SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Kannalife Inc

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018

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

For the transition period from _____ to _____

Commission file number 000-55657

KANNALIFE, INC.

(formerly known as TYG Solutions Corp.)
(Name of small business issuer in its charter)

Delaware	46-2645343	7372
(State or Other Jurisdiction of Incorporation or Organization)	IRS Employer Identification Number	Primary Standard Industrial Classification Code Number

3805 Old Easton Road
Doylestown, PA 18902
(858) 883-2642
(Address and telephone number of principal executive offices)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
Emerging growth company	[X]		

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of April 1, 2019, there were 69,854,141shares of common stock, par value $0.0001 outstanding.

FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K, the other reports, statements, and information that the Company has previously filed with or furnished to, or that we may subsequently file with or furnish to, the SEC and public announcements that we have previously made or may subsequently make include, may include, or may incorporate by reference certain statements that may be deemed to be “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and that are intended to enjoy the protection of the safe harbor for forward-looking statements provided by that Act. To the extent that any statements made in this report contain information that is not historical, these statements are essentially forward-looking. Forward-looking statements can be identified by the use of words such as “anticipate”, “estimate”, “plan”, “project”, “continuing”, “ongoing”, “expect”, “believe”, “intend”, “may”, “will”, “should”, “could”, and other words of similar meaning. These statements are subject to risks and uncertainties that cannot be predicted or quantified and, consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, marketability of our products; legal and regulatory risks associated with trading publicly; our ability to raise additional capital to finance our activities; the future trading of our common stock; our ability to operate as a public company; our ability to protect our proprietary information; general economic and business conditions; the volatility of our operating results and financial condition; our ability to attract or retain qualified senior management personnel and research and development staff; and other risks detailed from time to time in our filings with the SEC, or otherwise.

Information regarding market and industry statistics contained in this report is included based on information available to us that we believe is accurate. It is generally based on industry and other publications that are not produced for purposes of securities offerings or economic analysis. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. We do not undertake any obligation to publicly update any forward-looking statements. As a result, investors should not place undue reliance on these forward-looking statements.

PART I

ITEM 1. BUSINESS.

Overview

We are a biopharmaceutical company focused on discovering, developing and commercializing novel therapeutics from our proprietary cannabinoid product platform in a broad range of disease areas. In our 8 years of operations, we have been principally involved in the research and development of synthetic cannabidiol ("CBD") therapeutics through pre-clinical drug discovery and development processes. We have developed our own intellectual property portfolio and established relationships with globally recognized third parties who are considered leaders in active pharmaceutical ("API") contract manufacturers, formulators and contract bulk drug manufacturers. All of the operations of the Company to date have been in the pre-clinical stage of drug discovery.

CBD is a naturally occurring cannabinoid constituent of cannabis. It was discovered in 1940 and is known to exhibit neuroprotective properties in many experimental systems. However, development of CBD as a drug has been confounded by the following: 1) low potency; 2) a large number of molecular targets; 3) marginal pharmacokinetic properties; and 4) designation as a schedule 1 controlled substance. Our present work has compared the properties of CBD with our patented novel cannabidiol derived molecule, KLS-13019, that has structural similarities to CBD. The design strategy for KLS-13019 was to increase hydrophilicity while optimizing neuroprotective potency against oxidative stress toxicity relevant to hepatic encephalopathy. In early pre-clinical studies, the responses of CBD and KLS-13019 were compared in dissociated rat hippocampal cultures in a pre-clinical model for overt hepatic encephalopathy ("OHE") and also chemotherapy induced peripheral neuropathy ("CIPN").

Comparisons between CBD and KLS-13019 have been published in peer reviewed articles in ACS Medicinal Chemistry Letters (2016, 7, 424-428) and Journal of Molecular Neuroscience (14 August 2018). In the ACS abstract and paper, Notably, KLS-13019 was 50-fold more potent and >400-fold safer than cannabidiol and exhibited an in vitro profile consistent with improved oral bioavailability. In the JOMN abstract and paper, the protective responses of CBD and KLS-13019 were compared in dissociated rat hippocampal cultures co-treated with toxic levels of ethanol and ammonium acetate. This comparison revealed that KLS-13019 was 31-fold more potent than CBD in preventing neuronal toxicity from the combined toxin treatment, while both compounds exhibited complete protective efficacy back to control values.

The Company has been the only licensee from the National Institutes of Health ("NIH") for the licensed use of the U.S. Government's patent 6,630,507 – "Cannabinoids as Antioxidants and Neuroprotectants" (the "'507 Patent") in the disease indications of hepatic encephalopathy ("HE") and Chronic Traumatic Encephalopathy ("CTE"). Having been the only licensee to the '507 Patent has given the Company an early start in the research and development of cannabinoid therapeutics within this emerging market. The Company is the only company that has had use of the '507 Patent and corresponding licenses from NIH-OTT.

The jurisdictions in which the '507 Patent is valid are: the U.S., the U.K., Ireland, the E.U., and Australia. The patent life in these jurisdictions is good until April 21, 2019.

The Company believes that these licenses with the NIH have given the Company, through the years, the preclinical lead time to evaluate both HE and CTE without stress of competition. The Company also believes that such advances in preclinical have led to a drug development program regarding cannabidiol based therapeutics that focuses on neurodegenerative and oxidative stress related diseases described in the '507 Patent, and also the development of the Company's own intellectual property underlying U.S. Patents 9,611,213 and 10,004,722.

Furthermore, it is on the Company's belief and knowledge that while the U.S. Government patent 6,630,507 is due to expire on April 21, 2019, there may be additional opportunities related to the original licensing of the '507 Patent in which the Company may engage with the NIH and certain collaborators of the aforementioned patent to enter into a Cooperative Research and Development Agreement ("CRADA") with the NIH for one or more disease indications underlying the '507 Patent, including but not limited to HE and CTE. Moreover, the weight of the Company's future success, drug development program regarding cannabidiol based therapeutics is not centered on the '507 Patent, but rather its own intellectual property underlying U.S. Patents 9,611,213 and 10,004,722.

HE, is an altered level of consciousness as a result of liver failure. Onset may be gradual or sudden. Other symptoms may include movement problems, changes in mood, or changes in personality. In the advanced stages it can result in a coma.

CTE, formerly known as dementia pugilistica, is a neurodegenerative disease found in people who have had multiple head injuries. Symptoms may include behavioral problems, mood problems, and problems with thinking.

The Company's lead target drug candidate, KLS-13019, is part of an estate of new chemical entities ("NCEs") underlying U.S. Patent 9,611,213 titled "Functionalized 1,3 Benzene-diols and their Method of Use for the Treatment of Hepatic Encephalopathy". This patent is part of a divisional patent application by the Company to the USPTO whereby the Company sought separate claims for composition of matter, covered in Pat. 9,611,213 and separate claims for method for treatment; and U.S. Patent 10,004,722 titled "Method for Treating Hepatic Encephalopathy or a Disease Associated with Free Radical Mediate Stress and Oxidative Stress with Novel Functionalized 1,3 Benzene-diols."

KLS-13019 and its related molecules under the aforementioned patents, describe novel functionalized 1,3-benzenediols ("Cannabidiol Derived Molecules") and methods that may be useful and have potential for the treatment of hepatic encephalopathy and related conditions. The present invention further describes a novel chemotype that may be useful and have potential for the treatment of diseases associated with hepatic encephalopathy. The present invention further describes a novel chemotype that may be useful and have potential as neuroprotective agents. The Cannabidiol Derived Molecules under the present invention may be useful and have potential for treating and preventing diseases associated with free radical mediated stress and oxidative stress including, for example, as previously mentioned, hepatic encephalopathy, Parkinson's disease, Alzheimer's, Huntington's disease, traumatic head injury, stroke, epilepsy, neuropathic pain, Chronic Traumatic Encephalopathy (CTE), Post Cardiac Arrest Hypoxic Ischemic Encephalopathy, and Epileptic Encephalopathy.

To date, we have synthesized, pre-clincally tested and patented our proprietary CBD derived new chemical entities ("NCEs"), including KLS-13019 and also formulated a new CBD based molecule, KLS-13023.

In pre-clinical studies performed pursuant to a Phase 1 small business technology transfers ("STTR") agreement between us, and Temple University, funded by the NIH – National Institute on Drug Abuse ("NIDA"), our research determined that one of our patented CBD derived target drug candidates, KLS-13019 was superior to CBD in the potential treatment of chemotherapy induced peripheral neuropathy ("CIPN").

Results from pharmacokinetic ("PK") and pharmacodynamic ("PD") studies performed in evaluating CBD versus KLS-13019 have shown KLS-13019 to be superior in aqueous solubility (potential for drug absorption after oral administration); Log P (ratio which measures difference in solubility in two phases); bioavailability (proportion of the drug that enters the circulation); and C max at 10 mg/kg, p.o. (peak serum concentration).

Results from our pre-clinical efforts in the potential treatment of OHE and the potential treatment of CIPN have shown a marked improvement over 99.7% pure pharmaceutical grade synthetic CBD in side by side pre-clinical comparison. In a pre-clinical comparison for neuroprotection between CBD and KLS-13019, results indicated increased potency for the new molecule (KLS-13019) as determined by six assays, while both molecules exhibited complete efficacy in preventing oxidative stress-related toxicities back to control values.

However, treatment with KLS-13019 alone was 5-fold less toxic than CBD. Previous studies suggested that CBD targeted the Na^+ Ca^{2+} (sodium-calcium) exchanger in mitochondria to regulate intracellular calcium levels, an important determinant of neuronal survival. After treatment with an inhibitor, the mNCX inhibitor ("CGP-37157"), no detectable neuroprotection from ethanol toxicity was observed for either CBD or KLS-13019. Furthermore, AM630 (a CB2 antagonist) significantly attenuated CBD-mediated neuroprotection, while having no detectable effect on KLS-13019 neuroprotection. Our studies indicated KLS-13019 was more potent and less toxic than CBD. Both molecules can act through mNCX. KLS-13019 may provide an alternative to CBD as a therapeutic candidate to treat disease associated with oxidative stress.

Again, here, comparisons between CBD and KLS-13019 have been published in peer reviewed articles in ACS Medicinal Chemistry Letters (2016, 7, 424-428) and Journal of Molecular Neuroscience (14 August 2018)

Sodium-Calcium Exchanger ("NCX") (often denoted Na^+/Ca^{2+} exchanger, NCX, or exchange protein) is an antiporter membrane protein that removes calcium from cells. The exchanger exists in many different cell types and animal species. The NCX is considered one of the most important cellular mechanisms for removing Ca^{2+} (calcium ions) from cells. The exchanger is usually found in the plasma membranes and the mitochondria and endoplasmic reticulum of excitable cells.

Mitochondria is a double-membrane-bound organelle found in most eukaryotic organisms. Mitochondria generate most of the cell's supply of adenosine triphosphate ("ATP"), used as a source of chemical energy. Adenosine Triphosphate ("ATP") is a complex organic chemical that provides energy to drive many processes in living cells, including muscle contractions, nerve impulse propagation and chemical synthesis.

According to Fallon, et al. in the March/April 2006 edition of Clinical Medicine, pain is uncontrolled with opioid treatments in approximately 20% of patients with advanced cancer, or 420,000 people in the United States. There are currently no approved non-opioid treatments for patients who do not respond to, or experience negative side effects with, opioid medications. We believe that KLS-13019 has the potential to address a significant unmet need in this large market by treating patients with a product that employs a differentiated non-opioid mechanism of action, and offers the prospect of pain relief without increasing opioid-related adverse side effects.

We expect to open an Investigational New Drug Application, or IND to pursue a clinical development program with either the U.S. Food and Drug Administration ("FDA") or the Therapeutic Goods Administration ("TGA"), the regulatory body for therapeutic goods (including medicines, medical devices, gene technology, and blood products) in Australia,

Additionally, the Company plans on screening and conducting preliminary research and development of some of its patented, proprietary cannabidiol-derived new chemical entities ("NCEs"), for use as topical solutions, ointments, and creams for disorders such as diabetic neuropathies, diabetic ulcers, and for use as an anti-pruritic. Anti-pruritics are known as anti-itch drugs and medications that inhibit the itching often associated with a variety of disorders and diseases.

To date there has been only one cannabidiol based medicament, Epidiolex Ò approved for use in humans by the U.S. Food and Drug Administration ("FDA"). The drug, EpidiolexÒ, is used to treat seizures due to certain medical conditions (such as Lennox-Gastaut syndrome, Dravet syndrome). It is not known how this medication works for these seizures. Cannabidiol belongs to a class of drugs known as cannabinoids. Additionally, the FDA's Office of Orphan Products Development ("OOPD") has designated cannabidiol eighteen (18) times since 2013 for a multitude of diseases ranging from rare forms of epilepsy to prevention of reperfusion injury due to organ transplantation to glioblastoma multiforme to autoimmune hepatitis. While the Company's primary indications of OHE and CIPN have not, heretofore, been targeted by CBD-based or CBD-derived drugs and cleared by the FDA or other foreign regulatory agency, neither have the aforementioned eighteen orphan designated indications targeted by cannabidiol.

Corporate Strengths and Weaknesses

We believe that we offer the following key distinguishing characteristics:

- We believe we are the first commercial drug discovery company in the cannabinoid therapeutics space to synthesize CBD derived new chemical entities and pre-clinically test lead NCEs for potential treatment of oxidative stress related diseases, including OHE and CIPN.
- We are the only commercial drug discovery company in the cannabinoid therapeutics space to license the '507 Patent from NIH on two separate occasions.
- We have completed pharmacokinetic and pharmacodynamic pre-clinical studies with high purity scale, pharmaceutical grade CBD and KLS-13019 for potential treatment of oxidative stress related disease – OHE and CIPN.
- We anticipate commencing a Phase 1 trial in CIPN sometime in the 2 nd quarter of 2020.
- We anticipate commencing a Phase 1 trial in OHE sometime in the 4 th quarter of 2020.
- We anticipate commencing a Phase 1 trial in Mild Traumatic Brain Injury in the 2 nd quarter of 2021.
- We have a firm understanding of the mechanism of action of CBD and KLS-13019 in certain oxidative stress related disorders.
- We believe we have a strong next generation intellectual property estate on cannabidiol derived NCEs. On this basis, we believe we can expand the approved indications KLS-13019 and develop additional cannabinoid therapeutic agents to add to our IP portfolio.
- We believe that our pre-clinical drug development program points to a significant opportunity in cancer pain, a large market.
- We believe that our pre-clinical drug development program points to a significant opportunity in opioid replacement / reduction market.

While the Company believes it is well positioned to be competitive in the cannabinoid therapeutics space, it also believes it will face significant challenges in successfully completing one or more clinical trials. In addition, there is a competitive landscape that exists in the market for the Company's target indications of OHE and CIPN. The competitive landscape is challenging. Competition in OHE and CIPN is well established, with significantly greater resources than the Company and leaders in the current standard of care for these diseases.

The current standard of care for patients suffering with OHE is 550mg of Xifaxan Ò, originally an antibiotic useful in treating traveler's diarrhea and irritable bowel syndrome. It's exact mechanism of action is not known, however it is theorized that XifaxanÒ clinical activity may be attributed to effects on metabolic function of gut microbiota, rather than a change in the relative bacterial abundance. Currently, there is no drug in the market for OHE that is being used to treat the toxic effects on the hippocampus, the cognitive and behavioral dysfunction associated with OHE, and the action of neuroprotection from ammonia and ethanol toxicity.

Given the competitive landscape in OHE, the Company believes it can participate in the OHE market with primary and adjunctive therapeutics currently under pre-clinical development, and potentially obtain orphan drug designation for one or more of its target therapeutic agents.

With respect to competitive landscape for CIPN, eight agents have been studied in randomized controlled trials for the treatment of CIPN, but there has been limited success. The characteristics and results of these studies are summarized in the study and abstract "Management of Chemotherapy Induced Peripheral Neuropathy" (Physician's Education Resource LLC, Meghna S. Trivedi, MD; Dawn L. Hershman, MD, MS; Katherine D. Crew, MD, MS). Clinical trials of the antiepileptic agents gabapentin and lamotrigine and the antidepressants nortriptyline and amitriptyline have all been negative.

Addtionally, there have been several small placebo-controlled trials which have shown that intravenous administration of glutathione with platinum-based chemotherapy regimens can decrease the incidence of neurotoxicity without diminishing the effect of chemotherapy. In a North Central Cancer Treatment Group / Alliance trial in 2014, this trial studied the use of glutathione with carboplatin and paclitaxel and found no improvement in neurotoxicity symptoms, suggesting that glutathione may not help in taxane-induced CIPN.

Furthermore, the continuous use of opiates in the current standard of care to treat CIPN has resulted in mixed results, addiction problems and dose tolerance problems.

The Company believes that, while the current standard of care is well positioned in the market, there is an unmet need for the treatment of CIPN in the reduction of use of opiates. This presents itself as an opportunity for the Company to participate with a novel therapeutic agent to treat CIPN.

Clincal Timelines

Product Candidate	Target Indication	Delivery Method	Current Development Status	Expected Next Steps
KLS-13019	Chemotherapy Induced Peripheral Neuropathy	Oral Gel Capsule	Preclinical	2Q20: Initiate Phase 1
	Mild Traumatic Brain Injury	Oral Gel Capsule	Preclinical	2Q21: Initiate Phase 1
KLS-13023	Overt Hepatic Encephalopathy	Oral Gel Capsule	Preclinical	4Q20: Initiate Phase 1
	Mild Traumatic Brain Injury	Oral Gel Capsule	Preclinical	2Q21: Initiate Phase 1

Corporate History

TYG Solutions Corp. was incorporated in the State of Delaware on March 25, 2013. Our original business plan was to develop iPhone and Android smartphone apps for companies who need an app for their internal and external operations. We subsequently expanded our operations to offering corporate website design services.

On July 25, 2018, the Company entered into a Share Exchange Agreement with Kannalife Sciences, Inc., a Delaware corporation ("Kannalife Sciences") and certain stockholders of Kannalife Sciences (the "Kannalife Sciences Stockholders"). Pursuant to the terms of the Share Exchange Agreement, the Company acquired approximately nearly all of the issued and outstanding shares of Kannalife Sciences by means of a share exchange with the Kannalife Sciences Stockholders in exchange for newly issued shares of the common stock of the Company (the "Share Exchange"). As a result of the Share Exchange, Kannalife Sciences became a 99.7% owned subsidiary of the Company. The business operations of the Company regarding iPhone and Android smartphone apps shall be reduced significantly to focus efforts on target therapeutics and drug discovery, and accordingly, by virtue of the Share Exchange, the Company acquired the business of Kannalife Sciences including all of its assets. The Share Exchange was accounted for as a reverse acquisition and change in reporting entity, whereby Kannalife Sciences was the accounting acquirer.

Kannalife Sciences was incorporated in the State of Delaware on August 11, 2010. Kannalife Sciences is a developmental stage phyto-medical/pharmaceutical and drug discovery company that specializes in the research, development of cannabinoid and cannabinoid-based therapeutic products derived from synthetic and botanical sources, including the Cannabis *"taxa"* (the word "taxa" is the plural of "taxon" which defines a group of one or more populations of an organism or organisms to form a unit.).

On November 9, 2018, the Company filed an amendment to its certificate of incorporation with the Delaware Secretary of State to change its name to Kannalife, Inc. The Company concurrently submitted a request to FINRA for approval of the name change as well as a ticker symbol change to "KLFE" and such action went effective on January 17, 2019.

Controlled Substances Laws and Regulations

Our drug candidates contain controlled substances as defined in the Controlled Substances Act (CSA). Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA.

Despite recent approvals by the FDA and DEA for a newly approved medication which contains cannabidiol (CBD), the scheduling of these substances, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market KLS-13019 or KLS-13023. Moreover, because our business is almost entirely dependent upon these two product candidates, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects. See our full description of the impact controlled substances laws and regulations have on our business in the "Risk Factors" section of this prospectus.

KLS-13019 does not contain cannabidiol and is a new chemical entity that would not fall under the Controlled Substances Act ("CSA") or be deemed a Schedule 1 controlled substance. A new chemical entity ("NCE") is a molecule developed by the innovator company in the early drug discovery stage, which after undergoing clinical trials could translate into a drug that could be a treatment for some disease. Under the Food and Drug Administration Amendments Act of 2007, all new chemical entities must first be reviewed by an advisory committee before the FDA can approve these products.

KLS-13023 is a formulation that does contain cannabidiol. At present, cannabidiol is deemed a Schedule 1 controlled substance by the U.S. Drug Enforcement Agency under the Controlled Substances Act. And like the drug molecule EpidiolexÒ, which was recently approved by the FDA for marketing and sale for use in treating Dravet's Syndrome and Lennox-Gasteau Syndrome (forms of child epilepsy), KLS-13023 would need to follow the guidance set forth by the CSA, complete a successful human clinical trial and apply for rescheduling, as was the case with EpidiolexÒ, now a Schedule 5 drug.

On January 14, 2019, the Company received written notice from the Drug Enforcement Administration ("DEA") Drug and Chemical Evaluation Section, as follows: "Please be advised that your material meets the definition of 'Hemp' and is not regulated under the CSA, as long as it consists of high purity Cannabidiol (CBD) that contains approximately 0.1% delta-9- THC. (However, if it contains more than 0.3% delta-9 THC, it is considered 'Marihuana' and would be in Schedule 1 of the CSA)."

Company has been the only licensee from the National Institutes of Health ("NIH") for the licensed use of the U.S. Government's patent 6,630,507 – "Cannabinoids as Antioxidants and Neuroprotectants" (the "'507 Patent") in the disease indications of hepatic encephalopathy ("HE") and Chronic Traumatic Encephalopathy ("CTE"). Having been the only licensee to the '507 Patent has given the Company an early start in the research and development of cannabinoid therapeutics within this emerging market. The Company is the only company that has had use of the '507 Patent and corresponding licenses from NIH-OTT. The jurisdictions in which the '507 Patent is valid are: the U.S., the U.K., Ireland, the E.U., and Australia. The patent life in these jurisdictions are good until April 21, 2019.

The Company believes that these licenses with the NIH have given the Company, through the years, the preclinical lead time to evaluate both HE and CTE without stress of competition. The Company also believes that such advances in preclinical have led to a drug development program regarding cannabidiol based therapeutics that focuses on neurodegenerative and oxidative stress related diseases described in the '507 Patent, and also the development of the Company's own intellectual property underlying U.S. Patents 9,611,213 and 10,004,722.

Furthermore, it is on the Company's belief and knowledge that while the U.S. Government patent 6,630,507 is due to expire on April 21, 2019, there may be additional opportunities related to the original licensing of the '507 Patent in which the Company may engage with the NIH and certain collaborators of the aforementioned patent to enter into a Cooperative Research and Development Agreement ("CRADA") with the NIH for one or more disease indications underlying the '507 Patent, including but not limited to HE and CTE. Moreover, the weight of the Company's future success, drug development program regarding cannabidiol based therapeutics is not centered on the '507 Patent, but rather its own intellectual property underlying U.S. Patents 9,611,213 and 10,004,722.

Corporate Operations

The Company is primarily involved in the research and development of novel therapeutic agents for use in and as U.S. Food and Drug Administration ("FDA") approved ethical pharmaceuticals (available by doctor prescription); FDA Monograph topical solutions; and Personal Care Products Council / International Nomenclature of Cosmetic Ingredients ("INCI") registered. The primary focus of the Company's research and development revolves around its patented, proprietary cannabidiol-derived new chemical entities and cannabidiol.

The Company has been the only licensee from the National Institutes of Health ("NIH") for the licensed use of the U.S. Government's patent 6,630,507 – "Cannabinoids as Antioxidants and Neuroprotectants" (the "'507 Patent") in the disease indications of hepatic encephalopathy ("HE") and Chronic Traumatic Encephalopathy ("CTE"). Having been the only licensee to the '507 Patent has given the Company an early start in the research and development of cannabinoid therapeutics within this emerging market. The Company believes that these licenses with the NIH have given the Company, through the years, the preclinical lead time to evaluate both HE and CTE without stress of competition. The Company also believes that such advances in preclinical have led to a drug development program regarding cannabidiol based therapeutics that focuses on neurodegenerative and oxidative stress related diseases described in the '507 Patent, and also the development of the Company's own intellectual property underlying U.S. Patents 9,611,213 and 10,004,722.

The Company's lead target drug candidate, KLS-13019, is part of an estate of new chemical entities (NCEs) underlying U.S. Patent 9,611,213 titled "Functionalized 1,3 Benzene-diols and their Method of Use for the Treatment of Hepatic Encephalopathy". This patent is part of a divisional patent application by the Company to the USPTO whereby the Company sought separate claims for composition of matter, covered in Pat. 9,611,213 and separate claims for method for treatment; and U.S. Patent 10,004,722 titled "Method for Treating Hepatic Encephalopathy or a Disease Associated with Free Radical Mediate Stress and Oxidative Stress with Novel Functionalized 1,3 Benzene-diols."

KLS-13019 and its related molecules under the aforementioned patents, describe novel functionalized 1,3-benzenediols ("Cannabidiol Derived Molecules") and methods that may be useful and have potential for the treatment of hepatic encephalopathy and related conditions. The present invention further describes a novel chemotype that may be useful and have potential for the treatment of diseases associated with hepatic encephalopathy. The present invention further describes a novel chemotype that may be useful and have potential as neuroprotective agents. The Cannabidiol Derived Molecules under the present invention may be useful and have potential for treating and preventing diseases associated with free radical mediated stress and oxidative stress including, for example, as previously mentioned, hepatic encephalopathy, Parkinson's disease, Alzheimer's, Huntington's disease, traumatic head injury, stroke, epilepsy, neuropathic pain, traumatic head injury, stroke, Chronic Traumatic Encephalopathy (CTE), Post Cardiac Arrest Hypoxic Ischemic Encephalopathy, and Epileptic Encephalopathy.

Management believes the claims made in the Pat. 9,611,213 and Pat. 10,004,722 sufficiently cover the use of the novel molecule KLS-13019 in the treatment of neuropathic pain, which is broadly defined and includes chemotherapy induced neuropathic pain (a/k/a: chemotherapy induced peripheral neuropathy).

The Company's core businesses are comprised of the following:

A drug development company focused on the research and development (R&D) of synthetic and phyto-medical products from:

- naturally recurring sources, including but not limited to cannabis, hemp, and other similar species of plantae;
- semi-synthetic sources; and
- synthetic and bio-synthetic sources.

Drug discovery platform to evaluate and potentially treat neurological and oxidative stress related disorders such as Overt Hepatic Encephalopathy ("OHE"), Chronic Traumatic Encephalopathy ("CTE") and Chemotherapy Induced Peripheral Neuropathy ("CIPN") with high quality assured, quality controlled cGMP pharmaceutical grade semi-synthetic and synthetic cannabinoids, cannabidiol ("CBD"), and cannabidiol-like molecules.

Topical skin care pre-clinical program designed to some of its patented, proprietary cannabidiol-derived new chemical entities ("NCEs"), for use as topical solutions, ointments, and creams for disorders such as diabetic neuropathies, diabetic ulcers, and for use as an anti-pruritic. Anti-pruritics are known as anti-itch drugs and medications that inhibit the itching often associated with a variety of disorders and diseases.

With respect to certain other proprietary molecules underlying Pat. 9,611,213, the Company plans on pursuing topical solutions as potential relief creams and/or ointments for neuropathic pain, anti-inflammation, anti-pruritic and skin ulcers. The Company is considering commercialization routes that include, but are not limited to, filing and FDA Monograph and/or pursing a path to the marketplace through INCI certification and registration with the PCPC. In preclinical testing, certain molecules under Pat. 9,611,213 were screened for neuroprotection and may have the potential mechanism of action for reducing inflammation and neuropathic pain. These molecules indicate that they are more soluble than cannabidiol, also deemed a neuroprotectant with potential anti-inflammatory properties. A molecule that is potentially more water soluble than cannabidiol in this regard may be good candidate(s) for use in topical applications.

The Company believes it has the sufficient capital to proceed forth with a Phase 1 human safety trial for the treatment of Chemotherapy Induced Peripheral Neuropathy. All preclinical work in this indication, including animal toxicity studies, are expected to be completed before the end of the third quarter 2019. The Company plans on entering into clinical trials sometime in the first quarter 2020. Additionally, the Company believes it has the sufficient capital to proceed forth with a Phase 1 human safety trial for the treatment of Overt Hepatic Encephalopathy. All preclinical work in this indication, including animal toxicity studies, are expected to be completed before the end of the fourth quarter 2019.

The Company intends on seeking additional capital to proceed forth with its business plan regarding additional drug pipeline opportunities.

The Company's current relationships with Noramco, a supplier of bulk active pharmaceutical ingredients (APIs), specifically pharmaceutical grade cannabidiol, and Catalent Pharma Solutions, a manufacturer of formulated and packaged pharmaceuticals, will enable the Company to meet its objectives in the production of target drug candidates that can be used in clinical trials and, beyond successful clinical trials, meet patient demand in commercial sales for each of the Company's target disease indications.

The Company has estimated that the cost of a Phase 1 trial, limited to 100 patients in CINP and 76 patients in the OHE indication will cost approximately $1,800,000 and $1,600,000, respectively. As part of the Company's plans to initiate Phase 1 clinical trials in Australia, the Australian government has provided incentives that provide for research and development rebates.

Research & Development tax incentives offered by the government actively encourage overseas sponsors to conduct research in Australia. These incentives have also made it attractive for global companies to access Australian research facilities, as holding the intellectual property within Australia is not mandatory. Sponsors wishing to be eligible for this benefit can either establish an affiliate company in Australia (which may take from 1 week to 1 month) or choose a Contract Research Organization (CRO) to act on their behalf. Non-Australian Sponsors should consider these options and how they can impact on eligibility for the 43.5% R&D tax incentive provided by the Australian government before proceeding.

Therapeutic Goods Administration (TGA) – Australia

Clinical trials conducted in Australia are subject to various regulatory controls to ensure the safety of participants. The TGA regulates the use of therapeutic goods supplied in clinical trials in Australia under the therapeutic goods legislation.

Clinical trial sponsors must be aware of the requirements to import, export, manufacture and supply therapeutic goods in Australia. The following avenues provide for the importation into and/or supply in Australia of 'unapproved' therapeutic goods for use in a clinical trial:

Clinical Trial Notification (CTN) scheme; and
Clinical Trial Exemption (CTX) scheme.

The CTN Scheme is a notification process involving the following:

The Australian clinical trial sponsor must notify us of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good. This must take place before starting to use the goods. The notification form must be submitted online and accompanied by the relevant fee.
The TGA may give the sponsor of the trial written notice to provide specified information relating to goods notified in the CTN form.
The TGA does not evaluate any data relating to the clinical trial at the time of submission. The Human Research Ethics Committee (HREC) reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol. The HREC is also responsible for monitoring the conduct of the trial.
The institution or organization at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

It is the responsibility of the sponsor to ensure that all relevant approvals are in place before supplying the 'unapproved' therapeutic goods in the clinical trial.

The CTX Scheme is an **approval** process involving the following:

A sponsor submits an application to us seeking approval to supply 'unapproved' therapeutic goods in a clinical trial. The application must be accompanied by the relevant fee.
The TGA evaluates summary information about the product including relevant, but limited, scientific data (which may be preclinical and early clinical data) prior to the start of a trial.
The HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol.
The sponsor must notify us of each trial conducted using the unapproved therapeutic good(s) approved in the CTX application.

Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTX schemes. It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good.

Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTX schemes. It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good.

On September 27, 2013, the TGA approved Nabiximols (Sativex ®), a pharmaceutical manufactured by GW Pharmaceuticals for its collaborator Novartis Pharmaceuticals Australia Pty Limited in the treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrated clinically significant improvement in spasticity related symptoms during the initial trial of therapy.

In Australia, in 2014, the Advisory Council on Medicines Scheduling recommended rescheduling cannabidiol from a prohibited substance to being a prescription medicine because, according to the Advisory Council on Medicines Scheduling, “there is a low risk of misuse or abuse as cannabidiol does not possess psychoactive properties”. The TGA accepted this recommendation and the decision took effect in July 2015.

Cannabidiol (CBD) is one of the cannabinoids which may be extracted as a therapeutic good from cannabis. From 1 June 2015, cannabidiol has been included under Schedule 4 (S4) Prescription Only Medicine of the Poisons Standard when preparations for therapeutic use contain 2% or less of other cannabinoids found in cannabis.

In February 2016, the Australian Federal Government passed legislation that amended the Narcotic Drugs Act, allowing the supply of suitable medicinal cannabis products for the management of painful and chronic conditions. This legislation does not relate to the decriminalization of cannabis for general cultivation or recreational use and it does not include the provision of medicinal grade herbal cannabis, only processed, non-smokable medicinal grade products.

Much of the detail remains unclear. For example, the legislation does not specify which products will be covered under the amendment, and it does not specify which particular conditions or symptoms will be eligible for treatment with cannabis-based products. Before products can be prescribed, they must be registered with the Therapeutic Goods Administration (TGA) or, in rare circumstances, receive special approval from the TGA. The registration process requires evidence of testing and efficacy and it is therefore unlikely Australia will see a TGA registered medicinal cannabis product that GPs can prescribe any time soon.

Whilst there are currently no cannabis-based products that are lawfully produced in Australia, the medicinal use of pharmaceutical products containing cannabinoids is not prohibited, as long as authorization for prescribing is granted from the Commonwealth Therapeutic Goods Administration and at this point in time, NSW Health.

Kannalife Intellectual Properties

Kannalife PCT Patent – PCT/US2015/010827

On January 13, 2014, the Company filed for a provisional patent with the USPTO for its "Novel Functionalized 1, 3-Benzene-diols and Their Treatment of Hepatic Encephalopathy", under application 61/926,869.

On January 9, 2015, the Company filed a non-provision patent application Patent Cooperation Treaty ("PCT") Application under application number PCT/US2015/010827 titled, "Novel Functionalized 1,3-Benzene Diols and Their Method of Use for the Treatment of Hepatic Encephalopathy" (the "PCT Patent"). Under the PCT Patent, the present invention describes novel functionalized 1,3-benzenediols ("Cannabidiol Derived Molecules") and methods that may be useful and have potential for the treatment of hepatic encephalopathy and related conditions. The present invention further describes a novel chemotype that may be useful and have potential for the treatment of diseases associated with hepatic encephalopathy. The present invention further describes a novel chemotype that may be useful and have potential as neuroprotective agents.

The Cannabidiol Derived Molecules under the present invention that may be useful and have potential for treating and preventing diseases associated with free radical mediated stress and oxidative stress including, for example, as previously mentioned, hepatic encephalopathy, Parkinson's disease, Alzheimer's, Huntington's disease, traumatic head injury, stroke, epilepsy, neuropathic pain, traumatic head injury, stroke, Chronic Traumatic Encephalopathy (CTE), Post Cardiac Arrest Hypoxic Ischemic Encephalopathy, and Epileptic Encephalopathy.

Regarding one of the Company's target indications, overt hepatic encephalopathy ("OHE"), it is a sub-set of the disease hepatic encephalopathy (HE), a neuropsychiatric disorder that includes learning deficits and impairment of long-term memory. If left unchecked, HE can progress to hepatic coma (also referred to as coma hepaticum) and ultimately death (Cordoba, 2011). The pathogenesis of HE includes damage to the prelimbic cortex, striatum and the hippocampus (Aria et al., 2013). Hepatic encephalopathy is caused by accumulation of toxic substances in the bloodstream that are normally removed by the liver.

The hippocampus, is a major component of the brains of humans and other vertebrates. The hippocampus belongs to the limbic system and plays important roles in the consolidation of information from short-term memory to long-term memory, and in spatial memory that enables navigation.

It has been previously demonstrated that impaired liver function and liver disease is associated with the production of free radical and oxidative stress (Bailey and Cunningham, 1998). The accumulation of these free radicals and oxidative stress contribute to cognitive impairment, learning deficits, memory impairment, as well as damage and death of neuronal tissue. There is a long felt need for neuroprotective agents that are both disease-modifying and effective in treating patients that are experiencing HE. The present invention addresses the need to prevent free radical mediated stress and oxidative stress, as well as to prevent the neural damage associated with HE. The present invention further addresses the need to prevent cognitive impairment, learning deficits, memory impairment, as well as damage and death of neuronal tissue associated with HE. Cognitive impairment is when a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life. Cognitive impairment ranges from mild to severe.

On November 29, 2016, as part of the Company's patent cooperation treaty global patent application the United States Patent and Trademark Office ("USPTO") granted allowance on the composition of matter portion, covering claims 1 through 14 of the Company's PCT Patent covering claims of its novel cannabidiol derived molecule. In January 2017, the Company filed a divisional application with the USPTO to cover the method claims, which were originally covered in claims 15 through 22 of the original PCT Patent. The Company currently holds a valid allowance in the United States on the composition of matter for a new cannabidiol derived molecules.

On April 4, 2017 the Company was awarded U.S. Patent 9,611,213 titled "Functionalized 1,3 Benzene-diols and their Method of Use for the Treatment of Hepatic Encephalopathy". This patent is part of a divisional patent application by the Company to the USPTO whereby the Company sought separate claims for composition of matter, covered in Pat. 9,611,213 and separate claims for method for treatment.

On June 26, 2018, the Company was awarded U.S. Patent 10,004,722 titled "Method for Treating Hepatic Encephalopathy or a Disease Associated with Free Radical Mediate Stress and Oxidative Stress with Novel Functionalized 1,3 Benzene-diols."

The Company has patent pending status of the same PCT Patent in Canada, the European Union, Brazil, Russia, India, China, Japan and Australia.

National Institutes of Health – Office of Technology Transfer ("NIH-OTT") – Patent 6,630,507

On June 12, 2010 the Company filed an application for an exclusive license with National Institutes of Health – Office of Technology Transfer ("NIH-OTT"), for the development and commercialization of a target drug candidate to be used in the treatment of patients suffering with hepatic encephalopathy ("HE"). The application for exclusive license was made for the license and use of U.S. patent 6,630,507 "Cannabinoids as Antioxidants and Neuroprotectants (the "'507 Patent").

