of any of these third parties or other financial difficulties, labor unrest, natural disasters or other factors adversely affecting their ability to conduct their business; and
- termination or non-renewal of an agreement by the third parties, at a time that is costly or inconvenient for us, because of our breach of the manufacturing agreement or based on their own business priorities.

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations for clinical materials or commercial products in the foreseeable future. We currently depend on third-party CMOs for all of our required raw materials and drug substance for our preclinical research and clinical trials. If any of these vendors are unable to perform its obligations to us, including due to violations of the FDA's requirements, our ability to meet regulatory requirements or projected timelines and necessary quality standards for successful manufacture of the various required lots of material for our development and commercialization efforts would be adversely affected. Further, if we were required to change vendors, it could result in delays in our regulatory approval efforts and significantly increase our costs. Accordingly, the loss of any of our current or future third-party manufacturers or suppliers could have a material adverse effect on our business, results of operations, financial condition and prospects.

We do not have contractual relationships for the manufacture of commercial supplies of all of our product candidates. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture drug substance and final drug product on a commercial scale is limited. Therefore, we may not be able to enter into such arrangements with third-party manufacturers in a timely manner, on acceptable terms or at all. Failure to secure such contractual arrangements would harm the commercial prospects for our product candidates, our costs could increase and our ability to generate revenues could be delayed.

Even if our product candidates receive regulatory approval in the United States, we or our collaborators may never receive approval to commercialize our product candidates outside of the United States.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. In territories where data is not freely available, we may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds.

In addition, regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that any of our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on their commercial potential or require costly post-marketing studies.

Guidelines and recommendations published by various organizations can reduce the use of our products and product candidates.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products and product candidates. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or product candidates or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our products or product candidates.

We are subject to uncertainty relating to payment or reimbursement policies which, if not favorable for our products or product candidates, could hinder or prevent our commercial success.

Our ability or our collaborators' ability to successfully commercialize our product candidates, will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers, managed care organizations and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. Government authorities and these third-party payors have attempted to control costs, in some instances, by limiting coverage and the amount of reimbursement for particular medications or encouraging the use of lower-cost generic AEDs. We cannot be sure that reimbursement will be available for any of the products that we develop and, if reimbursement is available, the level of reimbursement. Reduced or partial payment or reimbursement coverage could make our product candidates, less attractive to patients and prescribing physicians. We also may be required to sell our products or product candidates at a discount, which would adversely affect our ability to realize an appropriate return on our investment in our products or product candidates or compete on price.

We expect that private insurers and managed care organizations will consider the efficacy, cost effectiveness and safety of our product candidates, in determining whether to approve reimbursement for such products or product candidates and at what level. Because each third-party payor individually approves payment or reimbursement, obtaining these approvals can be a time consuming and expensive process that could require us to provide scientific or clinical support for the use of each of our products or product candidates separately to each third-party payor. In some cases, it could take several months or years before a particular private insurer or managed care organization reviews a particular product, and we may ultimately be unsuccessful in obtaining coverage. Our competitors generally have larger organizations, as well as existing business relationships with third-party payors relating to their products. Our business would be materially adversely affected if we do not receive approval for reimbursement of our products or product candidates from private insurers on a timely or satisfactory basis. Our products and product candidates, may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products or product candidates on a profitable basis. Our business would also be adversely affected if private insurers, managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which our products or product candidates will be reimbursed to a smaller set than we believe they are effective in treating.

In addition, many managed care organizations negotiate the price of products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. If our products or product candidates are not included within an adequate number of formularies or adequate payment or reimbursement levels are not provided, or if those policies increasingly favor generic products, our market share and gross margins could be negatively affected, which would have a material adverse effect on our overall business and financial condition.

We expect to experience pricing pressures due to the potential healthcare reforms discussed elsewhere in this prospectus,

as well as the trend toward programs aimed at reducing health care costs, the increasing influence of health maintenance organizations and additional legislative proposals.

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liabilities.

The use of our product candidates in clinical trials and the sale of any of our products will expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our products and product candidates. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, product liability claims may result in:

- decreased demand for any product or product candidate that has received approval and is being commercialized;
- impairment of our business reputation and exposure to adverse publicity;
- withdrawal of bioequivalence and/or clinical trial participants;
- initiation of investigations by regulators;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize any of our product candidates for which we obtain marketing approval.

Insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. We intend to expand our insurance coverage to include the sale of commercial products prior to the commercialization of our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim, or series of claims brought against us, could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our failure to successfully develop and market product candidates would impair our ability to grow.

As part of our growth strategy, we intend to develop and market product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Healthcare reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce healthcare costs may adversely affect our ability to set prices for any approved product candidate which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

In both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals and initiatives to change the health care system in ways that could affect our ability to sell any approved product profitably.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We will need to manage our anticipated growth and increased operational activity. Our personnel, systems and facilities currently in place will not be adequate to support this future growth. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth. Our need to effectively execute our growth strategy requires that we:

- manage our regulatory approvals and clinical trials effectively;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities;
- commercialize our product candidates;
- improve our operational, financial and management controls, reporting systems and procedures; and
- attract and motivate sufficient numbers of talented employees.

This future growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy.

We may not be able to manage our business effectively if we are unable to attract and motivate key members or if we lose key members of our current management team.

We may not be able to attract or motivate qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our objectives.

We are highly dependent on the development, regulatory, commercial and financial expertise of our management. We do not have any employment agreements with any member of our management team except Mr. Grunewald. If we lose key members of our management team, we may not be able to find suitable replacements in a timely fashion, if at all. We cannot be certain that future management transitions will not disrupt our operations and generate concern among employees and those with whom we do business.

We also have scientific and clinical advisors who assist us in formulating our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the PPACA requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- the FDCA, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations could be costly. If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

We employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors and, as such, we may be subject to claims that we or these employees have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. For example, the loss of data from completed or ongoing bioequivalence and/or clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. We have in the past been required to change a proposed product name. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to Our Finances and Capital Requirements

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

In recent years, we have focused primarily on developing our current product candidates, with the goal of commercializing these products and supporting regulatory approval for these product candidates. We have financed our operations primarily through private placements of convertible securities, our collaboration and license arrangements, and the monetization of certain future royalty streams under our existing licenses. We have incurred significant operating losses since our inception. We incurred net losses of approximately $6.5 million for the year ended December 31, 2017, and $16.8 million and $8.0 million, in the years ended December 31, 2016 and 2015, respectively. As of December 31, 2017, we had an accumulated deficit of approximately $41.5 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs and from selling, general and administrative and interest costs associated with our operations. We expect our research and development costs to continue to be substantial and to increase with respect to our product candidates as we advance those product candidates through preclinical studies, clinical trials, manufacturing scale-up and other pre-approval activities. We expect to incur significant and increasing marketing and selling costs prior to and during the commercial launch of our current products. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when, or if, we will become profitable.

Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. In this regard, the report of our independent registered public accounting firm with respect to our consolidated financial statements as of and for the year ended December 31, 2017 contains an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern. In addition, we will need to obtain additional funds to develop and commercialize our other product candidates. The inclusion of a going concern statement by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

We will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing product candidates, conducting clinical trials, establishing manufacturing relationships and marketing drugs are expensive and uncertain processes. We will need to obtain additional capital through equity offerings, debt financing, payments under new or existing licensing and research and development collaboration agreements, or any combination thereof, in order to become cash flow positive and to develop and commercialize additional product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs, which may have a material adverse effect on our business, results of operations and financial condition.

In addition, unforeseen circumstances may arise, or our strategic imperatives could change, causing us to consume capital significantly faster than we currently anticipate, requiring us to seek to raise additional funds sooner than expected. We have no committed external sources of funds.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our trials and other product development programs for our product candidates;
- the costs and timing of in-licensing additional product candidates or acquiring other complementary companies;
- the timing of any regulatory approvals of our product candidates;
- our ability to successfully launch our products and to continue to increase the level of sales in the marketplace;
- the actions of our competitors and their success in selling competitive product offerings;
- the costs of establishing sales, marketing, manufacturing and distribution capabilities for our products; and
- the status, terms and timing of any collaborative, licensing, co-promotion or other arrangements.

Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

We have never generated any revenues from our own sales of our products, and we may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate revenues from sales of our products and our product candidates. To date, we have not generated any revenues from our sales of our product candidates and have incurred significant operating losses. Our ability to generate product revenues is dependent on our ability to receive regulatory approval of our product candidates, and to successfully commercialize these products. Our ability to successfully commercialize our products depends on, among other things:

- our successful completion of clinical trials for our product candidates; and
- our obtaining regulatory approvals for our product candidates.

After our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercialization. It is possible that we will never have sufficient product sales revenues to achieve profitability.

Our operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly and annual fluctuations. Prior to commercializing any of our product candidates, we expect that any revenues we generate (if any) will fluctuate from quarter to quarter and year to year as a result of the timing and amount of development milestones and royalty revenues received under our collaboration license agreements, as our revenues from these arrangements are principally based on the achievement of clinical and commercial milestones outside of our control.

Once we commercialize one or more of our products, our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- any delays in regulatory review and approval of product candidates in clinical development;
- potential side effects of our future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- any intellectual property infringement lawsuit in which we may become involved;
- our ability to establish an effective sales and marketing infrastructure;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- competition from existing products or new products that may emerge;
- regulatory developments affecting our products and product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- the level of market acceptance for any approved product candidates and underlying demand for that product and buying patterns.

Due to the various factors mentioned above, and others, the results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We have limited experience operating as a public company and complying with public company obligations. Complying with these requirements has increased our costs and requires additional management resources, and we still may fail to meet all of these obligations.

We face increased legal, accounting, administrative and other costs and expenses as a public company. Compliance with the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act of 2010, as well as rules of the Securities and Exchange Commission and OTCQB, for example, has resulted in significant cost to us as well as ongoing increases in our legal, audit and financial compliance costs. The Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition. Our board of directors, management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and require us to incur substantial costs to maintain the same or similar coverage.

As a public company, we are subject to Section 404 of the Sarbanes-Oxley Act relating to internal controls over financial reporting and we expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. We cannot assure you that our internal controls over financial reporting will prove to be effective.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. If we continue to fail to maintain the adequacy of our internal accounting controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an on–going basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes–Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could cause us to face regulatory action and also cause investors to lose confidence in our reported financial information, either of which could have a material adverse effect on our business, financial condition, results of operations and future prospects.

Our ability to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code, and may be subject to further limitation as a result of the transactions contemplated by this offering.

Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, contain rules that limit the ability of a company that undergoes an ownership change, which is generally any change in ownership of more than 50% of its stock over a three-year period, to utilize its net operating loss and tax credit carryforwards and certain built-in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5% or more of the stock of a company and any change in ownership arising from a new issuance of stock by the company. Generally, if an ownership change occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built-in losses is equal to the product of the applicable long-term tax exempt rate and the value of the company's stock immediately before the ownership change. We may be unable to offset our taxable income with losses, or our tax liability with credits, before such losses and credits expire and therefore would incur larger federal income tax liability.

In addition, it is possible that future transactions, including issuances of new shares of our common stock, will cause us to undergo one or more additional ownership changes. In that event, we generally would not be able to use our pre-change loss or credit carryovers or certain built-in losses prior to such ownership change to offset future taxable income in excess of the annual limitations imposed by Sections 382 and 383 and those attributes already subject to limitations as a result of our prior ownership changes may be subject to more stringent limitations. As of December 31, 2017, we had approximately $40 million of federal net operating loss carryforwards. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. Our ability to utilize the aforementioned carryforwards and tax credits may be limited. As a result, we may not be able to take full advantage of these carryforwards or tax credits for federal and state tax purposes.

Risks Related to Our Indebtedness

Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.

In order to fund operations we have periodically borrowed money. These debts may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- we may have difficulty obtaining financing in the future for working capital, capital expenditures, acquisitions or other purposes; and

- our failure to comply with the restrictive covenants in our loan and security agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and the lenders could seek to enforce their security interests in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above would increase. .

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

Since our inception, we have generated minimal revenue from product sales and have incurred significant operating losses. As of December 31, 2017, we had an accumulated deficit of $41,539,533. We expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to develop and seek marketing approval for our product candidates, and expand our sales channels for Venodol. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations would be significantly limited, and we may be required to delay, significantly curtail or eliminate one or more of our programs.

Failure to satisfy our current and future debt obligations under our secured credit facility could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under our secured credit facility as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in the collateral securing such indebtedness.

Risks Related to Securities Markets and Investment in Our Stock

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit your ability to influence certain corporate matters.

Our directors and their affiliated entities, and our executive officers will beneficially own, in the aggregate, approximately 48.9% of our outstanding common stock. As a result, these stockholders are collectively able to significantly influence or control all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets. The concentration of ownership may delay, prevent or deter a change in control of our Company even when such a change may be in the best interests of some stockholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our Company or our assets and might adversely affect the prevailing market price of our common stock.

The price of our common stock may fluctuate substantially.

The market price for our common stock is likely to be volatile, in part because our common stock has been previously traded publicly for only a short time. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, including:

- the commercial performance of any of our product candidates that receive marketing approval;
- plans for, progress in and results from clinical trials of our product candidates generally;
- FDA or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- variations in our quarterly operating results;
- changes in accounting principles;
- litigation or public concern about the safety of our potential products;
- actual and anticipated fluctuations in our quarterly operating results;
- additions or departures of key personnel;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders; and
- discussion of us or our stock price in the financial or scientific press or in online investor communities.

The realization of any of the risks described in these "Risk Factors" could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility. Any such litigation brought against us could result in substantial costs and a diversion of management attention, which could hurt our business, operating results and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide this information.

ITEM 2. PROPERTIES.

Through December 15, 2016 our principal office space was located at 6750 Westown Parkway, Suite 200-226, West Des Moines, Iowa 50266. On December 15, 2016, we entered into a commercial sublease (the "Sublease") with K-4 Enterprises, LLC (an entity which is fifty percent owned by the President, Chief Operating, Chief Executive Officer and Chairman of the Board of the Company), and relocated our principal office to 11147 Aurora Avenue, Aurora Business Park, Building 3, Urbandale, Iowa 50322. Sublease is for a term of five years, and automatically continues on a year-to-year basis thereafter, unless terminated in accordance with the provisions thereof. Monthly rent is $1,314, which increases by 2% annually, plus a proportionate share of expenses, which will initially be $800 per month.

