10-K 1 form10-k.htm

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

FORM 10-K

(Mark One)

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

For the fiscal year ended **June 30, 2019**

OR

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

0-55320
(Commission File Number)

NEXIEN BIOPHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**26-2049376**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4340 East Kentucky Avenue, Suite 206 Glendale, Colorado 80246	**80246**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(303) 495-7583**

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

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

Common Stock, $0.0001 Par Value
(Title of class)

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. [ ] YES [X] NO

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. [X] YES [ ] 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). [X] YES [ ] NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in a 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	[ ]	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 [X] NO

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the

average bid and asked price of the common stock as of December 31, 2018 was $2,826,071.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date: **53,984,004 shares of common stock are outstanding as of September 25, 2019.**

DOCUMENTS INCORPORATED BY REFERENCE

List hereunder the following documents if incorporated by reference and the Part of the Form 10-K into which the document is incorporated: **None**

TABLE OF CONTENTS

Forward-Looking Statements

This annual report contains forward-looking statements or information (collectively "forward-looking statements") that relate to the Company's management's current expectations and views of future events. In some cases, these forward-looking statements can be identified by words or phrases such as "may", "will", "expect", "anticipate", "aim", "estimate", "intend", "plan", "seek", "believe", "potential", "continue", "is/are likely to" or the negative of these terms, or other similar expressions intended to identify forward looking statements. The Company has based these forward-looking statements on its current expectations and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, among other things, statements relating to:

- the Company's expectations regarding its revenue, expenses and operations;
- the Company's anticipated cash needs and its needs for additional financing;
- the Company's intention to grow the business and its operations;
- expectations with respect to future operations costs;
- expectations with respect to the approval of the Company's licenses;
- expectations with respect to the approval of the Company's patent applications;
- expectations with respect to the future growth of its medical cannabis products;
- the Company's competitive position and the regulatory environment in which the Company operates;
- any commentary related to the legalization of medical cannabis and the timing related to such legalization;
- the Company's expected business objectives for the next twelve months;
- the Company's ability to obtain additional funds through the sale of equity or debt commitments; and
- the Company's ability to obtain approval by the FDA and/or from pharmaceutical and other regulatory authorities in other countries and regions.

In addition to statements relating to the matters set out above, this report contains forward-looking statements related to the Company's target operating model. The model speaks to its objectives only, and is not a forecast, projection or prediction of future results of operations. See Item 7 - "*Management's Discussion and Analysis of Financial Condition and Results of Operations* ".

Forward-looking statements are based on certain assumptions and analysis made by the Company in light of its experience and perception of historical trends, current conditions and expected future developments and other factors it believes are appropriate and are subject to risks and uncertainties. Although the Company's management believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect. Given these risks, uncertainties and assumptions, prospective purchasers and current holders of the Company's securities should not place undue reliance on these forward-looking statements. Whether actual results, performance or achievements will conform to the Company's expectations and predictions is subject to a number of known and unknown risks, uncertainties, assumptions and other factors, including those listed under Item 1A - "*Risk Factors.*"

Although the forward-looking statements contained in this report are based upon what the Company's management believes are reasonable assumptions, these risks, uncertainties, assumptions and other factors could cause the Company's actual results, performance, achievements and experience to differ materially from its expectations, future results, performances or achievements expressed or implied by the forward-looking statements.

Further, any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by applicable law, the Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for management to predict all such factors and to assess in advance the impact of each such factor on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement.

Potential investors should read this report with the understanding that the Company's actual future results may be materially different from what it expects.

PART I

ITEM 1. BUSINESS.

In this report, unless the context requires otherwise, references to the "Company", "BioPharma", "we", "us" and "our" are to Nexien BioPharma, Inc., a Delaware corporation, formerly Intiva BioPharma Inc.

Corporate History

The Company was incorporated on November 10, 1952 in Michigan as Gantos, Inc. On July 21, 2008, the Company completed its change in domicile to Delaware and subsequently changed its name to Kinder Holding Corp. Since bankruptcy liquidation in June 2000, the Company has not had any operations and adopted "fresh-start" accounting as of June 21, 2000 in accordance with procedures specified by AICPA Statement of Position No. 90-7, "Financial Reporting by Entities in Reorganization under the Bankruptcy Code."

As of October 13, 2017, the Company completed a reverse acquisition (the "Share Exchange Transaction") of Intiva BioPharma Inc., a private Colorado corporation ("Colorado BioPharma"). In connection with the completion of the reverse merger the Company changed its name to Intiva BioPharma Inc. on November 8, 2017.

Colorado BioPharma was formed under the laws of the State of Colorado in March 2017 as a wholly-owned subsidiary of Kanativa USA Inc. (formerly Intiva USA Inc.) engaged in the business of developing drugs containing cannabinoids for the treatment of various diseases, disorders and medical conditions; the development or licensing of proprietary delivery systems for cannabinoid-based[1] pharmaceutical medications; and the investment in companies and the acquisition of technologies or medications, focused on cannabinoid-based science through special purpose vehicles, discussed more fully below. Kanativa USA Inc. is a wholly-owned subsidiary of Kanativa Inc., formerly Intiva Inc., an Ontario, Canada corporation.

The Company changed its name to Nexien BioPharma, Inc. in September 2018.

On October 26, 2018, we entered into a Limited Liability Company Interest Purchase Agreement (the "Purchase Agreement") with the members of CRx Bio Holdings LLC, a Delaware limited liability company ("CRx"), to acquire all of the membership interest in CRx in exchange for 11,000,000 restricted shares of our common stock (the "Acquisition"). CRx is engaged in the research and development of advanced cannabinoid formulations and drug delivery systems with a focus on bioavailability and related pharmacokinetics and pharmacodynamics (PK/PD) optimization. The Acquisition transaction was consummated on October 26, 2018. By acquiring CRx as a wholly-owned subsidiary, we acquired all of its assets, which consist primarily of three U.S. provisional patent applications relating to cannabinoid formulations to treat convulsive disorders, chronic traumatic encephalopathy, and neuropathic pain. At the closing, we issued to the six members of CRx (the "Sellers") 1,100,000 shares not subject to any forfeiture restrictions and 9,900,000 shares which shall be released from forfeiture restrictions according to the following vesting schedule:

- 30% shall be fully vested 12 months following the Closing (October 26, 2019);
- 30% shall be fully vested 24 months following the Closing (October 26, 2020); and
- 30% shall be fully vested 36 months following the Closing (October 26, 2021).

Any Seller who is not then providing services to us or any of our subsidiaries on any vesting date, whether through voluntary termination or termination "for cause," will forfeit his unvested shares, which will be cancelled.

[1] A cannabinoid is one of a class of diverse chemical compounds that acts on cannabinoid receptors in cells that alter neurotransmitter release in the brain. Ligands for these receptor proteins include the endocannabinoids (produced naturally in the body by animals), the phytocannabinoids (found in cannabis and some other plants), and synthetic cannabinoids (manufactured artificially). The most notable cannabinoid is the phytocannabinoid tetrahydrocannabinol (THC), the primary psychoactive compound in cannabis. Cannabidiol (CBD) is another major constituent of the plant. There are at least 113 different cannabinoids isolated from cannabis, exhibiting varied effects.

Effective December 31, 2018, one of the sellers resigned from the Company and forfeited 1,732,500 unvested shares previously issued. In May 2019, that seller returned to the Company an additional 142,500 vested shares issued in accordance with the Purchase Agreement. The fair value of the returned shares was credited to the operations as of June 30, 2019.

Immediately after closing, Alex Wasyl, the CEO of CRx, was elected to serve as a director and our CEO. Alain Bankier, who had been serving as our interim CEO, was elected to serve as our Executive Chairman of the Board of Directors and Chief Strategy Officer. Richard Greenberg resigned his position as Chairman of the Board, but continues to serve on the Board. As of April 1, 2019, Mr. Bankier resigned as an officer and director of the Company.

Business Plan

The Company's business objective is to develop and commercialize novel FDA-compliant cannabinoid pharmaceuticals, drug delivery systems, and related technologies for diseases, disorders and medical conditions. The Company is utilizing cannabinoids as the active pharmaceutical ingredients to develop synthetic pharmaceuticals in strict accordance with the U.S. Food and Drug Administration ("FDA") pre-clinical and clinical pathways.

The Company's current flagship research and development programs are focused on advancing formulations that have the potential to significantly improve the treatment outcomes of certain convulsive disorders and neuromuscular disorders. Subject to obtaining the necessary funding, the Company proposes to collaborate on pre-clinical research addressing convulsive disorders with a leading Ivy League medical school.

Our Objectives and Business Strategy

The Company has developed a three-pronged growth strategy:

1) Drug development – Developing, licensing and commercializing cannabinoid-based pharmaceuticals for specific medical conditions and disorders, which will be undertaken in accordance with FDA or comparable development pathways in other countries. Any medications the Company develops will be physician-prescribed.

2) Drug delivery system development – Developing and licensing proprietary delivery systems for cannabinoid medications, which would include parenteral (i.e., taken into the body in a manner other than through the digestive canal) formulations, as well as advanced tablet (oral and sublingual) technology.

3) Investment – Investing in companies and the acquisition of technologies, or medications, focused on cannabinoid-based research, through special purpose vehicles controlled by the Company.

Our drug development strategy incorporates the following general steps:

- determination of diseases, disorders and medical conditions that could potentially benefit from cannabinoid-based drugs;
- conducting and assessing the technology landscape of potentially new therapeutic drugs along with "freedom to operate" investigations on these conditions;
- preparation and submission of patent applications world-wide and securing such applications and/or the licensing of existing patents;
- identifying the regulatory pathway with the FDA; and
- proceeding with pre-clinical studies and clinical trials under FDA protocols for submission and obtaining approval for the particular drug development project(s).

We operate in a highly-controlled regulatory environment with strict regulations and established requirements by the FDA and drug regulatory agencies in other countries and jurisdictions, relating to analytical, toxicological and clinical standards and protocols with respect to the research and development of pharmaceuticals. Regulations specifically cover research, development, manufacturing and reporting procedures, both pre- and post-approval.

Governmental authorities in many countries require that a new pharmaceutical product be approved or exempted from approval before any such pharmaceutical product can be marketed. The time to obtain approval varies by country and some pharmaceutical drugs may fail in pre-clinical or clinical trials and therefore may never be approved. The approval process is typically a lengthy process that requires conducting pre-clinical studies and clinical trials to seek and then hopefully receive regulatory approval, in compliance with applicable statutes and regulations and the expenditure of substantial capital resources.

The steps required to obtain approval and the commercialization of a new drug in the United States are lengthy, complex and expensive, and the outcome is far from certain. These steps generally include:

- completion of formulation studies, preclinical studies, and animal studies and in compliance with the FDA's good laboratory protocols;
- submission to the FDA of an Investigational New Drug Application ("IND") to support animal and/or human clinical testing in the United States;
- approval by an Institutional Review Board ("IRB") before each trial may be initiated;
- performance of controlled clinical trials in accordance with FDA regulations and with current good clinical practice ("GCP") to establish the safety and efficacy of the drug candidate for each target indication;
- submission of an application for New Chemical Entity ("NCE") or New Drug Application, ("NDA"), to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the drug will be produced to assess compliance with current good manufacturing practices ("GMP"), and to assure that the facilities, methods and controls are adequate; and
- FDA review and approval of the NCE or NDA, as applicable.

If a drug, such as those contemplated by the Company, contains a Controlled Substance and is categorized in Schedule I, II, or III under the U.S. *Federal Controlled Substances Act of 1970* , it will likely require scheduling by the Drug Enforcement Agency ("DEA") prior to any potential commercialization, which may never be achieved. This step may be required for drugs containing plant-derived cannabinoids, as well as synthetic cannabinoids.

The Company may establish a separate subsidiary for each of its drug development projects in order to provide additional flexibility regarding financing. Given the significant cost of drug development, the Company anticipates that it will need substantial additional financing and there can be no assurance that additional financing will be available with terms and conditions satisfactory to the Company, if at all. Nevertheless, the Company believes that this corporate structure could provide the potential alternatives of either being able to finance its drug development activities at the parent level, or by potentially involving financial and/or strategic partners interested in a specific drug development direction, at the specific subsidiary level. In any of these situations, the Company's ability to proceed with its drug development activities would be dependent upon its being able to obtain the requisite financing on terms that are acceptable to the Company, of which there can be no assurance. Nor can there be assurance that the Company will be able to obtain requisite financing in a timely manner.