On November 17, 2011 the Company received notice of publication in the Federal Register of NIH-OTT's Prospective Grant of Exclusive License – Development of Cannabinoid(s) and Cannabidiol(s) Based Therapeutics to treat hepatic encephalopathy in humans.

On June 12, 2012, the Company entered into an exclusive license with NIH-OTT for the use of the '507 Patent in the commercialization of one or more cannabinoid therapeutics to treat HE.

In addition to the exclusive use of the '507 Patent for the treatment of hepatic encephalopathy, On July 16, 2014, the Company formally entered into a second license agreement with NIH-OTT for the non-exclusive license of the '507 Patent for the treatment of Chronic Traumatic Encephalopathy ("CTE").

The Company is the only company that has use of the '507 Patent and corresponding licenses from NIH-OTT. The jurisdictions in which the '507 Patent is valid are: the U.S., the U.K., Ireland, the E.U., and Australia. The patent life in these jurisdictions are good until April 21, 2019.

To date, while the Company has properly maintained and paid all of the minimum annual royalties and past prosecution fees underlying its two (2) licenses of the '507 Patent, the Company has not been able to secure the necessary funds to advance its drug discovery efforts into human clinical trials and met the additional financial benchmarks set forth in the NIH licenses L-113-2012/0 and L-302-2014/0.

From the time of the issuance of the L-113 License on June 15, 2012 and the issuance of the L-302 License on July 17, 2014, the Company has paid initial license fees of $25,000 per license, minimum annual royalties of $10,000 per license; and a total of approximately $100,000 in past patent prosecution fees on the '507 Patent (covering both the L-113 and L-302 Licenses). The Company's commitment to date to NIH has totaled approximately $290,000.

Pursuant to Section 6 of both the L-113 and L-302 Licenses, "a patent or patent application licensed under this Agreement shall cease to fall within the Licensed Patent Rights for the purpose of computing earned royalty payments in any given country on the earliest of the dates that: (a) the patent application has been abandoned and not continued; (b) the patent expires or irrevocably lapses; or (c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency."

The '507 Patent, underlying both the L-113 and L-302 Licenses, expires on April 21, 2019 in the remaining jurisdictions of the United States, Australia and Europe and the Company's obligation to NIH effectively ends under both, the L-113 and L-302 License agreements.

PRE-CLINICAL DRUG DISCOVERY

Since inception in 2010, the Company's primary drug discovery plans have revolved around neuroprotection and the use of cannabidiol as well as the development of proprietary cannabidiol-derived molecules as a target drug candidates to treat neurodegenerative and oxidative stress related diseases.

Conceptual Drug Discovery of Cannabidiol Derived Molecules

An emerging concept is that blockade of free radical mediated stress and oxidative stress will prevent the neural damage associated with hepatic encephalopathy and prevent cognitive impairment, learning deficits, memory impairment, as well as damage and death of neuronal tissue associated with HE. Cannabidiol Derived Molecules may have the potential of acting as neuroprotective agents by blocking the damage caused by free radicals and oxidative stress may prevent the neural damage associated with hepatic encephalopathy and may also prevent cognitive impairment, learning deficits, memory impairment, as well as damage and death of neuronal tissue associated with HE.

It has been discovered that prevention of free radical mediated stress and oxidative stress can prevent damage and death of neuronal tissue, as well as prevent cognitive impairment, learning deficits, and memory impairment associated with damage and death of neuronal tissue. Without wishing to be limited by theory, it is believed that the neuroprotective agents of the disclosure can ameliorate, abate, otherwise cause to be controlled, diseases associated free radical mediated stress and oxidative stress.

Free radical mediated stress and oxidative stress is also known to contribute to additional pathological conditions including, but not limited to epilepsy, neuropathic pain, traumatic head injury, stroke, Chronic Traumatic Encephalopathy (CTE), Post Cardiac Arrest Hypoxic Ischemic Encephalopathy, Epileptic Encephalopathy, and neurodegenerative diseases such as Parkinson's disease, Alzheimer's, Huntington's disease, and amyotrophic lateral sclerosis (ALS). Under the present invention, these Cannabidiol Derived Molecules, may be capable of acting as neuroprotective agents, and may be useful for the treatment of epilepsy, neuropathic pain, traumatic head injury, stroke, Chronic Traumatic Encephalopathy (CTE), Post Cardiac Arrest Hypoxic Ischemic Encephalopathy, Epileptic Encephalopathy, and neurodegenerative diseases such as Parkinson's disease, Alzheimer's, Huntington's disease, and amyotrophic lateral sclerosis (ALS).

Current Pre-clinical Discovery Efforts

The Company's research and development efforts at the Pennsylvania Biotechnology Center are centered on the creation of novel synthetic cannabinoid and cannabinoid-like molecules, the pre-clinical and *in vitro* efficacy of CBD, a non-psychotropic molecule, and the testing and control of Kannalife's lead target drug candidates alongside CBD for the treatment of OHE and CTE. As part of the Company's research and development efforts, the Company has sought to establish the pre-clinical efficacy of CBD, which along with Kannalife's novel and proprietary lead target molecules, have shown to be high level neuroprotectants. The Company is currently conducting preclinical evaluation and formulation of a CBD based target drug candidate that the Company is calling KLS-13023, and the subject of the Company's ongoing feasibility study with Catalent Pharma Solutions. While the Company has evaluated CBD on its own, in a highly purified form, its plans on bringing a CBD based target drug therapeutic revolve around a formulated product in oral dose administration capsule (KLS-13023) which is currently the subject of the Company's ongoing feasibility study with Catalent Pharma Solutions.

As of October 2013, the Company had performed six (6) distinct pre-clinical studies on murine specimens, including functional assay screens on twenty-four (24) viable analogues and pre-clinical studies against CBD as a therapeutic control. Analogues are compounds or molecules having a structure similar to that of another compound or molecule, but differing from it in respect to a certain component.

As a result of the screening process, the Company found that there were four (4) target candidates along with CBD that were screened for final pre-clinical in vitro testing for pharmacokinetics ("PK"), CACO permeability, lethal dose ("LD"), EC50 and IC90 testing. "Pharmacokinetics" or "PK" relate to the branch of pharmacology concerned with the movement of drugs within the body. Factors in PK studies include CACO permeability which relates to assays that measure the ability of a drug to be absorbed from the gastrointestinal tract and thereby to evaluate whether the drug can be suitably dosed via an oral route. EC50 and IC90 relate to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after a specified exposure time. It is commonly used as a measure of a drug's potency (EC50); and the concentration of a medication in the blood that will inhibit the replication of a specified percentage of microorganisms (IC90).

The Company's lead target drug candidate was then analyzed using a mouse model to determine, among other things, blood brain barrier concentrations, tissue and organ distribution, bioavailability, administration (IV vs. Oral), spinal fluid concentration, and blood plasma concentration. A route of "administration" in pharmacology and toxicology is the path by which a drug, fluid, poison, or other substance is taken into the body. Whereas, "bioavailability' is a subcategory of absorption and relates to a fraction of an administered dose of a drug that reaches systemic circulation in the body. "Blood plasma concentration", otherwise known as volume of distribution is a theoretic concept that relates the amount of drug in the body (dose) to the concentration (C) of drug that is measured (in blood, plasma, and unbound in tissue water).

In May 2014, the Company commissioned the first of two animal behavioral studies via research pact with Temple University. The aim of the study was to test the effects of CBD and KLS-13019 on cognitive function in a mouse model of overt hepatic encephalopathy (OHE) in support of the identification of molecules with in vivo efficacy. An established model of OHE, the thioacetamide model (TAA, 200 mg/kg i.p.), was used to assess the effect of CBD (5.0 mg/kg i.p.) and KLS-13019 (0.5 – 5.0 mg/kg i.p.) on learning and memory in male C57Bl6 mice. The autoshaping procedure, an operant learning and memory assay that rapidly assesses acquisition and retention of a simple task, was the primary cognitive assay used. The task is an operant conditioning task wherein food restricted mice are placed in experimental chambers and must learn how to make a behavioral response to gain access to food rewards.

In summary, thioacetamide induced a robust but variable toxicity associated with cognitive impairment, morbidity, and mortality. KLS13019, administered in the absence of thioacetamide, produced no negative behavioral or general health effects, and actually appeared to improve cognitive functioning in the behavioral task. The 5.0 mg/kg dose of KLS 13019 also significantly prevented thioacetamide-induced cognitive performance deficit, and the lower dose of 1.0 mg/kg showed a trend in this direction.

Dr. Ward is regarded as one of the foremost experts in pre-clinical and clinical animal model based behavioral studies using cannabinoid molecules and agents. The Company believes that upon successful conclusion of this study and conclusive animal toxicity studies to be performed thereafter, that it will be able to file an IND with the FDA for the use of the Company's novel target drug candidate in the treatment of overt hepatic encephalopathy.

The Company believes that, as a result of the completion of most of its pharmacokinetic ("PK") and pharmacodynamics ("PD") studies to date, that to complete the remainder of its pre-clinical evaluation and drug master file, what remains in the most part, is one animal toxicity study and one drug interaction study before the Company can file an investigative new drug application with the FDA, for the clinical evaluation of KLS-13023 (containing CBD) in OHE.

Kannalife Studies on CBD

In March 2013, the Company began its pre-clinical research and discovery efforts at the Pennsylvania Biotechnology Center/Baruch Blumberg Institute in Doylestown, PA. The Company began the research and development, and pre-clinical work focused on the identification, synthesis and/or extraction of novel Cannabis-derived molecules for the treatment of impairments associated with oxidative stress in overt hepatic encephalopathy (OHE). Prior research (published on April 16, 2011, in the British Journal of Pharmacology under the title "Cannabidiol Improves Brain and Liver Function in a Fulminant Hepatic Failure Induced Model of Hepatic Encephalopathy in Mice") has produced substantial behavioral and histochemical evidence demonstrating the effectiveness of certain Cannabis-derived molecules such as CBD in the improvement of brain and liver function in fulminant hepatic failure. Findings from the above referenced study include reversal of locomotors and cognitive pathologies, reversal of structural changes such as Alzheimer's Type II astrogliosis, and reversal of increases in ammonia levels.

The Company published an abstract on its completed studies regarding CBD at the 24th Annual International Cannabinoid Research Society symposium, titled "Cannabidiol Provides Protection from Ethanol and Ammonium Toxicity in a Hippocampal Model of Hepatic Encephalopathy." In the present study, an in vitro model of HE has been utilized to evaluate the protective properties of CBD, a substance with demonstrated protective properties against oxidative stress in pre-clinical studies targeting the OHE range of neuronal toxicity.

HE is a known oxidative stress related disorder. Although ammonia is considered the main factor involved in the pathogenesis of hepatic encephalopathy (HE), it correlates well with the severity of HE in acute liver failure, but not in chronic liver disease. Oxidative stress is another factor believed to play a role in the pathogenesis of this syndrome; it represents an imbalance between the production and neutralization of reactive oxygen species, which leads to cellular dysfunction ("Oxidative Stress: A Systemic Factor Implicated in the Pathogenisis of Hepatic Encephalopathy", Metabolic Brain Disease, 28 June 2013, 175-178).

On January 22, 2015, the Company signed an agreement with Catalent Pharma Solutions LLC ("Catalent"), a $3.9 billion pharmaceutical manufacturer, for the performance of a feasibility study named "Solution for Cannabidiol Softgel Feasibility" (the "CBD OTC Feasibility Study"). Catalent has over seventy-five (75) years of experience in capsule and softgel manufacturing capabilities and experience.

The purpose of the CBD OTC Feasibility Study with Catalent is to advance the Company's plans to one or more products for FDA clinical trials to treat certain oxidative stress related and neurodegenerative related diseases such as Traumatic Brain Injury ("TBI").

Traumatic Brain Injury ("TBI"), also known as intracranial injury, occurs when an external force injures the brain. TBI can be classified based on severity, mechanism (closed or penetrating head injury), or other features (e.g., occurring in a specific location or over a widespread area). Head injury is a broader category that may involve damage to other structures such as the scalp and skull. TBI can result in physical, cognitive, social, emotional, and behavioral symptoms, and outcome can range from complete recovery to permanent disability or death.

The Centers for Disease Control and Prevention (the "CDC") has compiled statistics on traumatic brain injury (TBI), which occurs more with children and older adults. According to the CDC, total combined rates for traumatic brain injury (TBI)-related emergency department (ED) visits, hospitalizations and deaths have increased over the past decade. Total combined rates of TBI-related hospitalizations, ED visits, and deaths climbed slowly from a rate of 521.0 per 100,000 in 2001 to 615.7 per 100,000 in 2005. The rates then dipped to 595.1 per 100,000 in 2006 and 566.7 per 100,000 in 2007. The rates then spiked sharply in 2008 and continued to climb through 2010 to a rate of 823.7 per 100,000 according to the CDC. See *Rates of TBI-Related Emergency Department Visits*, Hospitalizations, and Deaths – United States 2001-2010, Centers for Disease Control and Prevention, January 22, 2016.

On March 4, 2015, the Company and Catalent commenced the feasibility study named "Solution for Cannabidiol Softgel Feasibility."

On March 16, 2015, the Company received notice from Catalent that the U.S. Drug Enforcement Agency ("DEA") that the cannabidiol (CBD) drug code 7360 has been added to Catalent's Schedule 1 registration and that a quota for a certain quantum of cannabidiol was successfully submitted for the importation of 150 grams of 99.7% pure synthetic cannabidiol from Noramco.

Additionally, on July 13, 2018, the Company received notice from the DEA that it was approved for its own Schedule 1 Controlled Substance license for the purpose of research activity. The addition of this license will further assist the Company in the bailment and delivery of cannabidiol to and from research collaborators like Catalent and Temple University as well as others.

The Company's relationship with Catalent was founded on the Company's efforts to produce a formulated version of a CBD based gel capsule, herein referred to as KLS-13023 for further advancements in the treatment of oxidative stress related disorders, such as overt hepatic encephalopathy. Catalent does not share in any royalties, or ownership of intellectual property that is provided to Catalent by the Company or developed under the feasibility study with Catalent described herein. The current feasibility study being performed is for the Company's efforts to create a high quality controlled and assured pharmaceutical grade product for use in an FDA clinical trial to treat patients suffering with overt hepatic encephalopathy. Catalent's efforts in this instance is as a contract manufacturer involved in the advancement of the Company's intellectual property and for Catalent to be a third party contract manufacturer for the commercial production of KLS-13023.

A satisfactory and successful completion of the feasibility study with Catalent, followed by the completion of the Company's pre-clinical evaluation of KLS-13023 in and animal toxicity model, and thereafter the application of KLS-13023 under an NDA with the FDA would lead to a bulk commercial drug manufacturing agreement between the Company and Catalent. The Company has only committed to completing the feasibility study with Catalent and is under no obligation to enter into a commercial drug manufacturing agreement with Catalent. Thereafter the completion of its feasibility study with Catalent, management believes the logical next step in its commercial development plans for KLS-13023 is to engage with Catalent as its contract drug manufacturer for KLS-13023.

CBD Reclassified by DEA for Epidiolex

In a significant decision relating to the classification of CBD, currently a Schedule I narcotic by the DEA under the Controlled Substances Act, on September 27, 2018, the Department of Justice and the DEA announced that Epidiolex, the newly approved medication by the Food & Drug Administration, is being placed in schedule V of the Controlled Substances Act, the least restrictive schedule of the CSA. On June 26 2018, the FDA announced it approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex contains cannabidiol (CBD), a chemical constituent of the cannabis plant (commonly referred to as marijuana). The CBD in Epidiolex is extracted from the cannabis plant and is the first FDA-approved drug to contain a purified extract from the plant. Schedule V drugs represents the least potential for abuse. Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.

We believe this is a significant reclassification that validates the efforts by the Company in the research and development of ethical pharmaceuticals containing CBD as an active pharmaceutical ingredient and reduces the regulatory and market risks associated with the use of CBD, currently and still a Schedule I narcotic.

The Company has maintained since its inception, that the only clear path to reclassification is to follow the regulatory path of proving medical purpose through traditional Phase 1 through Phase 3 clinical trials. The approval of Epidiolex by the FDA on June 26, 2018 and reclassification of CBD as it relates to Epidiolex by the DEA on September 27, 2018, is clear evidence of the need to follow the regulatory path in order to meet the requirements of reclassification of a Schedule I controlled substance.

Kannalife CBD Target Drug Candidate – Orphan Drug Potential for OHE

An Orphan Drug is a pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease. In the US and EU it is easier to gain marketing approval for an orphan drug, and there may be other financial incentives, such as extended exclusivity periods, all intended to encourage the development of drugs which might otherwise lack a sufficient profit motive. The target threshold in epidemiology for patient population in any rare disease is 200,000.

The assignment of orphan status to a disease and to any drugs developed to treat it is a matter of public policy in many countries, and has resulted in medical breakthroughs that may not have otherwise been achieved due to the economics of drug research and development. Existing data on CBD, as well as the Company's target drug candidate have indicated that cannabinoids may be effective for use in clinical trials for the treatment of HE and would, thus provide a new mechanism of action as well as be useful as an adjuvant in combination with existing treatments.

This combination of mechanisms of action could lead to additive or synergistic effects. Existing treatment methods, such as lactulose, Rifaximin and others under study (e.g., AST-120), manage symptoms by reducing ammonia uptake in the digestive system. However, once blood ammonia levels have increased, they putatively provide limited benefits. CBD, as well as the Company's target drug candidate, instead, act in the central nervous system ameliorating the downstream pathological effects of ammonia.

In June 2016, the Company filed for Orphan Drug Designation with the Office of Orphan Products Development ("OOPD") at the U.S. Food and Drug Administration ("FDA") for the use of CBD to treat a sub-set of hepatic encephalopathy. It is estimated that approximately 121,000 +/- hospitalizations occur every year from overt hepatic encephalopathy ammonia neurotoxicity traumas, which put the patient in severe cognitive and behavioral impairment. The current standard of care for the treatment of these traumatic events includes diuretics and anti-biotics, but none currently deal with the neurotoxic aspects of the brain.

In November 2016, the Company received an initial abeyance letter from the OOPD regarding the Company's orphan drug application. The abeyance letter seeks clarification on the epidemiology regarding the Company's target sub-set of the HE disease. In October 2017, the Company responded to the questions set forth in the epidemiology and disease sub-set. The Company received a response on November 30, 2017 from the OOPD agreeing with the Company's position on the orphan disease threshold of patients suffering from the target sub-set of the HE disease. However, the OOPD requested additional information to support the limiting use for hospitalized patients in the sub-set of the HE disease. The Company believes it has the necessary information and data to support its position in requesting orphan drug designation for CBD (as the active pharmaceutical ingredient) in the target sub-set of the HE disease, also referred to as OHE. Accordingly, the Company plans to provide adequate rationale for limiting use of the drug to the orphan sub-set of HE patients requiring inpatient hospital treatment by November 2019.

Kannalife Strategic Third Party Business Relationships, Licenses and Joint Ventures

Natural Products Discovery Institute – Pennsylvania Biotechnology Center

In December 2013, the Company entered into a Materials Transfer and Testing Agreement ("MTTA") with the Institute for Hepatitis and Virus Research and their division, the Natural Products Discovery Institute ("NPDI") located at Pennsylvania Biotechnology Center in Doylestown, PA. The purpose of the MTTA, is among other things, the research of original material made up of plants, plant matter, and plant extracts (the "Plant Materials") to identify bioactive molecules contained in these Plant Materials which may lead to the commercial production of bioactive molecules. To date, the Company has screened one plant source and has fractionated extracts to determine its neuroprotective activity. This plant source and extracted material has shown a high degree of neuroprotectant factor in the face of ethanol and ammonium toxicity in neuronal cell cultures. The Company plans on furthering the commercial development of this material and also filing for patent protection on the process, method and use of this material in the treatment of neurodegenerative diseases.

Under the terms of the MTTA, once the Company agrees to license the biologically active compound from the NPDI, the Company will pay the Baruch S. Blumber Institute ("BSBI"), the parent of the NPDI, (1.) an upfront license fee of $30,000, followed by minimum annual royalties of $10,000; (2.) a three percent (3%) net sales royalty; (3.) milestone payments as follows: (a.) $40,000 upon initiation of Phase 1 clinical trial or foreign equivalent, (b.) $100,000 upon initiation of Phase 2 clinical trial or foreign equivalent, (c.) $250,000 upon initiation of Phase 3 clinical trial or foreign equivalent, and (d.) $500,000 upon first marketing approval by FDA or foreign equivalent; and (4.) additional sub-licensing royalties of twelve percent (12%) on the fair market value of any consideration received for granting each sub-license.

The NPDI, as an institute, is dedicated to making productive use of one of the world's greatest collections of natural products. The NPDI provides microbial and plant extracts, fermentation optimization, purification chemistry to support bioassay driven fractionation, and structure elucidation. It houses a collection of >30,000 fungi and actinomycete microorganisms, and genomic DNA. This previously private collection of natural products is provided to qualified researchers in academia and industry. Research activity has led to the discovery of novel molecules with biological activity and to the formation of new life sciences companies that will seek to commercialize discoveries centered on natural products. Businesses include those developing pharmaceutical, nutritional, flavor enhancing, cosmetic ingredient, agricultural, and animal health products.

To date, the Company's research and development efforts with NPDI have been centered on selective screening of certain natural product for the purpose of identifying extracts and further isolating molecules that may be effective as potential anti-inflammatory, neuro-protective and oxidative stress relieving molecules. The Company has identified one or more selected extracts that it will continue pre-clinical screening for furtherance of developing potential novel therapeutic agents. The Company's agreement with NPDI, provides for certain royalties to be paid to NPDI in connection with the commercialization of products derived from its research and development efforts with NPDI.

Kannaway LLC – Product Development and Marketing Agreement

On March 29, 2014 we signed a five (5) year product development agreement with Kannaway LLC ("Kannaway"), a lifestyle network and relationship marketing company that sells lifestyle products containing ingredients derived from cannabidiol (CBD) rich hemp oil and hemp based (i.) botanical products, (ii.) naturopathic and nutritional supplements, and (iii.) nutraceuticals. Kannaway currently has over 50,000 independent sales and marketing representatives in its network. Kannaway sells lifestyle products containing ingredients derived from cannabidiol (CBD) rich hemp oil and hemp based (i.) botanical products, (ii.) naturopathic and nutritional supplements, and (iii.) nutraceuticals. The product development agreement between Kannaway and the Company includes, among other things, product development milestone revenues for the Company totaling $750,000 and a stock swap of 4.99% of the Common Stock of the Company in exchange for 4.99% interest in Kannaway.

In January 2015, after we entered into the product development agreement with Kannaway, Kannaway was sold, by its parent company, to MJNA for 833,333,333 shares of MJNA common stock. We made demands upon MJNA and Kannaway's former parent company to deliver 41,583,333 shares of MJNA common stock as part of the stock swap in the product development agreement between us and Kannaway. A dispute arose between us, MJNA and Kannaway's former parent which held up the delivery of the 41,583,333 shares of common stock to the Company. The dispute between the Company and MJNA revolved around a corporate relocation clause found in the terms underlying the product development agreement.

In June 2018, we entered into a settlement agreement with MJNA, Kannaway, and the former parent company of Kannaway. The settlement agreement called for the release of all obligations in exchange for the issuance of 41,583,333 shares of common stock in MJNA to the Company. On June 1, 2018, the Company received 41,583,333 shares of Medical Marijuana, Inc. ("MJNA") common stock pursuant to a settlement agreement as part of the cancellation of the above agreement.

Temple University – Animal Behavioral/Pre-Clinical Model

On May 1, 2014, the Company signed a Research Services Agreement with Temple University to test the effects of cannabidiol and cannabidiol like molecules in a hepatic encephalopathy model of cognitive impairment in support of the identification of molecules with *in vivo* efficacy. The tests were performed by Temple University in the pre-clinical model for hepatic encephalopathy have involved a mouse model of overt hepatic encephalopathy ("OHE") and administration of CBD and KLS-13019 conducted by Dr. Sara Jane Ward and Dr. Ronald Tuma, with the study titled – "Cognitive, neurological, and motor function in a mouse model of hepatic encephalopathy: effects of CBD and CBD analogues (KLS-13019)." The results of this study have shown that KLS-13019 is superior to CBD in the intervention of cognitive impairment from associated neurotoxicity in the OHE model.

On January 4, 2017, the Company applied for a Phase 1 Small Business Technology Transfer ("STTR") grant from the National Institutes of Health. This grant application was made in collaboration with Temple University and titled "Development of KLS-13019 for Chemotherapy Induced Peripheral Neuropathy and Drug Dependence". In December 2017, the Company was informed that the Phase 1 grant was awarded.

The following is a summary outline of the aims proposed in the aforementioned grant.

Chemotherapy-induced peripheral neuropathy (CIPN) can be a chronic, severely debilitating consequence of cancer therapy for which there are no effective management strategies. Moreover, upwards of 80% of CIPN patients reported using prescription opioids for pain management despite the fact that there is only weak evidence that the long-term continuation of opioids provides clinically significant pain relief in these patients.

Mitochondrial dysfunction, oxidative stress, and inflammation have all been implicated in its etiology. We have shown that the non-psychoactive cannabinoid cannabidiol (CBD) prevents the development of CIPN in a mouse model of paclitaxel-induced cold and mechanical allodynia. This target, allodynia, refers to central pain sensitization (increased response of neurons) following normally non-painful, often repetitive stimulation. It can lead to the triggering of pain response from stimuli which normally do not provoke pain.

In vitro, we observe that paclitaxel increases microglial expression of several putative mediators of neuropathic pain, and that this effect can be blocked by CBD in a mitochondrial Na+/Ca2+ exchanger (mNCX)- dependent manner. We have also recently shown that a more potent, hydrophilic analogue of CBD, KLS-13019, protects against paclitaxel-induced oxidative stress in cultured dorsal root ganglia neurons, and that the mechanism underlying this neuroprotection is also regulation of intracellular calcium via the mNCX. Preliminary results demonstrate that KLS-13019 can attenuate mechanical sensitivity associated with CIPN while also reducing microglial activation and T cell infiltration into the spinal cord.

Dorsal root ganglia (“DRG”) is a cluster of neurons (a ganglion) in the dorsal root of a spinal nerve. The cell bodies of sensory neurons known as the first-order neurons are located in the dorsal root ganglia. Even though dorsal root ganglia are a part of the system of peripheral nerves, they lie very close to the spine, and therefore to the central nervous system. That makes them an important connection between the two systems. These nerve clusters help transmit messages toward the brain and play a key role in neuropathic pain development and maintenance. Peripheral nerve injury-induced neuropathic pain is one of major clinical disorders characterized by spontaneous ongoing or intermittent burning pain, sensory abnormalities (dysesthesia), an increased response to painful stimuli (hyperalgesia), and pain in response to normally innocuous stimuli (allodynia).

Our central hypothesis is that administration of CBD or KLS-13019 helps preserve Ca2+ homeostasis by promoting activity of the mNCX, which in turn protects from both mitochondrial dysfunction and microglial activation to prevent the neuronal and glial changes associated with the development and maintenance of paclitaxel-induced neuropathic pain. Results from experiments in AIM 1 will demonstrate that the neuroprotective properties of CBD and KLS-13019 can be reduced by pharmacological or gene knockdown of the mNCX in a statistically significant manner. Results from experiments in AIM 2 will further confirm the i.p. and p.o. efficacy of KLS-13019 vs CBD to prevent or reverse mechanical sensitivity and neuroinflammation in a mouse model of paclitaxel-induced neuropathic pain and that repeated administration of these molecules does not lead to analgesic tolerance. Remarkably, the non-psychoactive CBD has also been shown to inhibit cue-induced heroi-seeking and neurochemical correlates thereof in a rat model of relapse and decrease heroin craving in a small human study. Experiments in AIM 3 are designed to test the hypothesis that KLS-13019 and CBD will attenuate reinstatement of morphine seeking behavior in a rat model of opioid relapse. The overall impact of the results from the proposed research will be significant advancements into 1) identification of specific mechanisms that induce CIPN, 2) application of this knowledge to facilitate design of novel treatment strategies for neuropathic pain, and 3) novel treatment strategies to reduce or replace prescription opioid use and decrease prescription opioid abuse.

Chemotherapy-induced peripheral neuropathy (CIPN) can be a chronic, severely debilitating consequence of cancer therapy for which there are no effective management strategies. Moreover, upwards of 80% of CIPN patients reported using prescription opioids for pain management, despite the weak evidence of their efficacy and the risks of long term dependence. Mitochondrial dysfunction, calcium dysregulation, oxidative stress, and inflammation have all been implicated in its etiology. In pre-clinical studies, cannabidiol (CBD), a non-psychoactive component of cannabis sativa, has shown evidence in a murine model to be a potentially effective treatment for CIPN and relieving opiate dependence currently experienced by certain patients undergoing current therapeutic chemotherapy and pain management regimens in cancer treatment. However, CBD has severe limitations in terms of potency, safety, oral bioavailability, and regulatory restrictions. KLS-13019 is a novel new chemical entity that, as per pre-clinical testing, may be able to target these problems. This grant research seeks to demonstrate the efficacy of KLS- 13019 in models of CIPN and opiate dependence, and also further elucidate its mechanism of action in regulation of calcium levels and inflammatory sequelae.

Proposed Study for Traumatic Brain Injury

To investigate the mechanisms of action through which cannabidiol and a cannabinoid analogue (KLS-13019) provide neuroprotection form neurotoxicity factors (glutamate and CCL11) relevant to TBI. Neural damage associated with TBI has been associated with multiple processes including excitotoxicity, oxidative stress and neuroinflammation. Because of the recognized protective effects of cannabinoids on all of these toxic processes, we have chosen to explore the effects and mechanism of action of two molecules: 1) cannabidiol (CBD), a substance found in cannabis; and 2) KLS-13019, a novel CBD-like analogue that has been shown to protective from various toxicity associated with oxidative stress (Kinney et al., 2016). In this proposal, we intend to investigate the protective mechanisms related to the attenuation of CCL11 for both molecules in disease-relevant in vitro test systems that utilized glutatmate as a relevant toxin and then explore their effectiveness in animal models of TBI.

Catalent Pharma Solutions

In December 2014, the Company signed a feasibility study contract with Catalent Pharma Solutions (“Catalent”), for among other things, to commence a feasibility study on a dose controlled soft-gel containing cannabidiol as the main active pharmaceutical ingredient (the “CBD Feasibility Study”). The purpose of the CBD Feasibility Study with Catalent is to enable the Company to develop a proprietary drug product formulation using CBD that has suitable solubility and stability characteristics for IND enabling pre-clinical studies in animals and clinical studies in humans, as part of Kannalife’s ongoing research and development of a cannabinoid therapeutic for the treatment of neurodegenerative diseases, including chronic traumatic encephalopathy (CTE) and overt hepatic encephalopathy (OHE). Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics, consumer health and animal health products. With over 80 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs approximately 8,700 people, including over 1,000 scientists, at 31 facilities across 5 continents, and in fiscal 2015 generated more than $1.8 billion in annual revenue. Catalent is headquartered in Somerset, N.J.

Noramco, Inc.

In April 2015, the Company entered into discussions with Noramco, Inc. (“Noramco”), for among other things, the long term supply of high purity, pharmaceutical grade, synthetic cannabidiol for the purpose of delivering CBD as an active pharmaceutical ingredient to Catalent in connection with the Company’s CBD Feasibility Study.

In addition to the procurement of CBD through Noramco, the Company and Noramco have discussed an additional feasibility study for the scale-up and commercial production of KLS-13019.

Noramco, Inc. (“Noramco”) was formed in 1979 to provide a secure source of Codeine Phosphate. With the acquisition of Tasmanian Alkaloids and addition of the Athens, Georgia site in 1982, and continuous expansions over the past three decades at both US facilities, Noramco now contributes to billion dollar affiliate franchises, as well as to significant 3rd party generic and branded pharmaceutical products worldwide.

Noramco is a world leader in specialty active pharmaceutical ingredients, with a particular focus in controlled substances. The Company’s headquarters and primary production facility is in Wilmington DE, with additional sites in Athens, GA and Schaffhausen Switzerland.

SK Capital Partners (“SK Capital”) acquired Noramco from Johnson & Johnson in July 2016. SK Capital is a private investment firm with a disciplined focus on the specialty materials, chemicals and healthcare sectors. The firm builds strong and growing businesses that generate substantial long-term value for our investors. SK Capital utilizes its industry, operating and investment experience to identify opportunities to transform businesses into higher performing organizations with improved strategic positioning, growth and profitability as well as lower operating risk. The firm currently has more than $1.5 billion of third party capital under management.

Quintiles IMS / IQVIA (formerly Coté Orphan LLC)

In May 2016, the Company engaged with Coté Orphan LLC (“Coté Orphan”) to assist the Company in its filing of an application with the FDA for Orphan Drug Designation in the use of CBD to treat a sub-set of HE. (also referred to herein as OHE).Coté Orphan is a boutique full-service regulatory group with a primary focus on Orphan Drugs. From the lab to the market, Coté Orphan takes concepts to Orphan Drug and Clinical Trial applications before the FDA and EMA for approval. Coté Orphan is led by Dr. Tim Coté, the former Director of the FDA’s Office of Orphan Products Development (“OOPD”).

The advantages of having a strategic relationship with Coté Orphan is as follows:

As director of the OOPD at the FDA, Dr. Tim Coté personally signed off on 1,400 orphan designation applications, awarding designations to 800 and withholding approval of 600.
Oversaw the progress to full marketing approval of 150+ orphan drugs from 2007 to 2011.
Team of twenty-five (25) professionals of whom over seventy percent (>70%) are doctoral-level trained.
Regulatory scientists who have deep knowledge and experience in the “unwritten rules” of the FDA regarding orphan drugs.
Coté Orphan is the largest submitter of FDA and EMA orphan designations worldwide.
Coté Orphan does not merely opine, they do the work of creating quality regulatory filings.

On June 2, 2017, Coté Orphan LLC was purchased and is now wholly owned by Quintiles IMS. The Company has continued its efforts through IQVIA, a division of Quintiles IMC, in petitioning the FDA’s OOPD in furtherance of the Company’s application for orphan designation for CBD to treat a sub-set of HE.

The Company has filed for orphan designation with the U.S. Food and Drug Administration (“FDA”) for the use of CBD in the treatment overt hepatic encephalopathy (“OHE”). The Company has received notice from the FDA that its current application qualifies for a patient population of less than 200,000, but is currently in abeyance to resolve clinical use of CBD in this sub-set of hepatic encephalopathy. The Company has retained Coté Orphan to continue the process of responding to the FDA’s abeyance letter. On November 5, 2018, the FDA has granted the Company a one year extension to respond to the abeyance letter until November 30, 2019.

PRIMARY TARGETS FOR DRUG DISCOVER AND MARKET SIZE

Target 1: Hepatic Encephalopathy – $2+ Billion Market in the U.S.

Hepatic encephalopathy (a complication of liver cirrhosis) is one of the most important clinical manifestations in decompensated liver cirrhosis. Accepted concepts regarding the pathophysiology of hepatic encephalopathy are that the endogenous neurotoxic substances, including ammonia: (i.) escape from catabolism by the liver due both to the impaired function of the cirrhotic liver and also to the presence of portal systemic shunting; (ii.) circulate at elevated concentrations in the systemic blood flow; (iii.) reach the brain through the blood-brain barrier; and (iv.) impair cerebral function leading to disturbances of consciousness. See *Discovery of KLS-13019, a Cannabidiol-Derived Neuroprotective Agent, with Improved Potency, Safety, and Permeability.* William A. Kinney, Mark E. McDonnell, Hua Marlon Zhong, Chaomin Liu, Lanyi Yang, Wei Ling, Tao Qian, Yu Chen, Zhijie Cai, Dean Petkanas, and Douglas E. Brenneman – ACS Med. Chem. Lett., 2016, 7 (4), pp 424–428.

The majority of these toxins are produced in the intestine by the bacterial flora, and are absorbed into the portal venous flow. In spite of improved therapeutic options for encephalopathy, the long-term survival is still low. Thus, hepatic encephalopathy remains a serious complication of liver cirrhosis. We believe that the establishment of truly effective prevention modalities and broader application of liver transplantation will help rescue patients suffering from this complication of liver cirrhosis in the near future.

The Company's exclusive license and use of the '507 Patent and the Company's commercial development plan will focus on the identification, synthesis and/or extraction of novel Cannabis-derived molecules for the treatment of impairments associated with oxidative stress in Hepatic Encephalopathy (HE).

According to an article published in the British Journal of Pharmacology Research over the past decade has produced substantial behavioral and histochemical evidence demonstrating the effectiveness of certain Cannabis-derived molecules such as Cannabidiol ("CBD") in the improvement of brain and liver function in fulminant hepatic failure. Findings include reversal of locomotors and cognitive pathologies, reversal of structural changes such as Alzheimer's Type II astrogliosis, and reversal of increases in ammonia levels. Beyond the supportive preclinical evidence, multiple factors provide reasons for enthusiasm in the pursuit of the HE indication:

New mechanism of action: Cannabinoids, if shown effective in clinical trials, would provide a new mechanism of action and thus be an incremental clinical tool to combine with existing treatments. This combination of mechanisms of action could lead to additive or synergistic effects. Existing treatment methods, such as lactulose, Rifaximin and others under study (e.g., AST-120), manage symptoms by reducing ammonia uptake in the digestive system. However, once blood ammonia levels have increased, they putatively provide limited benefits. Cannabinoids, instead, act in the central nervous system ameliorating the downstream pathological effects of ammonia.

Multiple preventive benefits: According to National Institute of Health, pre-clinical studies have shown that CBD, the major constituent in Kannalife's intended lead target drug molecule and candidate, may provide benefits in the secondary prevention of HE.

- Steatosis: *In vitro* studies have shown CBD to reverse the histopathology associated with steatosis or fatty liver syndrome. This is particularly relevant because fatty liver is a major cause of liver cirrhosis, and has no current drug-based treatment. In addition, multiple currently marketed drugs are known to induce steatosis. These include steroids (e.g., triamcinolone, cortisone, prednisone), the anti-cancer drug Tamoxifen (a breast cancer drug), HIV anti-retrovirals and anti-arrythmic drug Amiodarone.