ITEM 3. LEGAL PROCEEDINGS.

Management is not aware of any legal proceedings contemplated by any governmental authority or any other party involving us or our properties. As of the date of this Form 10-K, no director, officer or affiliate is (i) a party adverse to us in any legal proceeding, or (ii) has an adverse interest to us in any legal proceedings. Management is not aware of any other legal proceedings pending or that have been threatened against us or our properties.

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

Market For Common Equity

Shares of our common stock commenced trading on the OTC Bulletin Board under the symbol "AEXP" in December 2008, and in December 2013 our symbol changed to "STLT." Shares of our common stock are currently trading on the OTCQB. The market for our common stock is limited and can be volatile. The following table sets forth the high and low bid prices relating to our common stock on a quarterly basis for the periods indicated as quoted by the OTCQB market. These quotations reflect inter-dealer prices without retail mark-up, mark-down, or commissions, and may not reflect actual transactions.

Quarter Ended	High Bid	Low Bid
December 31, 2017	$ 0.25	$ 0.08
September 30, 2017	$ 0.25	$ 0.08
June 30, 2017	$ 0.42	$ 0.11
March 31, 2017	$ 0.74	$ 0.33
December 31, 2016	$ 1.48	$ 0.49
September 30, 2016	$ 0.93	$ 0.35
June 30, 2016	$ 0.62	$ 0.34
March 31, 2016	$ 0.94	$ 0.55

As of April 17, 2018, we had 97 shareholders of record, which does not include shareholders whose shares are held in street or nominee names.

Dividends

No dividends have ever been declared by the Board of Directors on our common stock. Our losses do not currently indicate the ability to pay any cash dividends, and we do not have the intention of paying cash dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

During the year ended December 31, 2017, the Company issued the following securities:

- On January 4, 2017, the Company issued 127,714 shares of common stock in settlement of stock payable with a fair value of $50,000.
- On May 05, 2017, the Company issued 5,641,218 shares of common stock in settlement of stock payable with a fair value of $3,876,973.
- On October 4, 2017, the Company issued 1,143,091 shares of common stock in settlement of a stock payable with a fair value of $400,082.
- In the months indicated below the Company issued a total of 1,708,750 shares of common stock for employee services in lieu of cash compensation in 2017. The table below details the issuances:

	Shares issued	Fair value at issue date
January	1,360,000	$ 884,000
April	136,250	48,450
September	106,250	14,864
December	106,250	13,813
Total	**1,708,750**	**$ 961,127**

- The Company issued 100,000 shares of common stock for vendor services in accordance with a vendor agreement. The fair value of the common stock at issuance was $50,000 and has been recorded as a legal expense.
- During the year ended December 31, 2017, the Company issued warrants to purchase 662,245 shares of common stock. These warrants were issued in connection with the Company's private placement conducted during the year ended December 31, 2017. These warrants have an exercise price equal to the closing price of the common stock of the Company on the six-month issuance thereof.

A summary of the warrant activity for the years ended December 31, 2017 and 2016 is presented below:

	Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2016	5,826,271	$ 1.19
Granted	1,162,245	1.08
Exercised	-	-
Expired/forfeited	(836,671)	1.27
Outstanding December 31, 2017	6,151,845	$ 1.16
Exercisable December 31, 2017	6,151,845	$ 1.16

The sale and issuance of the securities described above were exempt from registration under the Securities Act of 1933, as amended, by virtue of section 4(2) and Rule 506 promulgated under Regulation D.

ITEM 6. SELECTED FINANCIAL DATA.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide this information.

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

The following discussion should be read in conjunction with our audited financial statements and the related notes that appear elsewhere in this Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to those discussed below and elsewhere in this Annual Report, particularly in the section entitled "Risk Factors." Our audited financial statements are stated in United States Dollars and are prepared in accordance with United States Generally Accepted Accounting Principles.

Overview

We are a pharmaceutical company focused on acquiring the intellectual property rights to innovative and proprietary therapeutics designed to address unmet medical needs, with an emphasis on rare, emerging, or neglected diseases. To find and evaluate unique opportunities, we leverage our extensive relationships with leading scientists, academic institutions and other sources. We provide value-added development capability to accelerate progress. When scientifically significant benchmarks have been achieved, we will endeavor to partner with proven market leaders via sale, out-license or strategic alliances.

Generally, we have financed operations to date through the proceeds of the private placement of equity and debt instruments. Management anticipates additional increases in operating expenses and capital expenditures relating to retention of additional personnel, and advancement of our technologies. We anticipate that we will finance these expenses with further issuances of equity securities and debt issuances. During the year ended December 31, 2017, the Company raised $2,207,482 of which $890,000 was raised prior to the April 18, 2017 amendment and expansion of the subscription agreement from a maximum aggregate $2,500,000 to a maximum aggregate $11,500,000 with $1,317,482 raised under the amended and expanded subscription agreement. in convertible debt proceeds. Additional issuances of equity or convertible debt securities could result in dilution to our current shareholders. Further, such securities may have rights, preferences or privileges senior to our common stock. Additional financing may not be available upon acceptable terms, or at all.

Plan of Operations

As of December 31, 2017, the Company had four subsidiaries: Celtic Biotech Iowa, Inc., Caretta Therapeutics, LLC, SMA Therapeutics, LLC, and Zika Therapeutics, LLC.

Cancer

On June 4, 2014, Celtic Biotech Iowa, Inc. (hereinafter "Celtic Iowa," a subsidiary of the Company) acquired Celtic Biotech Limited (hereinafter "CBL"). CBL was founded in 2003 in Dublin, Ireland and is developing novel and highly specialized compounds derived from snake venom, for the treatment of solid cancers and cancer imaging.

Pain Management

Caretta Therapeutics, LLC ("Caretta") was formed in August 2016 to develop and commercialize over-the-counter chronic pain relief products. Caretta holds a license agreement to develop, manufacture and sell certain products derived from cobra venom that may have analgesic properties.

Spinal Muscular Atrophy

In October 2016, the Company entered into an Exclusive License Agreement with Indiana University Research and Technology Corporation to commercialize STL-182, an orally-available small molecule that may have therapeutic potential for treating spinal muscular atrophy. Spinal muscular atrophy is an autosomal recessive disorder that is a leading genetic cause of death in infants and toddlers. Synthesis and early preclinical testing of STL-182 was accomplished through a research collaboration between Professors Elliot Androphy of Indiana University School of Medicine, and Kevin Hodgetts, director of the Laboratory for Drug Discovery in Neurodegeneration at Brigham and Women's Hospital. Their work was supported in part by the National Institute of Neurological Disorders and Stroke and the National Institute of Child Health and Human Development. Professor Androphy and Professor Hodgetts are members of the Company's Scientific Advisory Board.

On June 21, 2017, the Company entered into a Sponsored Research Agreement with The Brigham and Women's Hospital Inc. ("BWH") to support research directed by BWH professor Kevin Hodgetts aimed at developing safe and effective drugs to treat patients with spinal muscular atrophy.

On August 14, 2017, the Company entered into a Sponsored Research Agreement with The Trustees of Indiana University ("IU") to support research directed by IU professor Dr. Elliot Androphy aimed at developing safe and effective drugs to treat patients with spinal muscular atrophy.

Spinal muscular atrophy affects between 1 in 6,000 and 1 in 10,000 newborns. Approximately 1 in 40 to 1 in 50 adults have only a single intact spinal motor neuron 1 (SMN1) gene, which encodes a protein (SMN) required for proper neuromuscular function. An infant who inherits no intact SMN1 gene from either parent may develop spinal muscular atrophy and lose the ability to sit, stand, walk, swallow, and/or breathe. In about 60% of cases, patients with spinal muscular atrophy die by age two. Even in spinal muscular atrophy patients, low levels of functional spinal muscular atrophy protein are produced by an SMN1-related gene called SMN2. One therapeutic strategy to treat spinal muscular atrophy is to increase levels of functional SMN protein encoded by SMN2. In mouse models of spinal muscular atrophy, STL-182 may restore neuromuscular function by stabilizing endogenous SMN protein.

The Company has engaged a top-tier contract research organization (CRO) to conduct additional preclinical mouse studies of STL-182. These studies are ongoing and are expected to continue throughout 2018.

Zika Virus Infection

In August 2016, the Company entered into a sponsored research agreement with Florida State University ("FSU") to support research directed by FSU Professor Hengli Tang aimed at developing safe and effective drugs to treat patients infected with the Zika virus (ZIKV). Prof. Tang is a member of the Company's Scientific Advisory Board.

In November 2016, the Company obtained from the Florida State University Research Foundation ("FSURF") exclusive, worldwide rights to develop and commercialize certain compounds for the treatment of viral infections, including Zika virus infection. Included among the licensed compounds are those identified in a study co-authored by Prof. Tang that was published in *Nature Medicine.*

In January 2017, the Company entered into a second license agreement with FSURF for the development and commercialization of additional anti-Zika virus compounds. As with the initial license agreement, this agreement grants the Company exclusive, worldwide rights to develop and commercialize certain compounds for the treatment of viral infections, including Zika virus infection.

Critical Accounting Policies

The following describes the critical accounting policies used in reporting our financial condition and results of operations. In some cases, accounting standards allow more than one alternative accounting method for reporting. In those cases, our reported results of operations would be different should we employ an alternative accounting method.

The significant accounting policies and bases of presentation for our consolidated financial statements are described in Note 2 "Summary of Significant Accounting Policies." The preparation of our financial statements in accordance with U.S. generally accepted accounting principles (GAAP) requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

We believe the following accounting policies and estimates to be critical:

Investment in SOLX

The Company has a net 7% interest in SOLX, a private company that develops innovative surgical technologies to treat refractory glaucoma and preserve vision. On September 30, 2017, the U.S. Food and Drug Administration denied approval of the application for the SOLX glaucoma treatment. With this development, the Company has determined that the note receivable is fully impaired and wrote off such investment.

In-Process Research and Development

In-process research and development ("IPR&D") represents the estimated fair value assigned to research and development projects acquired in a purchased business combination that have not been completed at the date of acquisition and which have no alternative future use. IPR&D assets acquired in a business combination are capitalized as indefinite-lived intangible assets. These assets remain indefinite-lived until the completion or abandonment of the associated research and development efforts. During the periods prior to completion or abandonment, those acquired indefinite-lived assets are not amortized but are tested for impairment annually, or more frequently, if events or changes in circumstances indicate that the asset might be impaired. During periods after completion, those acquired indefinite-lived assets are amortized based on their useful life. The fair value of the assets acquired was $6,977,347. These assets are still subject to research and development completion and accordingly, no amortization has been recorded.

Impairment of Long-Lived Assets and Intangibles

The Company performs impairment tests on its long-lived assets when circumstances indicate that their carrying amounts may not be recoverable. If required, recoverability is tested by comparing the estimated future undiscounted cash flows of the asset or asset group to its carrying value. If the carrying value is not recoverable, the asset or asset group is written down to fair value. For the year ended December 31, 2017, the Company has evaluated and recorded no impairment to the Company's intangible assets.

Stock-Based Compensation

The Company measures the cost of employee services received in exchange for stock and stock options based on the grant date fair value of the awards. The Company determines the fair value of stock option grants using the Black-Scholes option pricing model. The Company determines the fair value of shares of non-vested stock (also commonly referred to as restricted stock) based on the last quoted price of our stock on the date of the share grant. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. As share-based compensation expense is recognized based on awards ultimately expected to vest, the Company reduces the expense for estimated forfeitures based on historical forfeiture rates, if historical forfeiture rates are available. Previously recognized compensation costs may be adjusted to reflect the actual forfeiture rate for the entire award at the end of the vesting period. Excess tax benefits, if any, are recognized as an addition to paid-in capital.

Results of Operations

Fiscal Year Ended December 31, 2017 Compared to Fiscal Year Ended December 31, 2016

For fiscal year ended December 31, 2017, our loss from continuing operations was $6,493,649, compared to a loss from continuing operations of $16,872,110 for the fiscal year ended December 31, 2016, a decrease of $10,378,461.

For fiscal year ended December 31, 2017, there was no gain from discontinued operations, compared to a gain from discontinued operations of $53,106 for the fiscal year ended December 31, 2016.

During fiscal year ended December 31, 2017, we generated $2,226 of revenue as compared to zero revenues for the year ended December 31, 2016. Operating expenses decreased by $2,163,726 in 2017 as compared to 2016, interest expense decreased by $8,061,988 due to the termination of debt agreements and conversion of debt during the year ended December 31, 2016, as the Company continues to improve our capitalization structure with the conversion debt instruments into common stock.

General and administrative expenses decreased by $2,673,216 from $6,432,389 to $3,759,173 for the years ended December 31, 2016 and December 31, 2017, respectively. Share based compensation decreased by $2,340,243 from $3,346,643 to $1,006,400 for the years ended December 31, 2016 and December 31, 2017, respectively.

Operating Activities

Cash flow from operations – continuing operations. Net cash used in operating activities from continuing operations was $3,552,560 for the year ended December 31, 2017, compared to $2,947,010 for the year ended December 31, 2016. Net cash used in operating activities for the year ended December 31, 2017 was derived from our net loss, which included stock-based compensation of $1,006,400, amortization of debt discount of $873,093, impairment of note receivable of $1,116,075. Our net loss from continuing operations for the year ended December 31, 2017 included a loss on debt extinguishment of $0, compared to a loss of $3,134,507 for the year ended December 31, 2016.

Cash flow from operations – discontinued operations. Net cash used in operating activities from discontinued operations was $0 for the year ended December 31, 2017, compared to net cash used by operations of $179,353 for the year ended December 31, 2016.

Investing Activities

Cash flow from investing activities – continuing operations. Our investing activities from continuing operations used cash of $57,156 during the year ended December 31, 2017, primarily as a result of additional purchases from the SOLX note in the amount of $56,382, required as part of the note agreement and purchase of property and equipment of $774. For the year ended December 31, 2016, our investing activities used cash of $616,390, primarily as a result of cash paid for notes receivables of $1,000,000 and purchase of property and equipment of $6,360, offset by proceeds from sale of interest in Caretta, Zika, and SMA of $390,000.