Our Drug Development Activities

Due to the significant amount of financing needed to develop and commercialize a new drug and the Company's limited resources, it is focusing its efforts on advancing formulations that have the potential to significantly improve the treatment of epilepsy and myotonic dystrophy.

Convulsive Disorders: Epilepsy and Refractory Epilepsy

Epilepsy is a neurological disorder marked by sudden recurrent episodes of sensory disturbance, loss of consciousness, or convulsions, associated with abnormal electrical activity in the brain. It is caused by an imbalance in inhibitory and excitatory neurotransmission resulting in synchronous neural activity. Refractory epilepsy occurs when standard of care medicine is not bringing seizures under control. This condition, which may be called by other names, such as uncontrolled, intractable, or drug-resistant epilepsy, is not age specific. Up to one of every three epilepsy patients will develop what is considered refractory epilepsy.

Our near-term objective is to secure adequate funding to engage in sponsored research collaboration with a leading Ivy League university medical school in order to develop a pre-clinical proof of concept for the Company's proposed parenteral-delivered formulations. CRx had entered into discussions and subsequently, into a Master Service Agreement (MSA) with the medical school prior to its acquisition by the Company. The study design involves pre-clinical mouse models in two phases: I – MTD and PK/PD modeling, and II – efficacy modeling in mice bred to be genetically prone to convulsions/seizures, with a primary focus of advancing a rigorous study design and improving new meritorious research and development by continued collaboration with our academic partners.

Myotonic Dystrophy

Myotonic dystrophy ("DM") is part of a group of genetic disorders called muscular dystrophies, and is the most common form of muscular dystrophy that begins in adulthood. DM is characterized by progressive muscle wasting and weakness. People with this disorder often have prolonged muscle contractions (myotonia) and are not able to relax certain muscles after use. Also, affected people may have slurred speech or temporary locking of their jaw. Signs and symptoms overlap between DM Type 1 ("DM1") and Type 2 ("DM2"), although DM2 tends to be milder than DM1. The muscle weakness associated with DM1 particularly affects the lower legs, hands, neck and face, while muscle weakness in DM2 primarily involves the muscles of the neck, shoulders, elbows, and hips. The two types of DM are caused by mutations in different genes.

The use of cannabinoid receptor modulators and/or terpenes for clinical symptom relief in DM patients has not been explored. Current scientific knowledge of the effects of cannabis on skeletal muscles or other multiple system symptoms in DM is rather limited. However, some anecdotal reports suggest that cannabis may be supportive in relief of the most common symptoms in both DM1 and DM2. Unfortunately, currently there is no standard treatment for these symptoms.

In February 2017, a provisional U.S. patent application was filed relating to the use of cannabinoid receptor modulators and/or terpenes to treat myotonic and muscular diseases such as dystrophia diseases (the "Sharir Development Project"). Our patent application relates to methods and compositions for treating such diseases with the use of cannabinoids and covers the administration of the drug(s) by such delivery systems as topical, oral, nasal, inhalation or a combination thereof. On February 19, 2018, a regular utility (non-provisional) U.S. Patent Application was filed relating to the use of cannabinoids and/or terpenes to treat dystrophies and myotonia. The application has been assigned U.S. Patent Application No. 15/899,160.

In April 2018, the Company retained Dr. Benedikt Schoser, a world-renowned expert in DM, to advise the Company. To elicit further information regarding whether DM patients have had any experience with cannabis and if so whether such experience has resulted in any symptom relief, a questionnaire was sent to a number of DM 1 and DM 2 patients by patient organizations. The results of the questionnaire suggest further exploration is appropriate. The survey was published in the Journal of Neurology, Neurosurgery & Psychiatry.

Shortly thereafter, a preliminary proof of concept examination under the guidance of Dr. Schoser was conducted with a preliminary formulation to obtain further insights. The results reflected that cannabis may be supportive in relief of DM symptoms and based upon the proof of concept examination and the survey, we will be conducting clinical studies. On August 13, 2019 we filed a pre-IND meeting request (the "Request") to discuss the requirements for submission of an Investigation New Drug Application for a combination of Cannabidiol and THC Sublingual Tablet for muscle relaxation in patients with myotonic dystrophy and for the treatment of myotonia. On August 16, 2019 we received a response from the FDA where they stated that we should be receiving a written response regarding the Request on or about the middle of October 2019.

The FDA pathway for the development of drugs for certain of these genetic muscular diseases may fall under the *Orphan Drug Act of 1983*, which was passed by the U.S. Congress to facilitate the development of 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. Such an orphan drug designation may entitle a recipient 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. See risk factor "*We may apply for orphan drug status granted by the FDA for some of our drug candidates for the treatment of rare diseases*" below.

An additional utility patent application (US16/435,756) was filed as a continuation-in-part on June 10, 2019 to incorporate some early formulation concepts that may show use in the relief of these DM symptoms. A corresponding application has been filed at the European Patent Office (EP19179559.0)

Potential Future Development Projects

We have also filed utility patent applications related to researching and developing cannabinoid-based formulations and/terpenes for the treatment of lipidosis and leukodystrophy, and lipofuscinosis, an international patent application for restless legs syndrome and a utility patent application for sexual health issues. Reference is made to the table under the heading "*Patents, Intellectual Property and Proprietary Rights*" below.

The Organophosphorus Exposure Development Project

In March 2017, we entered into a license agreement with Kotzker Consulting, LLC (the "Kotzker License Agreement"), an entity founded, and related to certain intellectual property developed, by Pennsylvania-based Dr. Joseph Morgan. The intellectual property includes patent applications relating to the use of cannabinoid receptor modulators and/or terpenes in acute treatment situations during exposure to organophosphorus nerve agents and/or organophosphorus insecticides (the "Kotzker Development Project"). The Company's patent counsel assumed responsibilities for the Kotzker Development Project patent applications, and has continued efforts to obtain patent protection on the invention. In furtherance of these efforts, a continuation application was filed in July 2018 and the Company is awaiting a response from the United States Patent and Trademark Office (USPTO).

Organophosphorus nerve agents are highly poisonous chemicals that work by preventing the nervous system from working properly and include tabun (Agent GA), sarin (Agent GB), soman (Agent GD), and Agent VX. Nerve agents and other organophosphate pesticides cause acetylcholinesterase inhibition, resulting in signs and symptoms such as pinpoint pupils, eye pain, sweating, drooling, tearing, vomiting, and seizure, also known as Pesticide Syndrome. Organophosphorus insecticides are chemicals used to kill many types of insects. These chemicals account for a large share of all insecticides used in the United States, including those used on food crops. Most home uses of organophosphorus insecticides have been phased out in the United States. Certain organophosphorus insecticides (e.g., malathion and naled) are also used for mosquito control in the United States.

We believe that a cannabinoid-based drug could be beneficial to treat the symptoms caused by organophosphorus nerve agents and we are hopeful that the regulatory pathway to treat the condition will be as expeditious as possible based upon the potential threat posed by the use of organophosphorus nerve agents by terrorists and countries.

On July 31, 2017, we submitted a pre-IND meeting package to the FDA to request comments on our proposed development plans. We received written responses from the FDA dated September 29, 2017, to questions that we raised in the pre-IND meeting request. In its response, the FDA presented pathway alternatives to progress our research and development plan and provided responses to a number of our questions. We are presently evaluating the responses as we seek to move our development plan forward.

On September 19, 2017, we entered into an agreement with a contract manufacturer with expertise in formulation and development for our drug candidate in the Kotzker Development Project with the objective of eventually applying for FDA approval. The contract manufacturer has been conducting formulation work with cannabidiol, Dronabinol and a placebo. In 2018, the contract manufacturer obtained a Schedule I license and quota for both CBD and THC to enable it to formulate product utilizing active pharmaceutical ingredients which it was able to obtain from companies experienced with FDA documentation requirements for active ingredients. Assuming the contract manufacturer is able to complete the formulation, pre-clinical studies will be performed, in accordance with applicable requirements, to determine if the formulation is safe and can be adequately characterized from the perspective of absorption, distribution, metabolism and excretion. Presuming the animal studies exhibit the appropriate safety profile, the Company will then make the appropriate submission to the FDA to seek approvals to conduct clinical studies under an Investigational New Drug exemption. The Company intends to meet with FDA before it conducts the clinical studies. Assuming the clinical studies meet the clinical endpoints, the Company will manufacture commercial lots, place three commercial size lots on stability and file a 505(b)(2) NDA. The Company estimates that the time from formulation completion to obtaining the approval for a product for the use and treatment immediately following exposure to organophosphorus and nerve agents would be approximately three to five years. The formulation of this drug candidate may be based on a synthetic cannabinoid, including Marinol or Dronabinol, or a synthetic CBD or a combination thereof and a blend of terpenes. We paid $75,000 to the contract manufacturer upon signing the contract, which requires us to pay an additional $20,000 upon completion of the drug formulation and $20,000 upon completion of Phase 1 development. No payment schedule has yet been agreed to upon completion of our Phase 2 and Phase 3 development stage and the contract may be terminated by either party.

Because of the implications of a nerve agent drug candidate for homeland defense, first responders and military applications, we may also seek government grants for funding the pre-clinical studies or clinical trials for this drug candidate. The Company has not investigated the existence or availability of any such grants, and there can be given no assurance that the Company will be able to obtain such grants, if available.

Rights and Obligations under the Kotzker License Agreement

Pursuant to the terms of the Kotzker License Agreement, the Company has agreed to devote reasonable and practicable business efforts to develop and commercialize the Licensed Products (defined to mean any and all doses, strengths, formulations, compositions and methods thereof containing cannabinoids alone or in combination with various other active pharmaceutical ingredients and/or excipients). The Company will be responsible for the costs and efforts associated with the design, manufacturing, preclinical, clinical, and regulatory development activities of the Licensed Products world-wide.

In addition, the Company shall be responsible, and shall have sole decision-making authority, for the preparation, filing, prosecution and maintenance of all patent applications, patents pending, and patents included within the licensed patents (collectively, the "Patents"). In the event the Company determines to cease the preparation, filing, prosecution and/or maintenance of any Patents, then Kotzker Consulting shall have the right to assume responsibility for such preparation, filing, prosecution and maintenance of any such Patents. Prior to abandoning any Patent, the Company is required to provide Kotzker an adequate opportunity to assume such Patent prosecution at its own expense before the Patent application is deemed abandoned under applicable rules of the USPTO.

Commencing with the first commercial sale in any country worldwide of any Licensed Product by the Company or any of its affiliates or sublicensees, the Company shall pay to Kotzker Consulting royalties for Licensed Products sold until the later to occur of: (i) the expiration date of the last to expire of the Licensed Patents; or (ii) when a competitive generic product utilizing the Licensed Technology is marketed in a particular country. The royalties shall be equal to 3% of the Company's net sales of Licensed Products or 10% of the total revenue received by the Company for sales of Licensed Products by sublicensees.

In addition to the royalty payments as described above, and as consideration for entering into the agreement, the Company agreed to: (i) pay Kotzker Consulting $180,000, (ii) pay patent prosecution costs incurred as of the date of the agreement of $15,000 and (iii) issue to Kotzker Consulting 31,550 shares of Kanativa Inc.'s common stock valued at $78,875 ($2.50 per share based on a contemporaneous private placement to third parties of Kanativa Inc.'s common stock).

The agreement also provides that development milestone payments will be paid by the Company to Kotzker Consulting as follows:

A. for the use of the Licensed Products as a preventative and therapeutic neuroprotective against nerve agents and pesticides, the Company shall make a onetime payment of $500,000; and

B. for the use of the Licensed Products in the treatment of diseases, the Company shall make a one-time payment of $500,000.

Upon approval of the first Licensed Product, Kotzker Consulting shall be issued US$180,000 value of the Company's Common Stock based upon the share price determined at the most recent private placement price per share with an unrelated third party, or if the Company's shares are publicly traded, the average closing price for the previous 30 days (the "Stock Consideration").