- Fibrogenesis: Animal studies have shown that endocannabinoids are involved in the regulation of fibrogenesis in the liver. CB2 -/- mice show increased fibrogenesis in response to CCl4 injection, whereas CB1 -/- mice have decreased hepatic fibrogenesis. This suggests an opportunity to modulate fibrogenesis, a critical intermediate step in liver cirrhosis, through a proper selection of cannabinoid antagonists.

Hepatic encephalopathy (HE) is a neuropsychiatric disorder that includes learning deficits and impairment of long-term memory. Hepatic encephalopathy can be caused by chronic and excessive ethanol ingestion along with the accumulation of toxic substances that are normally removed by the liver. The pathogenesis of HE in the central nervous system includes damage to the pre-limbic cortex, striatum and the hippocampus, and this pathology is believed to be mediated by the accumulation of free radicals and oxidative stress. Hepatic encephalopathy has primary epidemiological precursors in cirrhosis, hepatitis B, hepatitis C, and portal hypertension. The incidence rate of HE among alcohol induced cirrhosis patients is as high as 45%, making HE a leading opportunistic disease stemming from alcoholism. If left unchecked, HE can progress to hepatic coma and ultimately death. The pathogenesis of HE includes damage to the prelimbic cortex, striatum, and the hippocampus. Hepatic encephalopathy is caused by accumulation of toxic substances in the bloodstream that are normally removed by the liver.

It has been previously demonstrated that impairment of hepatocytes by ethanol is associated with the production of free radical and oxidative stress. The accumulation of these free radicals and oxidative stress contribute to cognitive impairment, learning deficits, memory impairment, as well as damage and death of neuronal tissue. An emerging concept is that blockade of free radical mediated stress and oxidative stress will prevent the neural damage associated with hepatic encephalopathy and prevent cognitive impairment, learning deficits, memory impairment, as well as damage and death of neuronal tissue associated with HE.

The Company's proposed commercialization of the '507 Patent is intended to benefit the public health by reducing the oxidative stresses and neurological complications that are prevalent in patients suffering with hepatic encephalopathy.

Currently in the United States, there are over 1.5 million sufferers of HE across four stages, including approximately 121,000 patients hospitalized each year from the overt hepatic encephalopathy (OHE) stage of the disease.

Cannabidiol (CBD) vs. KLS-13019 in Overt Hepatic Encephalopathy (OHE)

In a publication in American Chemical Society Medicinal Chemistry Letters on February 10, 2016, our abstract read as follows:

"Cannabidiol is the nonpsychoactive natural component of C. sativa (cannabis sativa) that has been shown to be neuroprotective in multiple animal models. Our interest is to advance a therapeutic candidate for the orphan indication overt hepatic encephalopathy (OHE). OHE is a serious neurological disorder that occurs in patients with cirrhosis or liver failure. Although cannabidiol has shown evidence in a murine model to be a potentially effective treatment for OHE, it has limitations in terms of safety and oral bioavailability. Herein, we describe a series of side chain modified resorcinols that were designed for greater hydrophilicity and "drug likeness", while varying hydrogen bond donors, acceptors, architecture, basicity, neutrality, acidity, and polar surface area within the pendent group. Our primary screen evaluated the ability of the test agents to prevent damage to hippocampal neurons induced by ammonium acetate and ethanol at clinically relevant concentrations. Notably, KLS-13019 was 50-fold more potent and >400-fold safer than cannabidiol and exhibited an in vitro profile consistent with improved oral bioavailability."

Cannabidiol has been shown to be neuroprotective by blocking the damage caused by free radicals and oxidative stress. This effect was independent of cannabinoid receptors because it could not be blocked by a cannabinoid antagonist. CBD has shown evidence in two a murine models to be a potentially effective treatment for HE, thioacetamide induced and bile duct ligation induced liver damage, at a dose of 5 mg/kg IP (intraperitoneal injection). Importantly, CBD treated animals in the first study exhibited improvements in both liver and brain function as compared to untreated control animals. Free radical mediated stress and oxidative stress are also known to contribute to additional pathological conditions including epilepsy, neuropathic pain, traumatic head injury, stroke, chronic traumatic encephalopathy (CTE), and neurodegenerative diseases such as Parkinson's disease, Alzheimer's disease, Huntington's disease, and amyotrophic lateral sclerosis (ALS).

Other examples of neuroprotection by CBD include use in hypoxia-ischemia and stroke models. A wide range of possible mechanisms have been attributed for CBD's neuroprotective effects including antioxidant, anti-inflammatory, adenosine signaling, cannabinoid receptor GPR55 (G Protein-coupled receptor 55), and serotonin mediated pathways; however, mitochondrial calcium modulation is fundamental. The GPR55 receptor is a G protein receptor in humans that is encoded by the GPR55 gene. The GPR55 receptor has been identified as a novel cannabinoid receptor. Receptors are sensing molecules which communicate signals between cells to illicit physiological changes in the body. To hedge our bets, we chose to interrogate the hippocampal neuron, as a phenotypic screen that will measure neuroprotection independent of a mechanism.

Target 2: Chronic Traumatic Encephalopathy (CTE) – $2+ Billion Market in the U.S.

Not unlike Overt hepatic encephalopathy, chronic traumatic encephalopathy is a neuro-degenerative disease of the brain and is associated with repeated head traumas like concussions. In the National Football League ("NFL"), the statistics are alarming. In 2010 there were .679 concussions per game (218 in 321 combined pre-season and regular season games). While there was a decrease in incidents in 2011 (.594 concussions per game), the statistics are still the source of significant concern. See *NFL to Follow Army's Lead on Helmet Sensors in Attempt to Prevent Head Injury* – L. Madden, SportsMoney, July 26, 2012.

Chronic Traumatic Encephalopathy ("CTE") is a form of encephalopathy that is a progressive neuro-degenerative disease, which can only be definitively diagnosed postmortem, in individuals with a history of multiple concussions and other forms of head injury. The disease was previously called dementia pugilistica ("DP"), as it was initially found in those with a history of boxing. CTE has been most commonly found in professional athletes participating in American football, ice hockey, professional wrestling and other contact sports who have experienced repetitive brain trauma.

It has also been found in soldiers exposed to a blast or a concussive injury, in both cases resulting in characteristic degeneration of brain tissue and the accumulation of tau protein. Individuals with CTE may show symptoms of dementia, such as memory loss, aggression, confusion and depression, which generally appear years or many decades after the trauma. Repeated concussions and injuries less serious than concussions ("sub-concussions") incurred during the play of contact sports over a long period can result in CTE. In the case of blast injury, a single exposure to a blast and the subsequent violent movement of the head in the blast wind can cause the condition.

The primary physical manifestations of CTE include a reduction in brain weight, associated with atrophy of the frontal and temporal cortices and medial temporal lobe. The lateral ventricles and the third ventricle are often enlarged, with rare instances of dilation of the fourth ventricle.

Other physical manifestations of CTE include pallor of the substantia nigra and locus ceruleus, and atrophy of the olfactory bulbs, thalamus, mammillary bodies, brainstem and cerebellum. As CTE progresses, there may be marked atrophy of the hippocampus, entorhinal cortex, and amygdala.

On a microscopic scale the pathology includes neuronal loss, tau deposition, TAR DNA- binding Protein 43 (TDP 43) beta-amyloid deposition, white matter changes, and other abnormalities. The tau deposition occurs as dense neurofibrillary tangles (NFT), neurites, and glial tangles, which are made up of astrocytes and other glial cells Beta-amyloid deposition is relatively uncommon feature of CTE.

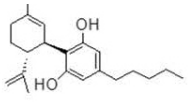
A small group of individuals with CTE have chronic traumatic encephalo-myopathy (CTEM), characterized by motor neuron disease symptoms and mimics Amyotrophic Lateral Sclerosis (ALS) or Lou Gehrig's disease. Progressive muscle weakness and balance and gait problems seem to be early signs of CTEM.

Target 3: Chemotherapy Induced Peripheral Neuropathy (CIPN) – $3+ Billion Market in U.S.

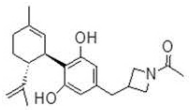
In December 2016, as part of a Small Business Technology Transfer ("STTR") program, the Company, in cooperation with Temple University, Kannalife and Temple University filed an STTR grant proposal with the National Cancer Institute ("NCI") to demonstrate improved in vivo efficacy of an orally administered KLS-13019, Kannalife's lead target drug candidate in a head-to-head comparison to intraperitoneal injection ("IP Injection") of CBD in a model of chemotherapy-induced peripheral neuropathy.

At the conclusion of Phase I STTR application, we will demonstrate that KLS-13019 (Per os – taken through the mouth) can control mechanical sensitivity and inflammation associated with CIPN in the absence of tolerance development, and also reduce opioid craving behavior with comparable efficacy to cannabidiol (intraperitoneal injection). In Phase II STTR, we will investigate a back-up series and will execute the CMC, pharmacokinetic, safety pharmacology, and toxicology assessments required for IND filing on KLS-13019.

A visual image of the chemical structure of cannabidiol and KLS-13019 can be seen as follows, along with selected data describing EC_{50} (the concentration of a drug that give half-maximum response); Safety Margin (pre-clinical toxicity), and Bioavailability (seen as "F"):



Cannabidiol
EC_{50} = 2,000 nM
Safety Margin = 16-fold
F = 8.5%



KLS-13019
EC_{50} = 40 nM
Safety Margin = 7,500-fold
F = 67%

KLS-13019 does not contain cannabidiol and is a new chemical entity that would not fall under the Controlled Substances Act ("CSA") or be deemed a Schedule 1 controlled substance.

KLS-13023 is a formulation that does contain cannabidiol. At present, cannabidiol is deemed a Schedule 1 controlled substance by the U.S. Drug Enforcement Agency under the Controlled Substances Act. And like the drug molecule EpidiolexÒ, which was recently approved by the FDA for marketing and sale for use in treating Dravet's Syndrome and Lennox-Gasteau Syndrome (forms of child epilepsy), KLS-13023 would need to follow the guidance set forth by the CSA, complete a successful human clinical trial and apply for rescheduling, as was the case with EpidiolexÒ, now a Schedule 5 drug.

The Company plans on using KLS-13019 as its lead target drug candidate for the treatment of CIPN.

A priority therapeutic opportunity is the treatment of chemotherapy-induced peripheral neuropathy (CIPN), because to date no one drug or drug class is considered to be safe and effective in this disabling disease. Tricyclic antidepressants are often the first choice in most patients but are associated with significant side effects including sedation and cardiovascular complications as well as marginal efficacy (Wolf et al 2008). Anticonvulsants, despite their efficacy in animal models of CIPN, are only partially effective in the majority of patients (Bosnjak et al 2002).

Even more problematic, upwards of 80% of CIPN patients report using prescription opioids for pain management despite lacking strong evidence for efficacy and increasing safety concerns in the face of the current devastating opioid epidemic. The exact mechanism of CIPN has not been fully elucidated and can differ across classes of chemotherapeutic agents. It is therefore necessary to identify novel therapies to prevent or treat CIPN that target one or more of these putative mechanisms. Recently there has been resurgence in interest in the potential medical utility of the Cannabis plant and its constituents, and mechanism-based basic research is warranted to develop safe and effective cannabinoid-based pain treatments. CBD is a non-psychoactive component of Cannabis sativa that is neuroprotective, independent of cannabinoid receptors (Hampson 1998).

Prior studies at Temple University revealed that CBD prevents the development of paclitaxel-induced mechanical sensitivity in mice in vivo (Ward et al 2011, 2014). Additionally, CBD attenuates morphine reward and heroin seeking behavior in animal models (Ren, Whittard et al. 2009; Katsidoni, Anagnostou et al. 2013) and a small trial in humans suggests attenuation of heroin craving in humans (Hurd, Yoon et al. 2015). However, CBD has limitations in terms of potency, safety, and oral bioavailability. The Company believes it may be able to address these problems in its fully owned series of side chain modified derivatives, which have been protected in a non-provisional patent application WO2015/106108A2.

One of the molecules covered by the patent is KLS-13019, which in pre-clinical studies, including PK studies, has shown evidence of improved in vitro efficacy, improved safety, and improved oral bioavailability over CBD in side by side preclinical evaluation, and is not a controlled substance. (Pharmacological Comparisons Between Cannabidiol and KLS-13019, Journal of Molecular Neuroscience, 14 August 2018)

Preliminary Effects of KLS-13019 in CIPN model: In a preliminary study, we treated 8 mice with saline and 16 mice with paclitaxel (Days 1, 3, 5, and 7, 8.0 mg/kg IP). Half of the paclitaxel-treated mice were pretreated with KLS-13019 (2.5 mg/kg IP) and half were pretreated with its vehicle alone. On days 9, 14, and 21 post initiation of injections, mechanical sensitivity was tested using von Frey filaments and compared with baseline sensitivities prior to treatment (Fig. 3). One-way ANOVA revealed a significant effect of KLS-13019 on Day 14 to prevent the development of paclitaxel-induced mechanical sensitivity [$F_{(2,\ 21)} = 4.67$, $p<0.05$]. Dunnett's multiple comparison's test revealed a significant difference between the saline and paclitaxel treated groups, but not between the saline and KLS-13019+paclitaxel treated groups. Preliminary flow cytometry results with pooled cords from three mice in each group revealed that paclitaxel-treated mice had increased numbers of CD4+ T cells and microglia in the whole spinal cord, and that this increase is prevented by KLS-13019 treatment.

E1. Aim 1. Research Plan.Determine target for the neuroprotective actions of CBD and KLS-13019. As mentioned above, DRG neurons are a primary cytotoxic target of chemotherapeutic agents. In addition, spinal microglia have been heavily implicated in the development and maintenance of neuropathic pain and have shown to become activated in animal models of CIPN. *At the conclusion of Aim 1, we will demonstrate that the neuroprotective properties can be reduced by pharmacological or gene knock-down of a relevant target in a statically significant manner.*

E2. Aim 2. Assess KLS-13019, CBD, and morphine against paclitaxel-induced peripheral neuropathy. *At the conclusion of Aim 2, we will have demonstrated that KLS-13019 performs as well as CBD (ip and po) against CIPN and CNS inflammation and shows no antinociceptive tolerance as compared to morphine.*

CIPN procedure: Experiments are designed to test the efficacy of novel CBD analogues in attenuating established mechanical sensitivity and inflammation associated with CIPN. Dr. Ward's laboratory has been using the CIPN procedure for eight years and has demonstrated that CBD treatment can both prevent the development of (Ward et al 2011, 2014) and reverse established (King et al in revision, *British Journal of Pharmacology*) CIPN in mouse models. CBD and KLS-13019 and their vehicle controls will be tested in groups of mice treated with paclitaxel (8.0 mg/kg IP, days 1, 3, 5 and 7). Testing of each dose for each molecule will require a final sample size of 8. Molecules will be administered daily for three weeks, starting on Day 11 when peak mechanical allodynia has already been achieved. In the initial study, CBD (0.05 - 5 mg/kg ip) will be compared with three doses of KLS-13019 (e.g., 0.05, 0.5 and 5 mg/kg ip) and three doses of morphine (1.0 – 10 mg/kg ip; Neelakantan et al 2016). This will be followed by a study in which KLS-13019 will be assessed at three oral doses. In preliminary studies, we have dosed the mice with KLS-13019 (2.5 - 5 mg/kg ip) with no adverse effects. In addition, KLS-13019 was shown to produce no impairment in the mouse rotorod test at 100 mg/kg po in studies conducted at the Anticonvulsant Screening Program (NIH).

Neuroinflammation assessment: Immunohistochemistry and flow cytometry will run in the PIs laboratory to evaluate markers of pain and inflammation associated with neuropathic pain, including astrocytic and microglial activation, CGRP, and T cell infiltration. Given the fact that we are observing CNS infiltration of T cells that is reversed by treatment with KLS-13019, cranial windows will be surgically implanted (as described in Ni, Tuma et al 2004) in additional groups of vehicle or KLS-13019 + paclitaxel treated mice prior to treatment to longitudinally assess the effect of paclitaxel with or without cannabinoid treatment on leukocyte rolling and adhesion across the development of CIPN.

E2. Aim 3. Assess KLS-13019 and CBD against reinstatement of morphine seeking. *At the conclusion of Aim 3, we will have demonstrated that KLS-13019 attenuates opioid-seeking behavior as well as CBD.*

Morphine Reinstatement: The Principal Investigator has 20 years of experience with behavioral assays with specific expertise in rodent models of substance abuse, including opioid self-administration. A standard rat model of morphine seeking will be used (Vassoler et al 2017) wherein rats make lever presses to receive infusions of morphine. Rats will be surgically implanted with chronically indwelling jugular catheters and trained to self-administer morphine (0.75 mg/kg/inf) in the presence of auditory and visual cues daily for 20 days, followed by 10 days of extinction wherein the morphine is replaced with saline and the conditioned cues are eliminated. During the last three days of extinction, rats will be treated with vehicle, CBD (5.0 mg/kg IP), or KLS-13019 (0.5 – 5.0 mg/kg IP). The following day rats will be exposed to a single reinstatement session wherein lever presses are again paired with auditory and visual cues but saline is delivered instead of morphine. This experimental design is based on Ren et al 2009 results with CBD on cue-induced reinstatement of heroin seeking in rats.

Status of Phase 1 STTR Grant Research

On January 4, 2017, the Company applied for a Phase 1 Small Business Technology Transfer ("STTR") grant from the National Institutes of Health. This grant application was made in collaboration with Temple University and titled "Development of KLS-13019 for Chemotherapy Induced Peripheral Neuropathy and Drug Dependence". In December 2017, the Company was informed that the Phase 1 grant was awarded.

The Company has completed all of its work related to the aforementioned grant and is currently in a peer review submission of its research results to the Journal of Molecular Neuroscience. Temple University has completed two of the three aims outlined in the grant proposal and is currently in the process of completing the third and final aim, morphine reinstatement. The Company believes that the grant study will be completed on or about June 2019 and the results will be published by Temple University.

The Company and Temple University believe that there is strong potential for a follow on Phase 2 STTR grant to further the research and development of the Company's treatment for CIPN. **Phase 2** is focused on the development, demonstration and delivery of the innovation. Only Phase 2 contract awardees are eligible to submit a proposal for a Phase II funding agreement.

Reduction in Addiction Based Opiate Dependency

The abuse of and addiction to opioids such as heroin, morphine, and prescription pain relievers is a serious global problem that affects the health, social, and economic welfare of all societies. It is estimated that between 26.4 million and 36 million people abuse opioids worldwide, with an estimated 2.1 million people in the United States suffering from substance use disorders related to prescription opioid pain relievers in 2012 and an estimated 467,000 addicted to heroin. The consequences of this abuse have been devastating and are on the rise. For example, the number of unintentional overdose deaths from prescription pain relievers has soared in the United States, more than quadrupling since 1999. There is also growing evidence to suggest a relationship between increased non-medical use of opioid analgesics and heroin abuse in the United States. See *America's Addiction to Opioids: Heroin and Prescription Drug Abuse* – N.D. Volkow, MD, Senate Caucus on International Narcotics Control, May 14, 2014.

NIDA Activities to Stem the Tide of Prescription Opioid and Heroin Abuse

The National Institute on Drug Abuse ("NIDA") first launched its prescription drug abuse public health initiative in 2001. Our evidence-based strategy calls for a comprehensive three-pronged approach consisting of (1) enhancing our understanding of pain and its management; (2) preventing overdose deaths; and (3) effectively treating opioid addiction.

Research on Pain and Next Generation Analgesics

Although opioid medications effectively treat acute pain and help relieve chronic pain for some patients, their addiction risk presents a dilemma for healthcare providers who seek to relieve suffering while preventing drug abuse and addiction. Little is yet known about the risk for addiction among those being treated for chronic pain or about how basic pain mechanisms interact with prescription opioids to influence addiction potential. To better understand this, NIDA launched a research initiative on "Prescription Opioid Use and Abuse in the Treatment of Pain." This initiative encourages a multidisciplinary approach using both human and animal studies to examine factors (including pain itself) that predispose or protect against opioid abuse and addiction. Funded grants cover clinical neurobiology, genetics, molecular biology, prevention, treatment, and services research. This type of information will help develop screening and diagnostic tools that physicians can use to assess the potential for prescription drug abuse in their patients. Because opioid medications are prescribed for all ages and populations, NIDA is also encouraging research that assesses the effects of prescription opioid abuse by pregnant women, children, and adolescents, and how such abuse in these vulnerable populations might increase the lifetime risk of substance abuse and addiction.

Another important initiative pertains to the development of new approaches to treat pain. This includes research to identify new pain relievers with reduced abuse, tolerance, and dependence risk, as well as devising alternative delivery systems and formulations for existing drugs that minimize diversion and abuse (*e.g.,* by preventing tampering and/or releasing the drug over a longer period of time) and reduce the risk of overdose deaths. New molecules are being developed that exhibit novel properties as a result of their combined activity on two different opioid receptors (*i.e.,* mu and delta). Pre-clinical studies show that these molecules can induce strong analgesia but fail to produce tolerance or dependence. Researchers are also getting closer to developing a new generation of non–opioid-based medications for severe pain that would circumvent the brain reward pathways, thereby greatly reducing abuse potential. This includes molecules that work through a type of cannabinoid receptor found primarily in the peripheral nervous system. NIDA is also exploring the use of non-medication strategies for managing pain.

An example is the use of “neurofeedback,” a novel modality of the general biofeedback approach, in which patients learn to regulate specific regions in their brains by getting feedback from real-time brain images. This technique has shown promising results for altering the perception of pain in healthy adults and chronic pain patients and could even evolve into a powerful psychotherapeutic intervention capable of rescuing the circuits and behaviors impaired by addiction.

PRIMARY TARGETS FOR TOPICAL MEDICAMENTS AND MARKET SIZE

The Company plans on screening and conducting preliminary research and development of some of its patented, proprietary cannabidiol-derived new chemical entities (“NCEs”), for use as topical solutions, ointments, and creams for disorders such as diabetic neuropathies, diabetic ulcers, and for use as an anti-pruritic. (see: Business – Kannalife Intellectual Properties)

In preclinical testing, certain molecules under Pat. 9,611,213 were screened for neuroprotection and may have the potential mechanism of action for reducing inflammation and neuropathic pain. These molecules indicate that they are more soluable than cannabidiol, also deemed a neuroprotectant with potential anti-inflammatory properties. A molecule that is potentially more water soluable than cannabidiol in this regard may be good candidate(s) for use in topical applications.

Neuropathic Pain, Anti-Inflammation, Anti-Pruritic & Skin Ulcers

Target 1: Anti-Puritics (Anti-Itch) – $16+ Billion Market in U.S.

Global Pruritus Therapeutics Market is expected to reach USD 16.38 Billion by 2025, according to a new study by Grand View Research, Inc. Growing worldwide prevalence of atopic dermatitis, allergic contact dermatitis and urticaria is expected to drive market growth during the forecast period. Introduction of new products based on scientific mechanistic understanding such as the identification of new T-cell subsets, particularly Th17, and Th22 and the patent expiration of PROTOPIC (tacrolimus) is expected to open up new avenues for manufacturers to capitalize on over the forecast period.

Corticosteroids were the leading product segment in 2013 owing to high efficacy exhibited by this class of drugs in treating pruritic conditions by reducing inflammation and itching. Topical applications of corticosteroids have been found to be extremely effective in the treatment and maintenance therapies pertaining to pruritus.

Itching is a sensation that, if sufficiently strong, will provoke scratching or the desire to scratch. It is a frequent and distressing symptom of various dermatological and systemic diseases. It can also occur in some patients without any skin symptoms. Knowledge has accumulated about the initiation of itch by external stimuli, but the neuronal substrate in the skin has not been completely identified. This has fortunately changed to some degree since a group of histamine-sensitive C-fibers were recently identified, which probably represent the afferent units that mediate itch sensations. Histamine, derived from mast cells, is the best known pruritogen. It induces different degrees of itching when applied in different concentrations into the skin. In most dermatological and systemic diseases, except urticaria, histamine is not the main mediator. There are other proinflammatory mediators to consider such as substance P, proteases, interleukin-2, acetylcholine, vasoactive intestinal peptide (VIP) and opioid peptides. The different types of pruritus (see Table 2) have different etiological factors, which in most cases have not yet been clarified. As well, the mechanisms of excitatory and inhibitory processing in the central nervous system are not defined. See *Systemic Drugs with Antipruritic Potency* – E. Weisshar, MD, H. Gollnick, MD, PhD., Departments of Dermatology and Venerology, Otto-von-Guericke-University, Magdeburg, Germany, Skin Therapy Letter, Vol. 5 Number 5

Calcineurin inhibitor is identified as the most lucrative segment of the market on account of high usage rate of these drugs in combination therapy for the treatment of pruritus in patients suffering from chronic pruritus and growing market penetration rates. Moreover, the introduction of new products such as Pimecrolimus cream and Tacrolimus ointment is expected to further drive this market.

Anti-histamines owing to its growing use as a first line treatment and presence of drugs in pipeline with expected commercialization is also expected to grow at a healthy rate during the forecast period.

North America led the overall market in terms of revenue in 2013 majorly on account of the presence of high prevalence of diseases associated with pruritus, introduction of new products targeting the unmet medical needs and growing patient awareness levels.

The Asia Pacific pruritus therapeutics market is expected to grow at a CAGR of over 5.0% during the forecast period. Presence of high unmet healthcare needs and increasing prevalence of allergic contact dermatitis and urticaria in this region are some factors attributing to its rapid growth rate.

Some key participants of the pruritus therapeutics market include Sanofi, Pfizer, Tai Guk Pharmaceutical Company, Actavis, Trevi Therapeutics, Cara Therapeutics, Ocera Therapeutics Inc. and NeRRe Therapeutics.

Manufacturers adhere to rigorous R&D in an attempt to develop cost effective products and avoid barriers such as product recalls. In addition, this strategy is implemented keeping the unmet needs in consideration. For Instance, Creabilis has a molecule in the pipeline – CT327, which caters to the unmet needs associated with pruritus in patients suffering from psoriasis.

Target 2: **Anti Inflammatory – $80+ Billion Market in U.S.**

Anti-Inflammatory Therapeutics Market is expected to garner $106.1 billion by 2020, registering a CAGR of 5.9% during the forecast period 2015-2020. Inflammation is triggered by the defense system of the body in response to harmful stimuli, damaged cells, irritants and microorganisms. Inflammation is the mechanism of innate immunity, which seeks to eliminate the cause of injury, clear dead and necrotic cells and heal injured tissues. Sometimes, the body defense system inappropriately triggers inflammation against its own cells, resulting in incurable inflammatory autoimmune diseases such as arthritis, asthma and chronic obstructive pulmonary disease (COPD). See *Anti-Inflammatory Therapeutics Market by Indication (Arthritis, Respiratory Diseases, Multiple Sclerosis, Psoriasis, Inflammatory Bowel Disease) and Drug Class (Anti-Inflammatory Biologics, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Corticosterioids) – Global Opportunity Analysis and Industry Forecast*, 2014-2020 – O. Sumant, Allied Market Research – September 2015.

According to World Health Organization (WHO), approximately 235 million people suffer from asthma in the world. Symptomatic relief during the inflammation provides relief to the patients suffering from inflammatory autoimmune diseases. Although there are multiple anti-inflammatory drugs approved in the market, there is an indispensable need for better and novel anti-inflammatory therapeutics with lesser side effects and better efficacy.

In addition, they are also difficult to imitate due to their complex molecular structure and origin. The global anti-inflammatory market has been driven by factors such as increasing autoimmune and respiratory conditions, new drugs in pipeline and increasing adoption of anti-inflammatory drugs.

Moreover, increasing awareness of anti-inflammatory therapeutics and attractive government initiatives in the Asia-Pacific and LAMEA region are expected to drive the market during the analysis period. Factors, such as side effects of anti-inflammatory drugs and patent expiry issues of blockbuster drugs (such as Remicade), are known to impede the market growth.

The global anti-inflammatory therapeutics market is segmented on the basis of indication, drug class and geography. The indications considered in this report include arthritis, respiratory diseases, multiple sclerosis, psoriasis, inflammatory bowel disease and other inflammatory diseases. Among indications, arthritis holds tremendous potential for growth accounting for 38.2% of the global anti-inflammatory therapeutics market. Anti-inflammatory biologics are the most preferred drugs for treatment of arthritis. On the basis of drug class, the market is segmented into anti-inflammatory biologics, non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids. Anti-inflammatory biologics holds the largest share among drug classes accounting for 54.8% share of the global anti-inflammatory therapeutics market, and is expected grow rapidly during the forecast period.

Geographically, the market is segmented into four regions namely North America, Europe, Asia-Pacific and LAMEA. Among regions, North America holds the largest share accounting for 45.7% share of the global anti-inflammatory therapeutics market; however, the Asia-Pacific region is expected to exhibit the fastest growth during the forecast period. Major market players have adopted innovative strategies such novel drug development and product launch (novel and indication expansion) to increase their market presence. In 2014, AstraZeneca had five anti-inflammatory drugs in the final stages of drug development. These drugs are lesinurad, sifalimumab, anifrolumab, mavrilimumab and brodalumab. The companies have filed new patents to overcome the issues of patent expiries of their existing drugs, and to gain a prominent market share. The key companies profiled in this report include Pfizer, Inc., Abbvie, Inc., Johnson & Johnson, GlaxoSmithKline, Merck & CO., Inc., Novartis, F. Hoffman, La Roche AG, Eli Lily and Company, AstraZeneca PLC, and Amgen.

Target 3: Eczema – $3+ Billion Market in U.S.

They estimated the global eczema therapeutics market to value $2.035 billion in 2010. It is expected to grow a Molecule Annual Growth Rate (CAGR) of 8.2% to $3.834 billion by 2018. This growth is primarily attributed to an increased prevalence rate and increased patient awareness of the disease pattern. In 2010, the prevalence of eczema reported in seven major geographies (the US, the UK, Germany, France, Spain, Italy and Japan), was between 10-20%. GlobalData expects that the number of eczema patients will increase, along with an increase in prevalence. See *Eczema Therapeutics Market is Forecast to Show Significant Growth Until 2018* – February 23, 2012, ASDMedia BV, Amsterdam.

Some factors associated with an increased risk of eczema include environmental factors, hygiene conditions, lack of awareness and levels of education. In the pipeline, presence of novel molecules with improved safety, efficacy and tolerability is expected to further drive the market during the forecast period. However, an increase in product competition due to genericization is a barrier for the market which will decrease the growth over the forecast period in comparison to historic growth.

Another factor that could restrain the market is that patients are opting for alternative therapies over conventional therapies. Different forms of complementary or alternative treatment options for eczema are meant to compliment drug treatment, not replace them. Complementary or alternative medicine can be classified as herbal therapies (treatments using plant species), and nonherbal therapies, such as homeopathy, acupuncture and aromatherapy. The most commonly used herbal formulations are based on Traditional Chinese Medicines (TCM). Increasing acceptance of these therapies is proving to be a negative growth factor for existing therapeutics products. Globally, the US is the major contributor to the overall eczema therapeutics market, followed by Japan.

The Eczema Therapeutics Market is Dominated by Topical Corticosteroids (TCSs)

Current competition in the eczema therapeutics market is weak. The market contains conventional forms of therapy such as topical corticosteroids, topical immunomodulators and emollients as the most prominent therapies. Among all the available treatment options, topical corticosteroids hold a large share and dominate the market. Topical corticosteroids are available in various strengths (mild, moderate, potent and very potent) and formulations (ointment, cream, lotion and many more), so that they can be used according to the severity of eczema. Calceurin inhibitors (Protopic (tacrolimus) and Elidel (pimecrolimus)) showed higher efficacy in comparison to corticosteroids and these products were widely used after their respective launches. However, in 2005 the FDA issued black box warnings for the calceurin inhibitors (Protopic and Elidel), this has resulted in declining sales of these products. Emollients have good efficacy as well as good safety. They hydrate, moisturize and repair the skin. These products do not offer first line treatment but they are useful as maintenance therapy in eczema patients.

Strong Pipeline Molecules Would Lead to a Significant Impact in the Eczema Therapeutics Market in Forecast Period

The analyze that the eczema therapeutics pipeline is strong; with 65 molecules in various stages of clinical development. Out of these molecules, one molecule is in filed stage, four molecules are in Phase III. 32 molecules are in Phase II, seven in Phase I and 21 molecules are in preclinical stage. There are 41 FIC, six me-too, one product extension and one generic molecule in the total pipeline. Research is prominent in Phase II, which contains 19 FIC, five me-too and one product extension. Only one molecule is in filed stage; the LAS41002, which belongs to me-too class. These novel molecules target unmet need through the provision of better safety and efficacy profiles.

Significant Unmet Need in Eczema Therapeutics Market Could Drive Market

Eczema is a chronic condition characterized by frequent relapses known as flare-ups. The market has various products which are effective, but their safety profile is not always satisfactory, leaving a significant unmet need in the market. The unmet need is also a result of the lack of effective treatment options for severe conditions; the need for a controlled and targeted drug delivery system; low patience compliance and the black box warnings issued to Elidel and Protopic. The unmet need in eczema therapeutics could be filled by a new entrant with a better safety profile; enhanced patient compliance and competitive pricing with respect to the available products.

TNF-α inhibitors were the first class of biologics that succeeded in delivering clinical improvements to moderate to severe psoriasis patients while still having manageable safety profiles. Enbrel was the first TNF-α inhibitor to be approved (2004), followed by Remicade (2006) and Humira (2008). Within a span of five years before the next biologic with a new mode of action became available in the United States, the psoriasis market skyrocketed from $700 M (2003) to $2 B (2009). In 2009, biologics accounted for 70% of total sales in psoriasis.

This was primarily driven by these agents' potent efficacy, and increasing physician familiarity and comfort with the use of biologics, which elevated the overall biologic treatment rate. Among the TNF-α inhibitors approved for psoriasis, Remicade is the most effective as measured by PASI 75 response rates at 3 months, while Enbrel is slightly weaker than the rest of the agents in this class. Although Humira was the third TNF-α inhibitor approved for psoriasis in the United States, it quickly gained market share on the strengths of its positive clinical profile, subcutaneous formulation compared with intravenous formulation for Remicade, and more-convenient dosing schedule compared with Enbrel (every other week instead of once or twice weekly).

On the safety side, Enbrel is generally considered the safest TNF-α inhibitor, which has helped maintain its preferred first-line biologic position among some dermatologists.

In a 2008 study titled "Mediation of Cannabidiol Anti-inflammation in the Retina by Equilibrative Nucleoside Transporter and A2A Adenosine Receptor", published in Investigative Ophthalmology & Visual Science, cannabidiol was evaluated for adenosine signaling and the release of TNF-α.

Target 4: Psoriasis – $5+ Billion Market in U.S.

Psoriasis is a common chronic skin disorder affecting approximately 9.3 million Americans. It is also associated with several comorbidities such as obesity, hypertension, psoriatic arthritis, depression, and diabetes. Psoriasis is characterized by skin flares and inflammation that vary in severity, from minor localized patches to substantial body surface involvement. Around 20% of diagnosed patients have moderate to severe psoriasis. Currently, in the United States, psoriasis is a $5 billion market, of which 90% are from drugs targeting moderate to severe psoriasis patients where the skin manifestation affects more than 3% of the body. See *Treatment of Psoriasis in Adults* – Steven R. Feldman, MD, PhD, August 24, 2018. For such patients, psoriasis is often a debilitating condition impacting their quality of life and psychological well-being. Over the past decade, biologics have altered the landscape in the management of moderate to severe psoriasis by achieving improved skin clearance, control of symptoms and quality of life for hundreds of thousands of individuals affected.

Psoriasis is linked to pathogenesis caused by dysregulation of T-cell-dependent immune response, as well as hyperproliferation of keratinocytes, the predominant cell type on the outer layer of skin. Biologics target the cytokines usually upregulated as a result of the abnormal immune response. Currently, there are six FDA-approved biologics for the treatment of psoriasis belonging to three separate drug classes: TNF-α inhibitors including Humira (adalimumab, AbbVie), Enbrel (etanercept, Amgen), and Remicade (infliximab, Janssen Biotech), the IL-12/23 inhibitor Stelara (ustekinumab, Janssen Biotech), and the IL-17 inhibitors Cosentyx (secukinumab, Novartis) and Taltz (ixekizumab, Elli Lilly). Two biologics, Amevive (alefacept, Astellas Pharma) and Raptiva (efalizumab, Merck Serono), initially approved for psoriasis in 2003 were withdrawn from the market in 2011 and 2009 respectively due to insufficient response in patients on Amevive and safety concerns with Raptiva. See *Biologics continue to flare up the psoriasis market, indicating opportunities in the larger dermatology space* – Decision Resources Group – DRG Blog.

Target 5: Diabetic Foot Ulcers – $3+ Billion Market in U.S.

The market for Diabetic Foot Ulcers in the U.S. is $3+ billion and growing. There are 29 million people living with diabetes and 86 million pre-diabetics in the U.S. Approximately 25% of diabetics will acquire a non-healing ulcer in their lifetime which equates to approximately 3 million diabetic ulcers annually. Diabetic foot ulcers lead to over 73,000 amputations annually at a cost that is estimated to exceed $5 billion annually. Hospitalization costs are approximately $20,000 per patient with diabetic foot ulcers and $70,000 for an amputation. The global numbers are more startling. 400 million people are currently living with diabetes worldwide and that number is expected to increase to approximately 600 million by 2035.

The current approach to treating diabetic foot ulcers requires offloading the wound by using appropriate therapeutic footwear, daily saline or similar dressings to provide a moist wound environment, debridement when necessary, antibiotic therapy if osteomyelitis or cellulitis is present, optimal control of blood glucose, and evaluation and correction of peripheral arterial insufficiency. Wound coverage by cultured human cells or heterogeneic dressings/grafts, application of recombinant growth factors, and hyperbaric oxygen treatments also may be beneficial at times, but only if arterial insufficiency is not present. Among people with diabetes, most severe foot infections that ultimately require some part of the toe, foot or lower leg to be amputated start as a foot ulcer. See *Diabetic Ulcers Treatment & Management*, V.L. Rowe, MD, R. Khardori MD, PhD, FACP, Medscape, March 12, 2018.