Cash flow from investing activities – discontinued operations. Our investing activities from discontinued operations used cash of $0 for the years ended December 31, 2017 and 2016.

Financing Activities

Cash flow from financing activities – continuing operations. During the year ended December 31, 2017, our financing activities from continuing operations provided cash of $3,339,462, primarily as a result of proceeds from convertible notes $2,207,482, proceeds from related party loans, $1,537,500, proceeds from demand notes $1,777,916 offset by repayments of related party loans of $1,180,136 and repayments of line of credit of $1,003,300. Our financing activities provided cash of $3,813,767 during the year ended December 31, 2016, primarily as a result of proceeds from convertible debentures of $2,932,000, proceeds from a demand note of $1,450,000, proceeds from a line of credit of $115,000, and proceeds from sale of common stock and warrants of $55,140, offset primarily by payments on convertible debt of $738,373.

Cash flow from financing activities – discontinued operations. During the years ended December 31, 2017 and 2016, our financing activities from discontinued operations provided cash of $0.

Liquidity and Capital Resources

We are an early stage company and have generated only minimal revenues to date. We have incurred recurring losses to date. Our financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation.

We expect we will require additional capital to meet our long term operating requirements. We expect to raise additional capital through, among other things, the sale of equity or debt securities, although there is no guarantee we will be able to raise such funds.

Below is a description of the material financing activities of the Company during 2017:

During the year ended December 31, 2017, the Company issued convertible notes in the aggregate principal amount of $890,000 under the Private Placement. During the year ended December 31, 2017, the Company recorded $192,134 and $510,751 of derivative liability and royalty liability, respectively, associated with these convertible notes. In addition, the Company also recorded debt discount related to the relative fair value of the warrants in the amount of $34,755. As of December 31, 2017, the convertible notes converted into shares 2,091,170 of common stock, fair valued at $846,646. The Company also recorded a gain on extinguishment of debt and related derivative liability in the amount of $243,716 and extinguishment on related party debt and derivative liability as contributed capital of $49,251. For the year ended December 31, 2017, the Company recorded an unrealized gain on the change of present value of the royalty liabilities in the amount of $95,674.

Prior to April 18, 2017, the Company conducted a private offering with offering for sale certain convertible notes up to an aggregate of $2,500,000. After April 18, 2017, the Company amended and expanded the private offering to allow for the issuance of up to $11,500,000. Under the amended and expanded offering , the Company conducted a private offering (the "Private Placement 2017"), which bear interest at the rate of 7.5% per annum. The Company issued convertible notes in the aggregate principal amount of $1,317,482. The notes are convertible into shares of common stock of the Company based upon the table below:

			Automatic Conversion Upon Maturity		
Dollar amount of debt	**Number of convertible debentures**	**Holder Optional Conversion**	**Fixed price auto conversion**	**20 consecutive trading days**	**Floor**
$400,000	1*	$0.35	$0.35	None	None
$490,000	9**	90% of closing bid price 20 consecutive days prior to conversion	None	80% of 20 consecutive prior to conversion	None
$475,000	3	90% of closing bid price 20 consecutive days prior to conversion	None	90% of the closing bid price 20 consecutive days prior to conversion and the Floor conversion price	See schedule below
$842,482	12	90% of the closing bid price 20 consecutive days prior to conversion	None	90% of the closing bid price 20 consecutive days prior to conversion and the Floor conversion price	$0.60

* Converted into shares of Common Stock during the year ended December 31, 2017.

** All notes with the exeption of $25,000 have been converted into shares of Common Stock during the year ended December 31, 2017.

Conversion Date (by calendar quarter)	Floor Conversion Price
2017 Q2	$ 0.60
2017 Q3	$ 0.70
2017 Q4	$ 0.85
2018 Q1	$ 1.00
Each Subsequent Quarter	Increase $0.10 per Quarter

The term of the royalty for OTC Roll-On Venodol and OTC Oral Venodol begins October 1, 2018 and ends on December 21, 2023. The royalty term of prescription strength shall be from October 1, 2018 and ending December 31, 2024. Notwithstanding the forgoing, the royalty shall terminate upon the maximum royalty amount as described in the table below:

Investment parameter	Per unit royalty per $100,000 Roll-on	Per unit royalty per $100,000 Oral	Per Unit royalty per $100,000 Prescription	Maximum Royalty Amount
Less than $400,000	$0.00304348	$0.00304348	$0.00347826	8 times
Greater than $400,000	$0.00391304	$0.00391304	$0.00608696	12 times

Twelve investors have royalty agreements which contain the following: The royalty for a particular royalty period shall be calculated as follows: (a) the Royalty Pool accrued for the applicable royalty period, multiplied by (b) the royalty percentage for the applicable royalty period. The term “Royalty Pool” means the aggregate of (i) $.60 for each unit of OTC Roll-On Venodol sold, (ii) $.60 for each unit of OTC Oral Venodol sold, and (iii) $.80 for each unit of Prescription Strength Venodol sold during the relevant royalty period. The number of units sold during the relevant period shall mean the number of individual products sold during such period, less any returns received during such period. For purposes of clarity, multipack products shall count as multiple units based on the number of included units of product (i.e. a bulk package of 6 OTC Roll-On Venodol bottles shall constitute six units).

During the year ended December 31, 2017, under the Private Placement 2017, the Company recorded $7,092 and $1,000,395 of debt discount related to the relative fair value of warrants and royalty liability, respectively, associated with these convertible notes.

The holders of the notes were issued a warrant entitling the holder the right to purchase shares of Spotlight Innovation Common Stock, with a par value of $0.001 equal to thirty per cent (30%) of the value of their original convertible note. The warrant has a three-year (3) term with an exercise price of $1.30 per share. Under the amended and expanded subscription the Company has issued 395,245 warrants to purchase common stock of the Company with a fair value of $7,092.

Letters of Credit

On April 4, 2014, the Company entered into a letter of credit (the “April Letter of Credit”) with Denver Savings Bank in the principal amount of $752,325. The April Letter of Credit provides that the Company can borrow up to the aforementioned principal amount from the Denver Savings Bank until April 1, 2017. Interest accrues at the rate of 4.25% per year. Through December 31, 2016, the Company has drawn down on the full principal amount of the April Letter of Credit. The loan is repayable on demand, but if no demand is made, then quarterly payments of accrued interest calculated on the amount outstanding is due and payable.

On July 29, 2014 the Company entered into a letter of credit (the "July Letter of Credit") with Denver Savings Bank in the principal amount of $250,975. The July Letter of Credit provides that the Company can borrow up to the aforementioned principal amount from the Bank until April 1, 2017. Interest accrues at the rate of 4.25% per year. To date, the Company has drawn down on $250,975 of the July Letter of Credit. The loan is repayable on demand, but if no demand is made, then quarterly payments of accrued interest calculated on the amount outstanding is due and payable.

On July 24, 2017 the Company repaid the two letters of Credit from Denver Savings Bank. The Company secured funds through a loan from a related party (an entity partially owned and controlled by the President, COO and interim CEO of our Company). The $1,500,000 note carries a 4.5% interest rate calculated on a 365-day basis. The note matures on the third anniversary of the execution date. As consideration of entering into the note, the Company paid the lender a $300,000 origination fee.

Purchase of Significant Equipment

We have not previously, nor do we intend to purchase any significant equipment during the next twelve months.

Off-Balance Sheet Arrangements

As of the date of this Annual Report, we do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Going Concern

The independent auditors' report accompanying our December 31, 2017 and 2016 consolidated financial statements contains an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. The financial statements have been prepared "assuming that we will continue as a going concern," which contemplates that we will realize our assets and satisfy our liabilities and commitments in the ordinary course of business. We have suffered recurring losses from operations, have a working capital deficit and are currently in default of the payment terms of certain note agreements. These factors raise substantial doubt about our ability to continue as a going concern.

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

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide this information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the board of directors of
Spotlight Innovation Inc.
Urbandale, Iowa

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Spotlight Innovation Inc. (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations, changes in equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Other matters

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GBH CPAs, PC

We have served as the Company's auditor since 2009.

GBH CPAs, PC
www.gbhcpas.com
Houston, Texas
April 17, 2018

SPOTLIGHT INNOVATION INC.
CONSOLIDATED BALANCE SHEETS
AS OF DECEMBER 31, 2017 AND 2016

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash	$ 66,118	$ 313,333
Inventory	192,726	-
Prepaid expenses	4,012	214,500
Notes receivables	-	1,000,000
Total current assets	262,856	1,527,833
Property and equipment, net	9,033	13,155
In-process research and development	6,977,347	6,977,347
Total assets	$ 7,249,236	$ 8,518,335
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 592,696	$ 395,849
Accounts payable – related parties	337,091	3,560
Accrued liabilities	644,220	699,567
Stock payable	-	3,921,973
Notes payable	171,006	174,769
Line of credit, net of debt discount of $0 and $4,929, respectively	-	998,370
Short-term debt – related party	948,073	290,064
Total current liabilities	2,693,086	6,484,152
Long-term liabilities:		
Notes payable - related party, net of debt discounts of $256,284 and $0, respectively	1,243,716	-
Convertible debentures, net of debt discounts of $675,273 and $0 respectively	332,209	-
Convertible debentures - related party, net of debt discounts of $245,407 and $0, respectively	89,593	-
Derivative liability	13,508	-
Royalty liability	2,128,916	713,442
Total liabilities	6,501,028	7,197,594
Commitments and contingencies		
Equity:		
Series A convertible preferred stock, $0.001 par value, 3,000,000 shares authorized, 0 shares issued and outstanding	-	-
Series C preferred stock, $0.001 par value, 500,000 shares authorized, 0 shares issued and outstanding	-	-
Preferred stock, $0.001 par value, 1,500,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock, $0.001 par value, 4,000,000,000 shares authorized, 34,290,934 and 27,276,054 shares issued and outstanding, respectively	34,291	27,276
Additional paid-in capital	39,949,116	34,035,015
Accumulated deficit	(41,539,553)	(35,369,670)
Total equity (deficit) attributable to Spotlight Innovation Inc.	(1,556,126)	(1,307,379)
Non-controlling interest	2,304,334	2,628,120
Total equity	748,208	1,320,741
Total liabilities and equity	$ 7,249,236	$ 8,518,335

The accompanying notes are an integral part of these consolidated financial statements.

SPOTLIGHT INNOVATION INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Year Ended December 31, 2017	Year Ended December 31, 2016
Revenue	$ 2,226	$ -
Cost of sales	126,721	-
Operating expenses:		
General and administrative	3,759,173	6,432,389
Depreciation expense	4,896	4,726
Research and development expenses	742,118	232,798
Total operating expenses	4,506,187	6,669,913
Loss from operations	(4,630,682)	(6,669,913)
Other income (expense):		
Loss on debt settlement	-	(3,134,507)
Gain on options exchanged for common stock with third parties	-	490,462
Gain on settlement of debt	-	167,824
Gain on extinguishment of debt and related derivative liability	243,716	753,125
Gain/(loss) on change in value of derivative liability	(4,364)	700,026
Gain due to present value change in royalties	95,674	-
Other income	77,192	7,990
Impairment of notes receivable and accrued interest receivable	(1,116,075)	-
Gain/(loss) on foreign currency transactions	(23,039)	10,942
Interest expense	(1,136,071)	(9,198,059)
Total other income (expense)	(1,862,967)	(10,202,197)
Net loss from continuing operations	(6,493,649)	(16,872,110)
Net income (loss) from discontinued operations	-	53,106
Net loss	(6,493,649)	(16,819,004)
Net loss attributable to non-controlling interest	(323,786)	(92,986)
Net loss attributable to Spotlight Innovation Inc.	$ (6,169,863)	$(16,726,018)
Net loss per common share – basic and diluted:		
Continuing operations	$ (0.20)	$ (0.93)
Discontinued operations	0.00	(0.00)
Total	$ (0.20)	$ (0.93)
Weighted average number of common shares outstanding – basic and diluted	32,233,925	18,020,614

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

SPOTLIGHT INNOVATION INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Common Stock		Additional Paid-In	Accumulated	Non-controlling	
	Shares	Par	Capital	Deficit	Interest	Total
Balances at December 31, 2015	14,627,026	$ 14,627	$18,760,400	$ (18,643,652)	$2,331,106	$ 2,462,481
Common shares issued for cash	100,000	100	55,040	-	-	55,140
Common shares issued for stock payable	25,000	25	21,475	-	-	21,500
Common shares issued for services	1,707,944	1,708	997,352	-	-	999,060
Common shares issued for settlement of payables	278,108	278	96,504	-	-	96,782
Shares issued in exchange for options	516,000	516	342,634	-	-	343,150
Stock exchanged for related party options as contributed capital	-	-	34,644	-	-	34,644
Amortization of stock options	-	-	1,484,078	-	-	1,484,078
Shares issued for extinguishment of debt and related derivative liability	4,265,403	4,265	3,215,667	-	-	3,219,932
Extinguishment of related party debt and related derivative liability as contributed capital	-	-	166,289	-	-	166,289
Warrants issued as debt inducement	-	-	156,552	-	-	156,552
Transactions with K4 Enterprises, LLC						
Extinguishment of related party debt and related derivative liability	1,756,573	1,757	2,029,418	-	-	2,031,175
Shares issued in extinguishment of debt to related party	4,000,000	4,000	3,756,000	-	-	3,760,000
Warrants issued as debt inducement to related party	-	-	1,362,373	-	-	1,362,373
Beneficial conversion feature on convertible notes	-	-	1,556,589	-	-	1,556,589
Sale of interest in Caretta	-	-	-	-	350,000	350,000
Sale of interest in Zika	-	-	-	-	20,000	20,000
Sale of interest in SMA	-	-	-	-	20,000	20,000
Net loss	-	-	-	(16,726,018)	(92,986)	(16,819,004)
Balance at December 31, 2016	27,276,054	$ 27,276	$34,035,015	$ (35,369,670)	$2,628,120	$ 1,320,741
Common shares issued for services	1,708,750	1,709	1,004,691			1,006,400
Common stock issued for stock payable	5,768,932	5,769	3,921,204			3,926,973
Common stock issued for settlement of payables	100,000	100	49,900			50,000
Shares issued for extinguishment of debt and related derivative liability	2,091,170	2,091	844,556			846,647
Extinguishment of related party debt and derivative liability as contributed capital			49,251			49,251
Warrants issued as debt inducement			41,845			41,845
Return and cancellation of commons stock	(2,653,972)	(2,654)	2,654			-
Net loss				(6,169,863)	(323,786)	(6,493,649)
Balance at December 31, 2017	34,290,934	$ 34,291	$39,949,116	$ (41,539,533)	$2,304,334	$ 748,208