If the parties determine that the development of the Licensed Product is unfeasible, as demonstrated by the failure to develop a formulation or to establish a satisfactory regulatory pathway or a determination that the formulation to be marketed may not be economically viable, but the Company elects to acquire an interest in the Licensed Patents, in consideration for the Company continuing to pay the cost of prosecuting the Licensed Patents and the issuance to Kotzker Consulting of the Stock Consideration referenced above, Kotzker Consulting and the Company shall, at the time the Company elects to no longer seek to develop the Product, agree that the Company shall acquire a 25% interest in the Licensed Patents, provided that the Company has paid Kotzker Consulting $180,000.

If either party shall fail to faithfully perform any of its obligations under this Agreement, the non-defaulting party may give written notice of the default to the defaulting party. Unless such default is corrected within 60 days after such notice, the notifying party may terminate the Agreement upon 30 days prior written notice; *provided, however,* in the event that prior to the expiration of any such 60-day period, such breaching party has in good faith commenced to use commercially reasonable efforts to remedy such breach and the completion of such remedy, due to reasons beyond the control of such breaching party, requires more than 60 days to complete, then such 60-day period shall be extended for so long as such breaching party is continuing in good faith to use commercially reasonable efforts to remedy such breach.

To date, the Company has paid Kotzker Consulting $180,000 and Kanativa Inc. has issued Kotzker Consulting 31,550 shares of Kanativa Inc. common stock as additional consideration valued at $78,875 on the date of issuance. Due to the Company's current limited financial and personnel resources, the Company has estimated that it may not be able to recover the carrying value of costs capitalized under the Kotzker License Agreement in the near term, and has recognized an impairment of $302,915 for the year ended June 30, 2019. This accounting action does not affect the Company's rights under the license agreement or its intention to monetize this asset when its resources permit.

The Lipidosis Development Project

In June 2018, we filed a utility U.S. patent application that claims the benefits of a provisional patent application that was filed in June of 2017 for methods and compositions to treat lipidoses and leukodystrophy, with cannabinoids and/or terpenes (the "Lipidosis Development Project"). The patent application methods involve the administration of a drug comprising of one or more cannabinoids and/or terpenes. Lipidosis is a term used to describe various lysosomal stage diseases in which there is abnormal accumulations of lipids in the reticuloendothelial cells. Leukodystrophy is generally classified as a disturbance of the white matter of the brain, particularly defects in the formation and maintenance of the white matter or myelin and includes a number of diseases that may also be included in the lipidoses classification. When the body is unable to properly digest fats, lipids accumulate in body tissues in abnormal amounts.

Potential diseases and medical conditions for our lipidoses and leukodystrophy drug candidate include:

- Gaucher's Disease
- Neimann-Pick Disease
- Fabry's Disease
- Wolman's Disease
- van Bogaert's Disease
- Generalized (GM1) Ganliosidosis
- Tay-Sachs Disease
- Sulfatide Lipidosis
- Krabbe's Disease
- Canavan Disease
- Adrenoleukosdystrophy
- Alexander Disease
- Pelizaeus-Merzbacher Disease
- Salle Disease

There is great variance in the symptoms, available treatments, and long-term consequences of these conditions. There are many different symptoms that accompany these disorders, some of which include chronic pain, in the palms, soles and abdomen, edema of the legs, osteoporosis, resulting in rigidity that leads to tonic seizures and convulsions. Some of these disorders can be controlled with changes in diet, medications, or enzyme supplements. However, for many of these diseases, no treatment is available. Some may cause death in childhood or contribute to a shortened life expectancy.

Leukodystrophy is very rare. The number of people affected depends on the specific disease, but for the cumulative diseases incidence is approximately one in 7,000 people. Some of these diseases have a higher prevalence in specific populations. Many are pediatric diseases or have a pediatric form.

The FDA pathway for the development of drugs as part of our Lipidosis Development Project falls under the *Orphan Drug Act of 1983*, which was passed to facilitate the development of 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. In the United States, orphan drug designation entitles a grant recipient of financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. See risk factor "*We may apply for orphan drug status granted by the FDA for some of our drug candidates for the treatment of rare diseases*" below.

The Lipofuscinosis Development Project

In June 2018, we filed a utility U.S. patent application that claims the benefit of a provisional patent application that was filed in June of 2017 for the method and compositions for treating Lipofuscinosis with cannabinoids and/or terpenes (the "Lipofucinosis Development Project").

Lipofuscinosis is any disorder associated with the abnormal storage of lipofuscins. Lipofuscins is a yellow to brownish pigment granule found in the muscle, heart, liver, kidney, adrenal, retina and nerve cells undergoing slow regressive changes and accumulating in lysomes with age. Lipofuscin is the product of oxidation and polymerization of the membrane lipids of autophagocytosed organelles.

Lipofuscin accumulation is believed to be a major risk factor in macular degeneration and Stargardt disease, which is an inherited juvenile form of macular degeneration. Abnormal accumulation of lipofuscin in the nerve cells can result in neurodegenerative disorders, referred to as neuronal ceroid lipofuscinoses ("NCLs"). NCLs collectively are often referred to as Batten disease.

The FDA pathway for the development of drugs as part of our Lipofucinosis Development Project falls under the *Orphan Drug Act of 1983*, which was passed to facilitate the development of 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. In the United States, orphan drug designation entitles a grant recipient of financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. See risk factor *"We may apply for orphan drug status granted by the FDA for some of our drug candidates for the treatment of rare diseases"* below.

The Restless Legs Syndrome Development Project

In June 2018, we filed under the International Patent Treaty an international patent application that claims the benefit of a provisional patent application that was filed in June of 2017 for methods and compositions to treat restless legs syndrome ("RLS") with cannabinoids and/or terpenes. RLS, also known as Willis-Ekbom Disease and Wittmaack-Ekbom Syndrome, is a term used to describe a neurological sensory disorder that also interferes with sleep and is thus also considered a sleep disorder.

The symptoms of RLS include the compelling, irresistible, or uncontrollable urge to move, restlessness, and abnormal, unpleasant, or uncomfortable sensations in the limbs or the skin of the feet, legs, arms, or elsewhere which includes pain, aching, throbbing, pulling, itching, crawling, creeping, burning, jerking, fidgety, antsy, electrical, pins and needles, buzzing, and twitching. The movements may be persistent, repetitive, periodic, or intermittent with symptoms.

The Sexual Health Development Project

In June 2018, we filed a utility patent application that claims the benefits of a provisional U.S. patent application that was filed in June of 2017 for method and compositions to treat sexual dysfunctions with cannabinoids and/or terpenes.

Sexual dysfunction may be the result of organic issues, psychological issues or a combination of both. Examples of organic issues include vascular diseases, such as those associated with hypertension or diabetes mellitus, prescription medication, and/or by psychiatric disease such as depression. Examples of psychological factors include fear, performance anxiety and interpersonal conflict. Sexual health issues and sexual dysfunction issues in particular may impair sexual performance, diminish self-esteem and disrupt personal relationships thereby inducing personal distress.

Our Drug Delivery System Development Activities

Accu-Break License Agreement

On February 28, 2018, we obtained a worldwide exclusive license from Accu-Break Pharmaceuticals, Inc., a Florida corporation ("Accu-Break") with respect to a proprietary delivery system for cannabinoid-based medications. We are required to use commercially reasonable efforts to develop and commercialize one or more products utilizing the licensed technology and will be responsible for the costs and efforts associated with the design, manufacturing, preclinical, clinical, and regulatory development activities of these licensed products worldwide.

Commencing with the first commercial sale in any country worldwide of any licensed product by the Company or any of its affiliates or sublicensees, the Company shall pay to Accu-Break royalties for licensed products sold, equal to 4% of the Company's net sales of licensed products or 25% of the total revenue received by the Company for sales of licensed products by sublicensees. Such royalties shall continue so long as the manufacture, use, sale, import or offer for sale of the licensed product infringes a valid claim of Accu-Break's licensed technology.

In addition to the royalty payments described above, and as consideration for entering into the agreement, the Company agreed to pay Accu-Break a license fee of $100,000, of which $35,000 was paid upon execution of the agreement, $10,000 in November 2018 and $20,000 in February 2019. The remaining $35,000 payment originally due February 28, 2019 was extended to August 31, 2019 and has been paid in shares of Common Stock of the Company.

The Company is also required to pay in cash or, at its option in shares of its Common Stock, milestone payments as follows:

- $100,000 upon approval of filing by each regulatory authority of each pharmaceutical licensed product;
- $100,000 upon approval by each regulatory authority of each pharmaceutical licensed product;
- $50,000 upon achievement of $10,000,000 of cumulative net sales for any and all of the licensed products;
- $50,000 upon achievement of $25,000,000 of cumulative net sales for any and all of the licensed products; and
- $50,000 upon achievement of $50,000,000 of cumulative net sales for any and all of the licensed products.

The license fee and milestone payments shall be offset against any amounts due to Accu-Break for royalties and sublicensee payments.

The license granted to the Company shall continue on a country by country basis and licensed product by licensed product basis so long as the manufacture, use, sale, import or offer for sale of such licensed product infringes a valid claim of any of Accu-Break's licensed technology. Upon such expiration, the license, with respect to such country and such licensed product, will be automatically converted to a fully paid-up royalty-free perpetual license.

The license may be terminated by Accu-Break only for the Company's default under the Agreement, which default shall not have been corrected within 60 days of having received notice of such default.

Due to the Company's current limited financial and personnel resources, the Company has estimated that it may not be able to recover the carrying value of costs capitalized under the Accu-Break license agreement in the near term, and has recognized an impairment of $65,000 for the year ended June 30, 2019. This accounting action does not affect the Company's rights under the license agreement or its intention to monetize this asset when its resources permit.

Market Opportunities for Our Drug Development Projects

Many pharmaceutical and biotechnology companies are seeking to capitalize on the anticipated growth in the pharmaceutical market for cannabinoid-based drugs by realizing and leveraging the growing set of data on the therapeutic effects of cannabis and cannabinoids. We believe that the potential applications for cannabinoids go beyond the three cannabinoid-based drugs derived from isolated synthetics: Marinol, Syndros and Casamet that have been approved by the FDA. We also believe that additional potential therapeutic value of cannabinoid-based drugs lies in the treatment of certain neurological disorders, as indicated by our drug development projects.

It is likely that the pharmaceutical market for cannabinoid-based drugs will eventually be classified as part of the specialty pharmaceutical market, the fastest growing segment of the overall pharmaceutical market. The increasing diagnoses of certain chronic diseases have resulted in the increased need for specialty drugs. According to an April 2014 report published by the United Health Care Group, "*The Growth of Specialty Pharmacy*," spending on drug development projects in the specialty pharmaceutical market in the U.S. in 2012 approximated $87 billion, and is estimated to reach $400 billion by 2020.

Cannabinoids have a diverse pharmacology and therefore could provide significant potential for therapeutic applications across many diseases, disorders and medical conditions in areas that define specialty pharmaceutical drugs. We believe that a conservative estimate on spending on drug development projects in the cannabinoid-based pharmaceutical market sector could represent 5% of the overall specialty pharmaceutical market by the year 2020, which would suggest a market size of around $20 billion. According to Statista, an online statistic, market research and business intelligence portal that provides access to data from market and opinion research institutions, the U.S. market for cannabinoid-based pharmaceuticals will increase to $50 billion by 2029. We believe these estimates are reasonable given the significant amounts of capital that have been allocated for the development of cannabinoid-derived pharmaceuticals by numerous companies in the U.S. and globally, with the objective of obtaining regulatory approval by the FDA and other international regulatory authorities.

Researchers have discovered approximately 111 cannabinoids, chemical compounds unique to the cannabis plant. The most common are cannabidiol ("CBD"), cannabinol ("CBN") and tetrahydrocannabinol ("THC"). CBN and THC interact with CB1 and CB2 receptors, which are located throughout the human body. CB1 receptors are primarily located in the brain and central nervous system. CB2 receptors are located throughout the body including the gastrointestinal and urinary tracts that are responsible for regulating neurotransmission. The CB1 and CB2 receptors help control bodily reactions such as inflammation and pain, which are areas are of great therapeutic interest with respect to drug development. Identifying cannabinoid receptors and the compounds that interact with them has helped accelerate clinical investigations of cannabinoid-based drugs. To date, due to the challenges of researching plant-derived cannabinoids in the United States, most U.S. research has been conducted utilizing synthetically produced cannabinoids, which as chemical compounds, are chemically identical to plant-derived cannabinoids.