Foot ulcers are especially common in people who have one or more of the following health problems:

Peripheral neuropathy. This is nerve damage in the feet or lower legs. Diabetes is the most common cause of peripheral neuropathy. When nerves in the feet are damaged, they can no longer warn about pain or discomfort. When this happens, tight-fitting shoes can trigger a foot ulcer by rubbing on a part of the foot that has become numb. People with peripheral neuropathy may not be able to feel when they've stepped on something sharp or when they have an irritating pebble in their shoes. They can injure their feet significantly and never know it, unless they examine their feet routinely for injury.

Many elderly people and diabetics with vision problems also can't see their feet well enough to examine them for problems.

Circulatory problems. Any illness that decreases circulation to the feet can cause foot ulcers. Less blood reaches the feet, which deprives cells of oxygen. This makes the skin more vulnerable to injury. And it slows the foot's ability to heal.

Poor circulation in the leg arteries is called peripheral artery disease. It also causes pain in the leg or buttock during walking. It is caused by atherosclerosis. This is a disease in which fatty deposits of cholesterol build up inside arteries.

Abnormalities in the bones or muscles of the feet. Any condition that distorts the normal anatomy of the foot can lead to foot ulcers. This is particularly true if the foot is forced into shoes that don't fit the foot's altered shape. Examples are claw feet, feet with fractures, and cases of severe arthritis.

More than any other group, people with diabetes have a particularly high risk of developing foot ulcers. This is because the long-term complications of diabetes often include neuropathy and circulatory problems. Without prompt and proper treatment, a foot ulcer may require hospital treatment. Or, it may lead to deep infection or gangrene and amputation.

Governmental Regulations

Manufacturing

Although the Company would be reliant upon the manufacturing of its target drug candidate and API from well-established manufacturers, manufacturers of therapeutic products and their facilities are subject to continual review and periodic inspections by the FDA, the EMA and other comparable foreign regulatory authorities for compliance with current good manufacturing practices (“cGMP”) regulations.

Further, manufacturers of controlled substances must obtain and maintain necessary DEA and state registrations and registrations with applicable foreign regulatory authorities and must establish and maintain processes to ensure compliance with DEA and state requirements and requirements of applicable foreign regulatory authorities governing, among other things, the storage, handling, security, recordkeeping and reporting for controlled substances.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

issue untitled letters or warning letters;
mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
seek an injunction or impose civil or criminal penalties or monetary fines;
suspend or withdraw regulatory approval;
suspend any ongoing clinical trials;

refuse to approve pending applications or supplements to applications filed by us; or
require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and may otherwise have a material adverse effect on our business, financial condition and results of operations.

Regulation of CBD

KLS-13023 contains controlled substances as defined in the CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While Cannabis is a Schedule I controlled substance, products approved for medical use in the United States that contain Cannabis or Cannabis extracts must be placed in Schedules II - V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when KLS-13023 receives FDA approval, the DEA will make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. If approved by the FDA, we expect the finished dosage forms of KLS-13023 to be listed by the DEA as a Schedule II or III controlled substance. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. The scheduling process may take one or more years beyond FDA approval, thereby significantly delaying the launch of KLS-13023. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that KLS-13023 may have potential for abuse, it may require us to generate more clinical data than that which is currently anticipated, which could increase the cost and/or delay the launch of KLS-13023.

Because KLS-13023 contains active ingredients of Cannabis, which are Schedule I substances, to conduct pre-clinical studies and clinical trials with KLS-13023 in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense KLS-13023 and to obtain the product from our manufacturer. If the DEA delays or denies the grant of a research registration to one or more research sites, the pre-clinical studies or clinical trials could be significantly delayed, and we could lose and be required to replace clinical trial sites, resulting in additional costs.

We expect that KLS-13023 will be scheduled as Schedule II or III, as a result of which we will also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the products to pharmacies and other healthcare providers, and these distributors would need to obtain Schedule II or III distribution registrations. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If KLS-13023 is a Schedule II drug, pharmacies would have to maintain enhanced security with alarms and monitoring systems and they must adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

We may manufacture the commercial supply of KLS-13023 outside of the United States. If KLS-13023 is approved by the FDA and classified as a Schedule II or III substance, an importer can import for commercial purposes if it obtains from the DEA an importer registration and files an application with the DEA for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of KLS-13023 and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third party comments to be submitted.

Individual states have also established controlled substance laws and regulations. Though state-controlled substance laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

We currently obtain the API for KLS-13023 from a bulk manufacturer of pharmaceutical grade API in Switzerland. For KLS-13023, we plan to conduct Phase 1 clinical trials in Australia, subject to applicable regulatory approval. In addition, we may decide to develop, manufacture or commercialize our product candidates in additional countries. As a result, KLS-13023 will also be subject to controlled substance laws and regulations from the Therapeutic Goods Administration in Australia, Health Canada's Office of Controlled Substances in Canada, and from other regulatory agencies in other countries where we may develop, manufacture or commercialize KLS-13023 in the future. We plan to submit NDA for KLS-13023 to the FDA upon completion of all requisite clinical trials and will require additional DEA approvals at such time as well.

September 27, 2018, the Department of Justice and Drug Enforcement Administration announced that Epidiolex, the newly approved medication by the Food & Drug Administration, is being placed in Schedule V of the Controlled Substances Act, the least restrictive schedule of the CSA. On June 26 2018, the FDA announced it approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex contains cannabidiol (CBD), a chemical constituent of the cannabis plant (commonly referred to as marijuana).

The CBD in Epidiolex is extracted from the cannabis plant and is the first FDA-approved drug to contain a purified extract from the plant. Schedule V drugs represents the least potential for abuse. Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

Despite the approvals by the FDA and DEA for Epidiolex, any of these foregoing factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market KLS-13019 or KLS-13023. Moreover, because our business is almost entirely dependent upon these two product candidates, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

KLS-13019 does not contain cannabidiol and is a new chemical entity that would not fall under the Controlled Substances Act ("CSA") or be deemed a Schedule 1 controlled substance.

KLS-13023 is a formulation that does contain cannabidiol. At present, cannabidiol is deemed a Schedule 1 controlled substance by the U.S. Drug Enforcement Agency under the Controlled Substances Act. And like the drug molecule EpidiolexÒ, which was recently approved by the FDA for marketing and sale for use in treating Dravet's Syndrome and Lennox-Gasteau Syndrome (forms of child epilepsy), KLS-13023 would need to follow the guidance set forth by the CSA, complete a successful human clinical trial and apply for rescheduling, as was the case with EpidiolexÒ, now a Schedule 5 drug.

On January 14, 2019, the Company received written notice from the Drug Enforcement Administration ("DEA") Drug and Chemical Evaluation Section, as follows: "Please be advised that your material meets the definition of 'Hemp' and is not regulated under the CSA, as long as it consists of high purity Cannabidiol (CBD) that contains approximately 0.1% delta-9- THC. (However, if it contains more than 0.3% delta-9 THC, it is considered 'Marihuana' and would be in Schedule 1 of the CSA)." While this notice is an official notice from the DEA regarding the scheduling of high purity CBD, the Company will continue to abide by the CSA in all respects with regards to its treatment and handling of CBD.

Foreign Regulatory Agencies

EMA

In order to market and sell our products in jurisdictions other than the United States and the European Union, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The regulatory approval process outside the United States and the European Union generally includes all of the risks associated with obtaining FDA and EMA approval, but can involve additional testing. We may need to partner with third parties in order to obtain approvals outside the United States and the European Union. In addition, in many countries worldwide, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States and the European Union on a timely basis, if at all. Even if we were to receive approval in the United States or the European Union, approval by the FDA or the EMA does not ensure approval by regulatory authorities in other countries or jurisdictions. Similarly, approval by one regulatory authority outside the United States and the European Union would not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or the EMA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in other foreign jurisdictions, the commercial prospects of those product candidates may be significantly diminished and our business prospects could decline.

Therapeutic Goods Administration (TGA)

Clinical trials conducted in Australia are subject to various regulatory controls to ensure the safety of participants. The TGA regulates the use of therapeutic goods supplied in clinical trials in Australia under the therapeutic goods legislation.

Clinical trial sponsors must be aware of the requirements to import, export, manufacture and supply therapeutic goods in Australia. The following avenues provide for the importation into and/or supply in Australia of 'unapproved' therapeutic goods for use in a clinical trial:

Clinical Trial Notification (CTN) scheme; and

Clinical Trial Exemption (CTX) scheme.

The CTN Scheme is a notification process involving the following:

The Australian clinical trial sponsor must notify us of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good. This must take place before starting to use the goods. The notification form must be submitted online and accompanied by the relevant fee.

We may give the sponsor of the trial written notice to provide specified information relating to goods notified in the CTN form.

We do not evaluate any data relating to the clinical trial at the time of submission. The Human Research Ethics Committee (HREC) reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol. The HREC is also responsible for monitoring the conduct of the trial.

The institution or organization at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

It is the responsibility of the sponsor to ensure that all relevant approvals are in place before supplying the 'unapproved' therapeutic goods in the clinical trial.

The CTX Scheme is an **approval** process involving the following:

A sponsor submits an application to us seeking approval to supply 'unapproved' therapeutic goods in a clinical trial. The application must be accompanied by the relevant fee.

We evaluate summary information about the product including relevant, but limited, scientific data (which may be preclinical and early clinical data) prior to the start of a trial.

The HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol.

The sponsor must notify us of each trial conducted using the unapproved therapeutic good(s) approved in the CTX application.

Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTX schemes. It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good.

Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTX schemes. It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good.

On September 27, 2013, the TGA approved Nabiximols (Sativex ®), a pharmaceutical manufactured by GW Pharmaceuticals for its collaborator Novartis Pharmaceuticals Australia Pty Limited in the treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrated clinically significant improvement in spasticity related symptoms during the initial trial of therapy.

In Australia, in 2014, the Advisory Council on Medicines Scheduling recommended rescheduling cannabidiol from a prohibited substance to being a prescription medicine because, according to the Advisory Council on Medicines Scheduling, "there is a low risk of misuse or abuse as cannabidiol does not possess psychoactive properties". The TGA accepted this recommendation and the decision took effect in July 2015.

Cannabidiol (CBD) is one of the cannabinoids which may be extracted as a therapeutic good from cannabis. From 1 June 2015, cannabidiol has been included under Schedule 4 (S4) Prescription Only Medicine of the Poisons Standard (/publication/poisonsstandard-susmp) when preparations for therapeutic use contain 2% or less of other cannabinoids found in cannabis.

In February 2016, the Australian Federal Government passed legislation that amended the Narcotic Drugs Act, allowing the supply of suitable medicinal cannabis products for the management of painful and chronic conditions[8]. This legislation does not relate to the decriminalization of cannabis for general cultivation or recreational use and it does not include the provision of medicinal grade herbal cannabis, only processed, non-smokable medicinal grade products.

Much of the detail remains unclear. For example, the legislation does not specify which products will be covered under the amendment, and it does not specify which particular conditions or symptoms will be eligible for treatment with cannabis-based products. Before products can be prescribed, they must be registered with the Therapeutic Goods Administration (TGA) or, in rare circumstances, receive special approval from the TGA. The registration process requires evidence of testing and efficacy and it is therefore unlikely Australia will see a TGA registered medicinal cannabis product that GPs can prescribe any time soon. Whilst there are currently no cannabis-based products that are lawfully produced in Australia, the medicinal use of pharmaceutical products containing cannabinoids is not prohibited, as long as authorization for prescribing is granted from the Commonwealth Therapeutic Goods Administration and at this point in time, NSW Health.

Facilities

Our principal executive offices are located at 3805 Old Easton Road, Doylestown, PA 18902. Our telephone number at that address is (858) 883-2642. We have additional offices located at 4 Knoll Court, Lloyd Harbor, N.Y. 11743. On April 1, 2014, the Company entered into a one year lease arrangement for office space, with the option to renew the lease annually. The monthly rent payment is $5,000 and a security deposit of $15,000. On September 15, 2015, the Company entered into a one year lease arrangement for office space. The Company has amended this lease to extend the term through September 30, 2018. The monthly rent payment is $229 and a security deposit of $183.

Employees

We currently have five full time employees and two part time employees. We plan to increase the number of employees in the areas of regulatory affairs, clinical research and testing, and marketing in 2019. There are no collective-bargaining agreements with our employees, and we have not experienced work interruptions or strikes. We believe our relationship with employees is good and we provide health and life insurance for all employees.

ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this annual report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, operating results, and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We are a preclinical stage specialty pharmaceutical company, engaged in developing next-generation synthetic cannabinoid therapeutics. Since our inception in August 2010, we have devoted substantially all of our resources to the development of our product candidates, KLS-13019 and KLS-13023. We have generated significant operating losses since our inception. Our net income (losses) for the years ended December 31, 2018 and 2017 were approximately $1.0 million and $(1.6 million), respectively. As of December 31, 2018, we had an accumulated deficit of $5.0 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses will increase as we continue the research and development of, and clinical trials for, our product candidates. In addition to budgeted expenses, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If either of our product candidates fails in clinical trials or does not gain regulatory approval, or even if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Due to our limited operating history and history of losses, any predictions about our future success, performance or viability may not be accurate.

We currently have no commercial revenue and may never become profitable.

To date, the only revenue we have generated has been from the receipt of research grants and payments for research services. Our ability to generate revenue and become profitable depends upon our ability to obtain regulatory approval for, and successfully commercialize, KLS-13019, KLS-13023 or other product candidates that we may develop, in-license or acquire in the future.

Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know what the reimbursement status of our product candidates will be or when any of these products will generate revenue for us, if at all. We have not generated, and do not expect to generate, any product revenue for the foreseeable future, and we expect to continue to incur significant operating losses for the foreseeable future due to the cost of research and development, preclinical studies and clinical trials and the regulatory approval process for our product candidates. The amount of future losses is uncertain and will depend, in part, on the rate of growth of our expenses. Our ability to generate revenue from our product candidates also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the remaining preclinical studies and planned clinical trials for our product candidates;
- complete and submit New Drug Applications (“NDAs”), to the U.S. Food and Drug Administration (the “FDA”), and Marketing Authorization Applications (“MAAs”), to the European Medicines Agency (the “EMA”), and obtain regulatory approval for indications for which there is a commercial market;
- complete and submit applications to, and obtain regulatory approval from, other foreign regulatory authorities;
- manufacture any approved products in commercial quantities and on commercially reasonable terms;
- develop a commercial organization, or find suitable partners, to market, sell and distribute approved products in the markets in which we have retained commercialization rights;
- achieve acceptance among patients, clinicians and advocacy groups for any products we develop;
- obtain coverage and adequate reimbursement from third parties, including government payors; and
- set a commercially viable price for any products for which we may receive approval.

We are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the processes described above, we anticipate incurring significant costs associated with commercializing our product candidates.

There is substantial doubt about our ability to continue as a going concern.

On October 2, 2018, the report of our independent registered public accounting firm on our December 31, 2017 audited financial statements includes an explanatory paragraph referring to our ability to continue as a going concern. However, the report of our independent registered public accounting firm on our December 31, 2018 audited financial statements does not include this paragraph. As of December 31, 2018 and 2017, we had cash balances of approximately $307,000 and $4,000, respectively. Additionally, we had approximately $2,279,640 in marketable securities (available for sale) as of December 31, 2018. Management plans to raise additional capital through the sale of our marketable securities. We expect that between our existing cash, cash equivalents and marketable securities we will be able to sufficiently fund our operations and capital requirements for the next 18 months. Additional funding will be required to continue our R&D and other operating activities as we have not reached successful commercialization of our product. These circumstances cast significant doubt as to our ability to continue as a going concern.

We will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete the development and commercialization of KLS-13019 or KLS-13023.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial and increasing amounts to conduct further research and development, preclinical testing and clinical trials of our product candidates, to seek regulatory approvals and reimbursement for our product candidates and to launch and commercialize any product candidates for which we receive regulatory approval.

As of December 31, 2018, we had approximately $ 307,000 in cash and cash equivalents. Additionally, we had approximately $2,579,000 in marketable securities (available for sale). We expect that between our existing cash, cash equivalents and marketable securities we will be able to sufficiently fund our operations and capital requirements through December 2019. We believe that these available funds will be sufficient to complete a Phase 1 clinical trials for KLS-13019 for patients with chemotherapy induced peripheral neuropathy. We anticipate, based on current estimates, that costs associated Phase 1 clinical trials for KLS-13019 will be approximately $2.75 million.

Management of the Company believes that it will need to seek additional sources of capital to facilitate and carry out its business plan of proceeding forth with commencing a Phase 2 clinical trial for KLS-13019 for patients with chemotherapy induced peripheral neuropathy; commencing a Phase 1 clinical trial for KLS-13019 for patients suffering from the effects of mild traumatic brain injury; and commencing a Phase 1 clinical trial for KLS-13023 for patients suffering with overt hepatic encephalopathy. The cost of commencing and conducting these trials will likely be in the tens of millions of dollars.

The progress of KLS-13019 and KLS-13023 for the target indication is uncertain due to numerous factors, including, without limitation, the rate of progress of clinical trials, the results of preclinical studies and clinical trials for such indication, the costs and timing of seeking and obtaining FDA and other regulatory approvals for clinical trials and FDA guidance regarding clinical trials for such indication. In addition, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. For these reasons, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Drug Enforcement Administration (the “DEA”), the FDA, the EMA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the effect of competing product and market developments;
- costs and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives.

Our federal and state government grants could subject us to audits and could require us to repay substantial amounts of funds previously awarded to us.

To date, most of our revenue has been from the receipt of state and federal research grants. As of December 31, 2018 we have been granted approximately $300,000 in federal research grants. In connection with these grants, we may be subject to routine audits by government agencies. As part of an audit, these agencies may review our performance, cost structures and compliance with applicable laws, regulations, policies and standards and the terms and conditions of the grant. If any of our expenditures are found to be unallowable or allocated improperly or if we have otherwise violated terms of the grant, the expenditures may not be reimbursed and/or we may be required to repay funds already disbursed. Accordingly, an audit could result in a material adjustment to our results of operations and financial condition.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interests will be diluted and the terms of such financings may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Risks Related to our Business and Industry

We are largely dependent on the success of our product candidates, KLS-13019 and KLS-13023, which are still in preclinical development and will require significant capital resources and years of clinical development effort.

We currently have no products on the market, and our product candidates, KLS-13019 and KLS-13023, are still in preclinical development. Our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of KLS-13019 and KLS-13023, and additional preclinical testing and substantial clinical development and regulatory approval efforts will be required before we are permitted to commence commercialization, if ever. It will be several years before we can commence and complete a pivotal study for KLS-13019 or KLS-13023, if ever. For KLS-13019 and KLS-13023, we plan to conduct Phase 1, and possibly Phase 2, clinical trials in Australia, subject to applicable regulatory approval.

We plan to submit NDAs for KLS-13019 and KLS-13023 to the FDA upon completion of all requisite clinical trials. The clinical trials and manufacturing and marketing of KLS-13019 and KLS-13023 will be subject to extensive and rigorous review and regulation by numerous government authorities in the United States, Australia, the European Union, Canada, and other jurisdictions where we intend to test and, if approved, market our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical trials that the product candidate is safe and effective for use in each target indication, and potentially in specific patient populations. This process can take many years and may include post-marketing studies and surveillance, which would require the expenditure of substantial resources. Of the large number of drugs in development for approval in the United States and the European Union, only a small percentage successfully complete the FDA or EMA regulatory approval processes, as applicable, and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research, development and clinical programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

Because the results of preclinical testing are not necessarily predictive of future results, KLS-13019 and KLS-13023 may not have favorable results in our planned clinical trials.

Any positive results from our preclinical testing of KLS-13019 and KLS-13023 may not necessarily be predictive of the results from our planned clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval. If we fail to produce positive results in our clinical trials of KLS-13019 and KLS-13023, the development timeline and regulatory approval and commercialization prospects for KLS-13019 and KLS-13023, and, correspondingly, our business and financial prospects, would be materially adversely affected.

We may not be able to commence clinical trials in 2019; even if KLS-13019 and KLS-13023 advance into clinical trials, we may experience difficulties in managing our growth and expanding our operations.

We have not begun clinical trials for any of our product candidates. While we expect to commence clinical trials in Australia in 2019 for KLS-13019 and KLS-13023, we have limited resources to carry out these objectives. Our company has no history of conducting clinical trials, which is a time-consuming, expensive and uncertain process. In addition, while we have experienced management and expect to contract out many of the activities related to conducting clinical trials, we are a small company with only five employees and therefore have limited internal resources both to conduct clinical trials and to monitor third-party providers. As our product candidates enter into and advance through preclinical studies and any clinical trials, we will need to expand our development, regulatory and manufacturing operations, either by expanding our internal capabilities or contracting with other organizations to provide these capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures.

Failures or delays in the completion of our preclinical studies or the commencement and completion of our planned clinical trials of KLS-13019 or KLS-13023 could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business.

To date, we have not commenced any clinical trials for KLS-13019 or KLS-13023. Successful completion of such clinical trials is a prerequisite to submitting an NDA to the FDA or an MAA to the EMA. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A product candidate can unexpectedly fail at any stage of clinical development. The historic failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. We expect to initiate clinical trials for KLS-13019 and KLS-13023 in the second half of 2019. However, we do not know whether our clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- delays in reaching or failing to reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- delays or inability in manufacturing or obtaining sufficient quantity or quality of a product candidate or other materials necessary to conduct clinical trials due to regulatory and manufacturing constraints;
- difficulties obtaining institutional review board, or IRB, DEA or comparable foreign regulatory authority, or ethics committee approval to conduct a clinical trial at a prospective site or sites;
- challenges in recruiting and enrolling patients to participate in clinical trials, including the size and nature of the patient population, the proximity of patients to clinical trial sites, eligibility criteria for the clinical trial, the nature of the clinical trial protocol, the availability of approved effective treatments for the relevant indication and competition from other clinical trial programs for similar indications;
- severe or unexpected toxicities or drug-related side effects experienced by patients in our clinical trials or by individuals using drugs similar to our product candidates;
- DEA or comparable foreign regulatory authority-related recordkeeping, reporting or security violations at a clinical trial site, leading the DEA, state authorities or comparable foreign regulatory authorities to suspend or revoke the site's controlled substance license and causing a delay or termination of planned or ongoing clinical trials;
- regulatory concerns with cannabinoid products generally and the potential for abuse of those products;
- difficulties retaining patients who have enrolled in a clinical trial who may withdraw due to lack of efficacy, side effects, personal issues or loss of interest;
- ambiguous or negative interim results; or
- lack of adequate funding to continue the clinical trial.

In addition, a clinical trial may be suspended or terminated by us, the FDA, IRBs, ethics committees, data safety monitoring board or other foreign regulatory authorities overseeing the clinical trial at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols;
- inspection of the clinical trial operations or clinical trial sites by the FDA, the DEA, the EMA or other foreign regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including the imposition of a clinical hold;
- unforeseen safety issues, including any safety issues that could be identified in our ongoing toxicology studies;
- adverse side effects or lack of effectiveness; and
- changes in government regulations or administrative actions.

We intend to expend our limited resources to pursue KLS-13019 and KLS-13023 for certain indications, and may fail to capitalize on other product candidates or other indications for KLS-13019 or KLS-13023 that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we are focusing on research programs relating to KLS-13019 and KLS-13023 for certain indications, which concentrates the risk of product failure in the event KLS-13019 or KLS-13023 proves to be unsafe or ineffective or inadequate for clinical development or commercialization. In particular, we intend to study KLS-13019 in patients with chemotherapy induced peripheral neuropathy, and we intend to study KLS-13023 in patients with mild traumatic brain injury. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for KLS-13019 or KLS-13023 that could later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on proprietary research and development programs relating to KLS-13019 and KLS-13023 may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for KLS-13019 and KLS-13023, we may relinquish valuable rights to KLS-13019 or KLS-13023 through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to KLS-13019 or KLS-13023.

The regulatory approval processes of the FDA, the EMA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to market our product candidates in the United States or the European Union until we receive approval of an NDA from the FDA or an MAA from the EMA, respectively, or in any foreign countries until we receive the requisite approval from such countries. Prior to submitting an NDA to the FDA or an MAA to the EMA for approval of our product candidates we will need to complete our ongoing preclinical studies, as well as Phase 1, Phase 2 and Phase 3 clinical trials. We are still conducting preclinical studies and have not yet commenced our clinical program or tested KLS-13019 or KLS-13023 in humans. For KLS-13019, we plan to conduct Phase 1, and possibly Phase 2, clinical trials in Australia, subject to applicable regulatory approval. We plan to conduct our Phase 1 clinical trials for KLS-13023 in Australia, subject to applicable regulatory approval. We plan to submit NDAs for KLS-13019 and KLS-13023 to the FDA upon completion of all requisite clinical trials. Successfully initiating and completing our clinical program and obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of our product candidates for many reasons, including, among others, because:

- we may not be able to demonstrate that our product candidates are safe and effective in treating patients to the satisfaction of the FDA or EMA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or EMA for marketing approval;
- the FDA or EMA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or EMA may require that we conduct additional clinical trials;
- the FDA or EMA or other applicable foreign regulatory authorities may not approve the formulation, labeling or specifications of our product candidates;
- the contract research organizations, or CROs, and other contractors that we may retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or EMA may find the data from preclinical studies and clinical trials insufficient to demonstrate that KLS-13019's or KLS-13023's clinical and other benefits outweigh its safety risks;
- the FDA or EMA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or EMA may not accept data generated at our clinical trial sites or may disagree with us over whether to accept efficacy results from clinical trial sites outside the United States where the standard of care is potentially different from that in the United States;

if and when our NDAs or MAAs are submitted to the FDA or EMA, as applicable, the regulatory agency may have difficulties scheduling the necessary review meetings in a timely manner, may recommend against approval of our application or may recommend or require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, which would use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks, as a condition of approval or post-approval, and the EMA may grant only conditional approval or impose specific obligations as a condition for marketing authorization, or may require us to conduct post-authorization safety studies;
the FDA, EMA, DEA or other applicable foreign regulatory agencies may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract or DEA or other applicable foreign regulatory agency quotas may limit the quantities of controlled substances available to our manufacturers; or
the FDA or EMA may change their approval policies or adopt new regulations.

On September 27, 2018, the Department of Justice and Drug Enforcement Administration announced that Epidiolex, the newly approved medication by the Food & Drug Administration, is being placed in Schedule V of the Controlled Substances Act, the least restrictive schedule of the federal Controlled Substances Act of 1970 (the “CSA”). On June 26, 2018, the FDA announced it approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex contains cannabidiol (CBD), a chemical constituent of the cannabis plant (commonly referred to as marijuana). The CBD in Epidiolex is extracted from the cannabis plant and is the first FDA-approved drug to contain a purified extract from the plant. Schedule V drugs represents the least potential for abuse. Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

KLS-13023 is a formulation that does contain cannabidiol. At present, cannabidiol is deemed a Schedule 1 controlled substance by the U.S. Drug Enforcement Agency under the Controlled Substances Act. And like the drug molecule Epidiolex, which was recently approved by the FDA for marketing and sale for use in treating Dravet’s Syndrome and Lennox-Gasteau Syndrome (forms of child epilepsy), KLS-13023 would need to follow the guidance set forth by the CSA, complete a successful human clinical trial and apply for rescheduling, as was the case with Epidiolex, now a Schedule 5 drug.

Despite the approvals by the FDA and DEA for Epidiolex, any of these foregoing factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market KLS-13019 or KLS-13023. Moreover, because our business is almost entirely dependent upon these two product candidates, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

On January 14, 2019, the Company received written notice from the Drug Enforcement Administration (“DEA”) Drug and Chemical Evaluation Section, as follows: “Please be advised that your material meets the definition of ‘Hemp’ and is not regulated under the CSA, as long as it consists of high purity Cannabidiol (CBD) that contains approximately 0.1% delta-9- THC. (However, if it contains more than 0.3% delta-9 THC, it is considered ‘Marihuana’ and would be in Schedule 1 of the CSA).” While this notice is an official notice from the DEA regarding the scheduling of high purity CBD, the Company will continue to abide by the CSA in all respects with regards to its treatment and handling of CBD.

Therapeutic Goods Administration (TGA)

Clinical trials conducted in Australia are subject to various regulatory controls to ensure the safety of participants. The TGA regulates the use of therapeutic goods supplied in clinical trials in Australia under the therapeutic goods legislation.

Clinical trial sponsors must be aware of the requirements to import, export, manufacture and supply therapeutic goods in Australia. The following avenues provide for the importation into and/or supply in Australia of 'unapproved' therapeutic goods for use in a clinical trial:

Clinical Trial Notification (CTN) scheme; and
Clinical Trial Exemption (CTX) scheme.

The CTN Scheme is a notification process involving the following:

The Australian clinical trial sponsor must notify us of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good. This must take place before starting to use the goods. The notification form must be submitted online and accompanied by the relevant fee.
We may give the sponsor of the trial written notice to provide specified information relating to goods notified in the CTN form.
We do not evaluate any data relating to the clinical trial at the time of submission. The Human Research Ethics Committee (HREC) reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol. The HREC is also responsible for monitoring the conduct of the trial.
The institution or organization at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.
It is the responsibility of the sponsor to ensure that all relevant approvals are in place before supplying the 'unapproved' therapeutic goods in the clinical trial.

The CTX Scheme is an approval process involving the following:

A sponsor submits an application to us seeking approval to supply 'unapproved' therapeutic goods in a clinical trial. The application must be accompanied by the relevant fee.
We evaluate summary information about the product including relevant, but limited, scientific data (which may be preclinical and early clinical data) prior to the start of a trial.
The HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol.
The sponsor must notify us of each trial conducted using the unapproved therapeutic good(s) approved in the CTX application.

Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTX schemes. It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good.

Clinical trials that do not involve 'unapproved' therapeutic goods are not subject to requirements of the CTN or CTX schemes. It is the responsibility of the Australian clinical trial sponsor to determine whether a product is considered an 'unapproved' therapeutic good.

On September 27, 2013, the TGA approved Nabiximols (Sativex ®), a pharmaceutical manufactured by GW Pharmaceuticals for its collaborator Novartis Pharmaceuticals Australia Pty Limited in the treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrated clinically significant improvement in spasticity related symptoms during the initial trial of therapy.

In Australia, in 2014, the Advisory Council on Medicines Scheduling recommended rescheduling cannabidiol from a prohibited substance to being a prescription medicine because, according to the Advisory Council on Medicines Scheduling, “there is a low risk of misuse or abuse as cannabidiol does not possess psychoactive properties”. The TGA accepted this recommendation and the decision took effect in July 2015.

Cannabidiol (CBD) is one of the cannabinoids which may be extracted as a therapeutic good from cannabis. From 1 June 2015, cannabidiol has been included under Schedule 4 (S4) Prescription Only Medicine of the Poisons Standard (/publication/poisonsstandard-susmp) when preparations for therapeutic use contain 2% or less of other cannabinoids found in cannabis.

In February 2016, the Australian Federal Government passed legislation that amended the Narcotic Drugs Act, allowing the supply of suitable medicinal cannabis products for the management of painful and chronic conditions[8]. This legislation does not relate to the decriminalization of cannabis for general cultivation or recreational use and it does not include the provision of medicinal grade herbal cannabis, only processed, non-smokable medicinal grade products.

Much of the detail remains unclear. For example, the legislation does not specify which products will be covered under the amendment, and it does not specify which particular conditions or symptoms will be eligible for treatment with cannabis-based products. Before products can be prescribed, they must be registered with the Therapeutic Goods Administration (TGA) or, in rare circumstances, receive special approval from the TGA. The registration process requires evidence of testing and efficacy and it is therefore unlikely Australia will see a TGA registered medicinal cannabis product that GPs can prescribe any time soon.

Whilst there are currently no cannabis-based products that are lawfully produced in Australia, the medicinal use of pharmaceutical products containing cannabinoids is not prohibited, as long as authorization for prescribing is granted from the Commonwealth Therapeutic Goods Administration and at this point in time, NSW Health.

We plan to conduct clinical trials for KLS-13019 and KLS-13023 outside the United States and the FDA may not accept data from such trials.

We plan to conduct clinical trials outside the United States. For KLS-13019, we plan to conduct Phase 1, and possibly Phase 2, clinical trials in Australia, subject to applicable regulatory approval. We plan to conduct our Phase 1 clinical trials for KLS-13023 in Australia, subject to applicable regulatory approval. We plan to submit NDAs for KLS-13019 or KLS-13023 to the FDA upon completion of all requisite clinical trials. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the clinical trial must be conducted in accordance with Good Clinical Practices ("GCP") requirements and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence, and the data is considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our development plan. In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
foreign exchange fluctuations;
manufacturing, customs, shipment and storage requirements;
cultural differences in medical practice and clinical research; and
diminished protection of intellectual property in some countries.

Even if KLS-13019 or KLS-13023 receive regulatory approval, they may still face future development and regulatory difficulties.

If we obtain regulatory approval for KLS-13019 or KLS-13023, such approval would be subject to extensive ongoing requirements by the DEA, FDA, EMA and other foreign regulatory authorities related to the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of any product will continue to be closely monitored by the FDA, EMA and other comparable foreign regulatory authorities. If the FDA, EMA or any other comparable foreign regulatory authority becomes aware of new safety information after approval of any of our product candidates, these regulatory authorities may require labeling changes or establishment of a REMS, impose significant restrictions on a product's indicated uses or marketing, impose ongoing requirements for potentially costly post-approval studies or post-market surveillance or impose a recall.

In addition, manufacturers of therapeutic products and their facilities are subject to continual review and periodic inspections by the FDA, the EMA and other comparable foreign regulatory authorities for compliance with current good manufacturing practices ("cGMP") regulations. Further, manufacturers of controlled substances must obtain and maintain necessary DEA and state registrations and registrations with applicable foreign regulatory authorities, and must establish and maintain processes to ensure compliance with DEA and state requirements and requirements of applicable foreign regulatory authorities governing, among other things, the storage, handling, security, recordkeeping and reporting for controlled substances. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may, among other things:

issue untitled letters or warning letters;
mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
seek an injunction or impose civil or criminal penalties or monetary fines;
suspend or withdraw regulatory approval;
suspend any ongoing clinical trials;
refuse to approve pending applications or supplements to applications filed by us; or
require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and may otherwise have a material adverse effect on our business, financial condition and results of operations.

KLS-13023 will be subject to controlled substance laws and regulations; failure to receive necessary approvals may delay the launch of our products and failure to comply with these laws and regulations may adversely affect the results of our business operations.

KLS-13023 contains controlled substances as defined in the CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While Cannabis is a Schedule I controlled substance, products approved for medical use in the United States that contain Cannabis or Cannabis extracts must be placed in Schedules II - V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when KLS-13023 receives FDA approval, the DEA will make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. If approved by the FDA, we expect the finished dosage forms of KLS-13023 to be listed by the DEA as a Schedule II or III controlled substance. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. The scheduling process may take one or more years beyond FDA approval, thereby significantly delaying the launch of KLS-13023. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that KLS-13023 may have potential for abuse, it may require us to generate more clinical data than that which is currently anticipated, which could increase the cost and/or delay the launch of KLS-13023.

Because KLS-13023 contains active ingredients of Cannabis, which are Schedule I substances, to conduct preclinical studies and clinical trials with KLS-13023 in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense KLS-13023 and to obtain the product from our manufacturer. If the DEA delays or denies the grant of a research registration to one or more research sites, the preclinical studies or clinical trials could be significantly delayed, and we could lose and be required to replace clinical trial sites, resulting in additional costs.

We expect that KLS-13023 will be scheduled as Schedule II or III, as a result of which we will also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the products to pharmacies and other healthcare providers, and these distributors would need to obtain Schedule II or III distribution registrations. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If KLS-13023 is a Schedule II drug, pharmacies would have to maintain enhanced security with alarms and monitoring systems and they must adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

We may manufacture the commercial supply of KLS-13023 outside of the United States. If KLS-13023 is approved by the FDA and classified as a Schedule II or III substance, an importer can import for commercial purposes if it obtains from the DEA an importer registration and files an application with the DEA for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of KLS-13023 and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third party comments to be submitted.

Individual states have also established controlled substance laws and regulations. Though state-controlled substance laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our product candidates as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

We currently obtain the API for KLS-13023 from a bulk manufacturer of pharmaceutical grade API in Switzerland. For KLS-13023, we plan to conduct Phase 1 clinical trials in Australia, subject to applicable regulatory approval. In addition, we may decide to develop, manufacture or commercialize our product candidates in additional countries. As a result, KLS-13023 will also be subject to controlled substance laws and regulations from the Therapeutic Goods Administration in Australia, Health Canada's Office of Controlled Substances in Canada, and from other regulatory agencies in other countries where we may develop, manufacture or commercialize KLS-13023 in the future. We plan to submit NDA for KLS-13023 to the FDA upon completion of all requisite clinical trials and will require additional DEA approvals at such time as well.

On September 27, 2018, the Department of Justice and Drug Enforcement Administration announced that Epidiolex, the newly approved medication by the Food & Drug Administration, is being placed in Schedule V of the Controlled Substances Act, the least restrictive schedule of the CSA. On June 26, 2018, the FDA announced it approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex contains cannabidiol (CBD), a chemical constituent of the cannabis plant (commonly referred to as marijuana). The CBD in Epidiolex is extracted from the cannabis plant and is the first FDA-approved drug to contain a purified extract from the plant. Schedule V drugs represents the least potential for abuse. Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

Despite the approvals by the FDA and DEA for Epidiolex, any of these foregoing factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market KLS-13019 or KLS-13023. Moreover, because our business is almost entirely dependent upon these two product candidates, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

Cannabis remains illegal under Federal law.