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

SPOTLIGHT INNOVATION INC
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Year Ended December 31, 2017	Year Ended December 31, 2016
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(6,493,649)	$(16,819,004)
Less: net income from discontinued operations	-	53,106
Net loss from continuing operations	(6,493,649)	(16,872,110)
Adjustments to reconcile net loss to cash used in operating activities:		
Share-based compensation	1,006,400	3,346,643
Impairment of notes receivable and accrued interest receivable	1,116,075	-
Depreciation	4,896	4,726
(Gain) Loss on change of fair value of derivative liability	4,364	(700,026)
Amortization of debt discount	873,093	6,080,353
Interest expense on derivative liability that exceeds face value	96,541	2,748,453
Unrealized gain on change in present value of royalties	(95,674)	-
Gain on options exchanged for common stock with third parties	-	(490,462)
Gain on settlement of debt	-	(167,824)
Gain on extinguishment of debt and related derivative liability	(243,716)	(753,125)
Loss on debt extinguishment	-	3,134,507
Changes in operating assets and liabilities:		
Inventory	4,445	-
Prepaid expenses	13,317	(197,000)
Accounts payable	246,847	536,605
Accounts payable – related parties	33,531	-
Accrued liabilities	(59,337)	382,250
Accrued interest note receivable	(59,693)	-
Cash used in continuing operating activities	(3,552,560)	(2,947,010)
Cash used in discontinued operating activities	-	(179,353)
Total cash used in operating activities	(3,552,560)	(3,126,363)
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash paid for notes receivable	(56,382)	(1,000,000)
Proceeds from sale of interest in Caretta, Zika and SMA	-	390,000
Purchases of property and equipment	(774)	(6,360)
Cash used in continuing investing activities	(57,156)	(616,360)
Cash used in discontinued investing activities	-	-
Total cash used in investing activities	(57,156)	(616,360)
CASH FLOWS FROM FINANCING ACTIVITIES		
Principle payments on convertible debentures	-	(738,373)
Proceeds from convertible debentures, net	1,792,482	2,932,000
Proceeds from convertible debenture, related party	415,000	-
Proceeds from demand notes, net	1,777,916	1,450,000
Proceeds from line of credit, net	-	115,000
Proceeds from related party notes	1,537,500	-
Repayment of related party notes	(1,180,136)	-
Repayment of line of credit	(1,003,300)	-
Proceeds from sale of common shares and warrants	-	55,140
Cash provided by continuing financing activities	3,339,462	3,813,767
Cash provided by discontinued financing activities	-	-
Total cash provided by financing activities	3,339,462	3,813,767
Increase/(decrease) in cash	(270,254)	71,044
Cash, beginning of the year	313,333	253,231
Effects of foreign currency translation adjustments	23,039	(10,942)
Cash, end of the year	$ 66,118	$ 313,333
Supplemental disclosure of cash flows information:		
Income taxes paid	-	-
Interest paid	$ 53,011	$ 84,120

Non-cash investing and financing transactions:		
Stock payable issued for convertible debentures	$ -	$ 2,500,000
Common shares issued for extinguishment of debt	$ -	$ 3,760,000
Common shares issued for extinguishment of debt and related derivative liability	$ 846,647	$ 3,834,733
Stock payable issued for extinguishment of debt and related derivative liability	$ -	$ 1,371,973
Debt discount for fair value of warrants issued with convertible debenture	$ 41,845	$ 1,518,925
Debt discount for fair value of royalties issued with convertible debenture	$ 1,511,146	$ 713,442
Beneficial conversion feature on convertible debentures	$ -	$ 1,556,589
Common shares issued for stock payable	$ 3,926,973	$ 21,500
Common shares issued for settlement of payables	$ 50,000	$ 96,782
Settlement of notes payable	$ -	$ 182,824
Debt discount on related party notes	$ 300,000	$ -
Debt discount for fair value of derivative liability	$ 288,676	$ 2,224,622
Return and cancellation of common stock	$ 2,654	$ -
Extinguishment of related party contributed capital	$ 49,251	$ 1,582,665

The accompanying notes are an integral part of these consolidated financial statements.

SPOTLIGHT INNOVATION INC.
NOTES TO FINANCIAL STATEMENTS

NOTE 1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Spotlight Innovation Inc. (the "Company") was organized under the laws of the state of Nevada on March 23, 2012 under the name Spotlight Innovation, LLC. In December 2013, the Company, through a reverse acquisition, merged with American Exploration Corporation ("American Exploration"). The Company is a pharmaceutical company focused on acquiring the intellectual property rights to innovative and proprietary therapeutics designed to address unmet medical needs, with an emphasis on rare, emerging, or neglected diseases. In late summer/early fall of 2016 the Company changed its disease focus and has revised its product offerings including the addition of new indications and the elimination of previous programs. To find and evaluate unique opportunities, we leverage our extensive relationships with leading scientists, academic institutions and other sources. We provide value-added development capability to accelerate progress. When scientifically significant benchmarks have been achieved, we will endeavor to partner with proven market leaders via sale, out-license or strategic alliance.

As of December 31, 2017, the Company had four subsidiaries: Celtic Biotech Iowa, Inc. "Celtic Iowa", Caretta Therapeutics, LLC ("Caretta"), SMA Therapeutics, LLC ("SMA"), and Zika Therapeutics, LLC ("Zika").

Cancer

On June 4, 2014, Celtic Biotech Iowa, Inc. acquired Celtic Biotech Limited (hereinafter "CBL"). CBL was founded in 2003 in Dublin, Ireland and is developing novel and highly specialized compounds derived from snake venom, for the treatment of solid cancers and cancer imaging.

Pain Management

Caretta Therapeutics, LLC was formed in August 2016 to develop the commercialization of over-the-counter products. Caretta holds a license agreement to develop, manufacture and sell certain products derived from snake venom that may have analgesic properties.

Zika Virus Infection

In August 2016, the Company entered into a sponsored research agreement with Florida State University ("FSU") to support research directed by FSU professor Hengli Tang aimed at developing safe and effective drugs to treat patients infected with the Zika virus (ZIKV). Prof. Tang is a member of the Company's Scientific Advisory Board.

In November 2016, the Company obtained from the Florida State University Research Foundation ("FSURF") exclusive, worldwide rights to develop and commercialize certain compounds for the treatment of viral infections, including Zika virus infection. Included among the licensed compounds are those identified in a study co-authored by Prof. Tang that was published in *Nature Medicine*

In January 2017, the Company entered into a second license agreement with FSURF for the development and commercialization of additional anti-Zika virus compounds. As with the initial license agreement, this agreement grants the Company exclusive, worldwide rights to develop and commercialize certain compounds for the treatment of viral infections, including Zika virus infection.

Spinal Muscular Atrophy

In October 2016, the Company entered into an Exclusive License Agreement with Indiana University Research and Technology Corporation ("IURTC") to commercialize STL-182, an orally-available small molecule that may have therapeutic potential for treating spinal muscular atrophy. Spinal muscular atrophy is an autosomal recessive disorder that is a leading genetic cause of death in infants and toddlers. Synthesis and early preclinical testing of STL-182 was accomplished through a research collaboration between Professors Elliot Androphy of Indiana University School of Medicine, and Kevin Hodgetts, director of the Laboratory for Drug Discovery in Neurodegeneration at Brigham and Women's Hospital. Their work was supported in part by the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute of Child Health and Human Development (NICHD). Professor Androphy and Professor Hodgetts are members of the Company's Scientific Advisory Board.

On June 21, 2017, the Company entered into a Sponsored Research Agreement with The Brigham and Women's Hospital Inc. ("BWH") to support research directed by BWH professor Kevin Hodgetts aimed at developing safe and effective drugs to treat patients with spinal muscular atrophy.

On August 14, 2017, the Company entered into a Sponsored Research Agreement with The Trustees of Indiana University ("IU") to support research directed by IU professor Dr. Elliot Androphy aimed at developing safe and effective drugs to treat patients with spinal muscular atrophy.

Spinal muscular atrophy affects between 1 in 6,000 and 1 in 10,000 newborns. Approximately 1 in 40 to 1 in 50 adults have only a single intact spinal motor neuron 1 (SMN1) gene, which encodes a protein (SMN) required for proper neuromuscular function. An infant who inherits no intact SMN1 gene from either parent may develop spinal muscular

atrophy and lose the ability to sit, stand, walk, swallow, and/or breathe. In about 60% of cases, patients with spinal muscular atrophy die by age two. Even in spinal muscular atrophy patients, low levels of functional spinal muscular atrophy protein are produced by an SMN1-related gene called SMN2. One therapeutic strategy to treat spinal muscular atrophy is to increase levels of functional SMN protein encoded by SMN2. In mouse models of spinal muscular atrophy, STL-182 may restore neuromuscular function by stabilizing endogenous SMN protein.

The Company has engaged a top-tier contract research organization (CRO) to conduct additional preclinical mouse studies of STL-182. These studies are ongoing and are expected to continue throughout 2018.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of consolidated 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 and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the Company's accounts, including those of the Company's subsidiaries. Accordingly, the Company has consolidated CBL, Celtic Iowa, CDT (Suspended), Caretta, Zika, and SMA. All significant intercompany accounts and transactions have been eliminated.

Loss per Common Share

Basic net income (loss) per common share is computed by dividing the net income (loss) attributable to common shareholders 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) attributable to common shareholders by the weighted-average number of common and common equivalent shares outstanding during the period. Common share equivalents included in the diluted computation represent shares issuable upon assumed exercise of stock options and warrants or the assumed conversion of convertible debt instruments, using the treasury stock and "if converted" method. For periods in which net losses are incurred, weighted average shares outstanding is the same for basic and diluted loss per share calculations, as the inclusion of common share equivalents would have an anti-dilutive effect.

For the years ended December 31, 2017 and 2016, the dilutive effect of 0 and 153,771 options, and 1,162,245 and 3,414,600 warrants, 0 and 0 common shares issuable for conversion of convertible debt, respectively, were excluded from the diluted earnings per share calculation because their effect would have been anti-dilutive.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturity of three months or less when purchased to be cash equivalents. The Company maintains its cash in institutions insured by the Federal Deposit Insurance Corporation ("FDIC"). The Company had $66,118, and $313,333 of cash equivalents at December 31, 2017 and 2016, respectively.

Financial instruments which potentially subject the Company to concentrations of credit risk include cash deposits placed with financial institutions. The Company maintains its cash in bank accounts which, at times, may exceed federally insured limits as guaranteed by the FDIC. As of December 31, 2017, the Company had cash balances of $0 that were uninsured.

Foreign exchange and currency translation

For the years ended December 31, 2017 and 2016, the Company maintained cash accounts in U.S. dollars as well as European Union euros, and incurred certain expenses denominated in U.S. dollars and European Union euros. The Company's functional and reporting currency is the U.S. dollar. Transactions denominated in foreign currencies are translated into U.S. dollars at exchange rates in effect on the date of the transactions. Assets and liabilities are translated using exchange rates at the end of each period. Exchange gains or losses on transactions are included in earnings. For all periods presented, any exchange gains or losses or translation adjustments resulting from foreign currency transactions are included in the statements of operations as other income (expense).

Inventory

Inventories are stated at the lower of cost or market, using an average cost method. Costs include materials, labor, and manufacturing overhead related to the purchase and production of inventories. We regularly review inventory quantities on hand, future purchase commitments with our suppliers, and the estimated utility of our inventory. If our review indicates a reduction in utility below carrying value, we reduce inventory to the new cost basis.

In-Process Research and Development

In-process research and development ("IPR&D") represents the estimated fair value assigned to research and development projects acquired in a purchased business combination that have not been completed at the date of acquisition and which have no alternative future use. IPR&D assets acquired in a business combination are capitalized as indefinite-lived intangible assets. These assets remain indefinite-lived until the completion or abandonment of the associated research and development efforts. During the periods prior to completion or abandonment, those acquired indefinite-lived assets are not amortized but are tested for impairment annually, or more frequently, if events or changes in circumstances indicate that the asset might be impaired. During periods after completion, those acquired indefinite-lived assets are amortized based on their useful life. The fair value of the assets acquired was $6,977,347. These assets are still subject to research and development completion and accordingly, no amortization has been recorded.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Maintenance and repairs are charged to expense as incurred. Renewals and betterments which extend the life or improve existing equipment are capitalized. Upon disposition or retirement of equipment, the cost and related accumulated depreciation are removed and any resulting gain or loss is reflected in operations. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, which is 3-10 years.

Impairment of Long-Lived Assets and Intangibles

The Company performs impairment tests on its long-lived assets when circumstances indicate that their carrying amounts may not be recoverable. If required, recoverability is tested by comparing the estimated future undiscounted cash flows of the asset or asset group to its carrying value. If the carrying value is not recoverable, the asset or asset group is written down to fair value. For the year ended December 31, 2017, the Company recorded an impairment to the Company's long-lived assets. On September 30, 2017, the U.S. Food and Drug Administration ("FDA") denied approval of the application for the SOLX glaucoma treatment. With this development, the Company has determined that the note receivable is fully impaired. See Note 7 below for further details.

Deferred Financing Costs

We have incurred debt origination costs in connection with the issuance of short-term convertible debt. These costs are capitalized as deferred financing costs and amortized using the straight-line method over the term of the related convertible debt.

Royalty Liability

The holders of certain convertible notes receive royalties as described in Footnote 10. The holders of the certain convertible notes referenced in Note 8 will receive, in the aggregate, pro rata based on investment, a total of five percent of the revenues of Caretta Therapeutics, LLC during the years ended December 31, 2017, 2018, 2019 and 2020. The Company records unrealized gains and losses on the change of present value of the royalty liabilities.