We believe cannabinoid-based drugs may provide a superior treatment model for patients suffering from certain diseases, disorders and medical conditions. Due to FDA and DEA restrictions, most companies involved in research and development of cannabinoid therapeutic applications currently use synthetics. These cannabinoid-based drug candidates typically, use CBD and THC, or a combination thereof, as their active ingredient(s). At present, there are two synthetic "THC" cannabinoids available, dronabinol and nabilone. Both have been approved in the U.S. for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have not responded adequately to conventional antiemetic treatments. Dronabinol capsules were also approved for treatment of anorexia associated with weight loss in patients with acquired immune deficiency syndrome, or AIDS. They are also often prescribed for pain control, as alternatives to opioids.

We believe that there will be rising demand for cannabinoid-derived drugs and that future growth is likely to be driven by favorable changes in legislation and demographic factors. Controlled substance laws differ between countries and legislation in certain countries may restrict or limit our ability to distribute or sell our drugs. We believe that the U.S. will represent a major market for our cannabinoid-based drug candidates. In the European Community, medical cannabis program regulatory frameworks exist in countries, including the Netherlands, Italy, Germany, Finland and the Czech Republic. It is also anticipated that there will be policy changes in many member countries of the European Union regarding the medical use of cannabis and cannabinoid-derived drugs.

Patents, Intellectual Property and Proprietary Rights

Our current patent applications are related to our drug development projects and their respective drug candidates. We intend to seek patent protection in the U.S. and other countries as appropriate, related to methods and compositions and proprietary technologies for the use of cannabinoids receptor modulators and/or terpenes to treat certain diseases, disorders and medical conditions.

To date, we have filed four utility patent applications that claim the benefit of provisional patent applications that were filed with the USPTO and one international patent application under the Patent Cooperation Treaty, all related to our drug development projects, specifically the use of cannabinoid receptor modulators and/or terpenes to treat certain diseases or medical conditions. Assuming the successful completion of clinical trials, of which there can be no assurance, we believe that we will be able to secure patent protection and retain applicable intellectual property rights.

The table below depicts the Company's patent applications:

Description of the Patent Application filed With USPTO	Filing Date
Method and Compositions for Treating Dystrophies and Myotonia	February 19, 2018
Method and Compositions for Treating Lipidosis and Leukodystrophy	June 15, 2018
Method and Compositions for Treating Lipofuscinosis	June 15, 2018
Method and Compositions for Sexual Health	June 29, 2018

Description of the International Patent Application Under the Patent Cooperation Treaty	Filing Date
Method and Compositions for Treating Restless Legs Syndrome	June 20, 2018

In addition, on June 5, 2015, a U.S. Patent Application was filed relating to the use of cannabinoid receptor modulators and/or terpenes to treat extreme health hazards due to exposure to organophosphorus nerve agents and/or organophosphorus insecticides.

As our research progresses, it is likely that we will file additional patent applications in conjunction with research related to our current drug development research projects including the Kotzker, Sharir, Lipidosis, Lipofucinosis, Restless Legs Syndrome, and Sexual Health Development Projects. We also plan to seek patent protection in the U.S. and other countries world-wide for future drug development projects and potentially technologies related to increased bioavailability and drug delivery technologies.

Our policy is to seek patent protection for the technology, inventions and improvements that we consider important to the development of our business, but only in those cases where we believe that the costs of obtaining patent protection is justified by the commercial potential of the drug candidate and/or proprietary technologies, and typically only in those jurisdictions that we believe present significant commercial opportunities. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our drug candidates, and successfully defending these patents against third-party challenges. Our ability to protect our drug candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

For each of our drug development projects, our decision to seek patent protection in specific foreign markets, in addition to the U.S., is based on many factors, including:

- our available resources;
- the number and types of patents already filed or pending;
- the likelihood of success of the drug candidate;
- the size of the commercial market;
- the presence of a potential competitor in the market; and
- whether the legal authorities in the market effectively enforce patent rights.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. In addition, there is no assurance as to the degree and range of protections any of our future patents, if issued, may afford us or whether patents will be issued. Patents which may be issued to us may be subjected to further governmental review that may ultimately result in the reduction of their scope of protection, and pending patent applications may have their requested breadth of protection significantly limited before being issued, if issued at all.

Competition

The emerging markets for cannabinoid-based drug research and development is and will likely remain competitive. In general, the biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary drugs.

We expect that we will be required to compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as drugs and processes being developed at universities and other research institutions. Our competitors may develop or may already have developed drugs comparable or competitive with our drug candidates. Competitive therapeutic treatments for diseases, disorders and medical conditions that are included in our drug development projects have already been approved and accepted by the medical community and any new treatments that may enter the market would face fierce competition.

We are aware of a number of companies that are engaged in cannabinoid-based drug development. In addition, several other U.S.-based companies are in early stage discovery and preclinical development utilizing synthetic and/or plant-derived CBD and/or THC.

Established companies may have a competitive advantage due to their size and experiences, positive cash flows and institutional networks. Many of our competitors may have significantly greater financial, technical and human resources than we do. Due to these factors, our competitors may have a range of competitive advantages and may obtain regulatory approval of their drug candidates before we are able to develop or commercialize our drug candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours. Furthermore, some of these competitors may make acquisitions or establish collaborative relationships among themselves or with third parties to increase their ability to rapidly gain market share and/or increase their drug line.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of competitors. Smaller and other early-stage companies, such as ours, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We compete with large and small companies 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 our research projects.

Government Laws and Regulations

As a development stage company that intends to have its drug candidates approved in the U.S., we are subject to extensive regulation by regulatory agencies. The U.S. *Food, Drug, and Cosmetic Act* and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our drugs. Generally, our activities in other countries will be subject to regulations that are similar in nature and scope as those in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union are addressed in a centralized way through the European Medicines Agency ("EMA") and the European Commission, but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be successful.

The US Regulatory Framework for the Marijuana Industry

On January 4, 2018, United States Attorney General Jeff Sessions and the Department of Justice ("DOJ") issued a Memorandum for all United States Attorneys entitled "Marijuana Enforcement" (the "Sessions Memo"). The effect of the Sessions Memo has been to rescind the guidance issued on August 29, 2013 relative to medical marijuana enforcement under the Cole Memorandum (the "Cole Memo").

The Sessions Memo instructs federal prosecutors to disregard the previous Obama-era Cole Memo guidance, and instead follow "the well-established principles that govern all federal prosecutions . . . as reflected in chapter 9-27.000 of the U.S. Attorney's Manual." The Sessions Memo continues, stating, "[t]hese principles require federal prosecutors deciding which cases to prosecute to weigh 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 in the community."

The effect of the Cole Memo's rescission remains to be seen. Since 1980, when chapter 9-27.000 of the U.S. Attorney's Manual was originally promulgated, the United States has undergone a dramatic shift in both national and state-level marijuana policy. In 1980, there were no states in the U.S. with marijuana decriminalization or legalization statutes. As of June 30, 2019, 33 states and the District of Columbia have enacted medical marijuana legislation in some form, with additional states considering similar legalization measures. As a result, the manner in which the factors identified in chapter 9-27.000 of the U.S. Attorney's Manual (e.g. "seriousness of the crime," "deterrent effect of criminal prosecution," and cumulative impact . . . in the community") are considered and interpreted today as a matter of prosecutorial discretion, will likely be different than the way in which they were considered and interpreted in 1980.

On the same day of the Sessions Memo's release, numerous government officials, legislators and federal prosecutors in states with medical and recreational marijuana statutes announced their intention to continue the Cole Memo-era status quo despite the DOJ's decision to rescind it. The impact that this lack of uniformity between state and federal authorities could have on individual state cannabis markets and the businesses that operate within them is unclear and the enforcement of relevant federal laws is a significant risk. Please see disclosure under Item 1A - "*Risk Factors*" below.

United States

We intend to conduct some of our research and development relating to our drug candidates in the United States, at which time, our research and development, future manufacturing, distribution and sale of our drugs will become subject to the United States *Federal Controlled Substances Act of 1970* and regulations promulgated thereunder. While cannabis is a Schedule I controlled substance, drugs 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 any of our drug candidates will receive approval by the FDA, it must be listed by the DEA as a Schedule II or III controlled substance to be allowed for commercialization. Consequently, the manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use of our future drugs will be subject to a significant degree of regulation by the DEA. In addition, individual states in the United States have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our drugs.

The European Community

Even though we do not currently intend to conduct research and development in the European Community, we may do so in the future. Approximately 250 substances, including cannabis, are listed in the Schedules annexed to the *United Nations Single Convention on Narcotic Drugs* (New York, 1961, amended 1972), the *Convention on Psychotropic Substances* (Vienna, 1971) and the *Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* (introducing control on precursors) (Vienna, 1988). The purpose of these listings is to control and limit the use of these drugs according to a classification of their therapeutic value, risk of abuse and health dangers, and to minimize the diversion of precursor chemicals to illegal drug manufacturers. The 1961 United Nations *Single Convention on Narcotic Drugs,* as amended in 1972 classifies cannabis as Schedule I ("substances with addictive properties, presenting a serious risk of abuse") and as Schedule IV ("the most dangerous substances, already listed in Schedule I, which are particularly harmful and of extremely limited medical or therapeutic value") narcotic drug. The 1971 United Nations *Convention on Psychotropic Substances* classifies THC - the principal psychoactive cannabinoid of cannabis - as a Schedule I psychotropic substance ("substances presenting a high-risk of abuse, posing a particularly, serious threat to public health which are of very little or no therapeutic value").

Most countries in Europe are parties to these conventions which govern international trade and domestic control of these substances, including cannabis. They may interpret and implement their obligations in a way that creates a legal obstacle to our obtaining manufacturing and/or marketing approval for our drugs in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit our drug candidates to be manufactured and/or marketed, or achieving such amendments to the laws and regulations may take a prolonged period. While some countries in Europe including the United Kingdom, Germany, the Czech Republic, France, Romania, and Finland have decriminalized cannabis or permit its use for medical purposes, no country has completely legalized it, although adult-use of recreational cannabis was legalized in Canada on October 17, 2018.

Israel

If we intend to develop drugs containing cannabis plant-derived cannabinoids, we may conduct our research and development activities in Israel. The cannabinoid-based drugs we intend to develop, contain controlled substance (cannabis) as defined in the *Israeli Dangerous Drugs Ordinance* [New Version], 5733 - 1973. In Israel, licenses to cultivate, possess and to use cannabis for medical research are granted by the Ministry of Health, IMCU - Israel Medical Cannabis Unit, on an ad-hoc basis. If we proceed in Israel, we intend to obtain necessary IMCU licenses to carry out our drug development projects. This will require our acquiring the cannabis needed for our research activities from an Israeli government-licensed medical cannabis grower. Because we do not have a license to possess cannabis, the cannabis that will be required for our studies must be transported from the licensed grower directly to our research facilities or those of a contract research organization, in compliance with a license to use cannabis for medical research. If we proceed with research in Israel, we will apply for all necessary licenses needed to conduct our drug development projects. There can be given no assurance that we will obtain all necessary licenses and approvals.

Regulations Related to the Drug Regulatory Process

We operate in a highly controlled regulatory environment. Strict regulations establish requirements relating to analytical, toxicological and clinical standards and protocols in respect to the testing of pharmaceuticals. Regulations also cover research, development, manufacturing and reporting procedures, both pre- and post-approval. Failure to comply with regulations can result in stringent sanctions, including product recalls, withdrawal of approvals, seizure of products and criminal prosecution. Further, many countries have stringent regulations relating to the possession and use of cannabis or drugs derived from cannabis

Before obtaining regulatory approvals for the commercial sale of our future drug candidates, we must demonstrate through preclinical studies and clinical trials that our drug candidates are safe and effective. Historically, the results from preclinical studies and early clinical trials often have not accurately predicted results of later clinical trials. In addition, many pharmaceuticals have shown promising results in clinical trials but subsequently failed to establish sufficient safety and efficacy results to obtain necessary regulatory approvals.