Despite the development of a regulated cannabis industry under the laws of certain states, these state laws regulating medical and adult cannabis use are in conflict with the CSA, which classifies cannabis as a Schedule I controlled substance and makes cannabis use and possession illegal on a national level. The United States Supreme Court has ruled that the Federal government has the right to regulate and criminalize cannabis, even for medical purposes, and thus Federal law criminalizing the use of cannabis preempts state laws that regulate its use.

On August 29, 2013, United States Deputy Attorney General James Cole issued the Cole Memo to United States attorneys guiding them to prioritize enforcement of Federal law away from the cannabis industry operating as permitted under certain state laws, so long as:

cannabis is not being distributed to minors and dispensaries are not located around schools and public buildings;

the proceeds from sales are not going to gangs, cartels or criminal enterprises;

cannabis grown in states where it is legal is not being diverted to other states;

cannabis-related businesses are not being used as a cover for sales of other illegal drugs or illegal activity;

there is not any violence or use of firearms in the cultivation and sale of marijuana;

there is strict enforcement of drugged-driving laws and adequate prevention of adverse health consequences; and

cannabis is not grown, used, or possessed on Federal properties.

The Cole Memo was a guide for United States attorneys and did not alter in any way the Department of Justice's authority to enforce Federal law, including Federal laws relating to cannabis, regardless of state law. As described below, as a result of the issuance of the Sessions Memo by the Department of Justice on January 4, 2018, the Cole memo was rescinded. We cannot provide assurance that our actions are or will be in compliance with the Cole Memo, the Sessions Memo or any other laws or regulations that currently exist or may be amended or adopted in the future.

On January 4, 2018, former Attorney General Jefferson B. Sessions, III issued a memo on federal marijuana enforcement policy announcing a return to the rule of law and the rescission of previous nationwide guidance by the Department of Justice (including, but not limited to, the Cole Memo). In the memorandum, Attorney General Jefferson Sessions directs all U.S. attorneys to enforce the laws enacted by Congress and to follow well established principles when pursuing prosecutions related to marijuana activities. These principles include weighing all relevant considerations, including federal law enforcement priorities set by the Attorney General, the seriousness of the crime, the deterrent effect of criminal prosecution, and the cumulative impact of particular crimes on the community. The effect of this memo is to shift federal policy from a hands-off approach adopted by the Obama administration to permitting federal prosecutors across the country to determine how to prioritize resources to regulate marijuana possession, distribution and cultivation in states where marijuana use is legal.

Although the prior administration determined that it was not an efficient use of resources to direct Federal law enforcement agencies to prosecute those lawfully abiding by state laws allowing the use and distribution of medical and recreational cannabis, the current administration issued the Sessions Memo announcing a return to the rule of law and the rescission of previous guidance documents. The Sessions Memo rescinds the Cole Memo which was adopted by the Obama administration as a policy of non-interference with marijuana-friendly state laws. The Sessions Memo shifts federal policy from a hands-off approach adopted by the Obama administration to permitting federal prosecutors across the country to decide how to prioritize resources to regulate marijuana possession, distribution and cultivation in states where marijuana use is regulated. There can be no assurance that federal prosecutors will not prosecute and dedicate resources to regulate marijuana possession, distribution and cultivation in states where marijuana use is regulated which may cause states to reconsider their regulation of marijuana which would have a detrimental effect on the marijuana industry. Any such change in state laws based upon the Sessions Memo and the Federal government's enforcement of Federal laws could cause significant financial damage to us and our stockholders.

Product shipment delays could have a material adverse effect on our business, results of operations and financial condition.

The shipment, import and export of KLS-13023 and the API used to manufacture KLS-13023 will require import and export licenses. In the United States, the FDA, U.S. Customs and Border Protection, and the DEA, in Canada, where our API is manufactured, the Canada Border Services Agency and Health Canada, in Australia, where we will commence clinical trials, the Australian Customs and Board Protection Service and the Therapeutic Goods Administration, and in other countries, similar regulatory authorities, regulate the import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export process requires the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of API and our product candidates may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in delays in clinical trials or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or KLS-13023. A delay in a clinical trial or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or KLS-13023 could have a material adverse effect on our business, results of operations and financial condition.

Failure to obtain regulatory approval in jurisdictions outside the United States and the European Union would prevent our product candidates from being marketed in those jurisdictions.

In order to market and sell our products in jurisdictions other than the United States and the European Union, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The regulatory approval process outside the United States and the European Union generally includes all of the risks associated with obtaining FDA and EMA approval, but can involve additional testing. We may need to partner with third parties in order to obtain approvals outside the United States and the European Union. In addition, in many countries worldwide, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States and the European Union on a timely basis, if at all. Even if we were to receive approval in the United States or the European Union, approval by the FDA or the EMA does not ensure approval by regulatory authorities in other countries or jurisdictions. Similarly, approval by one regulatory authority outside the United States and the European Union would not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or the EMA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in other foreign jurisdictions, the commercial prospects of those product candidates may be significantly diminished and our business prospects could decline.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

In the United States there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities or affect our ability to profitably sell any product candidates for which we obtain marketing approval.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact our business. A significant number of provisions are not yet, or have only recently become effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical and medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If we ever obtain regulatory approval and successfully commercialize KLS-13019, KLS-13023 or other product candidates that we may develop, these new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise our ability to generate revenue, attain profitability or commercialize our products.

On December 2, 2017, the U.S. Senate passed the Tax Cut and Jobs Act of 2017. The Senate bill repeals the individual mandate that requires all Americans under 65 to have health insurance or pay a penalty, effective starting in 2019. The CBO initially estimated that 13 million fewer persons would have health insurance by 2025, including 8 million fewer on the Affordable Care Act exchanges and 5 million fewer on Medicaid. Fewer persons with healthcare means lower costs for the government, so CBO estimated over $300 billion in savings. This allowed Republicans to increase the size of the tax cuts in the bill. Health insurance premiums on the exchanges could rise as much as 10 percentage points more than they would otherwise. CBO later revised this estimate in 2018 to 7 million fewer insured by 2026.

In addition to these changes, the corporate tax rate would fall from 35% to 21%, while some related business deductions and credits would either be reduced or eliminated. The Act would also change the U.S. from a global to a territorial tax system with respect to corporate income tax. Instead of a corporation paying the U.S. tax rate (35%) for income earned in any country (less a credit for taxes paid to that country), each subsidiary would pay the tax rate of the country in which it is legally established.

We plan to seek orphan drug status for KLS-13023 for the treatment of Overt Hepatic Encephalopathy, but we may be unable to obtain such designation or to maintain the benefits associated orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Regulatory authorities in some jurisdictions, including the United States and European Union, may designate drugs for relatively small patient populations as orphan drugs. The FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals annually in the United States, or, if the disease or condition affects more than 200,000 individuals annually in the United States, if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants Orphan Drug Designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union community. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug.

In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. In the European Union, Orphan Drug Designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug approval. This period may be reduced to six years if the Orphan Drug Designation criteria are no longer met, including where it is shown that the product is sufficiently profitable so that market exclusivity is no longer justified.

As a result, even if KLS-13023 receives orphan exclusivity in Overt Hepatic Encephalopathy, the FDA or EMA can still approve other drugs that have a different active ingredient for use in treating the same indication. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of KLS-13023 or the EMA could reduce the term of exclusivity if KLS-13023 is sufficiently profitable.

We plan to seek orphan drug designation for KLS-13023 in Overt Hepatic Encephalopathy, but exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA or EMA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for KLS-13023, we may never receive such designation, or there may be a delay in receiving such designation that would impact our expected timeframe for clinical development.

In June 2016, the Company filed for Orphan Drug Designation with the Office of Orphan Products Development (“OOPD”) at the U.S. Food and Drug Administration (“FDA”) for the use of CBD to treat a sub-set of hepatic encephalopathy. It is estimated that approximately 121,000 +/- hospitalizations occur every year from overt hepatic encephalopathy ammonia neurotoxicity traumas, which put the patient in severe cognitive and behavioral impairment. The current standard of care for the treatment of these traumatic events includes diuretics and anti-biotics, but none currently deal with the neurotoxic aspects of the brain.

In November 2016, the Company received an initial abeyance letter from the OOPD regarding the Company’s orphan drug application. The abeyance letter seeks clarification on the epidemiology regarding the Company’s target sub-set of the HE disease (also referred to herein as overt hepatic encephalopathy (OHE)) . In October 2017, the Company responded to the questions set forth in the epidemiology and disease sub-set. The Company received a response on November 30, 2017 from the OOPD agreeing with the Company’s position on the orphan disease threshold of patients suffering from the target sub-set of the HE disease. However, the OOPD requested additional information to support the limiting use for hospitalized patients in the sub-set of the HE disease. The Company believes it has the necessary information and data to support its position in requesting orphan drug designation for CBD in the treatment of the target sub-set of the HE disease. Accordingly, the Company plans to provide adequate rationale for limiting use of the drug to the orphan sub-set of HE patients requiring inpatient hospital treatment by November 2018.

There can be no assurance that the Company will be successful in obtaining orphan drug status for the target sub-set of the HE disease. Failure to obtain orphan designation in this instance may affect the Company’s plans to pursue a clinical treatment for the sub-set of the HE disease using CBD as the primary active pharmaceutical ingredient in a proposed target drug candidate to treat the sub-set of the HE disease.

Even if we are able to commercialize KLS-13019 or KLS-13023, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm our business.

The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates, if approved, will depend substantially on the extent to which the costs of these product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize KLS-13019 or KLS-13023. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that we receive for any of our approved products. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree.

The intended use of a drug product by a physician can also affect pricing. For example, CMS could initiate a National Coverage Determination administrative procedure, by which the agency determines which uses of a therapeutic product would and would not be reimbursable under Medicare. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

Outside the United States, particularly in member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations or the successful completion of health technology assessment procedures with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Certain countries allow companies to fix their own prices for medicines, but monitor and control company profits. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be adversely affected.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the U.S. federal healthcare Anti-Kickback Statute impacts our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent (including through impermissible promotion of our products for off-label uses) or making a false statement or record to avoid, decrease or conceal an obligation to pay money to the federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

HIPAA, and the rules and regulations promulgated thereunder, establish federal standards for maintaining the privacy and security of certain patient health information known as Protected Health Information, or PHI. As amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, HIPAA establishes federal standards for administrative, technical and physical safeguards relevant to the electronic transmission of PHI and imposes notification obligations in the event of a breach of the privacy or security of PHI. In addition to adhering to the requirements of HIPAA, entities considered "covered entities" under HIPAA (such as health plans, healthcare clearinghouses, and certain healthcare providers) are required to obtain assurances in the form of a written contract from certain business associates to which they transmit PHI (or who create, receive, transmit or maintain PHI on the covered entity's behalf) to ensure that the privacy and security of such information is maintained in accordance with HIPAA requirements. HITECH made changes to HIPAA including extending the reach of HIPAA beyond HIPAA covered entities to business associates, increased the maximum civil monetary penalties for violations of HIPAA, and granted enforcement authority to state attorneys general. Failure to comply with HIPAA/HITECH can result in civil and criminal liability, including civil monetary penalties, fines and imprisonment;

the U.S. federal physician payment transparency requirements under the Affordable Care Act require applicable manufacturers of covered drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and certain other healthcare providers and their immediate family members and applicable group purchasing organizations; and

analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and certain other healthcare providers or marketing expenditures. Additionally, state and foreign laws govern 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 HIPAA/HITECH, thus complicating compliance efforts.

Comparable laws and regulations exist in the countries within the European Economic Area ("EEA"). Although such laws are partially based upon European Union law, they may vary from country to country. Healthcare specific, as well as general European Union and national laws, regulations and industry codes constrain, for example, our interactions with government officials and healthcare practitioners, and the handling of healthcare data. Non-compliance with any of these laws or regulations could lead to criminal or civil liability.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, licensees or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could subject us to significant liability and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with DEA, FDA or EMA regulations or similar regulations of other foreign regulatory authorities or to provide accurate information to the DEA, FDA, EMA or other foreign regulatory authorities. In addition, misconduct by employees could include intentional failures to comply with certain manufacturing standards, to comply with U.S. federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We plan to adopt, and will implement and enforce, a Code of Business Conduct and Ethics, which will be effective as of the effectiveness of the registration statement of which this prospectus forms a part, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity, such as employee training on enforcement of the Code of Business Conduct and Ethics, may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

If we are unable to develop sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions on acceptable terms, we may be unable to generate revenue.

We do not currently have any sales, marketing or distribution capabilities. If KLS-13019 or KLS-13023 is approved, we will need to develop internal sales, marketing and distribution capabilities to commercialize such products, which would be expensive and time-consuming, or enter into collaborations with third parties to perform these services. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products or decide to co-promote products with collaborators, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance of any approved product. If we are not successful in commercializing any product approved in the future, either on our own or through third parties, our business, financial condition and results of operations could be materially adversely affected.

Our product candidates, if approved, may be unable to achieve broad market acceptance and, consequently, limit our ability to generate revenue from new products.

Even when product development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our products by physicians and patients. The market acceptance of any product depends on a number of factors, including the indication statement and warnings approved by regulatory authorities in the product label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payors such as government healthcare systems and insurance companies, the price of the product, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Any factors preventing or limiting the market acceptance of our product candidates could have a material adverse effect on our business, results of operations and financial condition.

If we receive regulatory approvals, we intend to market KLS-13019 and KLS-13023 in multiple jurisdictions where we have limited or no operating experience and may be subject to increased business and economic risks that could affect our financial results.

If we receive regulatory approvals, we plan to market KLS-13019 and KLS-13023 in jurisdictions where we have limited or no experience in marketing, developing and distributing our products. Certain markets have substantial legal and regulatory complexities that we may not have experience navigating. We are subject to a variety of risks inherent in doing business internationally, including risks related to the legal and regulatory environment in non-U.S. jurisdictions, including with respect to privacy and data security, trade control laws and unexpected changes in laws, regulatory requirements and enforcement, as well as risks related to fluctuations in currency exchange rates and political, social and economic instability in foreign countries. If we are unable to manage our international operations successfully, our financial results could be adversely affected.

In addition, controlled substance legislation may differ in other jurisdictions and could restrict our ability to market our products internationally. Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including Cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to us obtaining marketing approval for KLS-13019 or KLS-13023 in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit KLS-13019 or KLS-13023 to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. We would be unable to market KLS-13019 or KLS-13023 in countries with such obstacles in the near future or perhaps at all without modification to laws and regulations.

KLS-13023 contains a controlled substance, the use of which may generate public controversy.

Since our product candidates contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, our product candidates. These pressures could also limit or restrict the introduction and marketing of our product candidates. Adverse publicity from Cannabis misuse or adverse side effects from Cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable by our product candidates. The nature of our business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

KLS-13023 is a formulation that does contain cannabidiol. At present, cannabidiol is deemed a Schedule 1 controlled substance by the U.S. Drug Enforcement Agency under the Controlled Substances Act. And like the drug molecule EpidiolexÒ, which was recently approved by the FDA for marketing and sale for use in treating Dravet's Syndrome and Lennox-Gasteau Syndrome (forms of child epilepsy), KLS-13023 would need to follow the guidance set forth by the CSA, complete a successful human clinical trial and apply for rescheduling, as was the case with EpidiolexÒ, now a Schedule 5 drug.

On January 14, 2019, the Company received written notice from the Drug Enforcement Administration ("DEA") Drug and Chemical Evaluation Section, as follows: "Please be advised that your material meets the definition of 'Hemp' and is not regulated under the CSA, as long as it consists of high purity Cannabidiol (CBD) that contains approximately 0.1% delta-9- THC. (However, if it contains more than 0.3% delta-9 THC, it is considered 'Marihuana' and would be in Schedule 1 of the CSA)." While this notice is an official notice from the DEA regarding the scheduling of high purity CBD, the Company will continue to abide by the CSA in all respects with regards to its treatment and handling of CBD.

Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management and other specialized personnel, including Dean Petkanas, our chairman and chief executive officer, William A. Kinney, our chief scientific officer, Mark Corrao, our chief financial officer, and Thomas Kikis, our chief communications officer. The loss of one or more members of our management team or other key employees could delay our research and development programs and materially harm our business, financial condition, results of operations and prospects. The relationships that our team has cultivated within the life sciences industry makes us particularly dependent upon their continued employment with us. Because our management team is not obligated to provide us with continued service, they could terminate their employment or services with us at any time without penalty, subject to providing any required advance notice. We do not maintain key person life insurance policies for any members of our management team.

Our future success and growth will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of drugs is highly competitive. We compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as products and processes being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that enter the market. We believe that a significant number of products are currently available, under development, and may become commercially available in the future, for the treatment of indications for which we may try to develop product candidates. If either of our product candidates, KLS-13019 or KLS-13023, is approved for the indications we are currently pursuing, it will compete with a range of therapeutic treatments that are either in development or currently marketed.

We are aware of multiple companies that are working in the Cannabis therapeutic area, including pharmaceutical companies such as GW Pharmaceuticals PLC, or GW, which markets Sativex, a botanical cannabinoid oral mucosal for the treatment of spasticity due to multiple sclerosis and which is also in development in neuropathic pain in several foreign countries and is seeking FDA approval in the United States, and is developing Epidiolex, a liquid formulation of highly purified CBD extract, as a treatment for Dravet's Syndrome, Lennox Gastaut Syndrome, and various childhood epilepsy syndromes; Insys Therapeutics, Inc., which is seeking FDA approval for an orally-administered liquid formulation of its synthetic CBD compound as a treatment for Dravet's Syndrome, Lennox Gastaut Syndrome, and other childhood epilepsy syndromes; and Nemus Bioscience, Inc. which is focused on the discovery, development and commercialization of Cannabi*s* therapeutics.

On September 27, 2018, the Department of Justice and Drug Enforcement Administration announced that Epidiolex, the newly approved medication by the Food & Drug Administration, is being placed in Schedule V of the Controlled Substances Act, the least restrictive schedule of the CSA. On June 26, 2018, the FDA announced it approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex contains cannabidiol (CBD), a chemical constituent of the cannabis plant (commonly referred to as marijuana). The CBD in Epidiolex is extracted from the cannabis plant and is the first FDA-approved drug to contain a purified extract from the plant. Schedule V drugs represents the least potential for abuse.

We are also aware of Zynerba Pharmaceuticals, Inc. and its patent-protected synthetic transdermal cannabinoid product candidates, ZYN002 and ZYN001. These cannabinoid product candidates represent cannabinoid therapeutics for several indications including refractory epilepsy, FXS, OA, fibromyalgia and peripheral neuropathic pain. According to Zynerba Pharmaceuticals, Inc., ZYN002 is the first and only synthetic CBD formulated as a permeation-enhanced gel for transdermal delivery, and is patent-protected through 2030.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before we are able to, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours, and may also be more successful than us in manufacturing and marketing their products. These advantages could materially impact our ability to develop and commercialize KLS-13019 or KLS-13023 successfully

Our product candidates, most notably KLS-13023, may compete with non-synthetic cannabinoid drugs, including therapies such as GW's Sativex. Our product candidates may also compete with medical and recreational marijuana, in markets where the recreational and/or medical use of marijuana is legal. There is support in the United States for further legalization of marijuana. In markets where recreational and/or medical marijuana is not legal, our product candidates may compete with marijuana purchased in the illegal drug market. We cannot assess the extent to which patients may utilize marijuana obtained illegally for the treatment of the indications for which we are developing KLS-13019 and KLS-13023.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The market opportunity for chemotherapy induced peripheral neuropathy will be limited to those patients who are not currently receiving adequate relief from current treatment regimens, which may reduce our targeted market.

Pre-existing treatments may be adequate to treat certain patients with chemotherapy induced peripheral neuropathy. Whenever the first-line therapy fails or is unsuccessful, then second-line therapy may be administered. For chemotherapy induced peripheral neuropathy, KLS-13019 is particularly targeted to provide an additional treatment option for patients not currently receiving adequate relief from current treatment regimens. If a more successful first-line therapy is developed, it may significantly reduce the patient population to which we can supply, which may affect our ability to successfully commercialize KLS-13019 for chemotherapy induced peripheral neuropathy.

Product liability lawsuits against us could cause us to incur substantial liabilities.

Our planned use of KLS-13019 and KLS-13023 in clinical trials and the sale of KLS-13019 and KLS-13023, if approved, exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with KLS-13019 or KLS-13023. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we become subject to product liability claims and cannot successfully defend ourselves against them, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in, among other things:

withdrawal of patients from our clinical trials;
substantial monetary awards to patients or other claimants;
decreased demand for KLS-13019 or KLS-13023 following marketing approval, if obtained;
damage to our reputation and exposure to adverse publicity;
increased FDA or EMA warnings on product labels;
litigation costs;
distraction of management's attention from our primary business;
loss of revenue; and
the inability to successfully commercialize KLS-13019 or KLS-13023, if approved.

We will need to obtain product liability insurance coverage for our clinical trials. We may not be able to obtain such coverage at a reasonable cost or in sufficient amounts to protect us against losses, including if insurance coverage becomes increasingly expensive. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. The cost of any product liability litigation or other proceedings, even if resolved in our favor, could be substantial, particularly in light of the size of our business and financial resources. A product liability claim or series of claims brought against us could cause our share price to decline and, if we are unsuccessful in defending such a claim or claims and the resulting judgments exceed our insurance coverage, our financial condition, results of operations, business and prospects could be materially adversely affected.

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

Despite the implementation of security measures, our information technology and other internal infrastructure systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause delays in our research and development work. For instance, the loss of preclinical data or data from any future clinical trial involving our product candidates could result in delays in our development and regulatory filing 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.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on CROs, clinical data management organizations and consultants to design, conduct, supervise and monitor preclinical studies of our product candidates and may do the same for our planned clinical trials. We and our prospective CROs are required to comply with various regulations, including GCP, which are enforced by the FDA, and guidelines of the Competent Authorities of Member States of the EEA and comparable foreign regulatory authorities to ensure that the health, safety and rights of patients are protected in clinical development and clinical trials, and that trial data integrity is assured. Regulatory authorities ensure compliance with these requirements through periodic inspections of trial sponsors, principal investigators and trial sites. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If we or any of our prospective CROs fail to comply with applicable requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with such requirements. In addition, our clinical trials must be conducted with products produced under cGMP requirements, which mandate the methods, facilities and controls used in manufacturing, processing and packaging of a drug product to ensure its safety and identity. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process.

Our prospective CROs are not our employees, and except for remedies available to us under future agreements with such prospective CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. If the prospective CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our prospective CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third-party manufacturers and suppliers and we intend to rely on third parties to produce preclinical, clinical and commercial supplies of active pharmaceutical ingredients, or APIs, for KLS-13019 and KLS-13023.

We rely on third parties to supply the materials for, and manufacture, our research and development, preclinical and clinical trial APIs. We do not own manufacturing facilities or supply sources for such components and materials. There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our API manufacturer could require significant effort and expertise because there may be a limited number of qualified manufacturers.

The manufacturing process for our product candidates is subject to FDA, EMA, DEA and other foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards such as cGMP. In addition, our manufacturers must ensure therapeutic consistency among batches, including preclinical, clinical and, if approved, marketing batches. Demonstrating such consistency may require typical manufacturing controls as well as clinical data. Our manufacturers must also ensure that our batches conform to complex release specifications. Further, manufacturers of controlled substances must obtain and maintain necessary DEA and state registrations and registrations with applicable foreign regulatory authorities, and must establish and maintain processes to ensure compliance with DEA and state requirements and requirements of applicable foreign regulatory authorities governing, among other things, the storage, handling, security, recordkeeping and reporting for controlled substances. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of a collaborator;
- subjecting our product candidates to additional inspections by regulatory authorities; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

If a collaborative partner terminates or fails to perform its obligations under an agreement with us, the commercialization of KLS-13019 or KLS-13023, if approved, could be delayed or terminated.

We are not currently party to any collaborative arrangements for the commercialization of KLS-13019 or KLS-13023, if approved, or similar arrangements, although we may pursue such arrangements before any commercialization of KLS-13019 or KLS-13023, if approved. If we entered into future collaborative arrangements for the commercialization of any product candidate or similar arrangements and any of our collaborative partners does not devote sufficient time and resources to a collaboration arrangement with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be materially adversely affected. In addition, if any such future collaboration partner were to breach or terminate its arrangements with us, the commercialization of any product candidate could be delayed, curtailed or terminated.

Much of the potential revenue from future collaborations may consist of contingent payments, such as payments for achieving regulatory milestones or royalties payable on sales of drugs. The milestone and royalty revenue that we may receive under these collaborations will depend upon our collaborators' ability to successfully develop, introduce, market and sell new products. In addition, collaborators may decide to enter into arrangements with third parties to commercialize products developed under collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. Future collaboration partners may fail to develop or effectively commercialize products using our products or technologies, which could have a material adverse effect on our operating results and financial condition.

Business disruptions affecting our third-party suppliers, manufacturers and CROs could harm our future revenues and financial condition and increase our costs and expenses.

We rely on third parties to supply the materials for, and manufacture our APIs for, our preclinical and clinical trials. There are only a limited number of suppliers and manufacturers of our APIs and our ability to obtain these materials could be disrupted if the operations of these manufacturers is affected by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. We also rely on CROs, clinical data management organizations and consultants to design, conduct, supervise and monitor preclinical studies of our product candidates and will do the same for our planned clinical trials. If their facilities are unable to operate because of an accident or incident, even for a short period of time, some or all of our research and development programs may be harmed or delayed and our operations and financial condition could suffer.

Our third-party manufacturers may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

Our third-party manufacturers may use hazardous materials, including chemicals and compounds that could be dangerous to human health and safety or the environment. The operations of our third-party manufacturers may also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. In the event of contamination or injury, our third-party manufacturers could be held liable for damages or be penalized with fines in an amount exceeding their resources, which could result in our clinical trials or regulatory approvals being delayed or suspended.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. We do not know whether any of the pending patent applications for any of our product candidates will result in the issuance of patents that protect our technology or products, or if any of our issued patents will effectively prevent others from commercializing competitive technologies and products. The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our issued patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The United States Patent and Trademark Office (the "USPTO"), and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and various foreign national or international patent agencies in several stages over the lifetime of the patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may become subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, and to use our related proprietary technologies without violating the intellectual property rights of others. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing the applicable product candidate. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

While our preclinical studies and clinical trials are ongoing, we believe that the use of KLS-13019 and KLS-13023 in these preclinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA, or the Clinical Development Exemption. As KLS-13019 and KLS-13023 progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their uses we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by us is invalid or 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 proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our current and former employees, consultants, outside scientific collaborators, sponsored researchers, contract manufacturers, vendors and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets. Any party with whom we or they have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose such trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Therefore, we have filed applications and/or obtained patents only in key markets such as the United States, Canada, Japan and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may be able to export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, an April 2014 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. As a result, proceedings to enforce our patent rights in certain foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business and could be unsuccessful.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Risks Related to Ownership of Our Common Stock

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Historically, there has not been a market for shares of our common stock. An active trading market for our shares may never develop or be sustained in the future. The lack of an active market may impair the ability of our stockholders to sell their shares at the time and at such price as they consider reasonable. The lack of an active market may also reduce the fair market value of shares of our common stock. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into collaborations or acquire companies or products by using our shares of common stock as consideration.

The market price of our stock may be volatile, and stockholders could lose all or part of their investment.

Our common stock currently does not trade. In the event we do develop a trading market in our common stock, the trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, these factors include:

- trading volatility of low-priced stock;
- the success of competitive products;
- regulatory actions with respect to our product candidates or our competitors’ products and product candidates;
- actual or anticipated changes in our growth rate relative to our competitors;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
results of clinical trials of KLS-13019, KLS-13023 or product candidates of our competitors;
regulatory or legal developments in the United States and other countries;
developments or disputes concerning patent applications, issued patents or other proprietary rights;
the recruitment or departure of key personnel;
the level of expenses related to our preclinical and clinical development programs;
the results of our efforts to in-license or acquire additional product candidates or products;
actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
variations in our financial results or those of companies that are perceived to be similar to us;
fluctuations in the valuation of companies perceived by investors to be comparable to us;
share price and volume fluctuations attributable to inconsistent trading volume levels of our common stock;
announcement or expectation of additional financing efforts;
sales of our common stock by us, our insiders or our other stockholders;
changes in the structure of healthcare payment systems;
market conditions in the pharmaceutical sector; and
general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Moreover, some institutional investors and mutual funds cannot invest in stocks priced below $5.00 per share. The realization of any of these risks or any of a broad range of other risks, including those described in these “Risk Factors,” could have a dramatic and material adverse impact on the market price of our common stock.

We may be subject to securities litigation, which is expensive and could divert our management’s attention.

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

Our common stock is classified as a “penny stock” under SEC Rules and Regulations, which means there may be very limited trading market for our shares.

Our common stock is deemed to be “penny stock” as that term is defined in Rule 3a51-1 of the Securities Exchange Act of 1934, as amended (“the Exchange Act”). Penny stocks are stocks (i) with a price of less than five dollars per share; (ii) that are not traded on a “recognized” national exchange; (iii) whose prices are not quoted on an automated quotation system sponsored by a registered national securities association; or (iv) whose issuer has net tangible assets less than $2,000,000 (if the issuer has been in continuous operation for at least three years); or $5,000,000 (if in continuous operation for less than three years); or with average revenues of less than $6,000,000 for the last three years.

Section 15(g) of the Exchange Act and Rule 15g-2 promulgated thereunder require broker dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor’s account. Potential investors in our common stock are urged to obtain and read such disclosure carefully before purchasing any shares that are deemed to be “penny stock.”

Moreover, Rule 15g-9 of the Exchange Act requires broker dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker dealer to (i) obtain from the investor information concerning his, her or its financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor, and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor’s financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult for investors in our common stock to resell their shares to third parties or to otherwise dispose of such shares.

Insiders have substantial influence over us and could delay or prevent a change in corporate control.

As of April 1, 2019, our executive officers, directors, and holders of 5.0% or more of our capital stock collectively beneficially owned approximately 82.7% of our voting stock. This concentration of ownership could harm the market price of our common stock by:

delaying, deferring or preventing a change in control of our company;
impeding a merger, consolidation, takeover or other business combination involving our company; or
discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including by seeking a premium value for their common stock, and might negatively affect the prevailing market price for our common stock.

If we are unable to maintain effective internal control over our financial reporting, the reputational effects could materially adversely affect our business.

Under the provisions of Section 404(a) of the Sarbanes-Oxley Act of 2002, as amended by the Dodd Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC adopted rules requiring public companies to perform an evaluation of Internal Control over Financial Reporting (Internal Controls) and to report on our evaluation in our Annual Report on Form 10-K. Our Internal Controls constitute a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. In the event we discover material weakness in our internal controls and our remediation of such reported material weakness is ineffective, or if in the future we are unable to maintain effective Internal Controls, additional resulting material restatements could occur, regulatory actions could be taken, and a resulting loss of investor confidence in the reliability of our financial statements could occur.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have issued Preferred Stock.

Our Certificate of Incorporation authorizes the issuance of up to 5,000,000 shares of Preferred Stock with designations, rights and preferences determined from time to time by the Board of Directors. There are currently 75 shares of Series A Preferred Stock and 75 shares of Series B Preferred Stock outstanding. The holders of our Preferred Stock have voting control of the Company. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue Preferred Stock with dividend, liquidation, conversion, voting, or other rights which could adversely affect the voting power or other rights of the holders of the Common Stock. The issuance of Preferred Stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company. See “Description of Capital Stock” for more information.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal executive offices are located at 3805 Old Easton Road, Doylestown, PA 18902. Our telephone number at that address is (858) 883-2642. We have additional offices located at 4 Knoll Court, Lloyd Harbor, N.Y. 11743. On April 1, 2014, the Company entered into a one year lease arrangement for office space, with the option to renew the lease annually. The monthly rent payment is $5,000 and a security deposit of $15,000. On September 15, 2015, the Company entered into a one year lease arrangement for office space. The Company has amended this lease to extend the term through September 30, 2018. The monthly rent payment is $229 and a security deposit of $183. On February 1, 2018, the Company entered into a month to month lease arrangement for laboratory space. The monthly rent payment is $500. On July 1, 2018, the Company entered into a one year lease arrangement for office space, with the option to renew the lease annually. On September 1, 2018, the Company subleased this office space to a third party. The Subleasee will pay 100% of rent for months September through November 2018 and will pay 50% of rent until expiration of lease on June 30, 2019. The monthly rent payment is $2,600 and a security deposit of $2,121.

ITEM 3. LEGAL PROCEEDINGS.

On or about September 18, 2013, a lawsuit was filed by two individuals against the Company and the Company's CEO. The plaintiffs allege that they provided business services to Kannalife Sciences, Inc. ("Kannalife") in the amount of $150,000, including but not limited to providing strategic introductions to Kannalife and Mr. Petkanas and were seeking 17% of the issued and outstanding stock of Kannalife. The Company believed, at all times, that the allegations to be without merit and vigorously defended itself.

On or about September 30, 2013, Kannalife and Mr. Petkanas filed a motion to dismiss all five causes of action alleged against Kannalife and Mr. Petkanas.

On May 12, 2014, the court dismissed all five causes of action alleged by one plaintiff against Kannalife and Mr. Petkanas.

On March 27, 2015, the court granted permission to this plaintiff to replead his complaint (the "Repleading Plaintiff").

On July 14, 2015, the court denied the Repleading Plaintiff's motion to reargue, affirming the dismissal of all of the Repleading Plaintiff's causes of action, which left, three causes of action remain open relating to the remaining plaintiff (the "Remaining Plaintiff").

In December 2016, Kannalife and Mr. Petkanas filed a motion for summary judgment to seek the court's decision in dismissing the remainder of the claims alleged by the Remaining Plaintiff.

On June 30, 2017, the motion for summary judgment made by Kannalife and Mr. Petkanas was granted. All remaining causes of action by the Remaining Plaintiff were dismissed.

On February 7, 2018, the Remaining Plaintiff, (the "Plaintiff-Appellant") appealed from the June 30, 2017 decision and order of the lower court, which granted the Kannalife's and Mr. Petkanas' (Defendants-Respondents) motion for summary judgment dismissing all of Plaintiff-Appellant's claims. In his amended complaint, Plaintiff-Appellant alleged the existence of an oral agreement between himself and Kannalife and Mr. Petkanas for the exchange of investments (including both money and services) from Plaintiff-Appellant in return for the transfer of 17% of Kannalife's shares. However, Plaintiff-Appellant's allegations consisted of nothing more than vague statements regarding what he promised to provide to Kannalife and to Mr. Petkanas in exchange for nearly one-fifth of Kannalife's shares. And after years of litigation, including extensive depositions and document exchanges, the evidence elicited by both parties failed to clarify either the precise terms of the alleged oral agreement or that Plaintiff-Appellant actually made any investments as he allegedly promised to do. In the lower court, Kannalife and Mr. Petkanas moved for summary judgment dismissing Plaintiff-Appellant's claims based on certain undisputed facts: that no evidence existed to show that Plaintiff-Appellant–or Stone Engineering, P.C., which is Plaintiff-Appellant's S Corporation–made any investment at all in Kannalife; that even if Plaintiff-Appellant did make any investments, the alleged agreement is unenforceable pursuant to General Obligations Law § 5-701(a)(1) (the Statue of Frauds) because the terms cannot be completed within one year; and the contract is unenforceable as a matter of hornbook law because Plaintiff-Appellant's own testimony establishes that he and Kannalife and Mr. Petkanas never reached a "meeting of the minds" with respect to the contours of Plaintiff-Appellant's supposed offer of investments or the time period for transferring the shares to Plaintiff-Appellant.

On appeal, Plaintiff-Appellant argues the lower court's decision was wrong because: (1) it was based upon an erroneous finding that Plaintiff-Appellant lacks standing to recover his shares in Kannalife; and (2) enforcement of the alleged contract is not barred by the Statute of Frauds because (a) its terms were capable of being performed within one year and (b) the alleged agreement constitutes a securities contract under UCC § 8-113 that does not require a writing to be enforceable. However, in Opposition Kannalife and Mr. Petkanas argued that the lower court's decision should primarily be affirmed based upon an argument raised by Kannalife and Mr. Petkanas in their motion: the undisputed evidence shows that there was no meeting of the minds between Plaintiff-Appellant, and Kannalife and Mr. Petkanas regarding the terms of the alleged oral agreement. Moreover, the terms of the alleged agreement that Plaintiff-Appellant himself asserted–if they are assumed to be true for purposes of the motion and appeal–indicate that it was impossible for him to perform his obligations within one year; and a review of UCC § 8-113 along with interpretive case law requires a conclusion that the alleged agreement in this case does not constitute the type of securities contract that does not require a writing to be enforceable. Thus, to the extent an oral agreement between Plaintiff-Appellant, and Kannalife and Mr. Petkanas was ever actually created, then its enforcement is barred by the Statute of Frauds—and the lower court's decision to dismiss Plaintiff-Appellant's claim seeking enforcement of the alleged oral agreement was properly reached for these reasons. Accordingly, Kannalife and Mr. Petkanas believe that the 2nd Department will affirm the lower court's decision and order entirely.

On September 28, 2018, in an attempt to correct fatal flaws in the Plaintiff-Appellant's original case dismissed on June 30, 2017. the Plaintiff-Appellant filed a new lawsuit against Kannalife and Mr. Petkanas, alleging much, if not all of the same claims as in the original case filed by the Plaintiff-Appellant, a case which was dismissed on June 30, 2017. This new lawsuit now seeks, instead of the relief sought in the case previously dismissed, a sum of no less than $21,250,000.

Kannalife and Mr. Petkanas believe that this new case is without merit and will be ultimately dismissed in the fullness of time.

Other than aforementioned, there are no pending legal proceeding relating to our company and its CEO to which we are a party, and to our knowledge there are no material proceedings to which any of our directors, executive officers or affiliates is a party adverse to us or which have a material interest adverse to us.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Our common stock is quoted on the OTC Pink Marketplace operated by the OTC Markets Group, Inc., or "OTC Pink," under the ticker symbol "KLFE," but there is no established public trading market in our securities at this time nor has there been since our initial public offering went effective on July 15, 2016.