Stock-Based Compensation

The Company measures the cost of employee services received in exchange for stock and stock options based on the grant date fair value of the awards. The Company determines the fair value of stock option grants using the Black-Scholes option pricing model. The Company determines the fair value of shares of non-vested stock (also commonly referred to as restricted stock) based on the last quoted price of our stock on the date of the share grant. The fair value determined represents the cost for the award and is recognized over the vesting period during which an employee is required to provide service in exchange for the award. As share-based compensation expense is recognized based on awards ultimately expected to vest, the Company reduces the expense for estimated forfeitures based on historical forfeiture rates, if historical forfeiture rates are available. Previously recognized compensation costs may be adjusted to reflect the actual forfeiture rate for the entire award at the end of the vesting period. Excess tax benefits, if any, are recognized as an addition to paid-in capital.

Income Taxes

The Company utilizes the asset and liability method in accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for operating loss and tax credit carry-forwards and for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not that the value of such assets will be realized.

Fair Value of Financial Instruments

The Company follows FASB ASC 820, *Fair Value Measurement* ("ASC 820"), which clarifies fair value as an exit price, establishes a hierarchal disclosure framework for measuring fair value, and requires extended disclosures about fair value measurements. The provisions of ASC 820 apply to all financial assets and liabilities measured at fair value.

As defined in ASC 820, fair value, clarified as an exit price, represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

As a basis for considering these assumptions, ASC 820 defines a three-tier value hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The Company's IPR&D assets were valued on a discounted cash flow model using the income approach. The inputs to the model were within Level 3 of the fair value hierarchy.

Subsequent Events

The Company evaluated subsequent events through the date when financial statements are issued for disclosure consideration.

Recent Accounting Pronouncements

There were various accounting standards and interpretations issued recently, none of which are expected to have a material effect on the Company's operations, financial position or cash flows.

NOTE 3. GOING CONCERN

The Company is an early stage company and as such has not generated substantial revenues from operations and there is no assurance of any future revenues. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. As of December 31, 2017, the Company has an accumulated deficit of $41,539,533 and has a working capital deficit of $2,430,230. These factors raise substantial doubt as to the Company's ability to continue as a going concern.

The ability of the Company to continue as a going concern is dependent upon the Company's successful efforts to raise sufficient capital and then attain profitable operations. Management is investigating all options to raise enough funds to meet the Company's working capital requirements through either the sale of the Company's common stock or other financings. There can be no assurances, however, that management will be able to obtain sufficient additional funds when needed, or that such funds, if available, will be obtained on terms satisfactory to the Company.

NOTE 4. DISCONTINUED OPERATIONS

Memcine

On October 12, 2016 the Company terminated its interests in Memcine pursuant to a Termination Agreement with Memcine, the University of Iowa Research Foundation, and Dr. Tony Vanden Bush. The Company has reclassified the results from operations of Memcine to discontinued operations.

The following table summarizes the results of the Memcine business included in the consolidated statement of income as discontinued operations:

	2016
Sales	$ -
General and administrative expenses	48,986
Depreciation	1,311
Research & development	125,652
Impairment of long-lived asset	-
Income before taxes	(175,949)
Income taxes	-
Results from discontinued operations	(175,949)
Gain from disposal of discontinued operations	229,055
Net income from discontinued operations	$ 53,106

NOTE 5: PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

Description	Useful lives (years)	December 31, 2017	December 31, 2016
Computers	5	$ 9,620	$ 9,620
Software	3	761	761
Furniture	5	1,973	1,200
Equipment	10	9,000	9,000
Subtotal		21,355	20,581
Less accumulated depreciation		(12,322)	(7,426)
Property and equipment, net		$ 9,033	$ 13,155

NOTE 6. INVENTORY

Inventory consisted of the following:

	December 31, 2017
Venom	$ 28,771
Packaging	19,577
Bottles, Caps & Roll-Ons	2,025
Finished Goods	142,352
Total Inventory	$ 192,775

NOTE 7. NOTES RECEIVABLE

During 2016, the Company made two investments in SOLX, Inc. (“SOLX”), a private company that develops innovative surgical technologies to treat refractory glaucoma and preserve vision. The Company purchased $200,000 and $800,000 in Senior Convertible Promissory notes, maturing October 1, 2017. The notes carry an interest rate of 10%. No periodic interest payments will be made, however upon maturity the principal balance and the accrued interest will be paid unless converted to equity. On a fully converted basis, the principal represents about a 10% interest in SOLX. Of the 10% interest, 3% has been assigned to K4 Enterprises, LLC (“K4”). During the year ended December 31, 2017, the Company purchased an additional note from SOLX in the amount of $36,771, and accrued interest income of $59,693 during 2017.

The Company was issued a warrant to purchase Series A Preferred stock or Series A-2 Preferred stock of SOLX. The warrant allows the Company to purchase 35% of the face value of the Company investment at a price of $0.8170 for Series A Preferred stock or $0.940 for Series A-2 Preferred stock. The expiration date is the earlier of (i) December 6, 2026, (ii) the closing of the initial public offering (IPO) of the SOLX Common Stock, (iii) the closing of the sale or substantially all of the assets of SOLX.

The Company was advised that on September 20, 2017, the FDA sent a formal denial to SOLX of the application for FDA approval of the treatment for refractory glaucoma. SOLX informed the Company that they will cease operations. The Company has determined, with the FDA denial of the application and SOLX’s assertion to cease operations, the note receivable is fully impaired, and the Company has charged the total balance of $1,116,075 (including the accrued interest) against earnings in 2017. The value of the warrants issued to the Company by SOLX have been written off given the assertion by SOLX.

NOTE 8. NOTES PAYABLE

During 2016, the Company conducted a private offering of up to $2,500,000 in principal amount of the Company's convertible promissory notes (the "Private Placement"), which bear interest at the rate of 7.5% per annum. The notes are convertible into shares of common stock of the Company at a price per share equal to 90% of the closing bid price of the common stock during the 20 consecutive trading days immediately preceding such conversion. The notes mature 24 months after issuance, if not converted prior to the maturity date, the notes automatically convert into shares of common stock of the Company at a per share price equal to 80% of the closing bid price of the common stock of the Company during the 20 consecutive trading days immediately preceding the maturity date. The holders of the notes will receive, in the aggregate, pro rata based on investment, a total of five percent of the revenues of Caretta Therapeutics, LLC during the years ending December 31, 2017, 2018, 2019 and 2020. The investors shall also receive warrants to purchase a number of shares equal to 30% of the amount invested, for a period of two years, at an exercise price per share equal to 110% of the closing bid price of the common stock of the Company on the six-month anniversary of the date of issuance of such warrant. During the year ended December 31, 2016, the Company issued convertible notes in the aggregate principal amount of $1,382,000, under the Private Placement.

During the year ended December 31, 2017, the Company issued convertible notes in the aggregate principal amount of $890,000 under the Private Placement. During the year ended December 31, 2017, the Company recorded $192,134 and $510,751 of derivative liability and royalty liability, respectively, associated with these convertible notes. In addition, the Company also recorded debt discount related to the relative fair value of the warrants in the amount of $34,755. As of December 31, 2017, the convertible notes converted into shares 2,091,170 of common stock, fair valued at $846,646. The Company also recorded a gain on extinguishment of debt and related derivative liability in the amount of $243,716 and extinguishment on related party debt and derivative liability as contributed capital of $49,251. For the year ended December 31, 2017, the Company recorded an unrealized gain on the change of present value of the royalty liabilities in the amount of $95,674.

Prior to April 18, 2017, the Company conducted a private offering with offering for sale certain convertible notes up to an aggregate of $2,500,000. After April 18, 2017, the Company amended and expanded the private offering to allow for the issuance of up to $11,500,000. Under the amended and expanded offering , the Company conducted a private offering (the "Private Placement 2017"), which bear interest at the rate of 7.5% per annum. The Company issued convertible notes in the aggregate principal amount of $1,317,482. The notes are convertible into shares of common stock of the Company based upon the table below:

			Automatic Conversion Upon Maturity		
Dollar amount of debt	**Number of convertible debentures**	**Holder Optional Conversion**	**Fixed price auto conversion**	**20 consecutive trading days**	**Floor**
$400,000	1*	$0.35	$0.35	None	None
$490,000	9**	90% of closing bid price 20 consecutive days prior to conversion	None	80% of 20 consecutive prior to conversion	None
$475,000	3	90% of closing bid price 20 consecutive days prior to conversion	None	90% of the closing bid price 20 consecutive days prior to conversion and the Floor conversion price	See schedule below
$842,482	12	90% of the closing bid price 20 consecutive days prior to conversion	None	90% of the closing bid price 20 consecutive days prior to conversion and the Floor conversion price	$0.60

* Converted into shares of Common Stock during the year ended December 31, 2017.

** All notes with the exeption of $25,000 have been converted into shares of Common Stock during the year ended December 31, 2017.

Conversion Date (by calendar quarter)	Floor Conversion Price
2017 Q2	$ 0.60
2017 Q3	$ 0.70
2017 Q4	$ 0.85
2018 Q1	$ 1.00
Each Subsequent Quarter	Increase $0.10 per Quarter

The term of the royalty for OTC Roll-On Venodol and OTC Oral Venodol begins October 1, 2018 and ends on December 21, 2023. The royalty term of prescription strength shall be from October 1, 2018 and ending December 31, 2024. Notwithstanding the forgoing, the royalty shall terminate upon the Maximum royalty amount as described in the table below:

Investment parameter	Per unit royalty per $100,000 Roll-on	Per unit royalty per $100,000 Oral	Per Unit royalty per $100,000 Prescription	Maximum Royalty Amount
Less than $400,000	$0.00304348	$0.00304348	$0.00347826	8 times
Greater than $400,000	$0.00391304	$0.00391304	$0.00608696	12 times

Twelve investors have royalty agreements which contain the following: The royalty for a particular royalty period shall be calculated as follows: (a) the Royalty Pool accrued for the applicable royalty period, multiplied by (b) the royalty percentage for the applicable royalty period. The term “Royalty Pool” means the aggregate of (i) $.60 for each unit of OTC Roll-On Venodol sold, (ii) $.60 for each unit of OTC Oral Venodol sold, and (iii) $.80 for each unit of Prescription Strength Venodol sold during the relevant royalty period. The number of units sold during the relevant period shall mean the number of individual products sold during such period, less any returns received during such period. For purposes of clarity, multipack products shall count as multiple units based on the number of included units of product (i.e. a bulk package of 6 OTC Roll-On Venodol bottles shall constitute six units).

During the year ended December 31, 2017, under the Private Placement 2017, the Company recorded $7,092 and $1,000,395 of debt discount related to the relative fair value of warrants and royalty liability, respectively, associated with these convertible notes.

The holders of the notes are issued a warrant entitling the holder the right to purchase shares of Company Common Stock, equal to thirty per cent (30%) of the value of their original convertible note. The warrant has a three-year (3) term with an exercise price of $1.30 per share. Under the amended and expanded subscription the Company has issued 395,245 warrants to purchase common stock of the Company with a fair value of $7,092.

On December 19, 2016, the Company issued a convertible note to K4 in the principal amount of $830,000; interest accrues at the rate of 6% per annum, and is convertible at the option of K4 into shares of common stock of the Company at a price equal to 70% of the average closing bid price of the common stock of the Company during the six months immediately prior to such conversion. The Company also issued K4 warrants to purchase 2,075,000 shares of the Company’s common stock at an exercise price of $1.20 per share until December 31, 2018. On December 16, 2016, the Company (i) issued 350,000 common membership units of its subsidiary Caretta Therapeutics, LLC to K4, (ii) issued 200,000 common membership units of its subsidiary Zika Therapeutics, LLC to K4, (iii) issued 200,000 common membership units of its subsidiary SMA Therapeutics and (iv) assigned to K4 30% of the distributions and income received by the Company from its investment in SOLX, Inc.

On December 31, 2016, the Company issued a convertible note to K4 in the principal amount of $170,000, at the rate of 6% per annum, and is convertible at the option of K4 into shares of common stock of the Company at a price equal to 70% of the average closing bid price of the common stock of the Company during the six months immediately prior to such conversion. The Company also issued K4 warrants to purchase 425,000 shares of the Company’s common stock at an exercise price of $1.20 per share until December 31, 2018.

NOTE 9. LINES OF CREDIT

On July 25, 2017, the Company settled its line-of-credit with the Denver Savings Bank through a promissory note from Mike Kemery, a Principal at K4 (an entity partially owned and controlled by the President of the Company), in the principal amount of $1,500,000. The note carries an interest rate of 4.5% and mature in 3 years. Pursuant to the terms of the agreement, the Company incurred a $300,000 loan origination fee, payable on demand. The Company recorded the fee as a debt discount.

NOTE 10. ROYALTY LIABILITY

The holders of the certain convertible notes referenced in Note 8 will receive, in the aggregate, pro rata based on investment, a total of five percent of the revenues of Caretta Therapeutics, LLC during the years ended December 31, 2017, 2018, 2019 and 2020.

On April 18, 2017 the Company revised the royalty agreement with the amendment and expansion of the subscription agreement from a maximum aggregate $2,500,000 to a maximum aggregate of $11,500,000. The revised terms are:

The term of the royalty for OTC Roll-On Venodol and OTC Oral Venodol begins October 1, 2018 and ends on December 21, 2023. The royalty term of prescription strength shall be from October 1, 2018 and ending December 31, 2024. Notwithstanding the forgoing, the royalty shall terminate upon the Maximum royalty amount as described in the table below:

Investment parameter	Per unit royalty per $100,000 Roll-on	Per unit royalty per $100,000 Oral	Per Unit royalty per $100,000 Prescription	Maximum Royalty Amount
Less than $400,000	$0.00304348	$0.00304348	$0.00347826	8 times
Greater than $400,000	$0.00391304	$0.00391304	$0.00608696	12 times

Twelve investors have royalty agreements which contain the following: The royalty for a particular royalty period shall be calculated as follows: (a) the Royalty Pool accrued for the applicable royalty period, multiplied by (b) the royalty percentage for the applicable royalty period. The term “Royalty Pool” means the aggregate of (i) $.60 for each unit of OTC Roll-On Venodol sold, (ii) $.60 for each unit of OTC Oral Venodol sold, and (iii) $.80 for each unit of Prescription Strength Venodol sold during the relevant royalty period. The number of units sold during the relevant period shall mean the number of individual products sold during such period, less any returns received during such period. For purposes of clarity, multipack products shall count as multiple units based on the number of included units of product (i.e. a bulk package of 6 OTC Roll-On Venodol bottles shall constitute six units).