We expect to incur substantial expense for, and devote a significant amount of time to, preclinical studies and clinical trials. Many factors can delay the commencement and rate of completion of clinical trials, including the inability to recruit patients at the expected rate, the inability to follow patients adequately after treatment, the failure to manufacture sufficient quantities of materials used for clinical trials, and the emergence of unforeseen safety issues and governmental and regulatory delays. If a drug candidate fails to demonstrate safety and efficacy in clinical trials, this failure may delay development of other drug candidates and hinder our ability to conduct related preclinical studies and clinical trials. Additionally, if we have failures, we may also be expected to experience challenges, delays or even the inability to obtain additional financing at acceptable terms and conditions.

Governmental authorities in all major markets require that a new drug be approved or exempted from approval before it is marketed, and have established high-standards for technical appraisal, which can result in an expensive and lengthy approval process. The time to obtain approval varies by country and some drugs are never approved. The lengthy process of conducting clinical trials, seeking approval and the subsequent compliance with applicable statutes and regulations, if approval is obtained, are very costly and require the expenditure of substantial resources.

United States

In the United States, the *Public Health Service Act* and the Federal *Food, Drug, and Cosmetic Act*, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the safety and effectiveness standards for our drugs and the raw materials and components used in the production of, testing, manufacture, labeling, storage, record keeping, approval, advertising and promotion of drug candidates on a product-by-product basis.

Preclinical tests include in vitro and in vivo evaluation of the drug candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Certain preclinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. After laboratory analysis and preclinical testing, testing, a sponsor files an Investigational New Drug Application, or IND, to begin human testing. Typically, a manufacturer conducts a three-phase human clinical testing program which itself is subject to numerous laws and regulatory requirements, including adequate monitoring, reporting, record keeping and informed consent. In Phase I, small clinical trials are conducted to determine the safety and proper dose ranges of drug candidates. In Phase II, clinical trials are conducted to assess safety and gain preliminary evidence of the efficacy of drug candidates. In Phase III, clinical trials are conducted to provide sufficient data for the statistically valid evidence of safety and efficacy. The time and expense that will be required for us to perform this clinical testing can vary and is substantial. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing within any specific period, if at all. Furthermore, the FDA, the IRB are responsible for approving and monitoring the clinical trials at a given site, the Data Safety Monitoring Board, where one is used, or we may suspend the clinical trials at any time on various grounds, including a finding that subjects or patients are exposed to unacceptable health risk.

If the clinical data from these clinical trials (Phases I, II and III) are deemed to support the safety and effectiveness of the drug candidate for its intended use, then we may proceed to seek to file with the FDA, a New Drug Application, or NDA, seeking approval to market a new drug for one or more specified intended uses. We have not completed our clinical trials for any candidate drug for any intended use and therefore, we cannot ascertain whether the clinical data will support and justify filing an NDA. Nevertheless, if and when we are able to ascertain that the clinical data supports and justifies filing an NDA, we intend to make such appropriate filing.

The purpose of the NDA is to provide the FDA with sufficient information so that it can assess whether it should approve the drug candidate for marketing for specific intended uses. The fact that the FDA has designated a drug as an orphan drug for a specific intended use does not mean that the drug has been approved for marketing. Only after an NDA has been approved by the FDA is marketing allowed. A request for orphan drug status must be filed before the NDA is filed. The orphan drug designation, though, provides certain benefits, including a seven-year period of market exclusivity subject to certain exceptions.

The NDA normally contains, among other things, sections describing the chemistry, manufacturing, and controls, non-clinical pharmacology and toxicology, human pharmacokinetics and bioavailability, microbiology, the results of the clinical trials, and the proposed labeling which contains, among other things, the intended uses of the candidate drug.

We cannot take any action to market any new drug or biologic drug in the United States until our appropriate marketing application has been approved by the FDA. The FDA has substantial discretion over the approval process and may disagree with our interpretation of the data submitted. The process may be significantly extended by requests for additional information or clarification regarding information already provided. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians. Satisfaction of these and other regulatory requirements typically takes several years, and the actual time required may vary substantially based upon the type, complexity and novelty of the drug. Government regulation may delay or prevent marketing of potential drugs for a considerable period and impose costly procedures on our activities. We cannot be certain that the FDA or other regulatory agencies will approve any of our drugs on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later-stage clinical trials. Even if a drug receives regulatory approval, the approval may be significantly limited to specific indications or uses and these limitations may adversely affect the commercial viability of the drug. Delays in obtaining, or failures to obtain regulatory approvals, would have a material adverse effect on our business.

Even after we obtain FDA approval, we may be required to conduct further clinical trials (i.e., Phase IV trials) and provide additional data on safety and effectiveness. We are also required to gain separate approval for the use of an approved drug as a treatment for indications other than those initially approved. In addition, side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the drug's use and, potentially, withdrawal of the drug from the market. Any adverse event, either before or after marketing approval, can result in product liability claims against us.

As an alternate path for FDA approval of new indications or new formulations of previously-approved drugs, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the *Food, Drug, and Cosmetic Act* was enacted as part of the *Drug Price Competition and Patent Term Restoration Act of 1984* , otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of drugs that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication. The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved drug or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved drug. The FDA may then approve the new drug for all or some of the labeled indications for which the referenced listed drug has been approved, as well as for any new indication supported by the NDA. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new drug must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved drug, the applicant is required to certify to the FDA concerning any patents listed for the approved drug in the FDA's "Orange Book" publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new drug. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference drug has expired. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its drugs only to be subject to significant delay and patent litigation before its drugs may be commercialized.

In addition to regulating and auditing human clinical trials, the FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of such drugs prior to providing approval to market a drug.

We may also be subject to various federal, state and international laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. The federal Anti-kickback law, which governs federal healthcare programs (e.g., Medicare, Medicaid), makes it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a specific drug. Many states have similar laws that are not restricted to federal healthcare programs. Federal and state false claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payers (including Medicare and Medicaid), claims for reimbursement, including claims for the sale of drugs or services, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. If the government or a whistleblower were to allege that we violated these laws there could be a material adverse effect on us, including our stock price. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, which could have a materially adverse effect on our business, results of operations and financial condition. A finding of liability under these laws could have significant adverse financial implications for us and can result in payment of large penalties and possible exclusion from federal healthcare programs. We will consult appropriate legal counsel concerning the potential application of these and other laws to our business and our sales, marketing and other activities and will make good faith efforts to comply with them. However, given their broad reach and the increasing attention given by law enforcement authorities, we cannot assure you that some of our activities will not be challenged or deemed to violate some of these laws.

Orphan Drug Designation in the U.S.

Under the *Orphan Drug Act*, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States. If the disease or condition affects more than 200,000 individuals in the United States, orphan drug designation may nevertheless be available 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 United States, a drug that has received orphan drug designation is eligible for financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. The Orphan Drug Act provides that, if a designated drug is approved for the rare disease or condition for which it was designated, the approved drug will be granted seven years of orphan drug exclusivity, which means the FDA generally will not approve any other application for a drug containing the same active moiety for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan drug 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 a 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 drug is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submission of an application for marketing approval. Products that qualify for orphan designation may also qualify for other FDA programs that are intended to expedite the development and approval process and, as a practical matter, clinical trials for orphan products may be smaller, simply because of the smaller patient population. Nonetheless, the same approval standards apply to orphan-designated products as for other drugs. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Priority Review, Fast Track, Breakthrough Therapy, and Accelerated Approval

The FDA has programs to expedite submission and consideration of certain drug drugs that address serious or life-threatening diseases or conditions. An application for a drug will receive priority review designation if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Priority review means that FDA will seek to complete its first-cycle review and take action on the application within six months rather than the customary ten-month standard review period. An applicant may request priority review at the time it submits its application. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, the fast track program is intended to expedite or facilitate the process for reviewing new drugs that demonstrate the potential to address unmet medical needs involving serious or life-threatening diseases or conditions. If a drug receives fast track designation, the FDA may consider reviewing sections of the NDA on a rolling basis, rather than requiring the entire application to be submitted to begin the review. Products with fast track designation also may be eligible for more frequent meetings and correspondence with the FDA about the drug's development. Other FDA programs intended to expedite development and review include accelerated approval (approval based on a surrogate endpoint that is reasonably likely to predict clinical benefit) and breakthrough therapy designation, which is available for drugs under development for serious or life-threatening conditions and where preliminary clinical evidence shows that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. If a drug receives breakthrough therapy designation, it will be eligible for the benefits of fast track designation, as well as for more intensive guidance from the FDA on an efficient drug development program and a commitment from the agency to involve senior FDA managers in such guidance. Even if a drug qualifies for fast track designation or breakthrough therapy designation, the FDA may later decide that the drug no longer meets the conditions for these designations, and/or may determine that the drug does not meet the standards for approval.

The Foreign Corrupt Practices Act

The *Foreign Corrupt Practices Act* (FCPA) prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

European and Other International Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our drugs. Regardless of whether we obtain FDA approval for a drug, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the drug in those countries. Some countries outside of the United States have a similar process that requires the submission of a clinical trial application ("CTA"), much like the submissions of an IND in the U.S. prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to the national health authority of each EU Member State in which the clinical trial is to be conducted and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain regulatory approval to commercialize a new drug under European Union regulatory systems, we must submit a marketing authorization application, or MAA. In the European Union, marketing authorization for a drug can be obtained through a centralized, mutual recognition, decentralized procedure, or the national procedure of an individual EU Member State. In accordance with the centralized procedure, the applicant may submit a single application for marketing authorization to the EMA. The agency will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization that permits the marketing of a drug in all 28 EU Member States and three of the four European Free Trade Associations, States, Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for certain medicinal drugs, including orphan drugs, drugs derived from certain biotechnological processes, advanced therapy drugs and certain other drugs containing a new active substance for the treatment of certain diseases. This route is optional for certain other drugs, including drugs that are a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the drug is to be marketed. This application process is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a drug by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

For countries outside of the European Union, including countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki.

In the European Union if a marketing authorization is granted for a drug containing a new active substance, that drug benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that drug may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic drugs may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

Orphan Drug Designation in the European Union

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of drugs 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. Additionally, orphan drug designation is granted for drugs 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. The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the drug. Once authorized, orphan drugs are entitled to ten years of market exclusivity. During this ten-year period, with a limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar drugs with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal drug with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal drug or if the manufacturer of the original orphan medicinal drug is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar drug with the same orphan indication if this latter drug is safer, more effective or otherwise clinically superior to the original orphan drug. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated based on available evidence that the original orphan medicinal drug is sufficiently profitable not to justify maintenance of market exclusivity.

Accelerated Review

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a MAA is 210 days (excluding "clock stops," when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal drug is expected to be of a major public health interest. Three cumulative criteria must be fulfilled in such circumstances: the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days.

Well-Established Medicinal Use

Under Article 10a of Directive 2001/83/EC, an applicant may, in substitution for the results of its own preclinical and clinical research, present detailed references to published literature demonstrating that the active substance(s) of a drug have a well-established medicinal use within the community with recognized efficacy and an acceptable level of safety. The applicant is entitled to refer to a variety of different types of literature, including reports of clinical trials with the same active substance(s) and epidemiological studies that indicate that the constituent or constituents of the drug have an acceptable safety/efficacy profile for a particular indication. However, use of the published literature exemption is restricted by stating that in no circumstances will constituents be treated as having a well-established use if they have been used for less than 10 years from the first systematic and documented use of the substance as a medicinal drug in the EU. Even after 10 years of systematic use, the threshold for well-established medicinal use might not be met. European pharmaceutical law requires the competent authorities to consider among other factors, the period over which a substance has been used, the amount of patient use of the substance, the degree of scientific interest in the use of the substance (as reflected in the scientific literature) and the coherence (consistency) of all the scientific assessments made in the literature. For this reason, different substances may reach the threshold for well-established use after different periods, but the minimum period is 10 years. If the applicant seeks approval of an entirely new therapeutic use compared with that to which the published literature refers, additional preclinical and/or clinical results is required.

Informed Consent

Under Article 10c of Directive 2001/83/EC, following the grant of a marketing authorization the holder of such authorization may consent to a competent authority utilizing the pharmaceutical, preclinical and clinical documentation that it submitted to obtain approval for a medicinal drug to assess a subsequent application relating to a medicinal drug possessing the same qualitative and quantitative composition with respect to the active substances and the same pharmaceutical form.

Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006) was adopted on December 12, 2006. This Regulation governs the development of medicinal drugs for human use to meet the specific therapeutic needs of the pediatric population. It requires any application for marketing authorization made after July 26, 2008 in respect of a drug not authorized in the European Community on January 26, 2007 (the time the Regulation entered into force), to include the results of all studies performed and details of all information collected in compliance with a pediatric investigation plan agreed by the Pediatric Committee of the EMA, unless the drug is subject to an agreed waiver or deferral or unless the drug is excluded from the scope of Regulation 1902/2006 (generics, hybrid medicinal drugs, biosimilars, homeopathic and traditional (herbal) medicinal drugs and medicinal drugs containing one or more active substances of well-established medicinal use). Waivers can be granted in certain circumstances where pediatric studies are not required or desirable. Deferrals can be granted in certain circumstances where the initiation or completion of pediatric studies should be deferred until appropriate studies in adults have been performed. Moreover, this regulation imposes the same obligation from January 26, 2009 on an applicant seeking approval of a new indication, pharmaceutical form or route of administration for a drug already authorized and still protected by a supplementary protection certificate granted under Regulation EC 469/2009 and its precursor (EEC) 1768/92 or by a patent that qualifies for the granting of such a supplementary protection certificate. The pediatric Regulation 1901/2006 also provides, subject to certain conditions, a reward for performing such pediatric studies, regardless of whether the pediatric results provided resulted in the grant of a pediatric indication. This reward comes in the form of an extension of six months to the supplementary protection certificate granted in respect of the drug, unless the drug is subject to orphan drug designation, in which case the 10-year market exclusivity period for such orphan drugs is extended to 12 years. If any of the non-centralized procedures for marketing authorization have been used, the six-month extension of the supplementary protection certificate is only granted if the medicinal drug is authorized in all member states.

Post-authorization Obligations

In the pre-authorization phase the applicant must provide a detailed pharmacovigilance plan that it intends to implement post-authorization. An authorization to market a medicinal drug in the EU carries with it an obligation to comply with many post-authorization organizational and behavioral regulations relating to the marketing and other activities of authorization holders. These include requirements relating to post-authorization efficacy studies, post-authorization safety studies, adverse event reporting and other pharmacovigilance requirements, advertising, packaging and labeling, patient package leaflets, distribution and wholesale dealing. The regulations frequently operate within a criminal law framework and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers. Because of the currently on-going overhaul of EU pharmacovigilance legislation the financial and organizational burden on market authorization holders will increase significantly, such as the obligation to maintain a pharmacovigilance system master file that applies to all holders of marketing authorizations granted in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004. Marketing authorization holders must furthermore collect data on adverse events associated with use of the authorized drug outside the scope of the authorization. Pharmacovigilance for biological drugs and medicines with a new active substance will be strengthened by subjecting their authorization to additional monitoring activities. The EU is currently in the process of issuing implementing regulations for the new pharmacovigilance framework.

Any authorization granted by member state authorities, which within three years of its granting is not followed by the actual placing on the market of the authorized drug in the authorizing member state ceases to be valid. When an authorized drug previously placed on the market in the authorizing member state is no longer actually present on the market for a period of three consecutive years, the authorization for that drug shall cease to be valid. The same two three-year periods apply to authorizations granted by the European Commission based on the centralized procedure.

Israel

To conduct clinical testing on humans in Israel, special authorization must first be obtained from the ethics committee and general manager of the institution where the clinical studies are scheduled to be conducted, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), as amended from time to time, and other applicable legislation. These regulations also require authorization from the Israeli Ministry of Health, except in certain circumstances, and in the case of genetic trials, special fertility trials and similar trials, an additional authorization of the overseeing institutional ethics committee. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered from the clinical testing. If we intend to proceed with clinical studies in Israel, we will be required to obtain authorization from the ethics committee and general manager of each institution in which we intend to conduct our clinical trials, and in most cases, from the Israeli Ministry of Health.

Israel's Ministry of Health, which regulates medical testing, has adopted protocols that correspond, generally, to those of the FDA and the EMA, making it comparatively straightforward for studies conducted in Israel to satisfy FDA and the European Medicines Agency requirements, thereby enabling medical technologies subjected to clinical trials in Israel to reach U.S. and EU commercial markets in an expedited fashion. Many members of Israel's medical community have earned international prestige in their chosen fields of expertise and routinely collaborate, teach and lecture at leading medical centers throughout the world. Israel also has free trade agreements with the United States and the European Union.

The Development of Licensing of Proprietary Delivery Systems

We also intend to develop or license proprietary delivery systems for cannabinoid-based medications. We envision that these delivery systems may be utilized for some of the drugs that we seek to develop, and that we may also license them to third-parties. There is no assurance that we will be able to develop or license any delivery system.

The Investment in Companies or Acquisition of Technologies or Medications

We also intend to invest in companies or acquire technologies or medications based on cannabinoid-based science, possibly through special purpose vehicles formed or controlled by the Company. There is no assurance that we will be able to invest in any of these companies or acquire any technology or medication, nor that we will be successful in forming or acquiring capital for any special purpose vehicle for these purposes.

Employees

As of the date of this report, all of our officers are serving without compensation and have no employees. To the extent not covered by the services of our offices, we expect to use third-party firms and individuals for our drug candidate development and management.

Our employees are not subject to any collective bargaining agreement.

Research and Development Activities

We have incurred $63,858 and $116,791 during the fiscal years ended June 30, 2019 and 2018, respectively, on research and development for the Company. None of these research or development costs are borne by the customer.

ITEM 1A. RISK FACTORS.

You should carefully consider the risks, uncertainties and other factors described below because they could materially and adversely affect our business, financial condition, operating results and prospects and could negatively affect the market price of our Common Stock. Also, you should be aware that the risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we do not yet know of, or that we currently believe are immaterial, may also impair our business operations and financial results. Our business, financial condition or results of operations could be harmed by any of these risks. The trading price of our Common Stock could decline due to any of these risks, and you may lose all or part of your investment.

In assessing these risks, you should also refer to the other information contained in or incorporated by reference to this Annual Report on Form 10-K, including our financial statements and the related notes.

Risks Related to Our Financial Position and Capital Requirements

Our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern.

The audited financial statements of BioPharma included in this Annual Report have been prepared assuming that we will continue as a going concern and do not include any adjustments that might result if we cease to continue as a going concern. The development of pharmaceuticals with the objective of obtaining approval by the FDA and other international regulatory authorities is not a short-term endeavor for any specific drug candidate. It also requires extremely significant amounts of capital funding for clinical trials and other matters. At June 30, 2019, the Company had working capital of $265,920. The Company will require significant additional capital to fund the implementation and execution of its business plan. This capital, which likely will be millions of dollars for a single drug candidate, will be required for research, regulatory applications, and clinical trials. We have incurred significant losses since our inception. We have funded these losses primarily through the sale of restricted shares of our Common Stock.

Based on our financial history, in its report on the financial statements for the year ended June 30, 2019, our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern. To date, we have not generated any revenues and we do not anticipate generating any significant revenues during the current fiscal year.

Notwithstanding BioPharma's success in raising approximately $2.1 million from the sale of its securities from inception in 2017 through June 2019, there can be no assurance that we will be able to continue to raise equity and/or debt capital from investors on terms and conditions satisfactory to the Company, find strategic or financial partners for a specific drug candidate, or have adequate capital resources required by us to fund our current and future planned operations. If we are unable to obtain adequate capital resources to fund operations, we may be required to delay, scale back or eliminate some or all of our plan of operations, which may have a material adverse effect on our business, results of operations and ability to operate as a going concern.

The Company has negative cash flow for the financial year ended June 30, 2019.

The Company had negative operating cash flow for the financial year ended June 30, 2019. To the extent that the Company has negative operating cash flow in future periods, it may need to allocate a portion of its cash reserves to fund such negative cash flow. The Company may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that the Company will be able to generate a positive cash flow from its operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favorable to the Company.

We face many of the risks and difficulties frequently encountered by relatively new companies with respect to our operations.

The Company's business objective is to conduct scientific research and development related to the use of cannabinoid receptor modulators and/or terpenes for medical treatment of certain medical conditions and diseases. We have no operating history as a medical research company engaged in cannabinoid-based research upon which an evaluation of the Company and its prospects could be based. There can be no assurance that our management will be successful in being able to commercially exploit the results, if any, from our drug development research projects or that we will be able to develop drugs and treatments that will enable us to generate sufficient revenues to meet our expenses or to achieve and/or maintain profitability.

If we are unable to raise sufficient capital as needed, we may be required to reduce the scope of our planned research and development activities, which could harm our business plans, financial condition and operating results, or cease our operations entirely, in which case, you will lose all your investment.

We currently have no revenues and may never become profitable.

Our ability to generate revenue and become profitable depends upon our ability to obtain regulatory approval for any of our drug development projects. Even if we are able to successfully achieve regulatory approval for any of our drug candidates, we do not know when any of these drugs will generate revenues, 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 drug candidates. The amount of future losses is uncertain and will depend, in part, on the rate of growth of our research and development expenses as well as other operating expenses. We are unable to predict the timing or amount of these expected increases in operating expenses. If we are able to obtain approval for any of our drug candidates, we will incur significant costs associated with commercializing our drug candidates.

We will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete any of our drug development projects

Our research operations are expected to require significant cash expenditures. We expect to spend substantial and increasing amounts to conduct our planned research and development, including preclinical testing and clinical trials of our drug candidates, to seek regulatory approvals to eventually market and commercialize any of our drug candidates. As of June 30, 2019, we had $146,356 in cash and cash equivalents. Through June 2019, we have raised approximately $2.1 million in equity under private placement offerings. We believe that current cash is sufficient to fund our overhead operations through the remainder of calendar 2019. We estimate that we will require additional capital of approximately $1.5 million for the first nine months of calendar 2020. As discussed below, determining a budget is subject to a number of factors. In general, this estimate may higher if our research efforts prove to be successful or lower if the research efforts are not fruitful. Any progress we make in our research efforts is uncertain because it is difficult to predict our budget for our drug development activities due to numerous factors, including, without limitation, the rate of progress of preclinical studies, clinical trials, the results of preclinical studies and clinical trials for such indication and the costs and timing of seeking and obtaining regulatory approvals for clinical trials. 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 anticipated due to changing circumstances beyond our control. Our future capital requirements may depend on a wide range of factors, including, but not limited to:

- the costs related to initiation, progress, timing, costs and results of preclinical studies and clinical trials for our drug candidates;
- any change in the clinical development plans for these drug candidates;
- the number and characteristics of drug candidates that we develop;
- the terms of any future collaboration agreements we may choose to enter;
- the events related to the outcome, timing and cost of meeting regulatory requirements established by the DEA, the FDA, the European Medicines Agency (“EMA”) or other comparable foreign regulatory authorities;
- the potential costs of filing, prosecuting, defending and enforcing our patent claims and other intellectual property;
- the cost of defending intellectual property disputes; and
- the cost of marketing and generating revenues for any of our drug candidates.

We cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital on terms acceptable to us, we may have to significantly delay, scale back or discontinue one or more of our drug development projects.

Raising additional capital may cause dilution to our existing stockholders and restrict our operations.

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 drug candidates**.**

The Company will be reliant on information technology systems and may be subject to damaging cyber-attacks.

The Company has entered into agreements with third parties for hardware, software, telecommunications and other information technology ("IT") services in connection with its operations. The Company's operations depend, in part, on how well it and its suppliers protect networks, equipment, IT systems and software against damage from a number of threats, including, but not limited to, cable cuts, damage to physical plants, natural disasters, intentional damage and destruction, fire, power loss, hacking, computer viruses, vandalism and theft. The Company's operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or increase in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Company's reputation and results of operations.

The Company has not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that the Company will not incur such losses in the future. The Company's risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cyber security and the continued development and enhancement of controls, processes and practices designed to protect systems, computers, software, data and networks from attack, damage or unauthorized access is a priority. As cyber threats continue to evolve, the Company may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

The Company's officers and directors may be engaged in a range of business activities resulting in potential conflicts of interest.