On November 9, 2018, the Company filed an amendment to its certificate of incorporation with the Delaware Secretary of State to change its name to Kannalife, Inc. The Company concurrently submitted a request to FINRA for the name change as well as a ticker symbol change. The Company's name change and ticker change was reviewed and processed by FINRA and went effective January 17, 2019.

Holders

As of April 1, 2019, there were approximately 81 holders of our common stock.

Dividends

We have not paid, nor declared, any cash dividends since our inception and do not intend to declare or pay any such dividends in the foreseeable future. Our ability to pay cash dividends is subject to limitations imposed by state law.

Recent Sales of Unregistered Securities

None.

Securities Authorized for Issuance under Equity Compensation Plan

None.

Issuer Repurchases of Equity Securities

We did not repurchase any shares of our common stock during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable to a "smaller reporting company" as defined in Item 10(f)(1) of SEC Regulation S-K.

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

You should read the following discussion and analysis of our financial condition and operating results together with our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" or in other parts of this prospectus. The last day of our fiscal year is December 31. Our fiscal quarters end on March 31, June 30, September 30, and December 31, and our current fiscal year ended on December 31, 2018.

Business Developments

The Company was originally incorporated in the State of Delaware on March 25, 2013 under the name TYG Solutions Corp. Our original business plan was to develop iPhone and Android smartphone apps for companies who need an app for their internal and external operations. We subsequently expanded our operations to offering corporate website design services.

On July 25, 2018, the Company entered into a Share Exchange Agreement with Kannalife Sciences, Inc., a Delaware corporation ("Kannalife Sciences") and certain stockholders of Kannalife Sciences (the "Kannalife Sciences Stockholders"). Pursuant to the terms of the Share Exchange Agreement, the Company acquired approximately nearly all of the issued and outstanding shares of Kannalife Sciences by means of a share exchange with the Kannalife Sciences Stockholders in exchange for newly issued shares of the common stock of the Company (the "Share Exchange"). As a result of the Share Exchange, Kannalife Sciences became a 99.7% owned subsidiary of the Company. The business operations of the Company regarding iPhone and Android smartphone apps shall be reduced significantly to focus efforts on target therapeutics and drug discovery, and accordingly, by virtue of the Share Exchange, the Company acquired the business of Kannalife Sciences including all of its assets. The Share Exchange was accounted for as a reverse acquisition and change in reporting entity, whereby Kannalife Sciences was the accounting acquirer.

On November 9, 2018, the Company filed an amendment to its certificate of incorporation with the Delaware Secretary of State to change its name to Kannalife, Inc. The Company has concurrently submitted a request to FINRA for approval of the name change as well as a ticker symbol change and is awaiting approval.

The Company's name change and ticker change was reviewed and processed by FINRA and went effective January 17, 2019.

Kannalife Sciences was incorporated in the State of Delaware on August 11, 2010. Kannalife Sciences is a developmental stage phyto-medical/pharmaceutical and drug discovery company that specializes in the research, development of cannabinoid and cannabinoid-based therapeutic products derived from synthetic and botanical sources, including the Cannabis *"taxa"* (the word "taxa" is the plural of "taxon" which defines a group of one or more populations of an organism or organisms to form a unit.)

Business Overview

As a result of the Share Exchange, the Company's core businesses are comprised of the following:

A drug development company focused on the research and development (R&D) of synthetic and phyto-medical products from:

- naturally recurring sources, including but not limited to cannabis, hemp, and other similar species of plantae;
- semi-synthetic sources; and
- synthetic and bio-synthetic sources.

Drug discovery platform to evaluate and potentially treat neurological and oxidative stress related disorders such as Overt Hepatic Encephalopathy ("OHE"), Chronic Traumatic Encephalopathy ("CTE") and Chemotherapy Induced Peripheral Neuropathy ("CIPN ") with high quality assured, quality controlled cGMP pharmaceutical grade semi-synthetic and synthetic cannabinoids, cannabidiol ("CBD"), and cannabidiol-like molecules.

Topical skin care pre-clinical program designed to some of its patented, proprietary cannabidiol-derived new chemical entities ("NCEs"), for use as topical solutions, ointments, and creams for disorders such as diabetic neuropathies, diabetic ulcers, and for use as an anti-pruritic. Anti-pruritics are known as anti-itch drugs and medications that inhibit the itching often associated with a variety of disorders and diseases.

The Company is primarily involved in the research and development of novel therapeutic agents for use in and as U.S. Food and Drug Administration ("FDA") approved ethical pharmaceuticals (available by doctor prescription); FDA Monograph topical solutions; Personal Care Products Council ("PCPC") / International Nomenclature of Cosmetic Ingredients ("INCI") registered. The primary focus of the Company's research and development revolves around its patented, proprietary cannabidiol-derived new chemical entities and cannabidiol. In preclinical testing, certain molecules under Pat. 9,611,213 were screened for neuroprotection and may have the potential mechanism of action for reducing inflammation and neuropathic pain. These molecules indicate that they are more soluble than cannabidiol, also deemed a neuroprotectant with potential anti-inflammatory properties. A molecule that is potentially more water soluble than cannabidiol in this regard may be good candidate(s) for use in topical applications.

The Company has been the only licensee from the National Institutes of Health ("NIH") for the licensed use of the U.S. Government's patent 6,630,507 – "Cannabinoids as Antioxidants and Neuroprotectants" (the "'507 Patent") in the disease indications of hepatic encephalopathy ("HE") and Chronic Traumatic Encephalopathy ("CTE"). Having been the only licensee to the '507 Patent has given the Company an early start in the research and development of cannabinoid therapeutics within this emerging market. The Company is the only company that has had use of the '507 Patent and corresponding licenses from NIH-OTT.

The jurisdictions in which the '507 Patent is valid are: the U.S., the U.K., Ireland, the E.U., and Australia. The patent life in these jurisdictions are good until April 21, 2019.

The Company believes that these licenses with the NIH have given the Company, through the years, the preclinical lead time to evaluate both HE and CTE without stress of competition. The Company also believes that such advances in preclinical have led to a drug development program regarding cannabidiol based therapeutics that focuses on neurodegenerative and oxidative stress related diseases described in the '507 Patent, and also the development of the Company's own intellectual property underlying U.S. Patents 9,611,213 and 10,004,722.

Furthermore, it is on the Company's belief and knowledge that while the U.S. Government patent 6,630,507 is due to expire on April 21, 2019, there may be additional opportunities related to the original licensing of the '507 Patent in which the Company may engage with the NIH and certain collaborators of the aforementioned patent to enter into a Cooperative Research and Development Agreement ("CRADA") with the NIH for one or more disease indications underlying the '507 Patent, including but not limited to HE and CTE. Moreover, the weight of the Company's future success, drug development program regarding cannabidiol based therapeutics is not centered on the '507 Patent, but rather its own intellectual property underlying U.S. Patents 9,611,213 and 10,004,722.

We intend to study KLS-13019 in patients with chemotherapy induced neuropathic pain, and we intend to study KLS-13023 in patients with mild traumatic brain injury.

We believe these product candidates will provide new treatment options for patients, as well as additional treatment options for patients not currently receiving adequate relief from current treatment regimens.

We are still conducting pre-clinical studies and have not yet commenced our clinical program or tested KLS-13019 or KLS-13023 in humans. For KLS-13019, we plan to conduct Phase 1, and possibly Phase 2, clinical trials in Australia, subject to applicable regulatory approval. We plan to conduct our Phase 1 clinical trials for KLS-13023 in Australia, subject to applicable regulatory approval. We plan to submit NDAs for KLS-13019 and KLS-13023 to the FDA upon completion of all requisite clinical trials. We expect to initiate clinical trials for KLS-13019 and KLS-13023 in the second half of 2019.

For KLS-13019, we plan to conduct Phase 1, and possibly Phase 2, clinical trials in Australia, subject to applicable regulatory approval. We plan to conduct our Phase 1 clinical trials for KLS-13023 in Australia, subject to applicable regulatory approval. We plan to submit NDAs for KLS-13019 and KLS-13023 to the FDA upon completion of all requisite clinical trials.

We plan to conduct our Phase 1, and possibly Phase 2, clinical trials for KLS-13019 in Australia, subject to applicable regulatory approval, and do not expect at this time to file an investigational new drug application, or IND, with the U.S. Food and Drug Administration, or the FDA, prior to the commencement of those clinical trials. We must file an IND with the FDA and receive approval from the U.S. Drug Enforcement Agency, or DEA, prior to commencement of any clinical trials in the United States.

We plan to conduct our Phase 1 clinical trials for KLS-13023 in Australia, subject to applicable regulatory approval. We plan to submit New Drug Applications, or NDAs, for KLS-13019 and KLS-13023 to the FDA upon completion of all requisite clinical trials.

We plan to seek orphan drug designation for KLS-13023 in Overt Hepatic Encephalopathy.

Cannabinoids are a class of molecules derived from Cannabis plants. The two primary cannabinoids contained in Cannabis are cannabidiol, or CBD, and D9-tetrahydrocannabinol, or THC. Clinical and preclinical data suggest that CBD has positive effects on treating refractory epilepsy, FXS and arthritis and THC has positive effects on treating pain. Interest in cannabinoid therapeutics has increased significantly over the past several years as preclinical and clinical data has emerged highlighting the potential efficacy and safety benefits of cannabinoid therapeutics. The cannabinoid therapeutics market is expected to grow significantly due to the potential benefits these products may provide over existing therapies. In addition to KLS-13019 and KLS-13023 potentially offering first-line therapies to patients suffering from chemotherapy induced peripheral neuropathy and mild traumatic brain injury, respectively.

KLS-13023 is target drug candidate that includes a synthetic CBD formulated in a gel capsule designed for potential use in humans. The formulation of this product is proprietary and currently held as a trade secret of the company. CBD is the primary non-psychoactive component of Cannabis. KLS-13023 has undergone a manufacturing feasibility study to improve some of the limitations associated with CBD, including but not limited to CBD's low bioavailability and limited drug like properties and improvement of the delivery of CBD through the first pass in the gut and into the circulatory system.

In addition to KLS-13023, the Company has developed a proprietary patented new chemical entity (NCE), KLS-13019. This NCE is a cannabidiol derived molecule which has undergone pre-clinical studies for the treatment of overt hepatic encephalopathy and chemotherapy induced peripheral neuropathy.

In pre-clinical studies, KLS-13019's advanced formulation is designed to improve on some of the limitations associated with CBD, including but not limited to CBD's low bioavailability and limited drug like properties.

These pre-clinical studies suggest increased bioavailability, consistent plasma levels and the avoidance of first-pass liver metabolism. In addition, an *in vitro* study performed by us demonstrated that CBD is degraded to THC in an acidic environment such as the stomach.

The Company has filed for orphan designation with the U.S. Food and Drug Administration ("FDA") for the use of CBD in the treatment overt hepatic encephalopathy ("OHE"). The Company has received notice from the FDA that its current application qualifies for a patient population of less than 200,000, but is currently in abeyance to resolve clinical use of CBD in this sub-set of hepatic encephalopathy. The Company has retained Coté Orphan to continue the process of responding to the FDA's abeyance letter. On November 5, 2018, the FDA has granted the Company a one year extension to respond to the abeyance letter until November 30, 2019.

KLS-13023 is a proprietary formulation containing CBD that intends to enable more effective delivery of CBD via a gel capsule. The use of CBD in this form remains patent-protected via the '507 Patent through 2019. In addition, we expect that KLS-13023 will be classified by the FDA as a new chemical entity, or NCE. In our preclinical animal studies, KLS-13023 demonstrated effective intervention of neurodegeneration in the OHE disease state. Our key development programs and expected timelines for the development of KLS-13019 and KLS-13023 are shown in the table below:

Clinical Timelines

Product Candidate	Target Indication	Delivery Method	Current Development Status	Expected Next Steps
KLS-13019	Chemotherapy Induced Peripheral Neuropathy	Oral Gel Capsule	Preclinical	2Q20: Initiate Phase 1
	Mild Traumatic Brain Injury	Oral Gel Capsule	Preclinical	2Q21: Initiate Phase 1
KLS-13023	Overt Hepatic Encephalopathy	Oral Gel Capsule	Preclinical	4Q20: Initiate Phase 1
	Mild Traumatic Brain Injury	Oral Gel Capsule	Preclinical	2Q21: Initiate Phase 1

With respect to certain other proprietary compounds underlying Pat. 9,611,213, the Company plans on pursuing topical solutions as potential relief creams and/or ointments for neuropathic pain, anti-inflammation, anti-pruritic and skin ulcers. The Company is considering commercialization routes that include, but are not limited to, filing and FDA Monograph and/or pursing a path to the marketplace through INCI certification and registration with the PCPC. In preclinical testing, certain molecules under Pat. 9,611,213 were screened for neuroprotection and may have the potential mechanism of action for reducing inflammation and neuropathic pain. These molecules indicate that they are more soluble than cannabidiol, also deemed a neuroprotectant with potential anti-inflammatory properties. A molecule that is potentially more water soluble than cannabidiol in this regard may be good candidate(s) for use in topical applications.

The Company believes it has the sufficient capital to proceed forth with a Phase 1 human safety trial for the treatment of Chemotherapy Induced Peripheral Neuropathy. All preclinical work in this indication, including animal toxicity studies, are expected to be completed before the end of the third quarter 2019. The Company plans on entering into clinical trials sometime in the first quarter 2020. Additionally, the Company believes it has the sufficient capital to proceed forth with a Phase 1 human safety trial for the treatment of Overt Hepatic Encephalopathy. All preclinical work in this indication, including animal toxicity studies, are expected to be completed before the end of the fourth quarter 2019.

The Company intends on seeking additional capital to proceed forth with its business plan regarding additional drug pipeline opportunities.

Through the year end 2017 we have not been profitable and have incurred net losses from operations since inception. Our net loss was $1,643,255 for the year ended December 31, 2017. Our loss from operations was $1,061,808 for the year ended December 31, 2018. Our net income, due to a gain in investment, was $931,059 for the year ended December 31, 2018. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability.

Financial Operations Overview

The following discussion sets forth certain components of our statements of operations as well as factors that impact those items.

Revenues

Our revenues consist of state and federal research grants and fees received from research services for third-party product development. These revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable and collectability is reasonably assured.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in development and preclinical studies relating to our product candidates, including:

expenses associated with preclinical development;
personnel-related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation;
payments to third-party contract research organizations, or CROs, contractor laboratories and independent contractors; and
depreciation, maintenance and other facility-related expenses.

We expense all research and development costs as incurred. Preclinical development expenses for our product candidates are a significant component of our current research and development expenses. Product candidates in later stage clinical development generally have higher research and development expenses than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We track and record information regarding external research and development expenses for each grant, study or trial that we conduct. From time to time, we intend to use third-party CROs, and have used contractor laboratories and independent contractors in preclinical studies. We recognize the expenses associated with third parties performing these services for us in our preclinical studies based on the percentage of each study completed at the end of each reporting period.

We incurred research and development expenses of $224,933 and $4,000 for the years ended December 31, 2018 and 2017, respectively.

We expect that our research and development expenses in 2019 and for the next several years will be higher than in 2018 as a result of the work needed for our expected initiation of our Phase 1 clinical trials of KLS-13019 in the second half of 2019 and KLS-13023 by early 2020. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of our preclinical development and clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

the number of sites included in the clinical trials;
the length of time required to enroll suitable patients;
the size of patient populations participating in the clinical trials;
the duration of patient follow-ups;
the development stage of the product candidates; and
the efficacy and safety profile of the product candidates.

Due to the early stages of our research and development, we are unable to determine the duration or completion costs of our development of KLS-13019 and KLS-13023. As a result of the difficulties of forecasting research and development costs of KLS-13019 and KLS-13023 as well as the other uncertainties discussed above, we are unable to determine when and to what extent we will generate revenues from the commercialization and sale of an approved product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal and human resource functions. Our general and administrative expenses also include facility and related costs not included in research and development expenses, professional fees for legal services, including patent-related expenses, consulting, tax and accounting services, insurance and general corporate expenses. We expect that our general and administrative expenses will increase with the continued development and potential commercialization of our product candidates.

We expect that our general and administrative expenses in 2019 and for the next several years will be higher than in 2018 as we increase our headcount. We also anticipate increased expenses relating to our operations as a public company, including increased costs for the hiring of additional personnel, and for payment to outside consultants, including lawyers and accountants, to comply with additional regulations, corporate governance, internal control and similar requirements applicable to public companies, as well as increased costs for insurance.

Interest Income (Expense), net

Interest expense consists of interest expense on our notes payable that are current and that of certain notes that were converted into common stock in 2018. Interest income consists primarily of interest earned on our money market bank account.

Income Taxes

As of December 31, 2018, we had $862,000 of federal operating loss carryforwards. These operating loss carryforwards will begin to expire in 2031. The Tax Reform Act of 1986, or the Act, provides for limitation on the use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit our ability to utilize these carryforwards. We may have experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, we may not be able to take full advantage of these carryforwards for federal income tax purposes.

The closing of the share exchange transaction, together with private placements and other transactions that have occurred since our inception, may trigger, or may have already triggered, an "ownership change" pursuant to Section 382 of the Internal Revenue Code of 1986. If an ownership change is triggered, it will limit our ability to use some of our net operating loss carryforwards. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could result in increased future tax liability to us.

Critical Accounting Policies and Use of Estimates

We have based our management's discussion and analysis of financial condition and results of operations on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to preclinical development expenses and stock-based compensation. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully discussed in note 2 to our audited consolidated financial statements appearing at the end of this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements.

Research and Development Expenses

We rely on third parties to conduct our preclinical studies and to provide services, including data management, statistical analysis and electronic compilation. Once our clinical trials begin, at the end of each reporting period, we will compare the payments made to each service provider to the estimated progress towards completion of the related project. Factors that we will consider in preparing these estimates include the number of patients enrolled in studies, milestones achieved and other criteria related to the efforts of our vendors. These estimates will be subject to change as additional information becomes available. Depending on the timing of payments to vendors and estimated services provided, we will record net prepaid or accrued expenses related to these costs.

Fair Value of Common Stock and Stock-Based Compensation

We account for grants of stock options and restricted stock to employees based on their grant date fair value and recognize compensation expense over the vesting periods. We estimate the fair value of stock options as of the date of grant using the Black-Scholes option pricing model, and we estimate the fair value of restricted stock based on the fair value of the underlying common stock as determined by our board of directors or the value of the services provided, whichever is more readily determinable. We account for stock options and restricted stock awards to non-employees using the fair value approach. Stock options and restricted stock awards to non-employees are subject to periodic revaluation over their vesting terms.

In the absence of a public trading market for our common stock, on each grant date, we develop an estimate of the fair value of our common stock for the option and restricted stock grants based in part on input from an independent third-party valuation firm. We determined the fair value of our common stock using methodologies, approaches and assumptions consistent with the AICPA Practice Guide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. In addition, our board of directors considered various objective and subjective factors, along with input from management and an independent third-party valuation firm, to estimate the fair value of our common stock, including external market conditions affecting the pharmaceutical industry, trends within the pharmaceutical industry, the prices at which we sold shares of our different series of preferred stock, the superior rights and preferences of each series of preferred stock relative to our common stock at the time of each grant, our results of operations and financial position, the status of our research and development efforts and progress of our preclinical programs, our stage of development and business strategy, the lack of an active public market for our common and our preferred stock, and the likelihood of achieving a liquidity event.

Common stock, restricted stock and stock options issued during and subsequent to the year ended December 31, 2018

In connection with and subsequent to our recapitalization in 2018, we issued 17,628,870 shares of common stock to certain management in exchange for all unpaid salary accruals, to certain debt holders, certain investors and third-party service providers for services rendered. In addition, our board of directors approved grants of restricted stock and stock options that were issued in 2016 and 2017.

In conducting a negotiated transaction in December 2017 for a share exchange between the Company and management of TYG Solutions (the “KLSI TYG Share Exchange”) and new third party investors to the KLSI TYG Share Exchange, we agreed to an enterprise value of approximately $45 million.

We then allocated the aggregate equity value between the common stock and the preferred stock using a Black-Scholes call option pricing method. Under this method, we estimated the fair value of our common stock as the net value of a series of call options, representing the present value of the expected future returns to the common stockholders. We considered the rights of the common stockholders to be equivalent to a call option on our future value in excess of the aggregate liquidation preferences payable on preferred stock, with adjustments to account for the rights retained by the preferred stockholders related to any value in excess of the applicable liquidation preferences. Using this method, we valued the common stock by estimating the value of a share of common stock in each of these call option rights.

We then reduced the value of the common stock using this approach by applying a lack of control discount and an illiquidity discount to account for the heightened level of risk associated with our shares compared to that of comparable, publicly traded companies.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

Revenues

Revenues for the year ended December 31, 2018, was $173,889 compared to $-0- the year ended December 31, 2017. Revenues in 2018 were entirely related to work performed in connection with grants received.

Research and Development Expenses

Research and development expenses increased by $220,933, or 5,523%, to $224,933 for the year ended December 31, 2018 from $4,000 for the year ended December 31, 2017. The increase was primarily the result of increased consulting and compensation expense related to increased product development activities.

General and Administrative Expenses

General and administrative expenses decreased by $179,598 or -15% to $1,010,764 for the year ended December 31, 2018 from $1,190,362 for the year ended December 31, 2017. This decrease was largely the result of a decrease of personnel cost due to our executive officers ceasing to take salaries for the first seven months of 2018.

Other Income (Expense)

Other income (expense), net was $2,804,851 and $(98,893) for the years ended December 31, 2018 and 2017, respectively.

Liquidity and Capital Resources

Since our inception in 2010, we have devoted most of our cash resources to research and development and general and administrative activities. We have financed our operations primarily with the proceeds from the sale of preferred stock and convertible promissory notes, state and federal grants and research services. To date, we have not generated any revenues from the sale of products, and we do not anticipate generating any revenues from the sales of products for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2018, our principal sources of liquidity were our cash and cash equivalents, which totaled $307,131. Our working capital was $2,456,560 as of December 31, 2018.

Equity Financings

For the years ended December 31, 2018 and 2017, we received net proceeds of $352,000 and $387,500, respectively, from the sale of convertible notes and promissory notes. Immediately prior to the Share Exchange, the Company received proceeds of $150,000 for the sale of 75 shares of Series A preferred stock and 75 shares of Series B preferred stock. Additionally, the Company received $203,000 for the sale of 2,030,000 shares of common stock.

Debt

We had the following schedule of debt for the years ended December 31, 2018 and 2017:

	Years ended December 31,	
	2018	**2017**
Outstanding Debt Obligations:		
Loan payable	$ 620,000	$ -
Loan payable – related party	41,995	367,500
Convertible notes payable	500,000	185,000
Convertible notes payable - related party	-	288,981
Total All Debt Obligations	$ 1,161,995	$ 841,481

In January 2018, prior to the Share Exchange, all Convertible Junior Debenture holders and all Senior Convertible Debenture holders accepted the Company's offer to exchange their debt instruments, including accrued interest thereunder for restricted common stock. The holders of the Convertible Junior Debentures, related parties, accepted a total of 973,946 shares of restricted common stock (on a post-Share Exchange basis) of the Company in exchange for the repayment of a total of $356,176 in debt, inclusive of accrued interest of $67,195. In addition to the conversion of the Convertible Junior Debentures, the holders of the Senior Convertible Debentures accepted a total of 563,063 shares of restricted common stock of the Company (on a post-Share Exchange basis) in exchange for the repayment of a total of $236,104 in debt, inclusive of accrued interest of $51,104.

In January 2018, prior to the Share Exchange, we converted outstanding accrued executive management salaries totaling $2,812,810, which had accrued from September 2014 through December 2017, in exchange for a total of 5,505,200 shares of restricted common stock of the Company (on a post-Share Exchange basis).

Future Capital Requirements

Prior to the Share Exchange, the Company issued a convertible note to an investor, face value $500,000, in exchange for $500,000 in cash. The note is unsecured, bears interest at the rate of 3% per annum and matures on February 16, 2030. The note is convertible into common stock of the Company at $0.10 per share at any time at the option of the holder, subject to a 4.9% blocking provision which prohibits the holder from converting into common stock of the Company if such conversion results in the holder owning greater than 4.9% of the outstanding common stock of the Company after giving effect to the conversion.

We expect that our existing cash and cash equivalents and securities held for sale on the Company's consolidated balance sheet will be sufficient to fund our operations and capital requirements through December 2019. We believe that these available funds will be sufficient to commence a Phase 1 clinical trials for KLS-13019 for patients with chemotherapy induced peripheral neuropathy. We anticipate, based on current estimates, that costs associated Phase 1 clinical trials for KLS-13019 will be approximately $2.75 million.

Our investment in Medical Marijuana, Inc. ("MJNA") represents a sizable portion of the total assets of the Company. On June 1, 2018, the Company received 41,583,333 shares of Medical Marijuana, Inc. ("MJNA") common stock pursuant to a settlement agreement. In 2014, the Company entered into a revenue sharing agreement with Kannaway LLC, whereas, among the considerations and obligations the parties agreed to a share exchange, whereby the Company issued 6,408,980 shares of its common stock in exchange of 4.99% ownership of Kannaway.

A significant shareholder of the Company owned the remaining ownership of Kannaway LLC. Subsequently, Kannaway was sold, by its parent company, to MJNA for 833,333,333 shares of MJNA common stock. The settlement agreement called for the release of all obligations in exchange for the issuance of 41,583,333 shares of common stock in MJNA to the Company. For the year ended December 31, 2018, the Company recorded a realized gain of $3,901,974 upon the settlement and receipt of these shares and an unrealized loss of $873,693 related to the investment in MJNA. The gain was netted against the Company's cost basis investment in Kannaway LLC.

The Company's shares in MJNA are eligible for re-sale under Rule 144 of the Securities Act and the Company intends to liquidate its holdings in MJNA in its discretion to help fund its operations. There are no contractual, affiliate or other restrictions on the Company's ability to re-sell its shares in MJNA. In the event that we are unable to sell our shares in MNA, management believes that it can locate additional sources of capital to facilitate and carry out its business plan and the Company's ability to conduct its business operations and clinical trials is not dependent on our ability to sell the Company's shares in MJNA.

Management of the Company believes that it will need to seek additional sources of capital to facilitate and carry out its business plan of proceeding forth with commencing a Phase 2 clinical trial for KLS-13019 for patients with chemotherapy induced peripheral neuropathy; commencing a Phase 1 clinical trial for KLS-13019 for patients suffering from the effects of mild traumatic brain injury; and commencing a Phase 1 clinical trial for KLS-13023 for patients suffering with overt hepatic encephalopathy. The cost of commencing and conducting these trials will likely be in the tens of millions of dollars.

Furthermore, it is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

Our expectations regarding future cash requirements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we make in the future. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies. We may need to raise substantial additional capital in order to engage in any of these types of transactions.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, subject to obtaining such approval, the eventual commercialization of our product candidates. If we obtain marketing approval for either of our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the DEA, the FDA, the EMA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- costs and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds. Additional equity or debt financing or collaboration and licensing arrangements may not be available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Cash Flows

Years ended December 31, 2018 and 2017 — The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2018 and 2017:

	Years ended December 31,	
	2018	**2017**
Consolidated Statement of Cash Flows Data:		
Total net cash provided by (used in):		
Operating activities	$ (1,210,907)	$ (392,360)
Investing activities	824,546	-
Financing activities	689,166	363,672
Increase (Decrease) in cash and cash equivalents	$ 302,805	$ (28,688)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 was $1,210,907, including net income of $931,059, partly offset by $2,017,355 of net non-cash expenses and a $124,611 net change in operating assets and liabilities. The net noncash expenses were predominantly related to the gain on settlement of $3,901,974. The change in operating assets and liabilities was primarily due to a $99,291 increase in other receivables.

Net cash used in operating activities was $392,360 for the year ended December 31, 2017 including a net loss of $1,643,255, partly offset by deferred tax asset of $350,000 and changes in operating assets and liabilities of $882,387 primarily related to payroll expense.

We expect cash used in operating activities to continue to increase in 2019 as compared to 2018 due to an expected increase in our operating losses associated with ongoing development of our product candidates.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2018 was $824,546. Cash provided by investing activities from the cash received from the reverse acquisition and the sale of marketable securities was $289,654 and $537,966, respectively, for the year ended December 31, 2018. Cash used for purchase of equipment was $3,074 for the year ended December 31, 2018.

There was no cashed used in investing activities for the year ended December 31, 2017.

Financing Activities

Cash provided by financing activities of $689,166 for the year ended December 31, 2018 was primarily due to $352,500 in net proceeds received on the issuance of certain debt instruments and $353,000 of proceeds for issuance of preferred and common stock.

Cash provided by financing activities for the year ended December 31, 2017 was $363,672, reflecting $387,500 of proceeds on the issuance of certain debt instruments and offset by payments to certain debt instruments.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, except for operating leases, or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (“Topic 606”), which is a new comprehensive revenue recognition model that will supersede all existing revenue recognition guidance under U.S. GAAP. The standard requires a company to recognize revenue when it transfers goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This standard is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted for interim and annual periods beginning after December 15, 2016. Entities will have the option of using either a full retrospective approach or a modified approach to adopt the guidance in the ASU. The Company is currently evaluating the impact of adopting this guidance, but expects the adoption will not have a material impact on the consolidated financial statements.

In November 2015, the FASB issued Accounting Standards Update (ASU) 2015-17, Balance Sheet Classification of Deferred Taxes, intended to improve how deferred taxes are classified on organizations' balance sheets. The ASU eliminates the current requirement for organizations to present deferred tax liabilities and assets as current and noncurrent in a classified balance sheet. Instead, organizations will now be required to classify all deferred tax assets and liabilities as noncurrent. The pronouncement is effective for reporting periods beginning after December 15, 2016. Early adoption is permitted as of the beginning of an interim or annual period. The adoption of ASU 2015-17 did not have any material impact on the Company's consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). Under ASU 2016-09, the tax effects of stock compensation will be recognized as income tax expense or benefit to the Company’s income statement and the tax effects of exercised or vested awards will be treated as discrete items in the reporting period in which they occur. Along with other income tax cash flows, excess tax benefits will be classified as operating activities, and cash paid by the Company when directly withholding shares for tax withholding purposes will be classified as financing activities. The Company has elected to continue to account for forfeitures when they occur. The adoption of ASU 2016-09 on January 1, 2017, did not have a material impact to the Company’s consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), requiring lessees to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis, and (2) a right-of-use (“ROU”) asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. The update is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The Company currently anticipates that upon adoption of the new standard, ROU assets and lease liabilities will be recognized in amounts that will be immaterial to the consolidated balance sheets.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40), which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern for each annual and interim reporting period. If substantial doubt exists, additional disclosure is required. This new standard was effective for the Company for annual and interim periods beginning after December 15, 2016. The Company has elected early adoption effective January 1, 2017, and continues to assess the impact of the adoption on its consolidated financial statements.

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

Not applicable to a "smaller reporting company" as defined in Item 10(f)(1) of SEC Regulation S-K.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The full text of the Company's audited consolidated financial statements for the fiscal years ended December 31, 2018 and 2017, begins on page F-1 of this Annual Report on Form 10-K.

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

We have had no disagreements with our independent auditors on accounting or financial disclosures.

On March 5, 2018, the Company received notification from the Securities and Exchange Commission (the "Commission") that its independent registered public accounting firm, Weinberg & Baer, LLC ("Weinberg"), had been suspended from appearing or practicing before the Commission. Weinberg audited the Company's financial statements for the years ended December 31, 2015 and December 31, 2016.

Thereafter, the Company engaged PLS CPA, A Professional Corp. ("PLS CPA") as its independent registered public accounting firm for the Company's fiscal years ended December 31, 2016 and December 31, 2017. The decision to engage PLS CPA as the Company's independent registered public accounting firm was approved by the Company's Board of Directors. On April 12, 2018, the Company received a letter from PLS CPA stating that PLS CPA had resigned as the Company's independent registered public accounting firm. PLS CPA did not perform any audits of the Company's Financial Statements and did not prepare any reports with any going concern language.

On April 23, 2018, the Board of Directors of the Company approved the engagement of Accell Audit and Compliance, P.A., 4806 West Gandy Boulevard, Tampa, FL 33611, Phone: (813) 440-6380 ("Accell") as its independent registered public accounting firm for the fiscal years ended December 31, 2017 and December 31, 2016. During the fiscal years ended December 31, 2017 and December 31, 2016, and the subsequent interim period through April 23, 2018, the date of engagement of Accell, the Company did not consult with Accell regarding either (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, or (ii) any matter that was either the subject of a disagreement (as defined in paragraph (a)(1)(iv) of Item 304 of Regulation S-K and the related instructions thereto) or a reportable event (as described in paragraph (a)(1)(v) of Item 304 of Regulation S-K).

On October 4, 2018, the Company's Board of Directors approved the engagement of dbb *mckennon*, 16959 Bernardo Center Drive, San Diego, CA 92128, Phone: (858) 217-4035 ("dbbmckennon") as its independent registered public accounting firm for the fiscal year ended December 31, 2018. During the fiscal years ended December 31, 2017 and December 31, 2016, and the subsequent interim period through October 4, 2018, the date of engagement of dbb*mckennon*, the Company did not consult with dbb *mckennon* regarding either (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements, or (ii) any matter that was either the subject of a disagreement (as defined in paragraph (a)(1)(iv) of Item 304 of Regulation S-K and the related instructions thereto) or a reportable event (as described in paragraph (a)(1)(v) of Item 304 of Regulation S-K).

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), the Company carried out an evaluation, with the participation of the Company's management, including the Company's Chief Executive Officer ("CEO") (the Company's principal executive officer) and Chief Financial Officer ("CFO") (the Company's principal financial and accounting officer), of the effectiveness of the Company's disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, the Company's CEO and CFO concluded that the Company's disclosure controls and procedures are not effective to ensure that information required to be disclosed by the Company in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Company's CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting.

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Our internal control system was designed to, in general, provide reasonable assurance to the Company's management and board regarding the preparation and fair presentation of published consolidated financial statements, but because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. The framework used by management in making that assessment was the criteria set forth in the document entitled "Internal Control – Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that assessment, our management has determined that as of December 31, 2018, the Company's internal control over financial reporting was ineffective for the purposes for which it is intended.

A material weakness is 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 the Company's annual or interim consolidated financial statements will not be prevented or detected on a timely basis. In its assessment of the effectiveness of internal control over our financial reporting as of December 31, 2018 the Company determined that the following items constituted a material weakness:

The Company does not have an independent audit committee that can review and approve significant transactions and the reporting process and provide independent oversight of the Company.

The Company is dependent on related parties for funding and decision making, which is provided on a very limited basis, therefore accurate accounting, record retention and financial disclosures are not performed in a timely and efficient manner.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm as we are a smaller reporting company and not required to provide the report.

Changes in Internal Controls over Financial Reporting

No change in our system of internal control over financial reporting occurred during the period covered by this report, 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

The following table sets forth the names, ages, and positions of our executive officers and directors:

Name	Age	Position
Dean Petkanas	55	Chief Executive Officer and Chairman of the Board
Mark Corrao	61	Chief Financial Officer
Thomas Kikis	41	Chief Communications Officer and Director
Dr. William Kinney	61	Chief Scientific Officer
Robert Malasek	51	Director
Blake Schroeder	40	Director
Dr. Timothy R. Scott	66	Director

Executive Officers

Dean Petkanas was appointed as our Chief Executive Officer and Chairman of the Board of Directors on July 25, 2018. Mr. Petkanas is a corporate finance and executive management professional with over 25 years of investment banking and capital markets experience. In 2010 Mr. Petkanas co-founded Kannalife Sciences, Inc. and for the past 8 years was principally responsible for the creation and execution of the Company's business model, including the licensing of US Patent #6630507 from the National Institutes of Health for disease indications Hepatic Encephalopathy (HE) and Chronic Traumatic Encephalopathy (CTE). Mr. Petkanas is a co-inventor of US Patent #9611213 "Novel Functionalized 1,3 Benzene Diols and Their Method of Use for the Treatment of Hepatic Encephalopathy." Mr. Petkanas' background in pharmaceutical extends to his work as investment banker and subsequently V.P. of Business Development for Xechem International, Inc. where he was principally responsible for Xechem's IPO and EXIM Bank rounds of financing. Mr. Petkanas was involved with Xechem from 1992 to 2007. While at Xechem, he was involved in the financing of Xechem's lead target drug candidate (generic paclitaxel) and later on from 2003 to 2007, was the lead petitioner for Xechem International in steering their federal anti-trust lawsuit against Bristol-Myers-Squibb for their illegal monopoly of the drug market for the anti-cancer drug, Taxol®. Mr. Petkanas also was an integral part of the development team that named, trademarked and commercialized Hemoxin (Nicosan), a phyto-pharmaceutical compound for the treatment of Sickle Cell disease. Mr. Petkanas brings his extensive business and industry experience to the board of directors as its chairman.

Mark Corrao was appointed as our Chief Financial Officer on July 25, 2018. Prior to joining the Company, Mr. Corrao served as the CFO of Kannalife Sciences, Inc. beginning in January 2012. Mr. Corrao currently serves as the Managing Director of The CFO Squad LLC, a CFO and accounting consulting business, and as CFO of Generex Biotechnologies, Inc. beginning in January 2017. Mr. Corrao was formerly a founder and CFO of Strikeforce Technologies, Inc., a publicly traded software development and services company specializing in the development of a suite of integrated computer network security products. In addition to the ten years of his service at Strikeforce, Mr. Corrao has spent numerous years in the public accounting arena specializing in certified auditing, SEC accounting, corporate taxation and financial planning. Mr. Corrao's background also includes numerous years on Wall Street with Merrill Lynch, Spear Leeds & Kellogg and Greenfield Arbitrage Partners. While on Wall Street, Mr. Corrao was involved in several initial public offerings and has been a guiding influence in several startup companies. Prior to joining StrikeForce, he was the Director of Sales at Applied Digital Solutions from December 2000 through December 2001. Mr. Corrao was the Vice President of Sales at Advanced Communications Sciences from March 1997 through December 2000. Mr. Corrao has a B.S. in Accounting from The City University of New York. Mr. Corrao's business and public company financial reporting experience is invaluable to the board of directors

Thomas Kikis was appointed as our Chief Communications Officer and a director on July 25, 2018. Prior to his appointment, Mr. Kikis co-founded Kannalife Sciences, Inc. in August 2010. Since co-founding Kannalife Sciences, Mr. Kikis handled all communications and marketing efforts of Kannalife Sciences serving in various executive roles and as a member of its board of directors. Mr. Kikis also designed and helped formulate Kannactiv – a skincare product line designed by Kannalife Sciences, Inc. on behalf of Kannaway LLC. Mr. Kikis is an entrepreneur who has a passion for great stories, new ideas, groundbreaking technologies, popular culture and their collective point of impact. Most recently, Mr. Kikis has designed dozens of commercial typographical software distributed for web, print and mobile applications and has produced several films and documentaries available on movie streaming platforms. Mr. Kikis holds a Bachelor of Science in Communications Management from New York University. Mr. Kikis' broad industry knowledge and strategic communication experience make him an asset to the board of directors.