During the year ended December 31, 2016, the Company recorded $713,442 of royalty liability, associated with these convertible notes. During the year ended December 31, 2017, the Company recorded $1,511,148 of debt discount related to the relative fair value of the royalty liability, associated with these convertible notes. For the year ended December 31, 2017, the Company recorded an unrealized gain on the change of present value of the royalty liabilities in the amount of $95,674.

NOTE 11. LEASES

As of December 31, 2017, the Company has one lease agreement. On December 15, 2016, the Company entered into a commercial sublease with K-4 in Urbandale, Iowa, for a term of five years, commencing December 15, 2016, ending December 1, 2021, and automatically continuing on a year-to-year basis thereafter, unless terminated in accordance with the provisions thereof. Monthly rent is $1,314, which will increase by 2% annually, plus a proportionate share of expenses, which will initially be $800 per month. Expenses in 2017 increased to $1,286/month.

NOTE 12. INCOME TAXES

At December 31, 2017 and 2016, the Company’s deferred tax assets consisted primarily of net operating loss carry forwards acquired from American Exploration in the merger. For the years ended December 31, 2017 and 2016, the material reconciling items between the tax benefit computed at the statutory rate and the actual benefit recognized in the financial statements consisted of expenses related to share-based compensation and the change in the valuation allowance during the applicable period. At December 31, 2017 and 2016, the Company has recorded a 100% valuation allowance as management believes it is likely that any deferred tax assets will not be realized.

As of December 31, 2017, the Company had a net operating loss carry forward of approximately $40 million, which will expire beginning in 2028. Due to the change in ownership provisions of the Tax Reform Act of 1986, our net operating loss carry forwards are expected to be subject to significant annual limitations for the change in ownership that resulted in the merger with American Exploration.

On December 22, 2017, new federal tax reform legislation was enacted in the United States (the "2017 Tax Act"), resulting in significant changes from previous tax law. The 2017 Tax Act reduces the federal corporate income tax rate to a flat rate of 21%, from a graduated rate structure with a top rate of 35%, effective January 1, 2018. The rate change, along with certain immaterial changes in tax basis resulting from the 2017 Tax Act, resulted in a reduction of the Company's net deferred tax assets of approximately $5.2 million, and a corresponding reduction in the valuation allowance.

NOTE 13. EQUITY

The Company has authorized 3,000,000 shares of Series A preferred stock, 500,000 shares of Series C preferred stock, 1,500,000 shares of preferred stock and 4,000,000,000 shares of common stock.

2017 Issuances

The Company issued 1,708,750 shares of common stock for employee services in lieu of cash compensation in 2017. The table below details the issuances:

Month	Shares issued	Fair Value at issue date
January	1,360,000	$ 884,000
April	136,250	48,450
September	106,250	14,864
October	106,250	13,813
Total	**1,708,750**	**$ 961,127**

The Company issued 100,000 shares of common stock for settlement of vendor services in accordance with a vendor agreement. The fair value of the common stock at issuance was $50,000 and has been recorded as a legal expense.

During 2017, 2,615,000 founder shares and 38,972 shares of the Company's common stock were returned and cancelled by a former CEO and a related party, respectively.

Options

Upon the acquisition of American Exploration, the Company adopted the 2009 Stock Option Plan (the "2009 Plan"). The 2009 Plan allows the Company to issue options to officers, directors and employees, as well as consultants, to purchase up to 7,000,000 shares of common stock. The Company, as part of the merger in 2013, issued and exchanged 5,200 stock options to individuals who previously held stock options in American Exploration.

2015 Equity Incentive Plan

On November 25, 2015, the Company authorized the Spotlight Innovation, Inc. 2015 Equity Incentive Plan (the "2015 Plan")

The total number of shares which may be issued under 2015 Plan shall not exceed the 3,600,000 Shares. The shares covered by the portion of any grant under the 2015 Plan which expires unexercised shall become available again for grant under the 2015 Plan.

In November 2015, the Company granted incentive stock options and non-qualified stock options to acquire an aggregate of 2,600,000 shares of the Company's common stock under the Company's 2015 Plan to various officers and consultants of the Company. The options have exercise prices of $1.10 to $1.21. Each option was granted under a three-year vesting term, 25% upon grant, and 25% on each of the first, second and third anniversary of grant date. Of the 2,600,000 options granted, 150,000 were issued to an executive officer and the remaining 2,450,000 were issued to certain consultants of the Company. The fair value of these options $2,382,078.

2016 Equity Incentive Plan

On December 13, 2016, the Company adopted the Spotlight Innovation Inc. 2016 Equity Incentive Plan (the "2016 Plan") and reserved 5,000,000 shares of common stock under the 2016 Plan.

On December 23, 2016, the Company issued an aggregate of 231,000 shares of its common stock pursuant to the 2016 Plan, in exchange for options to purchase 300,000 shares of the common stock as follows:

Name	Number of Shares issued	Number of Option Shares that were canceled as a result of the exchange
John Krohn (Our President, COO, CEO and a Director)	108,000	75,000
Craig Lang (A Director)	108,000	75,000
Cristopher Grunewald (Our former CEO)	15,000	150,000
Total	231,000	300,000

On December 23, 2016, the Company granted to John William Pim, the Company's Chief Financial Officer 125,000 shares of the Company's common stock, valued at $81,250 pursuant to the 2016 Plan. The Company also issued an aggregate of 235,000 shares of common stock pursuant to the 2016 Plan to certain non-executive officers and consultants of the Company in exchange for options to purchase an aggregate of 2,350,000 shares of the Company's common stock originally issued pursuant to the 2015 Plan.

Fair Value - Options

The fair value of each option award is estimated on the date of grant using a Black-Scholes valuation model that uses the assumptions noted in the following table.

	2015 Equity Incentive Plan	2016 Equity Incentive Plan
Expected Volatility	142.16%	301-320%
Expected Dividends	$ 0	0
Expected Term in years	3	3-4

The weighted-average grant-date fair value of options granted in 2016 is $0.54.

Summary Stock Option Activity

A summary of the stock option activity for the years ended December 31, 2017 and 2016 is presented below:

	Options	Weighted-Average Exercise Price
Outstanding December 31, 2015	2,605,200	$ 1.82
Granted	448,571	.54
Exercised	-	-
Expired/Forfeited	2,900,000	1.06
Outstanding December 31, 2016	153,771	$ 12.48
Granted	-	-
Exercised	-	-
Expired/Forfeited	-	-
Outstanding December 31, 2017	153,771	$ 12.48
Exercisable December 31, 2017	153,771	12.48

The following table provides information as of December 31, 2017, regarding shares authorized for issuance under our equity compensation plans, including individual compensation arrangements.

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding column (a))
Equity Compensation Plans Approved by Security Holders 2009 Plan	5,200	$ 359.04	5,050,000
Equity Compensation Plans Not Approved by Security Holders	4,964,171	1.40	-
Total	4,969,371	$ 2.77	5,050,000

Warrants

During the year ended December 31, 2017, the Company issued warrants to purchase 1,162,245 shares of common stock. These warrants were issued in connection with the Company's Amended and Restated Convertible Note dated October 18, 2016. These warrants have an exercise price equal ranging from $0.32 to $1.30 in accordance with the terms of the agreement. The relative fair value of the warrants based on the Black-Scholes model was $125,957. The Company also issued 500,000 warrants with an exercise price of $1.25 to the Company's former CEO with a relative fair value of $45,273. The fair value was recorded as stock compensation expense.

The fair value of the above warrants was determined by using the Black-Scholes option-pricing model. Variables used in the model for the warrants issued include: i) discount rates ranging from 0.0% to 2.00%; ii) expected terms ranging from 0 to 5.00 years; iii) expected volatility ranging from 0% to 136.4%; iv) zero expected dividends and v) stock price of $0.31 to $1.30.

A summary of the warrant activity for the years ended December 31, 2017 and 2016 is presented below:

	Warrants	Weighted-Average Exercise Price
Outstanding December 31, 2015	2,011,671	$ 1.29
Granted	4,394.,600	1.19
Exercised	(100,000)	1.68
Expired/forfeited	(480,000)	1.46
Outstanding at December 31, 2016	5,826,271	1.19
Granted	1,162,245	1.08
Exercised	-	-
Expired/forfeited/terminated	(836,671)	1.27
Outstanding December 31, 2017	6,151,845	$ 1.16
Exercisable December 31, 2017	6,151,845	$ 1.16

The weighted average remaining contractual term of the outstanding warrants and exercisable warrants as of December 31, 2017 is 1.55 years.

NOTE 14. RELATED PARTY TRANSACTIONS

On January 10, 2017, the Company entered into an Employment Agreement with Cristopher Grunewald pursuant to which he would continue to serve as the Company's Chief Executive Officer at a salary of $180,000 per annum. The agreement was to continue until the second anniversary thereof, unless terminated earlier pursuant to the agreement. Pursuant to such agreement Mr. Grunewald's employment may be terminated by either the Company or by Mr. Grunewald at any time and for any reason; provided that, unless otherwise provided in the agreement, either party shall be required to give the other party at least 30 days advance written notice of any termination of Mr. Grunewald's employment. In the event that Mr. Grunewald's employment is terminated Without Cause by the Company or by Mr. Grunewald for Good Reason (as these terms are defined in the agreement) or subject to the terms of the agreement as a result of a Change in Control (as defined in the agreement), Mr.Grunewald shall be entitled to monthly payments equal to 12 months' salary for the year in which the termination occurred as well as to receive payment for any Accrued Amounts (as defined in the agreement).

On May 22, 2017, Mr. Grunewald resigned as Chief Executive Officer of the Company. Pursuant to Mr. Grunewald's resignation, the Company issued Mr. Grunewald a warrant to purchase 500,000 shares of Common Stock of the Corporation with an exercise price of $1.25 per share for a term of three years. Mr. Grunewald also agreed to cancel 1,618,627 shares of Common Stock of the Company previously owned by Mr. Grunewald. Mr. Grunewald remains with the Company in an advisory capacity pursuant to a consulting agreement.

On April 21, 2017, Dr. Beetler (Director) purchased a convertible note in the principal amount of $25,000 from the Company, in a private placement, and received a warrant to purchase 7,500 shares of the Company's common stock. These warrants have an exercise price equal to the closing price of the Company common stock of the six-month issuance thereof. The material terms of the note are:

- At any time prior to the maturity date, the note is convertible into shares of common stock of the Company at a price per share equal to 90% of the closing bid price of the common stock during the 20 consecutive trading days immediately preceding such conversion.

- Interest will accrue at 7.5% computed on a 365-day basis. Interest is payable upon conversion of the convertible note at the applicable conversion price.

On June 7, 2017, Dr. Beetler purchased a convertible note in the principal amount of $250,000 from the Company, in a private placement, and received a warrant to purchase 82,500 shares of the Company's common stock. The warrants have an exercise price of $1.30 per share. The material terms of the note are:

- At any time prior to the maturity date, the note is convertible into shares of common stock of the Company at a price per share equal to 90% of the closing bid price of the common stock during the 20 consecutive trading days immediately preceding such conversion and the Floor Conversion price as described in the table below

Conversion Date (by calendar Quarter)	Floor Conversion Price
2017 Q2	$ 0.60
2017 Q3	$ 0.70
2017 Q4	$ 0.85
2018 Q1	$ 1.00
Each Subsequent Quarter	Increase $0.10 per Quarter

- Interest will accrue at 7.5% computed on a 365-day basis. Interest is payable upon conversion of the convertible note at the applicable conversion price.

On September 25, 2017, Mr. Arthur (Director) purchased a convertible note in the principal amount of $35,000 from the Company, in a private placement, and received a warrant to purchase 10,500 shares of the Company's common stock. The warrants have an exercise price of $1.30 per share. The material terms of the note are:

- At any time prior to the maturity date, the note is convertible into shares of common stock of the Company at a price per share equal to 90% of the closing bid price of the common stock during the 20 consecutive trading days immediately preceding such conversion and the Floor Conversion price shall mean $0.60 per share

- Interest will accrue at 7.5% computed on a 365-day basis. Interest is payable upon conversion of the convertible note at the applicable conversion price.

In connection with the issuance of the note, Caretta Therapeutics, LLC (a subsidiary of the Company) entered into a Royalty Agreement with Mr. Arthur pursuant to which Mr. Arthur will receive a pro rata share of a royalty during the years ended 2017, 2018, 2019 and 2020 of the Company's subsidiary Caretta Therapeutics, LLC as follows:

- Aggregate of 5% of net revenue.

- Net revenues defined as gross revenues, minus all license/royalty fees and cost of goods sold.

- Royalties will cease once investor has received two times the amount invested in the respective note.

As of December 31, 2017, the Company has a demand note with K4 in the amount of $730,031. There are no formal payment terms, this loan is payable upon demand.

On July 25, 2017, the Company settled its line-of-credit with the Denver Savings Bank through a promissory note from Mike Kemery, a Principal at K4 Enterprises, LLC (an entity partially owned and controlled by John Krohn, the President, COO, and CEO of the Company), in the principal amount of $1,500,000. The note carries an interest rate of 4.5% and mature in three years. Pursuant to the terms of the agreement, the Company incurred a $300,000 loan origination fee, payable on demand. The Company recorded the fee as a debt discount.

NOTE 15. SUBSEQUENT EVENTS

On January 22, 2018, the Company issued 74,973 shares of its common stock, valued at $26,671 pursuant to the conversion of a convertible note for a related party.

Subsequent to December 31, 2017, the Company has repaid $90,300 of the demand note outstanding to K4.

During 2018, the Company has accepted subscriptions for $350,000 of convertible notes in the Private Placement 2017 (See Note 8 above).