The Company may be subject to various potential conflicts of interest because some of its officers and directors may be engaged in a range of business activities. In addition, the Company's executive officers and directors may devote time to their outside business interests, so long as such activities do not materially or adversely interfere with their duties to the Company. In some cases, the Company's executive officers and directors may have fiduciary obligations associated with these business interests that interfere with their ability to devote time to the Company's business and affairs and that could adversely affect the Company's operations. These business interests could require significant time and attention of the Company's executive officers and directors.

In addition, the Company may also become involved in other transactions which conflict with the interests of its directors and the officers who may from time to time deal with persons, firms, institutions or companies with which the Company may be dealing, or which may be seeking investments similar to those desired by it. The interests of these persons could conflict with those of the Company. In addition, from time to time, these persons may be competing with the Company for available investment opportunities. Conflicts of interest, if any, will be subject to the procedures and remedies provided under applicable laws. In particular, if such a conflict of interest arises at a meeting of the Company's directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In accordance with applicable laws, the directors of the Company are required to act honestly, in good faith and in the best interests of the Company.

The Company is subject to uncertainty regarding legal and regulatory status and changes.

Achievement of the Company's Canadian and U.S. business objectives is also contingent, in part, upon compliance with other regulatory requirements enacted by governmental authorities and obtaining other required regulatory approvals. The regulatory regime applicable to the cannabis business in Canada and the U.S. is currently undergoing significant proposed changes and the Company cannot predict the impact of the regime on its business once the structure of the regime is finalized. Similarly, the Company cannot predict the timeline required to secure all appropriate regulatory approvals for its products, or the extent of testing and documentation that may be required by governmental authorities. Any delays in obtaining, or failing to obtain, required regulatory approvals may significantly delay or impact the development of markets, products and sales initiatives and could have a material adverse effect on the business, results of operations and financial condition of the Company. The Company will incur ongoing costs and obligations related to regulatory compliance. Failure to comply with regulations may result in additional costs for corrective measures, penalties or in restrictions on the Company's operations. In addition, changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to the Company's operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, results of operations and financial condition of the Company.

No guarantee on the use of available funds by the Company.

We cannot specify with certainty the particular uses of the Company's funds. Management has broad discretion in the application of our available funds. Accordingly, stockholders will have to rely upon the judgment of management with respect to the use of funds, with only limited information concerning management's specific intentions. Our management may spend a portion or all of the Company's available funds in ways that our stockholders might not desire, that might not yield a favorable return and that might not increase the value of a purchaser's investment. The failure by management to apply these funds effectively could harm our business. Pending use of such funds, we might invest the funds in a manner that does not produce income or that loses value.

Risks Relating to Our Drug Development Projects

Our future success will largely depend on the success of our drug candidates, which development will require significant capital resources and years of clinical development effort.

We currently have no drug products on the market, and none of our drug development projects has reached preclinical study or clinical trial status. Our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of our drug candidates. Investors need to be aware that substantial additional investments including clinical development and regulatory approval efforts will be required before we are permitted to market and commercialize our drug candidates, if ever. It may be several years before we can commence clinical trials, if ever. Any clinical trial will be subject to extensive and rigorous review and regulation by numerous government authorities in the United States, the European Union, and other jurisdictions where we intend, if approved, to market our drug candidates. Before obtaining regulatory approvals for any of our drug candidates, we must demonstrate through preclinical testing and clinical trials that the drug candidate is safe and effective for its specific application. 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 will successfully complete the FDA regulatory approval process or be granted authorization to be marketed in the European Commission or the other competent authorities in the European Union ("EU") Member States. Accordingly, even if we obtain the sufficient financing to fund our planned research, development and clinical programs, we cannot assure you that any of our drug candidates will be successfully developed or commercialized.

We may be unable to formulate or scale-up any or all of our drug candidates. There is no guarantee that any of the drug candidates will be or are able to be produced in a manner to meet the FDA's criteria for product stability, content uniformity and all other criteria necessary for product approval in the United States and other markets. Any of our drug candidates may fail to achieve their specified endpoints in clinical trials. Furthermore, drug candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a drug for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials (i.e., Phase IV trials). In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our drug candidates.

If we are unable to expand our pipeline and obtain regulatory approval for our drug candidates on the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would have a material adverse impact on our long-term business, results of operations, financial condition, and prospects.

Our drug development projects, if approved, may be unable to achieve the expected market acceptance and, consequently, limit our ability to generate revenue.

Even when drug development is successful and regulatory approval has been obtained, our ability to generate significant revenue depends on the acceptance of our drug candidates by physicians and patients. We cannot assure you that any of our drug candidates will achieve the expected market acceptance and revenue, if and when we obtain the regulatory approvals. The market acceptance of any drug depends on a number of factors, including the indication statement and warnings approved by regulatory authorities for the drug label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the drug, reimbursement from third-party payers such as government health care systems and insurance companies, the price of the drug, 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 drugs could have a material adverse effect on our business, results of operations and financial condition.

Results of preclinical studies and earlier clinical trials are not necessarily predictive indicators of future results.

Any positive results from future preclinical testing of our drug candidates and potential clinical trials may not necessarily be predictive of the results from Phase 1, Phase 2 or Phase 3 clinical trials. In addition, our interpretation of results derived from clinical data or our conclusions based on our preclinical data may prove inaccurate. Frequently, pharmaceutical and biotechnology companies have suffered significant setbacks in clinical trials after achieving positive results in preclinical testing and early clinical trials, and we cannot be certain that we will not face similar setbacks. These setbacks may be caused by the fact that preclinical and clinical data can be susceptible to varying interpretations and analyses. Furthermore, certain drug candidates may perform satisfactorily in preclinical studies and clinical trials, but nonetheless fail to obtain FDA approval, a marketing authorization granted by the European Commission, or appropriate approvals by government authorities in other countries. If we fail to produce positive results in our clinical trials for our drug candidates, the development timeline and regulatory approval and commercialization prospects for them and as a result our business and financial prospects, would be materially adversely affected.

The regulatory approval processes with the FDA, the EMA and other comparable foreign regulatory authorities is lengthy and inherently unpredictable.

We are not permitted to market our drug candidates in the United States or the European Union until we receive approval of a New Drug Application ("NDA") from the FDA or a Marketing Authorization Application ("MAA") from the European Commission, respectively, or in any foreign countries until we receive the approval from the regulatory authorities of such countries. Prior to submitting an NDA to the FDA or an MAA to the EMA for approval of our drug candidates we will need to have completed our preclinical studies and clinical trials. Successfully completing any 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 drug candidates for many reasons, including, among others, because:

- an inability to demonstrate that our drug candidates are safe and effective in treating patients to the satisfaction of the FDA or EMA;
- results of clinical trials that may not meet the level of statistical or clinical significance required by the FDA or EMA;

- disagreements with the FDA or EMA with respect to the number, design, size, conduct or implementation of clinical trials;
- requirements by the FDA and EMA to conduct additional clinical trials;
- disapproval by the FDA or EMA or other applicable foreign regulatory authorities of certain formulations, labeling or specifications of drug candidates;
- findings by the FDA or EMA that the data from preclinical studies and clinical trials are insufficient;
- the FDA or EMA may disagree with the interpretation of data from preclinical studies and clinical trials; and
- the FDA, European Commission or other applicable foreign regulatory agencies may change their approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could increase development costs or jeopardize our ability to obtain regulatory approval for our drug candidates.

We may apply for orphan drug status granted by the FDA for some of our drug candidates for the treatment of rare diseases.

Regulatory authorities in some jurisdictions, including the United States and the 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. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of drugs 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. Additionally, such designation is granted for drugs 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 drug receives the first FDA approval for the drug and indication for which it has orphan drug designation, the drug 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 drug with orphan drug 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 drug is sufficiently profitable so that market exclusivity is no longer justified.

Our drug candidates may become subject to controlled substance laws and regulations in the U.S.

While cannabis is a controlled substance under the CSA in the United States, we plan to initially focus our drug development projects using cannabinoids that are synthetically produced. Some of these synthetics, such as dronabinol, have been approved by the FDA for various medical research and conditions. While plant-derived cannabinoids are categorized as Schedule I substances under the CSA, dronabinol, which is synthetic tetrahydrocannabinol, or THC is a Schedule III substance in capsule form, although it is a Schedule I substance in bulk form. Even though dronabinol is still a controlled substance, research based on Schedule III substances, including trials in the United States, are substantially less restrictive.

However, if we decide to proceed with clinical trials using plant-derived cannabinoids, and are conducting those trials in the United States, we will become subject to the CSA laws and regulation in addition to FDA regulations. Currently the Company does not intend to proceed with clinical trials using cannabis-derived cannabinoids in the U.S. If the Company decides to proceed with plant-derived cannabinoids, it will evaluate where to conduct its research and preclinical trials.

Nevertheless, our final drugs may contain controlled substances as defined in the CSA. Controlled substances that are pharmaceutical drugs 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 and certain of its derivatives are Schedule I controlled substances, drugs 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 any of our drug candidates receive FDA approval, the DEA will make a scheduling determination and place it in a schedule other than Schedule I for it to be prescribed for patients in the United States. If approved by the FDA, we expect the finished dosage forms of any of our drug candidates 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 our drugs. However, the DEA must issue a temporary order scheduling the drug within 90 days after the FDA approves the drug and the DEA receives a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that any of our drugs 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 our drugs.

Clinical trials of cannabinoid-based drug candidates are novel with very limited or non-existing history; we face a significant risk that the trials will not result in commercially viable drugs and treatments.

At present, there is only a very limited documented clinical trial history from which we can derive any scientific conclusions, or prove that our present assumptions for the current and planned research are scientifically compelling. While we are encouraged by the limited results of clinical trials by others, there can be no assurance that any clinical trial will result in commercially viable drugs or treatments.

Clinical trials are expensive, time consuming and difficult to design and implement. We, as well as the regulatory authorities may suspend, delay or terminate our clinical trials at any time, may require us, for various reasons, to conduct additional clinical trials, or may require a particular clinical trial to continue for a longer duration than originally planned, including, among others:

- lack of effectiveness of any formulation or delivery system during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to regulatory and manufacturing constraints;
- delays in obtaining regulatory authorization to commence a trial, including Institutional Review Board ("IRB") approvals, licenses required for obtaining and using cannabis or cannabis derived substances for research, either before or after a trial is commenced;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- patients or investigators failing to comply with study protocols;
- patients failing to return for post-treatment follow-up at the expected rate;
- sites participating in an ongoing clinical study withdraw, requiring us to engage new sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or act in ways inconsistent with the established investigator agreement, clinical study protocol, good clinical practices, and other IRB requirements;
- third-party entities do not perform data collection and analysis in a timely or accurate manner or at all; or
- regulatory inspections of our clinical studies require us to undertake corrective action or suspend or terminate our clinical studies.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

Changes in consumer preferences and acceptance of cannabinoid-derived drugs and any negative trends will adversely affect our business.

We are substantially dependent on initial and continued market acceptance and proliferation of cannabinoid-derived drugs. We believe that as cannabinoid-derived drugs become more widely accepted by the medical and scientific communities and the public at large, the stigma associated with cannabinoid-derived drugs and treatments will moderate and, as a result, consumer demand will likely continue to grow. However, we cannot predict the future growth rate and size of the market, assuming that the regulatory framework is favorable, of which there can be no assurance. Any negative outlook on cannabinoid-derived drugs will adversely affect our business prospects.

In addition, while some may believe that large, well-funded pharmaceutical and other related businesses and industries may have material economic reasons to be in strong opposition to cannabinoid-based drugs, we don't believe that it is the case. Regardless, the pharmaceutical industry is well-funded with a strong and experienced lobbying presence at both the federal and state levels as well as internationally, that surpasses financial resources of the current group of medical cannabinoid research and development companies. Any effort by the pharmaceutical lobby could or might undertake to halt or delay the development of cannabinoid-based drugs and could have a detrimental impact on our business.

These pressures could also limit or restrict the introduction and marketing of any cannabinoid-derived drug. Adverse publicity regarding cannabis misuse or adverse side effects from cannabis or other cannabinoid-derived drugs may adversely affect the commercial success or marketability. The nature of our business attracts and may be expected to continue to attract a high-level of public and media interest and, in the event of any related adverse publicity; we may not succeed in monetizing our drugs.

Our drug candidates may contain controlled substances, the use of which may generate public controversy.