Dr. William Kinney was appointed as our Chief Scientific Officer on July 25, 2018. Mr. Kinney is a medicinal chemist and entrepreneur with more than 25 years of experience in large pharmaceutical (Wyeth, Johnson & Johnson), biotechnology (Magainin), and non-profit (Blumberg Institute) research and development. He has demonstrated expertise in drug design; synthesis; lead optimization and development of peptides, small molecules, and natural products; and is inventor of three molecules that advanced to human clinical trials – Perzinfotel (CNS disorders and pain), Squalamine (oncology, AMD, Parkinson's Disease), and Trodusquemine (obesity). Currently, Dr. Kinney is Senior VP at Enterin, Inc. (July 2016) and Chief Scientific Officer at KannaLife Sciences. His scientific contributions include more than 70 publications and presentations; and inventorship on 38 issued U.S. patents. Dr. Kinney is a co-inventor of Kannalife's recent US Patent #9611213 "Novel Functionalized 1,3 Benzene Diols and Their Method of Use for the Treatment of Hepatic Encephalopathy." Dr. Kinney obtained his B.S. (1979) and Ph.D. (1984) degrees from the Ohio State University. Dr. Kinney's breadth of scientific research and development work and industry knowledge are a great benefit to the board of directors.

Non-Employee Directors

Robert Malasek has served as a director of the Company since June 20, 2017 and previously served as its Chief Executive Officer and Chief Financial Officer from June 20, 2017 to July 25, 2018. Mr. Malasek's experience includes serving as the Assistant Controller for Starwood Hotel & Resorts Worldwide, Inc. and as Chief Financial Officer for NatureWell, Inc. From 2011 to 2015, Mr. Malasek served as the Chief Financial Officer, Secretary, Treasurer and a Director of Liberty Coal Energy Corp. Since 2015, Mr. Malasek has served as the Chief Financial Officer of Cannalink, Inc. and currently serves as the Chief Financial Officer of AXIM Biotechnologies, Inc. (OTC:AXIM). Mr. Malasek received his Bachelor of Science in Accountancy from San Diego State University. Mr. Malasek's public company governance and management experience make him a great fit to the board of directors.

Blake Schroeder was appointed as a director on July 25, 2018. Mr. Schroeder's career began as a litigator at a commercial litigation firm in Salt Lake City, UT. Beginning in 2008, Schroeder became involved in the sale and marketing of natural products, and opening international marketplaces to those products. From 2008 to 2015 Mr. Schroeder served in various capacities at MonaVie LLC developing international business plans and growing international businesses. From August 2014 to February 2016, Mr. Schroeder served as the chief operating officer of Forevergreen International, where he was responsible for global operation and sales of the multinational organization, including oversight of a global supply chain. From 2016 to the present, Mr. Schroeder serves as the chief executive officer of Kannaway, LLC, a wholly-owned subsidiary of Medical Marijuana, Inc. Mr. Schroeder is the COO for Medical Marijuana, Inc. and has served on the board of directors of Medical Marijuana, Inc. from March 2016 to the present. Mr. Schroeder holds a B.S. in Finance from Utah State University and a J.D. from Syracuse University's College of Law. Mr. Schroeder's blend of industry, legal and business knowledge give him and the board of directors a unique viewpoint that is invaluable to the board of directors.

Dr. Timothy R. Scott was appointed as a director on July 25, 2018. Mr. Scott brings years of enterprise board-level management expertise having served on the board of directors of NatureWell Inc. from 2001-2008. Prior to 2001, Mr. Scott served on the board of directors of ICH Corporation, which owned 265 restaurants with approximately $265M in revenues and 7,800 employees. Dr. Scott currently serves on the board of directors of Medical Marijuana, Inc. (OTC:MJNA) and Axim Biotechnologies, Inc. (OTC:AXIM). Dr. Scott received his Ph.D. in theology from Christian University. Dr. Scott holds decades of experience at senior management and board levels in public and private companies which is a great benefit to the company and its board of directors.

Scientific Advisory Board

Douglas Brenneman, Ph.D – Chief Biologist and Distinguished Senior Scientist – Scientific Advisory Board

Dr. Brenneman has over 30 years of research experience as a Section Chief within the intramural program at NICHD and as a Senior Research Fellow at Johnson & Johnson. He has more than 170 scientific publications and 15 patents focused on both evaluating neurotoxic and neuroprotective substances with various Central Nervous System preparations. At Johnson & Johnson, he was a team leader of the drug discovery group that advanced three compounds through discovery and preclinical testing. Two of these compounds are currently in clinical trials. As a result of his NIH work, a neuroprotective peptide (davunetide) that he co-discovered is currently in phase III clinical trials. Dr. Brenneman has demonstrated scientific experience to drive an innovative program of drug discovery focused on diseases of the central nervous system. Dr. Brenneman is the founder and Chief Scientific Officer of Advanced Neural Dynamics which is located at the Pennsylvania Biotechnology Center in Doylestown, PA.

Ryan B. Turner, MD – Scientific Advisory Board

Dr. Ryan Turner is a board certified dermatologist practicing general dermatology and has advanced training in Mohs Micrographic Surgery, laser surgery, and light therapies. His clinical interests include skin cancer surgery and cosmetic treatments that enhance and rejuvenate aging skin. He has extensive training in FRAXEL® laser treatments which reduce photodamage, wrinkles, and stimulate new collagen growth. His research interests vary from the treatment and management of skin cancers to the successful placement of injectable dermal fillers. He graduated summa cum laude and valedictorian of the University of Maryland Baltimore County. He received his Doctor of Medicine from Harvard Medical School and was honored with the Henry Asbury Christian Award for his research accomplishments. He completed his internship in medicine and his dermatology residency at the Harvard affiliated Brigham and Women's Hospital and the Massachusetts General Hospital, respectively. He has also completed an ACGME accredited fellowship in Procedural Dermatology at the Mt. Sinai Medical Center in NY.

Gerasimos Petratos, MD – Scientific Advisory Board

Dr. Gerasimos Petratos currently serves as a teacher in Northwestern's Masters in Medical Informatics Program and works as Global Head of Healthcare Data Strategy & Analytics at the Roche Group. His pharmaceutical career includes experience in the Development & Medical Affairs Divisions, specifically working for the past seven years on the development and commercialization of molecules in oncology, transplant, multiple sclerosis and rheumatoid arthritis. Prior to pharmaceuticals he conducted clinical research at Intermountain Healthcare and the University of Utah Health Sciences Center as part of a National Institutes of Health Fellowship with the National Library of Medicine in Biomedical Informatics. The research was centered on applied advanced methods of clinical information management to improve patient safety and measure outcomes related to adverse drug event detection capabilities for CNS (Multiple Sclerosis and Alzheimer's), Oncology, Pain Management, and Antibiotic drugs. Dr. Petratos obtained his bachelor's degree in Biology from Cornell University. He received his Doctor of Medicine degree from Howard University in Washington, D.C., and obtained a Master's in Health Service Administration and Medical Informatics from the University of Utah.

Ziva Cooper, PhD – Scientific Advisory Board

Dr. Cooper is currently an Assistant Professor of Clinical Neurobiology in the Department of Psychiatry at the College of Physicians and Surgeons of Columbia University. She completed her PhD in 2007 in Biopsychology from the University of Michigan where she investigated the behavioral and physiological effects of abused substances using animal models of addiction. Her current work focuses on investigating the direct physiological and behavioral effects of cannabinoids (i.e., chemical constituents of Cannabis and structurally similar synthetic compounds) as they pertain to their potential therapeutic effects and abuse liability. Dr. Cooper has published 30 scientific publications and three book chapters on the neurobiology of substance abuse, has received Early Career Investigator awards from prestigious professional societies including the American College of Neuropsychopharmacology and the College on Problems of Drug Dependence, and has been invited to speak at several national and international scientific meetings.

Michael Zelenetz, MD – Scientific Advisory Board

Dr. Michael Zelenetz specializes in the field of gastroenterology and liver diseases. He graduated and obtained his Medical Doctorate from St. George's University School of Medicine. His internship and residency in internal medicine were completed at SUNY Downstate Medical Center in Brooklyn, New York, where he also completed a subspecialty fellowship in gastroenterology and hepatology. His current practice involves performing colonoscopy and endoscopy examinations along with the treatment of diseases such as reflux, functional gastrointestinal disorders (IBS, functional dyspepsia, etc.), ulcerative colitis, Crohn's Disease and chronic liver diseases, including Hepatitis B and C, among many other conditions. Dr. Zelenetz is double board certified in internal medicine and gastroenterology. Dr. Zelenetz has authored several publications in American Journal of Gastroenterology. He has a strong clinical interest in colorectal cancer screening, inflammatory bowel diseases and Hepatitis C.

Director Independence

Dr. Timothy R. Scott and Blake Schroeder are independent as that term is defined under Nasdaq Rules.

Committees and Terms

The Board of Directors has not established any committees. Our Board of Directors as a whole acts as our audit committee, compensation committee, and nominating committee.

Code of Ethics

We have not adopted a written code of ethics.

Family Relationships

There are no family relationships between any director or executive officer.

Involvement in Certain Legal Proceedings

During the past ten years, none of our directors and executive officers has been involved in any of the events described in Item 401(f) of Regulation S-K.

Corporate Governance Matters

We have not adopted any material changes to the procedures by which security holders may recommend nominees to our Board of Directors.

Compliance with Section 16(A) of the Exchange Act.

Section 16(a) of the Exchange Act requires the Company's officers and directors, and persons who beneficially own more than 10% of a registered class of the Company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission and are required to furnish copies to the Company. Based solely on our review of copies of such forms that we have received, or written representations from reporting persons, we believe that during the fiscal year ended December 31, 2018, all executive officers, directors and greater than 10% stockholders complied with all applicable filing requirements, other than (i) Form 3's that were filed late on August 7, 2018 by Mark Corrao, Dean Petkanas, and James Arabia/Cross & Co., and (ii) a Form 4 that was filed late on August 8, 2018 by Kettner Investments, LLC.

ITEM 11. EXECUTIVE COMPENSATION.

The following table sets forth, for the fiscal years ended December 31, 2018 and 2017, the dollar value of all cash and noncash compensation earned by any person that was our principal executive officer, or PEO, during the preceding fiscal year.

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 ($)	Totals ($)
Dean Petkanas,	2018	240,000	-	-	-	-	-	-	240,000
Chief Executive Officer and Chairman	2017	(1) 300,080	-	-	-	-	-	-	300,080
Thomas Kikis,	2018	150,000	-	-	-	-	-	-	150,000
Chief Communications Officer and Director	2017	(1) 218,808	-	-	-	-	-	-	218,808
Mark Corrao,	2018	60,000	-	-	-	-	-	-	60,000
Chief Financial Officer	2017	(1) 200,053	-	-	-	-	-	-	200,053
William Kinney,	2018	30,000	-	-	-	-	-	-	30,000
Chief Scientific Officer	2017	(1) 200,053	-	-	-	-	-	-	200,053

(1) These amounts represent salaries accrued in the respective years. In January 2018, the Company converted all outstanding accrued salaries into shares of common stock.

Option Grants Table

There were no individual grants of stock options to purchase our common stock made to the executive officers named in the Summary Compensation Table for the fiscal year ended December 31, 2018.

Aggregated Option Exercises and Fiscal Year-End Option Value Table

There were no stock options exercised during the fiscal year ended December 31, 2018, by the executive officers named in the Summary Compensation Table.

Long-Term Incentive Plan ("LTIP") Awards Table

There were no awards made to a named executive officer in the last completed fiscal year under any LTIP.

Compensation of Directors

Directors are permitted to receive fixed fees and other compensation for their services as directors. The Board of Directors has the authority to fix the compensation of directors. No amounts have been paid to, or accrued to, directors in such capacity.

Executive Employment Agreements

In connection with the Share Exchange with Kannalife Sciences, Inc. on July 25, 2018, the newly-appointed officers entered into executive employment agreements with the Company.

Dean Petkanas

Mr. Petkanas will receive an annual base salary of $240,000 and will be eligible to receive equity awards in the future, as determined by the Board. In addition, Mr. Petkanas will have severance benefits in the form of salary continuation and health benefits through the employment term remaining on the contract. The employment agreement has a two-year term, provided, however, after the end of one year, the agreement will automatically renew for successive one year terms.

Thomas Kikis

Mr. Kikis will receive an annual base salary of $150,000 and will be eligible to receive equity awards in the future, as determined by the Board. In addition, Mr. Kikis will have severance benefits in the form of salary continuation and health benefits through the employment term remaining on the contract. The employment agreement has a one-year term, provided, however, after the end of one year, the agreement will automatically renew for successive six month terms.

Mark Corrao

Mr. Corrao will receive an annual base salary of $60,000 (adjusted from his initial annual base salary of $150,000 as permitted in his agreement) and will be eligible to receive equity awards in the future, as determined by the Board. In addition, Mr. Corrao will have severance benefits in the form of salary continuation and health benefits through the employment term remaining on the contract. The employment agreement has a one-year term, provided, however, after the end of one year, the agreement will automatically renew for successive six month terms.

Dr. William Kinney

Dr. Kinney will receive an annual base salary of $30,000 (adjusted from his initial annual base salary of $150,000 as permitted in his agreement) and will be eligible to receive equity awards in the future, as determined by the Board. In addition, Dr. Kinney will have severance benefits in the form of salary continuation and health benefits through the employment term remaining on the contract. The employment agreement has a one-year term, provided, however, after the end of one year, the agreement will automatically renew for successive six month terms.

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

The following table sets forth certain information regarding the beneficial ownership of our outstanding Common Stock, as of April 1, 2019 by: (i) each of our directors, (ii) each of our named executive officers (as defined by Item 402(a)(3) of Regulation S-K promulgated under the Exchange Act), (iii) all of our directors and named executive officers as a group, and (iv) each person known to us to beneficially own more than 5% of our outstanding Common Stock.

Beneficial ownership has been determined in accordance with Rule 13d-3 under the Exchange Act. The percentages in the table have been calculated on the basis of treating as outstanding for a particular person, all shares of our common stock outstanding on that date and all shares of our common stock issuable to that holder in the event of exercise of outstanding options, warrants, rights or conversion privileges owned by that person at that date which are exercisable within sixty (60) days of that date. Except as otherwise indicated, the persons listed below have sole voting and investment power with respect to all shares of our Common Stock owned by them, except to the extent that power may be shared with a spouse. The Company does not know of any arrangements the operation of which may at a subsequent date result in a change of control of the Company.

	Common Stock		Series A Preferred Stock		Series B Preferred Stock		% of Total Voting Power
Name of Beneficial Owner (1)	**Shares**	**%**	**Shares**	**%**	**Shares**	**%**	
5% or Greater Stockholders							
Medical Marijuana, Inc. (2)	20,342,076	29.2					29.2
Kettner Investments, LLC (3)	6,817,067	9.8					9.7
Naturewell, Incorporated (8)	75,000	*	75	100.0			*
Directors and Executive Officers							
Dean Petkanas (4)	22,266,721	31.8			75	100.0	31.8
Thomas Kikis (5)	5,454,125	7.8					7.8
Mark Corrao (6)	1,546,875	2.2					2.2
William Kinney (7)	1,326,875	1.9					1.9
Timothy R. Scott	-	-					-
Robert Malasek	-	-					-
Blake Schroeder	-	-					-
All officers and directors as a group (7 persons) (9)	30,594,596	43.8					43.8

_____

* Less than 1%

(1) 3805 Old Easton Road, Doylestown, PA 18902, is the address for all stockholders in the table except otherwise stated below. Applicable percentages are based on 69,854,141 shares of our common stock, 75 shares of our Series A Preferred Stock and 75 shares of our Series B Preferred Stock outstanding as of April 1, 2019, and are calculated as required by rules promulgated by the SEC.

(2) Consists of 20,342,076 shares of common stock owned of record by Medical Marijuana, Inc. (OTC:MJNA). MJNA is a publicly-traded company. MJNA's Executive Committee has joint voting and investment control of its portfolio investments, including Kannalife, Inc. The Executive Committee consists of three of MJNA's board members: Chris Prine, Robert L. Cunningham and Timothy R. Scott, PhD. Each of these committee members disclaims beneficial ownership of MJNA's portfolio securities, including Kannalife, Inc.

(3) Consists of 6,817,067 shares of common stock owned of record by Kettner Investments, LLC. Kettner Investments, LLC is managed by its three Managers which share joint voting and investment control of the entity: John Huemoeller, Stuart W. Titus and Timothy R. Scott, PhD. Each of these managers disclaims beneficial ownership of Kettner's portfolio securities, including Kannalife, Inc.

(4) Consists of (i) 21,073,626 shares of common stock owned of record by Mr. Petkanas, (ii) 600,000 shares of common stock owned of record by Powerlife Phytomedical, LLC of which Mr. Petkanas exercises shared voting and investment control, (iii) 518,095 shares of common stock owned of record by Golden Gate Capital Partners, LLC of which Mr. Petkanas is the Managing Member and shares voting and investment control, and (iv) 75,000 shares of common stock issuable to Mr. Petkanas on conversion of the 75 shares of Series B Preferred Stock held by Mr. Petkanas individually.

(5) Consists of 5,454,125 shares of common stock owned of record by Mr. Kikis individually.

(6) Consists of 1,546,875 shares of common stock owned of record by Mr. Corrao individually.

(7) Consists of 1,326,875 shares of common stock owned of record by Dr. Kinney individually.

(8) Consists of 75,000 shares of common stock issuable to Naturewell, Incorporated on conversion of the 75 shares of Series A Preferred Stock held by Naturewell, Incorporated. Robert Plomgren is the Chief Executive Officer of Naturewell, Incorporated and possesses voting and investment control of the shares.

(9) Consists of (i) 30,519,596 shares of common stock, and (ii) 75,000 shares of common stock issuable on conversion of the 75 shares of Series B Preferred Stock within 60 days of April 1, 2019 beneficially owned by our current directors and executive officers.

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

We describe below the transactions and series of similar transactions, since January 1, 2016, to which we were a party or will be a party, in which:

the amounts involved exceeded or will exceed $120,000; and
any of our directors, executive officers, holders of more than 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements with directors and executive officers, which are described where required under the section above titled “Executive Compensation.”

As of December 31, 2018 and 2017, loans and advances from related parties amounted to $41,995 and $656,481, respectively.

On December 27, 2014, the Company borrowed $150,000 from General Hemp and issued a convertible promissory note with a maturity date of December 31, 2015. The loan incurs 10% interest per annum and increasing to 17% per annum in the event of a default. This note is convertible to the Company’s common stock at a price of $1.00 per share. Accrued interest related to this note is $67,195 as of December 31, 2017.

During the year ended December 31, 2015, the Company borrowed $120,000 from the Chief Executive Officer and issued convertible promissory notes that are due on demand. The loans incur 10% interest per annum. These notes are convertible to the Company’s common stock at a price of $1.00 per share.

On November 20, 2015, the Company borrowed $5,000 from the Chief Executive Officer and issued a convertible promissory note that is due on demand. The loan incurs 10% interest per annum. This note is convertible to the Company’s common stock at a price of $0.40 per share.

During the year ended December 31, 2016, the Company borrowed $15,000 from the Chief Executive Officer and issued convertible promissory notes that are due on demand. The loans incur 10% interest per annum. These notes are convertible to the Company’s common stock at a price of $0.40 per share.

During the year ended December 31, 2016, the Company borrowed $10,000 from the Chief Executive Officer and issued convertible promissory notes with a maturity date of December 31, 2016. The loans incur 10% interest per annum and increasing to 17% per annum in the event of a default. These notes are convertible to the Company’s common stock at a price of $0.40 per share.

During the year ended December 31, 2016, the Company repaid $7,191 of principal and $21,252 of accrued interest towards the outstanding notes payable.

During the year ended December 31, 2017, the Company borrowed $20,000 from the Chief Executive Officer and issued convertible promissory notes with a maturity date of December 31, 2017. The loans incur 10% interest per annum and increasing to 17% per annum in the event of a default. These notes are convertible to the Company’s common stock at a price of $0.40 per share.

During the year ended December 31, 2017, the Company borrowed $367,500 and issued a promissory note with a maturity date of October 18, 2017. This note was later amended to extend the maturity to April 18, 2019. The loan incurs 3% interest per annum. On June 29, 2018, the note was amended to extend the maturity date to July 1, 2020 and the interest rate was changed to 8% per annum. All accrued interest prior the amendment date was forgiven.

During the year ended December 31, 2017, the Company repaid $23,828 of principal and $16,522 of accrued interest towards the outstanding notes payable.

On January 3, 2018, the Company converted these notes into 2,438,095 shares of common stock valued at $414,476. The difference of the $58,300 balance of the notes and the fair value of the shares issued was recorded as a loss on conversion of debt.

Prior to the share exchange agreement, the Company borrowed $25,822 and issued a promissory note with a maturity date of March 31, 2020. The loans represent working capital advances from shareholders, are unsecured, interest bearing 0.5%, and grant a security interest in the Company's assets as collateral.

Prior to the share exchange agreement, the Company borrowed $16,173 and issued a promissory note with a maturity date of March 31, 2020. The loans represent working capital advances from shareholders, are unsecured, non-interest bearing, and grant a security interest in the Company's assets as collateral.

The Company's Chief Executive Officer shares the use of the leased office space for personal living quarters. The CEO reimburses the Company for 50% of the monthly rent, or $2,700 per month.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

Audit Fees

The aggregate fees billed during the fiscal years ended December 31, 2018 and 2017 for professional services rendered by dbb*mckennon*, , with respect to the audits of our 2018 and 2017 financial statements, as well as their quarterly reviews of our interim financial statements and services normally provided by the independent accountant in connection with statutory and regulatory filings or engagements for these fiscal periods, were as follows:

	Year Ended December 31, 2018	Year Ended December 31, 2017
Audit Fees and Audit Related Fees	$ 33,000	$ 12,000
Tax Fees	-	-
All Other Fees	2,500	-
TOTAL	$ 35,500	$ 12,000

In the above table, "audit fees" are fees billed by our Company's former external auditor for services provided in auditing our Company's annual financial statements for the subject year. "Audit-related fees" are fees not included in audit fees that are billed by the auditor for assurance and related services that are reasonably related to the performance of the audit review of our company's financial statements. "Tax fees" are fees billed by the auditor for professional services rendered for tax compliance, tax advice and tax planning.

"All other fees" are fees billed by the auditor for products and services not included in the foregoing categories.

Pre-Approval Policies and Procedures

We do not have a separately designated Audit Committee. The Board of Directors pre-approves all services provided by our independent auditors. All of the above services and fees were reviewed and approved by the Board of Directors either before or after the respective services were rendered.

PART IV

ITEM 15. EXHIBITS, CONSOLIDATED FINANCIAL STATEMENT SCHEDULES

Please see the Exhibit Index which precedes the signature page to this annual report on Form 10-K and which is incorporated by reference herein.

ITEM 16. FORM 10-K SUMMARY

None.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated By Reference (Form Type)	Filing Date	Filed herewith
2.1	Share Exchange Agreement, dated as of July 25, 2018 by and among TYG Solutions Corp., Kannalife Sciences, Inc. and its stockholders	8-K	7/31/2018	
3.1	Certificate of Incorporation, as filed with the Delaware Secretary of State on March 25, 2013	10-K	3/30/2017	
3.2	Amended and Restated Certificate of Incorporation of TYG Solutions Corp., as filed with the Delaware Secretary of State on May 1, 2018	8-K	5/4/2018	
3.3	Certificate of Designation of Series A Preferred Stock of TYG Solutions Corp. as filed with the Delaware Secretary of State on May 3, 2018	8-K	5/4/2018	
3.4	Certificate of Designation of Series B Preferred Stock of TYG Solutions Corp. as filed with the Delaware Secretary of State on May 3, 2018	8-K	5/4/2018	
3.5	Bylaws of TYG Solutions Corp.	10-K	3/30/2017	
3.6	Amended and Restated Bylaws of TYG Solution Corp.	8-K	5/4/2018	
3.7	Amendment to Amended and Restated Certificate of Incorporation, as filed with the Delaware Secretary of State on November 9, 2018	S-1/A	12/28/2018	
4.1	Convertible Note dated February 16, 2018	10-K	7/24/2018	
4.2	Convertible Note Purchase Agreement dated February 16, 2018	10-K	7/24/2018	
10.1	Form of Lock-up Agreement (Kannalife Stockholders)	8-K	7/31/2018	
10.2	Form of Lock-up Agreement (Management Stockholders)	8-K	7/31/2018	
10.3	Form of Lock-up Agreement (Dean Petkanas Block)	8-K	7/31/2018	
10.4+	Executive Employment Agreement by and between TYG Solutions Corp. and Dean Petkanas	8-K	7/31/2018	
10.5+	Executive Employment Agreement by and between TYG Solutions Corp. and Thomas Kikis	8-K	7/31/2018	
10.6+	Executive Employment Agreement by and between TYG Solutions Corp. and Mark Corrao	8-K	7/31/2018	
10.7+	Executive Employment Agreement by and between TYG Solutions Corp. and William Kinney, PhD	8-K	7/31/2018	
10.8	Settlement Agreement by and between TYG Solutions Corp. and Medical Marijuana, Inc.	S-1/A	12/28/2018	
10.9**	Exclusive Patent License Agreement - Exclusive by and between the National Institutes of Health and Kannalife Sciences, Inc. for Hepatic Encephalopathy (HE).	S-1/A	12/28/2018	
10.10**	Nonexclusive Patent License Agreement - Nonexclusive by and between the National Institutes of Health and Kannalife Sciences, Inc. for Chronic Traumatic Encephalopathy (CTE).	S-1/A	12/28/2018	
10.11**	Feasibility Study Quotation by and between Kannalife Sciences, Inc. and Catalent Pharma Solutions, LLC.	S-1/A	12/28/2018	
10.12	Stock Purchase Agreement by and between Cross & Co. and the Company.	S-1/A	12/28/2018	
10.13**	Materials Transfer and Testing Agreement by and between Kannalife Sciences, Inc. and the Natural Products Discovery Institute	S-1/A	3/8/2019	
21.1	Schedule of Subsidiaries	S-1/A	12/28/2018	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 **			X
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 **			X
101.INS*	XBRL Instance Document			X
101.SCH*	XBRL Extension Schema Document			X
101.CAL*	XBRL Extension Calculation Linkbase Document			X

101.DEF*	XBRL Extension Definition Linkbase Document	**X**
101.LAB*	XBRL Extension Labels Linkbase Document	**X**
101.PRE*	XBRL Extension Presentation Linkbase Document	**X**

+ Indicates management contract or compensatory plan.

* In accordance with Rule 406T of Regulation S-T, this information is deemed not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

** This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the redaction pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, and Rule 406 of the Securities Act of 1933, as amended.

SIGNATURES

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

By */s/ Dean Petkanas*
Dean Petkanas
Chief Executive Officer and Chairman

Dated: April 9, 2019

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/ Dean Petkanas Dean Petkanas	Chief Executive Officer and Chairman (Principal Executive Officer)	April 9, 2019
/s/ Mark Corrao Mark Corrao	Chief Financial Officer (Principal Financial and Accounting Officer)	April 9, 2019
/s/ Thomas Kikis Thomas Kikis	Chief Communications Officer and Director	April 9, 2019
/s/ Dr. William Kinney Dr. William Kinney	Chief Scientific Officer	April 9, 2019
/s/ Robert Malasek Robert Malasek	Director	April 9, 2019
/s/ Blake Schroeder Blake Schroeder	Director	April 9, 2019
/s/ Dr. Timothy R. Scott Dr. Timothy R. Scott	Director	April 9, 2019

KANNALIFE, INC.
F/K/A/ TYG SOLUTIONS CORP.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2018

To the Board of Directors and
Stockholders of Kannalife, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kannalife, Inc. (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders’ equity (deficit), and cash flows, for the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated 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 audits to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ dbbmckennon

We have served as the Company's auditor since 2017.
San Diego, California
April 9, 2019

KANNALIFE, INC.
(FORMERLY KNOWN AS TYG SOLUTIONS CORP.)
CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 307,131	$ 4,326
Marketable security (available for sale)	2,579,640	-
Other receivables	99,691	400
Due from related party, net	16,334	-
Total Current Assets	3,002,796	4,726
Investment	-	256,359
Property and equipment, net	3,074	-
Security deposits	17,121	15,000
Deferred tax asset	-	772,000
TOTAL ASSETS	$ 3,022,991	$ 1,048,085
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 283,996	$ 453,632
Payroll and related liabilities	246,067	239,924
Notes payable	-	367,500
Loan payable - related party	16,173	-
Total Current Liabilities	546,236	1,061,056
LONG TERM LIABILITIES:		
Payroll and related liabilities - long term	-	2,812,810
Loan payable - long term	620,000	-
Loan payable - related party - long term	25,822	-
Convertible notes payable - long term	500,000	185,000
Convertible notes payable - related party - long term	-	288,981
Total Long Term Liabilities	1,145,822	3,286,791
TOTAL LIABILITIES	1,692,058	4,347,847
STOCKHOLDERS' EQUITY (DEFICIENCY):		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized		
Series A preferred stock, 75 shares designated, 75 and zero issued and outstanding, respectively (Liquidation preference of $75,000)	-	-
Series B preferred stock, 75 shares designated, 75 and zero issued and outstanding, respectively (Liquidation preference of $75,000)	-	-
Common stock, $0.0001 par value, 200,000,000 authorized, 69,854,141 and 53,281,932 issued and outstanding, respectively	6,985	5,328
Additional paid-in capital	6,381,755	2,683,776
Accumulated deficit	(5,052,051)	(5,988,866)
Non-controlling interest	(5,756)	-
TOTAL STOCKHOLDERS' EQUITY (DEFICIENCY)	1,330,933	(3,299,762)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	$ 3,022,991	$ 1,048,085

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

KANNALIFE, INC.
(FORMERLY KNOWN AS TYG SOLUTIONS CORP.)
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2018	**2017**
NET REVENUES:		
Grant Revenue	$ 173,889	$ -
TOTAL NET REVENUES	173,889	-
OPERATING EXPENSES:		
Research and development	224,933	4,000
General and administrative	1,010,764	1,190,362
TOTAL OPERATING EXPENSES	1,235,697	1,194,362
LOSS FROM OPERATIONS	(1,061,808)	(1,194,362)
OTHER (EXPENSE) INCOME:		
Interest income (expense), net	(30,764)	(98,893)
Other (expense) income, net	36,183	-
Loss on conversion of convertible debt	(61,815)	-
Gain on settlement	3,901,974	-
Realized loss on marketable security	(167,034)	-
Unrealized loss on marketable security	(873,693)	-
TOTAL OTHER (EXPENSE) INCOME	2,804,851	(98,893)
NET INCOME (LOSS) BEFORE INCOME TAX	$ 1,743,043	$ (1,293,255)
Income tax expense (benefit)	811,984	350,000
NET INCOME (LOSS)	$ **931,059**	$ **(1,643,255)**
Net income (loss) attributable to noncontrolling interests	(5,756)	-
Net income (loss) attributable to Kannalife, Inc.	$ **936,815**	$ **(1,643,255)**
Income (Loss) attributable to Kannalife, Inc. per common share - basic	$ 0.01	$ (0.03)
Income (Loss) attributable to Kannalife, Inc. per common share - diluted	$ 0.01	$ (0.03)
Weighted average common shares outstanding - basic	64,417,684	48,504,268
Weighted average common shares outstanding - diluted	68,849,054	48,504,268

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

KANNALIFE, INC.
(FORMERLY KNOWN AS TYG SOLUTIONS CORP.)
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIENCY)
FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2018

	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Additional Paid-In		Non-	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Accumulated Deficit	controlling interest	(Deficiency) Equity
Balance December 31, 2016	-	$ -	-	$ -	53,281,932	$ 5,328	$2,679,578	$(4,345,611)	$ -	$(1,660,705)
Issuance of stock options for services	-	-	-	-	-	-	4,198	-	-	4,198
Net loss	-	-	-	-	-	-	-	(1,643,255)	-	(1,643,255)
Balance December 31, 2017	-	-	-	-	53,281,932	5,328	2,683,776	(5,988,866)	-	(3,299,762)
Issuance of stock for conversion of notes payable	-	-	-	-	1,537,009	153	653,940	-	-	654,093
Issuance of stock for conversion of accrued salaries	-	-	-	-	5,505,200	551	2,812,260	-	-	2,812,811
Issuance of stock options for services	-	-	-	-	-	-	10,077	-	-	10,077
Issuance of Series A Preferred stock for cash	75	-	-	-	-	-	75,000	-	-	75,000
Issuance of Series B Preferred stock for cash	-	-	75	-	-	-	75,000	-	-	75,000
Issuance of common stock for cash	-	-	-	-	2,030,000	203	202,797	-	-	203,000
Effect of reverse recapitalization transaction	-	-	-	-	7,500,000	750	(131,095)	-	-	(130,345)
Net income (loss)	-	-	-	-	-	-	-	936,815	(5,756)	931,059
Balance December 31, 2018	75	$ -	75	$ -	69,854,141	$ 6,985	$6,381,755	$(5,052,051)	$ (5,756)	$ 1,330,933

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

KANNALIFE, INC.
(FORMERLY KNOWN AS TYG SOLUTIONS CORP.)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 931,059	$ (1,643,255)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Loss on issuance of stock for conversion of notes payable and accrued salaries	61,815	-
Gain on settlement	(3,901,974)	-
Realized loss on marketable security	167,034	-
Unrealized loss on marketable security	873,693	-
Amortization of debt discount	-	14,310
Issuance of options for services	10,077	4,198
Provision for deferred income taxes	772,000	350,000
Changes in operating assets and liabilities:		
Security deposits	(2,121)	-
Other receivables	(99,291)	-
Accounts payable and accrued expenses	(29,342)	(81,481)
Payroll and related liabilities	6,143	963,868
NET CASH USED IN OPERATING ACTIVITIES	(1,210,907)	(392,360)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash received upon reverse acquisition	289,654	-
Proceeds from sale of marketable securities	537,966	-
Purchase of equipment	(3,074)	-
NET CASH PROVIDED BY INVESTING ACTIVITIES	824,546	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Due from related party, net	(16,334)	-
Proceeds from issuance of Series A Preferred stock	75,000	-
Proceeds from issuance of Series B Preferred stock	75,000	-
Proceeds from issuance of common stock	203,000	-
Proceeds from notes payable	352,500	-
Proceeds from notes payable - related party	-	367,500
Proceeds from convertible notes payable - related party	-	20,000
Repayments on convertible notes payable related party	-	(23,828)
NET CASH PROVIDED BY FINANCING ACTIVITIES	689,166	363,672
Net increase (decrease) in cash	302,805	(28,688)
Cash and cash equivalents, beginning of year	4,326	33,014
Cash and cash equivalents, end of year	$ 307,131	$ 4,326
NON-CASH ACTIVITIES:		
Issuance of common stock for conversion of notes payable and accrued interest	$ 236,104	$ -
Issuance of common stock for conversion of notes payable and accrued interest - related party	$ 356,176	$ -
Issuance of common stock for conversion of accrued salaries	$ 2,812,811	$ -
Issuance of common stock upon for liabilities assumed in reverse acquisition	$ 130,345	$ -

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

NOTE 1 – ORGANIZATION AND NATURE OF OPERATIONS

Kannalife, Inc. (the "Company") was incorporated under the laws of the state of Delaware on March 25, 2013 under the name TYG Solutions Corp. The Company consummated a share exchange transaction on July 25, 2018 with Kannalife Sciences, Inc. ("Kannalife"), a privately held Delaware corporation formed in 2010, the accounting acquirer. Upon completion of the share exchange transaction, Kannalife is treated as the surviving entity and accounting acquirer although the Company was the legal acquirer. Accordingly, the Company's historical financial statements are those of Kannalife the surviving entity and accounting acquirer. All references that refer to (the "Company" or "we" or "us" or "our") are Kannalife, unless otherwise differentiated. Kannalife is a phytomedical/pharmaceutical company that specializes in the research and development of synthetic molecules and therapeutic products derived from botanical sources, including the cannabis taxa.

Share Exchange and Corporate Restructuring

On July 25, 2018, the Company entered into a Share Exchange Agreement (the "Share Exchange Agreement") with Kannalife Sciences, Inc., a Delaware corporation ("Kannalife") and certain stockholders of Kannalife (the "Kannalife Stockholders").

Pursuant to the terms of the Share Exchange Agreement, the Company acquired approximately 99.7% of the issued and outstanding shares of Kannalife by means of a share exchange with the Kannalife Stockholders in exchange for 60,324,141 newly issued shares of the common stock of the Company (the "Share Exchange"), which increased the Company's issued and outstanding shares of common stock to 69,854,141. As a result of the Share Exchange, Kannalife became a 99.7% owned subsidiary of the Company, which on a going forward basis will result in consolidated financial reporting by the Company to include the results of Kannalife. The initial closing of the Share Exchange occurred concurrently with entry into the Share Exchange Agreement (the "Initial Closing"). After the Initial Closing and for a period of no more than 120 days thereafter, unless extended in the sole discretion of the Company, the Company may issue, on the same terms and conditions as those contained in the Share Exchange Agreement, additional shares of the common stock of the Company to Kannalife Stockholders that did not participate in the Initial Closing, provided that each additional Kannalife Stockholder becomes a party to the transaction documents (the "Additional Closing").