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

CEO/CFO Certifications

Attached to this Annual Report on Form 10-K as Exhibits 31.1 and 31.2, there are two certifications, and the Section 302 certifications, one by each of our President and Chief Executive Officer (CEO), and our Chief Financial Officer (CFO). This Item 9A contains information concerning the evaluation of our disclosure controls and procedures and internal control over financial reporting that is referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Evaluation of Disclosure Controls and Procedures

We have performed an evaluation under the supervision and with the participation of our management, including our President, COO, CEO and CFO, of the effectiveness of our disclosure controls and procedures, (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2017. Based on that evaluation, our management, including our President, CEO and CFO, concluded that our disclosure controls and procedures were not effective as of December 31, 2017 to provide reasonable assurance that information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer, as appropriate to allow timely decisions regarding required disclosure due to the material weaknesses described below.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework Company to confirm what framework was used in connection with its evaluation of internal controls over financial reporting. Internal control over financial reporting is a process designed 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 and includes those policies and procedures that (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (b) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the Company are being made only in accordance with authorizations of the our management and directors; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Based on our evaluation under the framework described above, our management concluded that we had "material weaknesses" (as such term is defined below) in our control environment and financial reporting process consisting of the following as of the Evaluation Date:

1) lack of a functioning audit committee due to a lack of a majority of independent members and a lack of a majority of outside directors on our Board of Directors, resulting in ineffective oversight in the establishment and monitoring of required internal control and procedures;

2) inadequate segregation of duties consistent with control objectives

A "material weakness" is defined under SEC rules as a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls.

A system of controls, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the system of controls are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Inherent Limitations On Effectiveness Of Controls

We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our President and COO, CEO and CFO, has concluded that these controls and procedures are not effective at the "reasonable assurance" level.

Changes In Internal Controls Over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors and Executive Officers

All of our directors hold office until the next annual general meeting of the shareholders or until their successors are elected and qualified. Our officers are appointed by our board of directors and hold office until their earlier death, retirement, resignation or removal.

Our directors and executive officers as of December 31, 2017, their ages and positions held are as follows:

Name	Age	Position with the Company
John William ("Bill") Pim	63	Chief Financial Officer
John M. Krohn	58	Chief Operating Officer, Interim Chief Executive Officer, President and Chairman of the Board
Dr. June Beetler	58	Director
Craig A. Lang	65	Director
Ralph Arthur	70	Director
Dr. Sanjeev Agarwal	59	Director

Business Experience

The following is a brief account of the education and business experience of each director, executive officer and key employee during at least the past five years, indicating each person's principal occupation during the period, and the name and principal business of the organization by which he or she was employed, and including other directorships held in reporting companies.

John William ("Bill") Pim
Chief Financial Officer

Mr. Pim joined the Company as Chief Financial Officer in November 2015. Mr. Pim has over three decades of financial and business development experience with expertise in auditing, financial reporting, SEC compliance, strategic planning, risk management and mergers and acquisitions. Mr. Pim has held senior level financial positions with: Mark Seed Company; Adrian Carriers; Iowa Renewable Energy, Inc. (where Mr. Pim was a co-founder and a Director from October 2005 to October 2010); Iowa Foundation for Medical Care; and Heartland Express. Mr. Pim, a C.P.A. received a B.S. degree in Accounting from the University of Iowa.

John M. Krohn
President, Chief Operating Officer, Chief Executive Officer, Chairman of the Board

Mr. Krohn joined the Company as a member of the Board of Directors of the Company in February 2016, and became President and COO on December 27, 2016, and Interim CEO on May 22, 2017. Until 2017 Mr. Krohn was a Senior Financial Services Advisor with Principal Financial Group, a global investment management leader, offering retirement services, insurance solutions and asset management. Mr. Krohn is a registered investment advisor and holds Series 7, 63 and 65 licenses. He was inducted into the Principal Financial Group Agent Hall of Fame and is the 2014 recipient of the Lifetime Achievement Award for life insurance production. Mr. Krohn, a CPA, is a 1981 graduate of the University of Iowa with a B.S. degree in Accounting.

Craig A. Lang
Director

Mr. Lang joined the Company as a member of the Board of Directors of the Company in February 2016. Craig A. Lang is President of The Prairie Strategy Group, a policy, communication and logistics consulting company focused on the worldwide need for affordable food and energy. He is also President of Windward Iowa, an organization advocating for clean wind energy and the advancement and modernization of electric transmission lines across the United States. From 2001 to 2011, he was Chairman of the Board of FBL Financial, an insurance and annuity company, focusing on markets in the Midwest and Western states. From 2008 to 2013, Mr. Lang served as a board member of, and from 2011 to 2013, as President of, the Board of Regents of the State of Iowa, a group which governs five public educational institutions in the State. Mr. Lang received a Bachelor of Science degree from Iowa State University in 1973.

Ralph Arthur
Director

Ralph Arthur has been a member of the Company's Board of Directors since December 2016. Mr. Arthur joined Ruan Transport Corporation in 2000 and served, until his retirement at the end of 2016, as President of Dedicated Contract Carriage with responsibility for the operations of the dedicated private carriage lines and logistics. Since 2012, Mr. Arthur has been a member of the board of Iowa Motor Truck Association. Mr. Arthur has a Master's degree from the University of Northern Colorado and a Bachelor of Science degree from Virginia Tech.

Dr. Sanjeev Agarwal
Director

Dr. Sanjeev Agarwal has been a member of the Company's Board of Directors since December 2016. Dr. Agarwl has been President of Technochem International, Inc. Since 2000. Technochem builds equipment and infrastructure for the production of vegetable oils, biodiesel, glycerin and fermentation-based specialty-chemicals for clients worldwide. He has supervised the design, fabrication and installation of equipment for startup and existing facilities, has participated in numerous process development projects, and has incorporated novel technologies to improve plant efficiency and reduce waste. Dr. Agarwal has a Ph.D. in Business from Ohio State University, an MS in Chemical Engineering from University of California at Davis, and a BS in Chemical Engineering from Indian Institute of Technology at Roorkee, India.

Dr. June Beetler
Director

Dr. Beetler has been a member of the Company's Board of Directors since May 24, 2017. Dr. Beetler is Board Certified in Pediatrics and has over 20 years of experience in general practice and urgent care settings. Her experience and expertise span general pediatrics, integrative medicine and holistic care. She currently holds a medical license in Florida and practices at St. Petersburg Pediatrics in St. Petersburg, Florida. Before relocating to Florida, Dr. Beetler maintained her own practice, Johnston Pediatric Clinic, P.C., for 18 years, and was a staff physician at Iowa Lutheran Hospital, Iowa Methodist Medical Center, and Mercy Medical Center - Des Moines.

Committees of The Board Of Directors

In February 2016 we formed three committees: Audit Committee comprised of John Krohn, Steven Katz, and Jack Price; Compensation Committee comprised of Mssrs. Katz, Price, and Lang; Corporate Governance Committee comprised of Mssrs. Lang, Krohn, and Katz. Jack Price and Steven Katz served as members of the Board of Directors of the Company and respective committees from February 24, 2016, until their resignations from the Board of Directors on June 15, 2016, and June 14, 2016 respectively. Upon their resignations the entire board of directors acted as the Audit Committee, Compensation Committee, and Corporate Governance Committee.

Family Relationships

There are no family relationships among our directors or officers.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers, and the persons who beneficially own more than ten percent of our common stock, to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Copies of all filed reports are required to be furnished to us pursuant to Rule 16a-3 promulgated under the Exchange Act. Based solely on the reports received by us and on the representations of the reporting persons, we believe that these persons have complied with all applicable filing requirements during the fiscal year ended December 31, 2017, with the exception of the following reports which were filed late.

Reporting Person	Form Type
John William Pim	3
Craig Lang	3
John Michael Krohn	3
Michael Kemery	3
K4 Enterprises, LLC	3
Michael Kemery	4

ITEM 11. EXECUTIVE COMPENSATION.

The following table sets forth the compensation paid to our Chief Executive Officer, Chief Financial Officer and those executive officers that earned in excess of $120,000 during the last two fiscal years ended December 31, 2017 and 2016 (collectively, the "Named Executive Officers"):

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Cristopher Grunewald Former CEO (1)	2017	17,077	-	-	-	-	-	176,508	193,585
	2016	159,850	-	-	9,750	-	-	180,000	349,600
John William Pim, CFO (2)	2017	123,810	-	30,934	-	-	-	-	154,744
	2016	70,000	-	106,250	-	-	-	-	176,250
John M. Krohn, President, COO, Interim CEO (3)	2017	206,442	-	74,243	-	-	-	-	280,685
	2016	-	-	292,500	70,200	-	-	-	362,700

(1) Mr. Grunewald became President and CEO of the Company on July 24, 2013. Mr. Grunewald resigned as President and Director on December 29, 2016. On May 22, 2017, Mr. Grunewald resigned as Chief Executive Officer.

(2) Mr. Pim became CFO of the Company on November 6, 2015.

(3) Mr. Krohn became a Director of the Company on February 24, 2016. Mr. Krohn became President and Chief Operating Officer of the Company on December 27, 2016, and Interim CEO on May 22, 2017.

Agreements

Below are the agreements the Company is a party to with the named executive officers:

On December 28, 2016, the Company and Mr. Krohn entered into an employment agreement pursuant to which Mr. Krohn is serving as the Company's President and Chief Operating Officer. Mr. Krohn continues to serve as a member of the Company's Board of Directors. Pursuant to Mr. Krohn's employment agreement, he will receive a salary of $240,000 per annum. Mr. Krohn was also issued 450,000 shares of the Company's common stock, and provided the agreement remains in force, will be issued additional shares of common stock as follows: 75,000 shares shall be issued on or about January 2, 2017, 75,000 shares will be issued on or about April 2, 2017, 75,000 shares shall be issued on or about July 2, 2017 and 75,000 shares shall be issued on or about September 2, 2017. The agreement shall continue until the second anniversary thereof, unless terminated earlier pursuant to the agreement, provided that, on December 31, 2018 and each annual anniversary thereafter the Agreement shall be deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the Agreement at least 90 days prior to the applicable renewal date. Mr. Krohn's employment may be terminated by either the Company or by Mr. Krohn at any time and for any reason; provided that, unless otherwise provided therein, either party shall be required to give the other party at least 30 days advance written notice of any termination of Mr. Krohn's employment. In the event that Mr. Krohn's employment is terminated Without Cause by the Company or by Mr. Krohn for Good Reason (as these terms are defined in the agreement), or subject to the terms of the agreement as a result of a Change in Control (as defined in the Agreement), Mr. Krohn shall be entitled to a lump sum payment equal to one times the sum of the his then base salary, as well as to receive payment for any Accrued Amounts (as defined in the agreement).

On December 28, 2016, the Company and Mr. John William Pim entered into an employment agreement pursuant to which Mr. Pim is serving as the Company's Chief Financial Officer. Pursuant to Mr. Pim's employment agreement he will receive a salary of $120,000 per annum. In consideration of Mr. Pim's entering into the Agreement on the effective date, the Company granted the following equity awards to the Mr. Pim pursuant to the Company's 2016 Equity Incentive Plan, provided that the agreement remains in force: 125,000 restricted shares of Common Stock, of which 31,250 shares shall be issued on or about January 2, 2017, 31,250 shares will be issued on or about April 2, 2017, 31,250 shares shall be issued on or about July 2, 2017, and 31,250 shares shall be issued on or about September 2, 2017, provided the agreement remains in effect. The agreement shall continue until the second anniversary thereof.

On January 10, 2017, the Company entered into an Employment Agreement with Cristopher Grunewald pursuant to which he would continue to serve as the Company's Chief Executive Officer at a salary of $180,000 per annum. The agreement was to continue until the second anniversary thereof, unless terminated earlier pursuant to the agreement. Pursuant to such agreement Mr. Grunewald's employment may be terminated by either the Company or by Mr. Grunewald at any time and for any reason; provided that, unless otherwise provided in the agreement, either party shall be required to give the other party at least 30 days advance written notice of any termination of Mr. Grunewald's employment. In the event that Mr. Grunewald's employment is terminated Without Cause by the Company or by Mr. Grunewald for Good Reason (as these terms are defined in the agreement) or subject to the terms of the agreement as a result of a Change in Control (as defined in the agreement), Mr.Grunewald shall be entitled to monthly payments equal to 12 months' salary for the year in which the termination occurred as well as to receive payment for any Accrued Amounts (as defined in the agreement).

On May 22, 2017, Christopher Grunewald resigned as Chief Executive Officer of the Company. Pursuant to Mr. Grunewald's resignation, the Company issued Mr. Grunewald a warrant to purchase 500,000 shares of Common Stock of the Corporation with an exercise price of $1.25 per share for a term of three years. Mr. Grunewald also agreed to cancel 1,618,627 shares of Common Stock of the Company previously owned by Mr. Grunewald. Mr. Grunewald remains with the Company in an advisory capacity pursuant to a consulting agreement.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards at December 31, 2017 with respect to the named executive officers.

Outstanding Equity Awards at Fiscal Year-End

	Option awards					Stock awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
John William Pim	-	-	-	-	-	93,750	$19,684	-	-
John Krohn	-	-	-	-	-	225,000	$47,243	-	-

Equity Compensation Plans

We have three equity compensation plans, the Spotlight Innovation Inc. 2009 Stock Option Plan (the "2009 Plan"), the Spotlight Innovation Inc. 2015 Equity Incentive Plan (the "2015 Plan"), and the Spotlight Innovation Inc. 2016 Equity Incentive Plan (the "2016 Plan").

2009 Plan

The 2009 Plan provides that, subject to the provisions of the 2009 Plan, the Board of Directors may grant to any key individuals who are our employees eligible to receive options, one or more incentive stock options to purchase the number of shares of common stock allotted by the Board of Directors (the "Incentive Stock Options"). The option price per share of common stock deliverable upon the exercise of an Incentive Stock Option shall be at least 100% of the fair market value of our common shares, and in the case of an Incentive Stock Option granted to an optionee who owns more than 10% of the total combined voting power of all classes of our stock, shall not be less than 100% of the fair market value of our common shares. The option term of each Incentive Stock Option shall be determined by the Board of Directors, which shall not commence sooner than from the date of grant and shall terminate no later than ten (10) years from the date of grant of the Incentive Stock Option, subject to possible early termination as described above.

2015 Plan

Effective November 25, 2015, our Board of Directors adopted the Spotlight Innovation Inc. 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan allows us to grant certain options to our directors, officers, employees, and eligible consultants. A total of 3,600,000 shares of our common stock are available for issuance under the 2015 Plan. The 2015 Plan has not been approved by our stockholders. On November 25, 2015, the Company granted incentive stock options and non-qualified stock options to acquire an aggregate of 2,600,000 shares of the Company's common stock under the Company's 2015 Plan to various officers and consultants of the Company. Each option was granted under a three-year vesting term, Twenty Five Percent (25%) upon grant, and Twenty Five Percent (25%) on each of the first, second and third anniversary of grant date. Of the 2,600,000 options granted, 150,000 were issued to an executive officer and the remaining 1,600,000 were issued to certain consultants of the Company. In August 2016 the Company issued 148,571 options to a former director of the Company, with a term of four years.

2016 Plan

Effective December 13, 2016, our Board of Directors adopted the Spotlight Innovation Inc. 2016 Equity Incentive Plan (the "2016 Plan"). The 2016 Plan allows us to grant certain options and shares of stock to our directors, officers, employees, and eligible consultants. A total of 5,000,000 shares of our common stock are available for issuance under the 2016 Plan. The 2015 Plan has not been approved by our stockholders. On December 23, 2016, the Company issued an aggregate of 231,000 shares of its common stock pursuant to the 2016 Plan, in exchange for options to purchase 300,000 shares of the common stock as follows:

Name	Number of Shares issued	Number of Option Shares that were canceled as a result of the exchange
John Krohn (Our President, COO, Interim CEO and Director)	108,000	75,000
Craig Lang (Our Director)	108,000	75,000
Cristopher Grunewald (Our former President and CEO)	15,000	150,000
Total	231,000	300,000

On December 23, 2016, the Company and John William Pim, the Company's Chief Financial Officer, entered into a Restricted Stock Grant Agreement pursuant to which he was granted 125,000 shares of the Company's common stock pursuant to the 2016 Plan. The Company also issued an aggregate of 235,000 shares of common stock pursuant to the 2016 Plan to certain non-executive officers and consultants of the Company in exchange for options to purchase an aggregate of 2,350,000 shares of the Company's common stock originally issued pursuant to the 2015 Plan.

Director Compensation

During the year ended December 31, 2017, directors were not compensated in their capacity as members of the board of directors.

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

The following table sets forth certain information regarding beneficial ownership of our Common Stock as of March 31, 2018: (i) by each of our directors, (ii) by each of the Named Executive Officers, (iii) by all of our executive officers and directors as a group, and (iv) by each person or entity known by us to beneficially own more than five percent (5%) of any class of our outstanding shares.

As of April 25, 2017, there were 29,388,742 shares of our Common Stock outstanding.

Name and Address of Beneficial Owner (1)	Number of Shares Beneficially Owned (1)	Percentage of Shares Beneficially Owned (1)
Directors and Executive Officers:		
John William Pim (2)	368,750	*
John M. Krohn (3)	17,722,134	39.90%
Craig A. Lang (4)	484,038	1.20%
Ralph Arthur (5)	150,230	*
Sanjeev Agarwal (6)	899,486	2.22%
Dr. June Beetler (7)	233,636	*
All executive officers and directors as a group (6 persons)	18,190,055	44.98%
5% or Greater Beneficial Owners:		
Cristopher Grunewald (8)	4,503,627	11.14%
K4 Enterprises, LLC (9)	16,136,915	39.904%
Michael Kemery (10)	16,136,915	39.90%

* Less than one percent.

(1) In determining beneficial ownership of our common stock as of a given date, the number of shares shown includes shares of common stock which may be acquired on exercise of warrants or options or conversion of convertible securities within 60 days of March 31, 2017. In determining the percent of common stock owned by a person or entity on March 31, 2017, (a) the numerator is the number of shares of the class beneficially owned by such person or entity, including shares which may be acquired within 60 days on exercise of warrants or options and conversion of convertible securities, and (b) the denominator is the sum of (i) the total shares of common stock outstanding on March 31, 2017 and (ii) the total number of shares that the beneficial owner may acquire upon conversion of securities and upon exercise of the warrants and options, subject to limitations on conversion and exercise as more fully described below. Unless otherwise stated, each beneficial owner has sole power to vote and dispose of its shares and such person's address is c/o Spotlight Innovation, Inc., 11147 Aurora Avenue, Aurora Business Park, Building 3, Urbandale, Iowa 50322.

(2) Mr. Pim is the Chief Financial Officer of the Company. The number of shares beneficially owned consists of: 243,750 shares of common stock and (ii) 125,000 shares of common held jointly by Mr. Pim and Nancy J. Pim.

(3) Mr. Krohn is the President, Chief Operating Officer, Interim CEO, and a member of the Board of Directors of the Company. The number of shares beneficially owned includes of: (i) 1,505,219 shares of common stock; (ii) 80,000 shares of common stock held in the name of Jordan Krohn and in such capacity holds voting and dispositive power over the securities held by such individual. Mr. Krohn is a Managing Member of K-4 Enterprises, LLC ("K-4") and in such capacity holds voting and dispositive power over the securities held by such entity. The number of securities held directly by K-4 includes: (i) 11,656,915 shares of common stock; (ii) 4,480,000 shares of common stock underlying warrants exercisable within 60 days held by K4.

(4) Mr. Lang is a member of the Board of Directors of the Company. The number of shares beneficially owned consists of: (i) 108,000 shares of common stock; (ii) 352,038 shares of common stock held by Craig Lang, IRA ("IRA"); (iii) 24,000 shares of common stock underlying warrants held by IRA exercisable within 60 days; and (iv) 518,417 shares of common stock issuable upon conversion of a convertible note in the principal amount of $80,000 held by IRA. The address for Mr. Lang is 4245 180th Street, Brooklyn, Iowa 52211.

(5) Mr. Arthur is a member of the Board of Directors of the Company. The number of shares beneficially owned consists of (i) 133,730 shares of common stock and (ii) 16,500 shares of common stock issuable to upon exercise of warrants exercisable within 60 days (iii) 201,607 shares of common stock issuable upon conversion of a convertible note in the principal amount of $35,000.

(6) Dr. Agarwal is a member of the Board of Directors of the Company. The number of shares beneficially owned consists of (i) 794,486 shares of common stock and (ii) 105,000 shares of common stock issuable upon exercise of warrants exercisable within 60 days.

(7) Dr. Beetler is a member of the Board of Directors of the Company. The number of shares beneficially owned consist of (i) 113,636 shares of common stock, and (ii) 120,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days, (iii) 485,000 shares of common stock issuable upon the conversion of convertible notes in the principal amounts of $25,000 and $275,000.

(8) Cristopher Grunewald is the former Chief Executive Officer of the Company. The number of shares beneficially owned consists of: (i) 4,003,626 shares of Common Stock and (ii) 500,000 shares of common stock issuable upon the exercise of warrants (exercisable with 60 days).

(9) The number of securities held directly by K-4 includes: (i) 11.656,915 shares of common stock; and (ii) 4,480,000 shares of common stock underlying warrants exercisable within 60 days held by K4.

(10) Mr. Kemery is a Managing Member of K-4 Enterprises, LLC ("K-4") and in such capacity holds voting and dispositive power over the securities held by such entity. The number of securities held directly by K-4 includes: (i) 11,656,915 shares of common stock; (ii) 4,480,000 shares of common stock underlying warrants exercisable within 60 days held by K4. The address for Mr. Kemery is 124 62nd Street, West Des Moines, IA 50266.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth the aggregate information of our equity compensation plans in effect as of December 31, 2017:

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding column (a))
Equity Compensation Plans Approved by Security Holders 2009 Stock Option Plan	3,605,200	$ 3.95	3,100,000
Equity Compensation Plans Not Approved by Security Holders	1,364,171	1.40	-
Total	4,969,371	$ 2.77	5,050,000

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Since January 1, 2017, except as described herein and below, there has not been any transaction or series of transactions to which we were or are a party in which the amount involved exceeded or exceeds $120,000 and in which any director, executive officer, holder of more than 5% of any class of our voting securities or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest. We believe the transactions set forth below were executed on terms no less favorable to us than we could have obtained from unaffiliated third parties.

On January 10, 2017, the Company entered into an Employment Agreement with Cristopher Grunewald pursuant to which he would continue to serve as the Company's Chief Executive Officer at a salary of $180,000 per annum. The agreement was to continue until the second anniversary thereof, unless terminated earlier pursuant to the agreement. Pursuant to such agreement Mr. Grunewald's employment may be terminated by either the Company or by Mr. Grunewald at any time and for any reason; provided that, unless otherwise provided in the agreement, either party shall be required to give the other party at least 30 days advance written notice of any termination of Mr. Grunewald's employment. In the event that Mr. Grunewald's employment is terminated Without Cause by the Company or by Mr. Grunewald for Good Reason (as these terms are defined in the agreement) or subject to the terms of the agreement as a result of a Change in Control (as defined in the agreement), Mr.Grunewald shall be entitled to monthly payments equal to 12 months' salary for the year in which the termination occurred as well as to receive payment for any Accrued Amounts (as defined in the agreement).

On May 22, 2017, Christopher Grunewald resigned as Chief Executive Officer of the Company. Pursuant to Mr. Grunewald's resignation, the Company issued Mr. Grunewald a warrant to purchase 500,000 shares of Common Stock of the Corporation with an exercise price of $1.25 per share for a term of three years. Mr. Grunewald also agreed to cancel 1,618,627 shares of Common Stock of the Company previously owned by Mr. Grunewald. Mr. Grunewald remains with the Company in an advisory capacity pursuant to a consulting agreement.

On April 21, 2017, Dr. Beetler (Director) purchased a convertible note in the principal amount of $25,000 from the Company, in a private placement, and received a warrant to purchase 7,500 shares of the Company's common stock. These warrants have an exercise price equal to the closing price of the Company common stock of the six-month issuance thereof. The material terms of the note are:

- At any time prior to the maturity date, the note is convertible into shares of common stock of the Company at a price per share equal to 90% of the closing bid price of the common stock during the 20 consecutive trading days immediately preceding such conversion.

- Interest will accrue at 7.5% computed on a 365-day basis. Interest is payable upon conversion of the convertible note at the applicable conversion price.

On June 7, 2017 Dr. Beetler purchased a convertible note in the principal amount of $250,000 from the Company, in a private placement, and received a warrant to purchase 82,500 shares of the Company's common stock. The warrants have an exercise price of $1.30 per share. The material terms of the note are:

- At any time prior to the maturity date, the note is convertible into shares of common stock of the Company at a price per share equal to 90% of the closing bid price of the common stock during the 20 consecutive trading days immediately preceding such conversion and the Floor Conversion price as described in the table below

Conversion Date (by calendar Quarter)	Floor Conversion Price
2017 Q2	$ 0.60
2017 Q3	$ 0.70
2017 Q4	$ 0.85
2018 Q1	$ 1.00
Each Subsequent Quarter	Increase $0.10 per Quarter

- Interest will accrue at 7.5% computed on a 365-day basis. Interest is payable upon conversion of the convertible note at the applicable conversion price.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Principal Accounting Fees & Services	2017	2016
Audit Fees	$ 136,130	$ 273,716
Audit Related Fees		-
Tax Fees	$ 5,100	10,450
All Other Fees		-
Total Fees	$ 141,230	$ 284,166

Audit Fees

These amounts include fees for professional services rendered in auditing our financial statements set forth in our Forms 10-K for the years ended December 31, 2017 and 2016 year-end audit and the reviews of our quarterly financial statements set forth in our Forms 10-Q in 2017 and 2016.

Audit-Related Fees

These amounts consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the Company's consolidated financial statements and are not reported under "Audit Fees." These fees were for professional services incurred in connection with accounting consultations and consultation regarding financial accounting and reporting standards.

Tax Fees

These amounts consisted of fees for services including tax compliance and the preparation of tax returns and tax consultation services.

ITEM 15. EXHIBITS AND FINANCIAL SCHEDULES

(a)(1) Index to Consolidated Financial Statements

The Financial Statements listed in the Index to Consolidated Financial Statements are filed as part of this Annual Report on Form 10-K. See Part II, Item 8, "Financial Statement and Supplementary Data."

(a)(2) Financial Statement Schedules

Other financial statement schedules for the years ended December 31, 2017 and 2016 have been omitted since they are either not required, not applicable, or the information is otherwise included in the consolidated financial statements or the notes to consolidated financial statements.

(a)(3) Exhibits

The Exhibits listed in the accompanying Exhibit Index are attached and incorporated herein by reference and filed as part of this report.

SIGNATURES

Pursuant to the requirements of Securities 13 or 15(d) of the Securities and Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SPOTLIGHT INNOVATION INC.

Dated: April 17, 2018

By: */s/ John M. Krohn*
John M. Krohn, President/COO/Interim Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John M. Krohn John M. Krohn	President, Chief Operating Officer, Interim Chief Executive Officer, and Chairman of the Board (Principal Executive Officer)	April 17, 2018
/s/ William Pim William Pim	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 17, 2018
/s/ Dr. June Beetler Dr. June Beetler	Director	April 17, 2018
/s/ Craig A. Lang Craig A. Lang	Director	April 17, 2018
/s/ Ralph Arthur Ralph Arthur	Director	April 17, 2018
/s/ Dr. Sanjeev Agarwal Dr. Sanjeev Agarwal	Director	April 17, 2018

EXHIBIT NO.	DOCUMENT
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Documents.
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.

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT OF 1934
RULE 13a-14(a) OR 15d-14(a)

I, John M. Krohn, certify that:

1. I have reviewed this Annual Report on Form 10-K (the "Report") for Spotlight Innovation Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 17, 2018

By: */s/ John M. Krohn*
John M. Krohn
President, COO, CEO (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT OF 1934
RULE 13a-14(a) OR 15d-14(a)

I, John William Pim, certify that:

1. I have reviewed this Annual Report on Form 10-K (the "Report") for Spotlight Innovation Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 17, 2018

By: */s/ William Pim*
William Pim
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

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

In connection with the Annual Report of Spotlight Innovation Inc. (the "Company") on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John M. Krohn, President, COO and CEO of the Company, certify, pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 17, 2018

By: */s/ John M. Krohn*
John M. Krohn
President, COO, and CEO (Principal Executive Officer)

EXHIBIT 32.2

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

In connection with the Annual Report of Spotlight Innovation Inc. (the "Company") on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William Pim, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. sec. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 17, 2018

By: */s/ William Pim*
William Pim
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)