The Share Exchange has been accounted for as a reverse acquisition of the Company by Kannalife but in substance as a capital transaction, rather than a business combination since the Company had nominal operations and assets prior to and as of the closing of the Share Exchange. The former stockholders of Kannalife represent a significant constituency of the Company's voting power immediately following the Share Exchange and Kannalife's management has assumed operational, financial and governance control. The transaction is deemed a reverse recapitalization and the accounting is similar to that resulting from a reverse acquisition, except that no goodwill or other intangible assets should be recorded. For accounting purposes, Kannalife is treated as the surviving entity and accounting acquirer although the Company was the legal acquirer. Accordingly, the Company's historical financial statements are those of Kannalife.

All references to common stock, share and per share amounts have been retroactively restated to reflect the reverse recapitalization as if the transaction had taken place as of the beginning of the earliest period presented.

Company assets and liabilities pre- reverse acquisition:

Cash and cash equivalents	$	289,654
Note receivable		142,500
Total assets	$	432,154
Accounts payable and accrued expenses	$	20,504
Loan payable - related party - long term		41,995
Convertible notes payable – long term		500,000
Total liabilities		562,499
Total liabilities assumed	$	(130,345)

NOTE 1 – ORGANIZATION AND NATURE OF OPERATIONS (CONTINUED)

The following summarized unaudited consolidated pro forma information shows the results of operations of the Company had the reverse acquisition occurred on January 1, 2018 and 2017, respectively:

	Pro Forma (Unaudited) Years Ended December 31,	
	2018	2017
Total revenues	$ 173,889	$ 1,154
Net income (loss)	$ 819,105	$ (1,665,698)
Net income (loss) per common share, basic	$ 0.01	$ (0.03)
Net income (loss) per common share, diluted	$ 0.01	$ (0.03)

The summarized consolidated pro forma results are not necessarily indicative of results which would have occurred if the reverse acquisition had been in effect for the periods presented. Further, the summarized unaudited consolidated pro forma results are not intended to be a projection of future results.

Name Change

On November 9, 2018, the Company filed an amendment to its certificate of incorporation with the Delaware Secretary of State to change its name to Kannalife, Inc. The Company has concurrently submitted a request to FINRA for approval of the name change as well as a ticker symbol change and is awaiting approval. The Company's name change and ticker change was reviewed and processed by FINRA and went effective January 17, 2019.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies used in the preparation of the consolidated financial statements are as follows:

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP.

Principles of Consolidation

The Company evaluates the need to consolidate affiliates based on standards set forth in ASC 810 Consolidation ("ASC 810").

The consolidated financial statements include the accounts of the Company and its majority owned subsidiary, Kannalife. The non-controlling interest in Kannalife represents the 0.30% equity interest held by the original shareholders of Kannalife before the share exchange. All significant consolidated transactions and balances have been eliminated in consolidation. The operations of Kannalife, Inc. are included in the consolidated financial statement from the date of the Share Exchange.

Noncontrolling Interests

The Company accounts for its less than 100% interests in Kannalife in accordance with ASC Topic 810, Consolidation, and accordingly the Company presents noncontrolling interests as a component of equity on its consolidated balance sheet and reports the noncontrolling interest's share of Kannalife's net loss attributable to noncontrolling interests in the consolidated statement of operations.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Significant risks and uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company's products, the Company's ability to obtain regulatory approval to market its products, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company products, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital.

The Company currently has no commercially approved products and there can be no assurance that the Company's research and development will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and consultants and obtaining and protecting intellectual property.

Use of Estimates

The preparation of consolidated financial statements and accompanying notes in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the dates of the consolidated financial statements, and the reported amounts of revenues and expenses during the periods. Actual results could differ from those estimates. Significant matters requiring the use of estimates and assumptions include, but are not necessarily limited to, establishing the fair value of marketable securities and periodically evaluating marketable securities for potential impairment, fair value of the Company's stock, stock-based compensation, and valuation allowance relating to the Company's deferred tax assets. Management believes that its estimates and assumptions are reasonable, based on information that is available at the time they are made.

Cash and Cash Equivalents

Our cash and cash equivalents include short-term, highly liquid investments with original maturities of three months or less when purchased. At times throughout the year, the Company may maintain bank balances that could exceed Federal Deposit Insurance Corporation insured limits. The Company maintains its cash deposit accounts with high credit quality financial institutions, and therefore believes that its loss exposure is minimal.

Accounts Receivable

Accounts receivable are carried at original invoice amount less an estimate made for doubtful accounts based on a review of all outstanding amounts. Management determines the allowance for doubtful accounts by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions and sets up an allowance for doubtful accounts when collection is uncertain. Customers' accounts are written off when all attempts to collect have been exhausted. Recoveries of accounts receivable previously written off are recorded as income when received. As of December 31, 2018 and 2017, the Company had no allowance for doubtful account.

Concentration Risks

As of December 31, 2108, the Company's revenue had a concentration of 100% from one grant. The concentration of the Company's revenue creates a potential risk to future working capital in the event that the Company is not able to continue receiving the grant revenue.

As of December 31, 2108, the Company's accounts receivable had a concentration of 80% and 20% from two separate parties. The concentration of the Company's accounts receivable creates a potential risk to future working capital in the event that the Company is not able to collect all, or a majority, of outstanding accounts receivable balances.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Revenue Recognition

The FASB issued Accounting Standards Update ("ASU") No. 2014-09, codified as ASC 606: Revenue from Contracts with Customers, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The Company adopted ASC 606 effective January 1, 2018 using modified retrospective basis and the cumulative effect was immaterial to the consolidated financial statements.

Revenue consists of research funding from the Company's National Institute of Health ("NIH") Grant. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the award have been met for collection. Proceeds received prior to the costs being incurred or the conditions of the award being met are recognized as deferred revenue until the services are performed and the conditions of the award are met.

Equity Investments

Effective January 1, 2018, with the adoption of ASU 2016-01, our accounting treatment for equity investments differs for those with and without readily determinable fair values. Equity investments with readily determinable fair values are recorded at fair value with changes in fair value recorded in "Unrealized Gain/Loss On Investments." For equity investments without readily determinable fair values we have elected the "measurement alternative," and therefore carry these investments at cost, less impairment (if any), plus or minus changes in observable prices. On a quarterly basis, we review our equity investments without readily determinable fair values for impairment. We consider a number of qualitative factors such as whether there is a significant deterioration in earnings performance, credit rating, asset quality, or business prospects of the investee in determining if impairment exists. If the investment is considered impaired, an impairment loss equal to the amount by which the carrying value exceeds its fair value is recorded through a charge to earnings. The impairment loss may be reversed in a subsequent period if there are observable transactions for the identical or similar investment of the same issuer at a higher amount than the carrying amount that was established when the impairment was recognized. Impairment as well as upward or downward adjustments resulting from observable price changes in orderly transactions for identical or similar investments are included in "Income - other."

Realized gains or losses resulting from the sale of equity investments are calculated using the specific identification method and are included in "Realized loss on marketable security".

Income Taxes

The Company accounts for income taxes under FASB ASC Topic 740, *Income Taxes* ("ASC 740"). Deferred income tax assets and liabilities are determined based upon differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the assets will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years 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 statements of operations in the period that includes the enactment date.

Preferred Stock

The Company applies the guidance enumerated in FASB ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480"), when determining the classification and measurement of preferred stock. Preferred shares subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred shares (if any), which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred shares in stockholders' equity. The Company's preferred shares do not feature any redemption rights within the holders' control or conditional redemption features not within the Company's sole control as of December 31, 2018 and 2017. Accordingly, all issuances of preferred stock are presented as a component of stockholders' equity.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Convertible Instruments

The Company evaluates and accounts for conversion options embedded in convertible instruments in accordance with ASC Topic 815, *Derivatives and Hedging Activities* ("ASC 815").

Applicable U.S. GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria includes circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible instruments (when the Company has determined that the embedded conversion options should not be bifurcated from their host instruments) as follows. The Company records, when necessary, deemed dividends for the intrinsic value of conversion options embedded in preferred shares based upon the differences between the fair value of the underlying common stock at the commitment date of the transaction and the effective conversion price embedded in the preferred shares.

Stock Based Compensation

The Company accounts for share-based compensation in accordance with the fair value recognition provision of FASB ASC 718, *Compensation – Stock Compensation* ("ASC 718"), prescribes accounting and reporting standards for all share-based payment transactions in which employee services are acquired. Transactions include incurring liabilities, or issuing or offering to issue shares, options, and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the consolidated financial statements based on the estimated grant date fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period).

The Company accounts for stock-based compensation issued to non-employees and consultants in accordance with the provisions of FASB ASC 505, *Equity–based Payments to Non-Employees* ("ASC 505"). Measurement of share-based payment transactions with non-employees is based on the fair value of whichever is more reliably measurable: (a) the goods or services received; or (b) the equity instruments issued. The fair value of the share-based payment transaction is determined at the earlier of performance commitment date or performance completion date.

Net Income (Loss) per Share

Basic net loss per share is calculated by dividing the net loss for the period by the weighted-average number of common shares outstanding during the period. Diluted net income per share is calculated by dividing income for the period by the weighted-average number of common shares outstanding during the period, increased by potentially dilutive common shares ("dilutive securities") that were outstanding during the period. Dilutive securities include stock options and warrants granted, convertible debt, and convertible preferred stock. In accordance with ASC 260, "Earnings Per Share", the following table reconciles basic shares outstanding to fully diluted shares outstanding for the year ended December 31, 2018:

	December 31, 2018
Weighted average number of common shares outstanding - Basic	64,417,684
Series A preferred stock	37,603
Series B preferred stock	37,603
Convertible notes payable	4,356,164
Weighted average number of common and equivalent shares outstanding-Diluted	68,849,054

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Common stock equivalents are included in the diluted income per share calculation only when option exercise prices are lower than the average market price of the common shares for the period presented. One hundred thousand (100,000) options were not included in the calculation of net loss per common share for the year ended December 31, 2018 because their effect would be anti-dilutive.

The potentially dilutive securities were not included in the calculation of net loss per common share for the year ended December 31, 2017 because their effect would be anti-dilutive.

Research and Development

In accordance with FASB ASC 730, *Research and Development* ("ASC 730") research and development ("R&D") costs are expensed when incurred. R&D costs include supplies, clinical trial and related clinical manufacturing costs, contract and other outside service and facilities and overhead costs. Total R&D costs for the years ended December 31, 2018 and 2017 were $224,933 and $4,000, respectively.

Recently Issued Authoritative Guidance

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers ("Topic 606"), which is a new comprehensive revenue recognition model that will supersede all existing revenue recognition guidance under U.S. GAAP. The standard requires a company to recognize revenue when it transfers goods or services to a customer at an amount that reflects the consideration it expects to receive in exchange for those goods or services. This standard is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted for interim and annual periods beginning after December 15, 2016. Entities will have the option of using either a full retrospective approach or a modified approach to adopt the guidance in the ASU. We adopted this ASU in the first quarter of 2018 with no material impact to our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), requiring lessees to recognize for all leases (with the exception of short-term leases) at the commencement date: (1) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and (2) a right-of-use ("ROU") asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The update is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. The Company currently anticipates that upon adoption of the new standard, ROU assets and lease liabilities will be recognized in amounts that will be immaterial to the consolidated balance sheets.

NOTE 3 – GOING CONCERN AND MANAGEMENT'S LIQUIDITY PLANS

The Company's consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in our accompanying consolidated financial statements, the Company has had a net loss from operations of $1,061,808 and $1,194,362 for the years ended December 31, 2018 and 2017, respectively. The net cash used in operations were $1,210,907 and $392,360 for the years ended December 31, 2018 and 2017, respectively. Additionally, the Company had an accumulated deficit of $5,052,051 at December 31, 2018 and has not yet established an adequate ongoing source of revenues sufficient to cover its operating costs and to allow it to continue as a going concern.

As of December 31, 2018, we had $307,131 in cash and cash equivalents. Additionally, we had $2,579,640 in marketable securities (available for sale). Management plans to raise additional capital through the sale of our marketable securities. We expect that between our existing cash, cash equivalents and marketable securities we will be able to sufficiently fund our operations and capital requirements for the next 18 months.

The Company's history of recurring losses, and uncertainties as to whether its operations will become profitable and generate operating cash flows raise substantial doubt about its ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

NOTE 4 – FAIR VALUE MEASUREMENTS

The Company follows FASB ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820") to measure and disclosure the fair value of its financial instruments. ASC 820 establishes a framework for measuring fair value in U.S. GAAP and expands disclosures about fair value measurements and establishes a fair value hierarchy which prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The three levels of fair value hierarchy defined by ASC 820 are described below:

Level 1 Quoted market prices available in active markets for identical assets or liabilities as of the reporting date.

Level 2 Pricing inputs other than quoted prices in active markets included in Level 1, which are either directly or indirectly observable as of the reporting date.

Level 3 Pricing inputs that are generally unobservable inputs and not corroborated by market data.

Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable.

The fair value hierarchy gives the highest priority to quoted prices (unadjusted) in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The carrying amounts reported in the Company's consolidated financial statements for cash, accounts payable and accrued expenses approximate their fair value because of the immediate or short-term nature of these financial instruments.

Transactions involving related parties cannot be presumed to be carried out on an arm's-length basis, as the requisite conditions of competitive, free-market dealings may not exist. Representations about transactions with related parties, if made, shall not imply that the related party transactions were consummated on terms equivalent to those that prevail in arm's-length transactions unless such representations can be substantiated.

On March 7, 2014, Kannalife Sciences, Inc. ("Kannalife") entered into an agreement with General Hemp LLC ("General Hemp") through its wholly owned subsidiary Kannaway LLC ("Kannaway") for certain rights and agreements to where each company would exchange 4.99% of each Company's equity, by way of a stock swap. As such, Kannalife would receive a 4.99% equity stake in Kannaway and Kannaway would receive 6,408,980 shares of restricted common stock of Kannalife.

On or about April 2014, Kannalife delivered 6,408,980 of the aforementioned Kannalife restricted common stock to General Hemp on behalf of Kannaway and such shares were made to Kannaway as the beneficiary. The Company recorded the fair market value of the common stock at $256,359 or $0.04. The Company valued the shares based upon other transactions of the Company's common stock around the same time frame. The Company accounted for the transaction as a cost investment.

On or about December 2015, Medical Marijuana, Inc. ("MJNA") purchased Kannaway from General Hemp for which due to a dispute between the Company and General Hemp, the Company wasn't provided any of the consideration. On June 1, 2018, the Company received 41,583,333 shares of MJNA common stock pursuant to a settlement agreement effective July 15, 2017. MJNA is a significant shareholder of the Company and their Chief Executive Officer is also on the Company's Board of Directors.

The following table presents assets that are measured and recognized at fair value as of December 31, 2018, on a recurring basis:

	December 31, 2018			
	Level 1	Level 2	Level 3	Total Carrying Value
Marketable securities – Medical Marijuana, Inc.	$ 2,579,640	-	-	$ 2,579,640

NOTE 5 – ACCRUED PAYROLL AND PAYROLL TAXES

Accrued payroll and payroll taxes at December 31, 2018 and 2017 consisted of the following:

	2018	2017
Payroll	$ -	$ 2,812,810
Payroll taxes	246,067	239,924
Totals	$ 246,067	$ 3,052,734

As of December 31, 2018 and 2017, the Company has accrued payroll taxes in connection salaries paid and accrued to four officers of the Company.

In July of 2018, the Company entered into a new employment agreement with our CEO. The initial term of the agreement is for two years and automatically renews for successive one year terms.

In July of 2018, the Company entered into new employment agreements with three officers. The initial term of these agreements are for one year and automatically renew for successive six month terms.

See Note 13 for discussion of accrued payroll converted into common stock.

NOTE 6 – NOTES PAYABLE

During the year ended December 31, 2017, the Company borrowed $367,500 and issued a promissory note with a maturity date of October 18, 2017. This note was later amended to extend the maturity to April 18, 2019. During the year ended December 31, 2018, the Company borrowed an additional $352,500 and issued a promissory note with a maturity date of April 18, 2019. These loans incurred 3% interest per annum. On June 29, 2018, these notes were amended to extend the maturity date to July 1, 2020 and the interest rate was changed to 8% per annum. All accrued interest prior the amendment date was forgiven. Accrued interest related to these notes is $24,460 and $3,565 as of December 31, 2018 and 2017, respectively.

Upon the consolidation of the Company and Kannalife, $100,000 of the above-mentioned borrowings was eliminated due to it being an intercompany transaction. The total, above mentioned, notes payable due is $620,000 as of December 31, 2018.

Total interest expense on notes payable, amounted to $24,460 and $3,565 for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2017, this note holder was considered a related party. As of December 31, 2018, due to the proceeds from marketable securities this note holder has no significant influence on the Company and is no longer deemed a related party.

NOTE 7 – NOTES PAYABLE – RELATED PARTY

Prior to the share exchange agreement, the Company borrowed $25,822 and issued a promissory note with a maturity date of March 31, 2020. The loans represent working capital advances from shareholders, are unsecured, interest bearing 0.5%, and grant a security interest in the Company's assets as collateral. Accrued interest related to this note is $226 as of December 31, 2018.

As of December 31, 2018, due to related parties amounted to $16,173. The amounts due related parties represent working capital advances and fees for work performed by officers and shareholders, are unsecured, non-interest bearing and are due upon demand.

Total interest expense on notes payable, amounted to $54 and $0 for the years ended December 31, 2018 and 2017, respectively.

NOTE 8 – CONVERTIBLE NOTES PAYABLE

On May 15, 2015, the Company borrowed $35,000 and issued a convertible promissory note with a maturity date of April 30, 2016. The loan incurs 10% interest per annum. This note is convertible to the Company's common stock at a price of $1.00 per share. In addition, the Company issued 17,500 warrants to purchase common stock with an exercise price of $1.50 per share and a term of two years. These warrants were valued at $7,525 on a relative fair value basis and were recorded as a debt discount to be amortized over the term. Accrued interest related to this note is $0 and $9,196 as of December 31, 2018 and 2017, respectively.

On August 13, 2015, the Company borrowed $50,000 and issued a convertible promissory note with a maturity date of August 12, 2016. The loan incurs 10% interest per annum and increasing to 17% per annum in the event of a default. This note is convertible to the Company's common stock at a price of $1.00 per share. In addition, the Company issued 25,000 warrants to purchase common stock with an exercise price of $1.50 per share and a term of two years. These warrants were valued at $10,751 on a relative fair value basis and were recorded as a debt discount to be amortized over the term. Accrued interest related to this note is $0 and $16,659 as of December 31, 2018 and 2017, respectively.

On November 25, 2015, the Company borrowed $100,000 and issued a convertible promissory note with a maturity date of November 24, 2016. The loan incurs 10% interest per annum and increasing to 14% per annum in the event of a default. This note is convertible to the Company's common stock at a price of $1.00 per share. In addition, the Company issued 50,000 warrants to purchase common stock with an exercise price of $1.50 per share and a term of two years. These warrants were valued at $21,500 on a relative fair value basis and were recorded as a debt discount to be amortized over the term. Accrued interest related to this note is $0 and $25,249 as of December 31, 2018 and 2017, respectively.

Prior to the Share Exchange, the Company issued a convertible note to an investor, face value $500,000, in exchange for $500,000 in cash. The note is unsecured, bears interest at the rate of 3% per annum and matures on February 16, 2030. The note is convertible into common stock of the Company at $0.10 per share at any time at the option of the holder, subject to a 4.9% blocking provision which prohibits the holder from converting into common stock of the Company if such conversion results in the holder owning greater than 4.9% of the outstanding common stock of the Company after giving effect to the conversion. Accrued interest related to this note is $13,083 as of December 31, 2018.

Total interest expense on convertible notes payable, inclusive of amortization of debt discount of $0 and $14,310, amounted to $6,250 and $65,687 for the years ended December 31, 2018 and 2017, respectively.

On January 3, 2018, prior to the Share Exchange, the Company issued 563,063 shares of common stock (on a post-Share Exchange basis) for the conversion of $236,104 convertible notes payable and related accrued interest. The Company recorded a loss of $3,515 on conversion based upon the difference between the fair market value of the Company's common stock and the liabilities relieved.

The Company determined that the transaction should be recorded at fair value due to the difference between the conversion price and the price per the agreements.

NOTE 9 – CONVERTIBLE NOTES PAYABLE - RELATED PARTY

On December 27, 2014, the Company borrowed $150,000 from a stockholder and issued a convertible promissory note with a maturity date of December 31, 2015. The loan incurs 10% interest per annum and increasing to 17% per annum in the event of a default. This note is convertible to the Company's common stock at a price of $1.00 per share. Accrued interest related to this note is $0 and $67,195 as of December 31, 2018 and 2017, respectively.

During the year ended December 31, 2015, the Company borrowed $120,000 from the Chief Executive Officer and issued convertible promissory notes that are due on demand. The loans incur 10% interest per annum. These notes are convertible to the Company's common stock at a price of $1.00 per share.

NOTE 9 – CONVERTIBLE NOTES PAYABLE - RELATED PARTY (CONTINUED)

On November 20, 2015, the Company borrowed $5,000 from the Chief Executive Officer and issued a convertible promissory note that is due on demand. The loan incurs 10% interest per annum. This note is convertible to the Company's common stock at a price of $0.40 per share.

During the year ended December 31, 2016, the Company borrowed $15,000 from the Chief Executive Officer and issued convertible promissory notes that are due on demand. The loans incur 10% interest per annum. These notes are convertible to the Company's common stock at a price of $0.40 per share.

During the year ended December 31, 2016, the Company borrowed $10,000 from the Chief Executive Officer and issued convertible promissory notes with a maturity date of December 31, 2016. The loans incur 10% interest per annum and increasing to 17% per annum in the event of a default. These notes are convertible to the Company's common stock at a price of $0.40 per share.

During the year ended December 31, 2017, the Company borrowed $20,000 from the Chief Executive Officer and issued convertible promissory notes with a maturity date of December 31, 2017. The loans incur 10% interest per annum and increasing to 17% per annum in the event of a default. These notes are convertible to the Company's common stock at a price of $0.40 per share.

During the year ended December 31, 2017, the Company repaid $23,828 of principal and $16,522 of accrued interest towards the outstanding notes payable. As of December 31, 2017, $138,981 in principal and $0 of accrued interest was due.

On January 3, 2018, prior to the Share Exchange, the Company converted these notes into 973,946 shares of common stock (on a post-Share Exchange basis) valued at $414,476. The difference of the $58,300 balance of the notes and the fair value of the shares issued was recorded as a loss on conversion of debt.

The Company determined that the transaction should be recorded at fair value due to the difference between the conversion price and the price per the agreements.

Total interest expense on these convertible notes payable amounted to $0 and $16,552 for the years ended December 31, 2018 and 2017, respectively.

NOTE 10 – COMMITMENTS AND CONTINGENCIES

Legal Proceedings

From time to time the Company may get involved in legal proceedings arising in the ordinary course of business. Other than as set forth in "Legal Proceedings" in Part II below, the Company believes there is no litigation pending that could have, individually or in the aggregate, a material adverse effect on its results of operations or financial condition.

Occupancy Leases

On April 1, 2014, the Company entered into a one year lease arrangement for office space, with the option to renew the lease annually. The lease has been renewed through April 2020. The monthly rent payment is $5,400 and the security deposit is $15,000.

On September 15, 2015, the Company entered into a one year lease arrangement for office space. The Company has amended this lease to extend the term through September 30, 2018. The monthly rent payment is $249 and the security deposit is $183.

On February 1, 2018, the Company entered into a month to month lease arrangement for laboratory space. The monthly rent payment is $500.

On July 1, 2018, the Company entered into a one year lease arrangement for office space, with the option to renew the lease annually. On September 1, 2018, the Company subleased this office space to a third party. The Subleasee will pay 100% of rent for months September through November 2018 and will pay 50% of rent until expiration of lease on June 30, 2019. The monthly rent payment is $2,600 and a security deposit of $2,121.

NOTE 10 – COMMITMENTS AND CONTINGENCIES (CONTINUED)

Royalty Agreements

On June 12, 2012, the Company entered into a Patent License Agreement with agencies of the United States Public Health Services within the Department of Health and Human Services ("PHS"). Under the License Agreement, PHS granted the Company an exclusive right to use and develop certain patents relating to Cannabinoids as Antioxidants and Neuroprotectants. In exchange for the License, the Company has agreed to the following payments:

a $30,000 license issue royalty within 90 days of the execution of the agreement
a minimum annual royalty in the amount of $10,000
3% royalty on net sales from any sales of licensed products or practice of licensed processes
milestone payment of $40,000 upon initiation of first Phase I clinical trial
milestone payment of $100,000 upon initiation of first Phase II clinical trial
milestone payment of $250,000 upon completion of first Phase III clinical trial
milestone payment of $500,000 upon first marketing approval by FDA
a sublicensing royalty of 12% on the fair market value of any consideration received for granting each sublicense

On December 31, 2014, the Company executed five exclusive pharmaceutical license agreements with the Company's CEO, the Company's CMO, three advisory board members of the Company, and an unrelated third party. These agreements provide the Company the worldwide exclusive rights to certain drug technologies and methods (and systems) for collection, processing and use of data for the dispensing of phyto-medical and botanically derived materials for consumption. The license agreements grant to the Company from the inventors the rights to develop, market, make, use, and sell certain drug formulations, which are applied to humans through the use of certain drug technology. In return for these exclusive rights from the inventors, the Company has agreed to compensate the inventors under the agreements with royalties ranging from 1.5% to 2.5% on all net sales by the Company of licensed products covered by a valid claim of a patent or patent application of the inventor patent rights. Additionally, the Company retains the rights to sublicense the drug formulations, and upon such sublicense shall pay the inventors from 1.5% up to 5% of all royalties and sublicense fees paid to the Company on account of sublicenses under the inventor patent rights and inventor technology rights, less all appropriate expenses associated with such sublicenses incurred by the Company. However, if the inventor supplies licensed products to sublicensees of the Company pursuant to such sublicenses, the inventor shall supply such licensed products at its cost. Prior to the Share Exchange these royalty agreements were terminated.

NOTE 11 – RELATED PARTY TRANSACTIONS

The Company's Chief Executive Officer shares the use of the leased office space for personal living quarters. The CEO reimburses the Company for 50% of the monthly rent, or $2,700 per month.

From time to time the Company sends money to Golden Gate Capital ("GGCP"), a company owned by our CEO, for the advances of certain expenses and to be deposited into the bank account of Kannalife. Due to the timing of the funds transferred and expenses incurred, at times, there remains a balance due from GGCP. As of December 31, 2018, $16,334 is due from GGCP. Subsequent to the period end, GGCP has transferred all the remaining funds to Kannalife. As of the filing of these consolidated financial statements, there is no outstanding balance due from GGCP.

See Notes 7, 9 and 13 for additional related party transactions.

NOTE 12 – MARKETABLE SECURITY

On June 1, 2018, the Company received 41,583,333 shares of Medical Marijuana, Inc. ("MJNA") common stock pursuant to a settlement agreement. In 2014, the Company entered into a revenue sharing agreement with Kannaway LLC, whereas, among the considerations and obligations the parties agreed to a share exchange, whereby the Company issued 6,408,980 shares of its common stock in exchange of 4.99% ownership of Kannaway. A significant shareholder of the Company owned the remaining ownership of Kannaway LLC. Subsequently, Kannaway was sold, by its parent company, to MJNA for 833,333,333 shares of MJNA common stock. The settlement agreement called for the release of all obligations in exchange for the issuance of 41,583,333 shares of common stock in MJNA to the Company.

The investment in MJNA has been recorded as an investment in non-consolidated entities and is revalued every quarter with fluctuations in fair value recorded to earnings. The fair value of the investment is based on the closing price of the shares reported on the principal stock exchange on which they are traded. At December 31, 2018, the Company held 34,533,333 shares of MJNA which traded at a closing price of $0.0747, or value of $2,579,640. For the year ended December 31, 2018, the Company recorded a realized gain of $3,901,974 upon the settlement and receipt of these shares and an unrealized loss of $873,693 related to the investment in MJNA. The gain was netted against the Company's cost basis investment of $256,759 in Kannaway LLC. See note 2 for additional information.

NOTE 13 – STOCKHOLDERS' EQUITY (DEFICIENCY)

Series A Preferred Stock – Kannalife Pre-Share Exchange

As of December 31, 2017, the Company had a total of 20,000,000 shares of Series A Preferred Stock, $0.001 par value authorized for issuance. Each share of Series A Preferred Stock is convertible into one share of common stock without any additional consideration by the holder, at any time after the date of issuance. The holders of shares of Series A Preferred Stock are entitled to receive dividends, if and when declared by the Board of Directors, at the rate of 8% per annum of the original price of Series A Preferred Stock. In the event of the liquidation the holders of the Series A Preferred Stock are entitled to receive an amount equal to the original Series A price for each share of Series A then held by such holder. Each holder of shares of Series A Preferred Stock is entitled to the number of votes equal to the number of shares of common stock into which such holder's shares of Series A could be converted on the record date for the vote or written consent of the stockholders. The Series A Preferred Stock is nonredeemable.

As of December 31, 2017, there were 4,893,510 shares of Series A Preferred Stock issued and outstanding.

In July 2018, prior to the Share Exchange, the Company converted 4,893,510 shares of preferred stock into 4,893,510 shares of common stock (on a post-Share Exchange basis).

The presentation on the consolidated balance sheet shows as if these shares were converted as of December 31, 2017.

Series A Preferred Stock

Effective May 3, 2018, the Company's Board of Directors authorized and designated 75 shares of the Company's Preferred Stock as Series A Preferred Stock. Each share of the Series A Preferred Stock is entitled to a liquidation preference of $1,000 per share and is convertible into 1,000 shares of the Company's common stock. The holders of a majority of the Series A Preferred Stock are entitled to elect up to four (4) directors to the Company's board of directors and any annual or special meeting and have preferential rights in regard to the election of Series A directors. In all other voting matters, the holders of Series A Preferred Stock are entitled to cast 1,000 votes per share.

In July 2018, the Company issued 75 shares of Series A Preferred Stock, to Naturewell, Inc., an entity controlled by the former CEO of TYG Solutions Corp. in exchange for $75,000.

NOTE 13 – STOCKHOLDERS' EQUITY (DEFICIENCY) (CONTINUED)

Series B Preferred Stock

Effective May 3, 2018, the Company's Board of Directors authorized and designated 75 shares of the Company's Preferred Stock as Series B Preferred Stock. Each share of the Series B Preferred Stock is entitled to a liquidation preference of $1,000 per share and is convertible into 1,000 shares of the Company's common stock. The holders of a majority of the Series B Preferred Stock are entitled to elect up to three (3) directors to the Company's board of directors and any annual or special meeting and have preferential rights in regard to the election of Series B directors. In all other voting matters, the holders of Series B Preferred Stock are entitled to cast 1,000 votes per share.

In July 2018, the Company issued 75 shares of Series B Preferred Stock to our CEO in exchange for $75,000.

Common Stock

The Company is authorized to issue 200,000,000 shares of $0.0001 par value common stock. All common stock shares have equal voting rights, are non-assessable and have one vote per share. Voting rights are not cumulative and, therefore, the holders of more than 50% of the common stock could, if they choose to do so, elect all of the directors of the Company, subject to the rights of the preferred stockholders.

On January 3, 2018, prior to the Share Exchange, the Company issued 5,505,200 shares of common stock (on a post-Share Exchange basis) to four officers, valued at $2,342,813, for the conversion of accrued salaries. The difference of $469,997 between the balance of accrued salaries and the fair value of the shares issued was recorded as a capital contribution recorded within additional paid-in capital. The transaction was viewed as being on behalf of the Company in connection with the pending share exchange transaction.

In July 2018, the Company issued 2,030,000 shares of common stock, to an entity commonly controlled by the $500,000 convertible note holder, in exchange for $203,000.

As of December 31, 2018 and 2017, there were 69,854,141 and 53,281,932 shares of common stock issued and outstanding, respectively.

See Note 8 and 9 for discussion of the conversion of notes payable and accrued interest into common stock.

The Company determined fair value of its shares of common and preferred stock based on the price at which the Company was selling its shares of common and preferred stock to third party investors.

Stock Options

On September 1, 2017, the Company entered into an agreement for consulting services. As compensation the Company granted options to purchase 100,000 shares of common stock at a price of $2.00 per share and are exercisable for five years. The stock option vests in equal monthly installments of 24 months. These options were valued at $20,154 using a Black-Scholes Options Pricing Model. For the years ended December 31, 2018 and 2017, the Company recorded $10,077 and $4,198, respectively, as stock based compensation which is included in the general and administrative expenses in the consolidated statement of operations. The remaining compensation expense outstanding for future periods is $5,878.

The fair value of the options is estimated using a Black-Scholes Options Pricing Model with the following assumptions:

Market value of common stock on issuance date	$ 0.40
Exercise price	$ 2.00
Expected volatility	100%
Expected term (in years)	5
Risk-free interest rate	1.73%
Expected dividend yields	-

NOTE 13 – STOCKHOLDERS' EQUITY (DEFICIENCY) (CONTINUED)

Warrants

The following is a summary of outstanding and exercisable warrants:

	Number of Shares	Weighted Average Exercise Price	Year of Expiration
Balance at December 31, 2016	92,500	1.5	2017
Issued	-	-	-
Expired	(92,500)	1.5	2017
Balance at December 31, 2017	-	-	-
Issued	-	-	-
Expired	-	-	-
Balance at December 31, 2018	-	-	-

The Company did not issue any warrants for the years ended December 31, 2018 and 2017.

NOTE 14 – INCOME TAXES

We file income tax returns in the United States federal jurisdiction and in various state and local jurisdictions. In the normal course of business, we are subject to examination by taxing authorities. The tax years ending 2015 through 2018 remain subject to examination for federal tax purposes and remain subject to examination in significant state tax jurisdictions.

On December 22, 2017, the United States enacted significant changes to the U.S. tax law following the passage and signing of H.R.1, "An Act to Provide for Reconciliation Pursuant to Titles II and V of the Concurrent Resolution on the Budget for Fiscal Year 2018" (the "Tax Act") (previously known as "The Tax Cuts and Jobs Act"). The Tax Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the corporate tax rate from 35% to 21%. The Tax Act reduced the U.S. corporate income tax rate reduction to 21% becomes effective January 1, 2018. The Company re-measured its deferred tax assets and liabilities as of December 31, 2017, applying the reduced corporate income tax rate and recorded a provisional decrease to the deferred tax assets of $787,700, with a corresponding adjustment to the valuation allowance.

As of December 31, 2018 and 2017, the Company had federal and state net operating loss carry forwards of $862,000 and $3,425,000, respectively, that may be offset against future taxable income which will begin to expire in 2032 through 2038.

NOTE 14 – INCOME TAXES (CONTINUED)

The reconciliation of income tax expense computed at the U.S. federal statutory rate to the income tax provision for the years ended December 31, 2018 and 2017 is as follows:

	For the Years ended December 31,	
US	**2018**	**2017**
Income (loss) before income taxes	$ 1,743,043	$ (1,293,255)
Income tax expense (benefit) at statutory rates	366,039	(439,700)
State income taxes, net of federal benefit	48,035	(60,500)
Permanent Differences	10,724	3,300
Change in Federal Rates	-	788,100
Change in Valuation Allowance	387,517	58,800
Other	(331)	-
Income tax expense (benefit)	$ 811,984	$ 350,000

The change in the Company's net increase in the valuation allowance was caused by the change in estimation of NOL utilization.

Deferred income taxes reflect the net tax effects of: (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes; and (b) operating loss and tax credit carry-forwards. We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. Significant components of deferred tax assets as December 31, 2018 and 2017 were as follows:

	For the Years ended December 31,	
	2018	**2017**
Deferred Tax Assets:		
Federal net operating loss carryforwards	$ 181,023	$ 719,400
Capital Losses over Capital Gains	(17,290)	(16,700)
Non-cash interest	29,132	53,200
Non-cash accrued compensation	825,713	788,200
Mark to Market Adjustment - Investments held for sale	240,965	
State taxes	92,298	192,100
Net deferred tax assets before valuation allowance	1,351,841	1,736,200
Valuation Allowance	(1,351,841)	(964,200)
Net Deferred Tax Assets	$ -	$ 772,000

Reconciliation of the statutory federal income tax to the Company's effective tax:

	For the Years ended December 31,	
	2018	**2017**
	%	%
Statutory federal tax rate	21	34
State taxes, net of federal benefit	2.76	4.68
Change in Federal Rates	0	-60.94
Valuation allowance	22.23	-4.55
Other, net	0.6	-0.26
Provision for income taxes	46.59	-27.06

NOTE 14 – INCOME TAXES (CONTINUED)

Utilization of the net operating losses (NOL) carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code (IRC) of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOL carryforwards that can be utilized annually to offset future taxable income. In general, an “ownership change” as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders. At the time of closing the books, the Company had not yet completed a study to determine the extent of the limitation.

NOTE 15 – SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date these consolidated financial statements were issued.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dean Petkanas, certify that:

1. I have reviewed this Report on Form 10-K for Kannalife, Inc.;

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(s) 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(s) 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 9, 2019

/s/ Dean Petkanas
Dean Petkanas
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) AND 15(d)-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Corrao, certify that:

1. I have reviewed this Report on Form 10-K for Kannalife, Inc.;

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(s) 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(s) 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 9, 2019

/s/ Mark Corrao
Mark Corrao
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report of Kannalife, Inc., a Delaware Corporation, (the "Company") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify the following pursuant to Section 18, U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002:

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 9, 2019

/s/ Dean Petkanas
Dean Petkanas
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of Kannalife, Inc., a Delaware Corporation, (the "Company") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certify the following pursuant to Section 18, U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002:

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 9, 2019

/s/ Mark Corrao
Mark Corrao
Chief Financial Officer
(Principal Financial and Accounting Officer)