Since our drug candidates may 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 drug candidates. These pressures could also limit or restrict the introduction and marketing of our drug candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid-derived drugs may adversely affect the commercial success or market penetration achievable by our drug candidates. The nature of our business will likely attract a high-level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

The FDA has not approved any plant-derived cannabinoid drug as a safe and effective drug for any indication.

To date, the FDA has not approved any plant-derived cannabinoid drug as safe and effective for any indication. However, the FDA is aware that there is considerable interest in its use to attempt to treat a number of medical conditions. Before conducting testing in humans of a drug that has not been approved by the FDA, we will need to submit an investigational new drug ("IND") application to the FDA. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

At present we have no guaranteed or reliable source of synthetic cannabinoids at an economically feasible price – even though we intend to focus on the utilization of synthetic cannabinoids

Our primary objective is to focus our initial drug development utilizing synthetic cannabinoids. While we currently have arrangements with sources from which we are obtaining synthetic cannabinoids, without any guarantees of supply, there is no assurance that we will be able to access synthetic cannabinoids in the future, or at an economically feasible price for a reasonable period of time that would enable us to implement and execute our business plan.

Laws and regulations affecting therapeutic uses of cannabis are constantly evolving.

The potential ongoing evolution of laws and regulations affecting the research and development of cannabinoid-based medical drugs and treatments could detrimentally affect our business. Laws and regulations related to the therapeutic uses of cannabis and cannabinoid-based drugs may be subject to changing interpretations. These changes may require us to incur substantial costs associated with legal and compliance fees and may ultimately require us to alter our business plan. Furthermore, violations or alleged violation of these laws could disrupt our business and result in a material adverse effect on our operations. In addition, we cannot predict the nature of any future laws, regulations, interpretations or applications of laws and regulations and it is possible that new laws and regulations may be enacted in the future that will be directly applicable to our business.

Our research activities in the cannabinoid drug industry may make it difficult to obtain insurance coverage.

In the event that we decide to commence research based on plant-derived cannabinoids in the U.S., obtaining and maintaining necessary insurance coverage, for such things as workers compensation, general liability, product liability and directors and officers liability insurance, may be more difficult and/or expensive for us to find because of our research directions utilizing synthetic and/or plant-derived cannabinoids. There can be no assurance that we will be able to find such insurance, if needed, or that the cost of coverage will be affordable or cost-effective. If, either because of unavailability or cost prohibitive reasons, we are compelled to operate without insurance coverage, we may be prevented from entering certain business sectors, experience inhibited growth potential and/or expose us to additional risks and financial liabilities.

We face a potentially highly competitive market.

Demand for cannabinoid-derived drugs will likely be dependent on a number of social, political and economic factors that are beyond our control. While we believe that there will be a demand for such drugs, and that the demand will grow, there is no assurance that such demand will happen, that we will benefit from any demand or that our business, in fact, will ever generate revenues from our drug development activities or become profitable.

The emerging markets for cannabinoid-derived drugs and medical research and development is and will likely remain competitive. 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 by universities and other research institutions. Many of our competitors have developed, are developing, or will develop drugs and processes competitive with our drug candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that may enter the market. For some of our drug development directions, other treatment options are currently available, under development, and may become commercially available in the future. If any of our drug candidates is approved for the diseases and conditions we are currently pursuing, they may compete with a range of therapeutic treatments that are either in development or currently marketed.

We are aware of many companies that are engaged in cannabinoid-derived drug development activities. In addition, other U.S.-based and foreign-based companies are in early stage discovery and preclinical development utilizing the cannabinoids CBD and/or THC.

Established companies may have a competitive advantage over us due to their size and experiences, financial resources, and institutional networks. Many of our competitors may have significantly greater financial, technical and human resources than we do. Due to these factors, our competitors may have an advantage in marketing their approved drugs and may obtain regulatory approval of their drug candidates before we are able to, which may limit our ability to develop or commercialize our drug candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours. These advantages could materially impact our ability to develop and, if approved, commercialize our drug candidates successfully. Furthermore, some of these competitors may make acquisitions or establish collaborative relationships among themselves or with third parties to increase their ability to rapidly gain market share.

Our drug candidates may compete with other plant-derived or synthetic cannabinoid drugs, in addition to competing with state-licensed medical and recreational marijuana, in markets where the recreational and/or medical use of marijuana is legal. There is continuing support in the United States for further state legalization of marijuana. In markets where recreational and/or medical marijuana is not legal, our drug candidates, once approved by regulators, may compete with marijuana or marijuana-based products purchased in the illegal drug market.

Moreover, as generic versions of drug products enter the market, the price for such drugs may be expected to decline rapidly and substantially. Even if we are the first to obtain FDA approval of one of our drug candidates, the future potential approval of generics could adversely affect the price we are able to charge and the profitability of our product will likely decline.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in 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 companies may 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 our research projects.

Our 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. 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 in researching the medical benefits of cannabinoid-derived pharmaceuticals results in our being 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 not providing to us 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, whether as employees or consultants, as well as personnel with expertise in clinical testing, governmental regulation and commercialization. We face competition for personnel and consultants from other companies, universities, public and private research institutions, government entities and other organizations.

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 U.S. federal and state laws and regulations and similar laws and regulations established by other foreign regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. 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 a Code of Business Conduct and Ethics. However, it is not always possible to identify and deter employee misconduct and having adopted a Code of Business Conduct and Ethics may not be effective or sufficient in protecting us from governmental investigations or other actions or lawsuits. 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.

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

To market and sell our future drugs 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 approval or the approval from the European Commission, but may involve additional testing.

We may need to partner with third parties to obtain approvals outside the United States and the European Union. In addition, in many countries worldwide, it is required that the drug be approved for reimbursement before the drug 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 European Commission 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 European Commission. If we are unable to obtain approval of our drug candidates by regulatory authorities in other foreign jurisdictions, the commercial prospects of those drug candidates may be significantly reduced and our business prospects could decline.

Our failure to comply with existing and potential future laws and regulations relating to drug development could harm our plan of operations.

Our business is, and will be, subject to wide-ranging existing federal and state laws and regulations and other governmental bodies in each of the countries we may develop and/or market our drug candidates. We must comply with all regulatory requirements if we expect to be successful.

If any of our cannabinoid-derived drug candidates are approved in the United States, they will be subject to ongoing regulatory requirements including federal and state requirements. As a result, we and our collaborators and/or joint venture partners must continue to expend time, money and effort in all areas of regulatory compliance, including, if applicable, manufacturing, production, quality control and assurance and, of upmost importance, clinical trials. We will also be required to report certain adverse reactions and production problems, if any and applicable, to the FDA, and to comply with advertising and promotion requirements for our cannabinoid-derived drug candidates.

Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to conduct clinical trials which are prerequisites to our ability to commercialize our cannabinoid-based drugs and related treatments. If regulatory sanctions are applied or if regulatory approval, once obtained, is for any reason withdrawn, the value of our business and our operating results could be materially adversely affected.

Changes in legislation or regulation in the health care systems in the United States and foreign jurisdictions may affect us.

Our ability to successfully commercialize our drugs may depend on how the U.S. and other governments and/or health administrations provide coverage and/or reimbursements for any drugs that we are successful in developing. The ongoing efforts of governments, insurance companies, and other participants in the health care services industry to trim health care costs may adversely affect our ability to achieve profitability.

In certain foreign markets, including countries in the European Union, pricing of prescription pharmaceuticals is subject to governmental control. Price negotiations with governmental authorities may range from 6 to 12 months or longer after the receipt of regulatory marketing approval for a drug. Our business could be detrimentally affected if reimbursements of our drugs is unavailable or limited, if pricing is set at unacceptable levels.

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

At present, we are a very small company. We expect to experience a period of expansion in headcount, infrastructure and overhead and anticipate that further expansion will be required to address potential growth and market opportunities. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate new members of our management team, employees including researchers, and consultants. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We may not be able to successfully expand our business through acquisitions.

We may review corporate and product acquisition candidates as a part of our growth strategy. If we decide to undertake an acquisition to obtain, what we view as promising drug candidates, we may not be able to successfully integrate it in order to realize the full benefit of such acquisition. Factors which may affect our ability to grow successfully through acquisitions include:

- inability to identify suitable targets given the relatively narrow scope of our drug candidates;
- difficulties and expenses in connection with integrating the acquired companies and achieving the expected benefits;
- diversion of management's attention from current operations;
- the possibility that we may be adversely affected by risk factors facing the acquired companies;
- possible dilution of earnings, or in the case of acquisitions made through the issuance of our common shares to the stockholders of the acquired company, dilution in the percentage of ownership of our existing stockholders;
- potential losses resulting from undiscovered liabilities of acquired companies not covered by the indemnification we may obtain from the seller; and
- loss of key employees of the acquired companies.

Risks Related to Collaboration with Third Parties and Intellectual Property Rights

We will depend on third parties to conduct our research activities.

We will rely on third parties such as clinical data management organizations and consultants to design, conduct, supervise and monitor our preclinical studies and clinical trials (the "Third Parties"). We and the Third Parties are required to comply with various regulations and guidelines from 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. Relying on Third Parties does not relieve us of certain responsibilities and requirements. If we or any of the Third Parties fail to comply with applicable requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There is no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with such requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

The Third Parties will not be designated as our employees. We therefore cannot control whether they devote sufficient time and resources to our ongoing clinical and preclinical programs. If the Third Parties do not successfully carry out their contractual duties or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to clinical protocols and/or regulatory requirements, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully commercialize our drug candidates. As a result, our commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed or reduced.

Clinical trials are very expensive, time consuming and difficult to design and implement. Our drug candidates are in preclinical development, which is an extremely preliminary stage of development that includes no regulatory input. We estimate that clinical trials for these drug candidates, if and when initiated, may continue for several years and may take significantly longer than expected to complete. In addition, we, the FDA, an institutional review board (IRB), or other regulatory authorities, including state and local authorities, may suspend, delay or terminate our clinical trials at any time, or the DEA could suspend or terminate the registrations and quota allotments we require in order to procure and handle controlled substances, for various reasons, including:

- Lack of effectiveness of any product candidate during clinical trials;
- Discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- Slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- Difficulty in retaining subjects who have initiated a clinical trial but who may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process, or for any other reason;

- Delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials, in particular, obtaining sufficient quantities of synthetic or plant-derived cannabinoids due to regulatory and manufacturing constraints.
- Inadequacy of or changes in our manufacturing process or product formulation;
- Delays in obtaining regulatory authorization to commence a study, or "clinical holds" or delays requiring suspension or termination of a study by a regulatory agency, including by the FDA, before or after a study is commenced;
- DEA-related recordkeeping, reporting, or security violations at a clinical site, leading the DEA or state authorities to suspend or revoke the site's controlled substance license and causing a delay or termination of planned or ongoing studies;
- Changes in applicable regulatory policies and regulations;
- Delays or failure in reaching agreement(s) on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- Uncertainty regarding proper dosing;
- Unfavorable results from ongoing clinical trials and preclinical studies;
- Failure of the Third Parties or other third-party contractors to comply with all contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- Failure by us, our employees, our consultants, the Third Parties, or their employees to comply with all applicable FDA, DEA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for controlled substances;
- Scheduling conflicts with participating clinicians and clinical institutions;
- Failure to design appropriate clinical trial protocols;
- Insufficient data to support regulatory approval;
- Inability or unwillingness of medical investigators to follow our clinical protocols;
- Difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- Regulatory concerns with cannabinoid-derived drugs generally and the potential for abuse of the drugs.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of many other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in early trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. In the event that we abandon or are delayed in our clinical development efforts related to our drug candidates, we may not be able to execute on our business plan effectively, we may not be able to generate revenues from our drug development activities, become profitable, resulting in our reputation in the industry and in the investment community likely becoming significantly damaged and this could adversely affect the price of our shares.

We intend to rely upon Third Parties to formulate and produce our drug candidates in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's good clinical practice regulations and current good manufacturing practices and DEA and state regulations governing the handling, storage, security and recordkeeping for controlled substances. These Third Parties are anticipated to play a significant role in the formulation process and the development of our drug candidates. We intend to likely rely on these Third Parties for the formulation and development of the products to be utilized in our clinical and preclinical studies, and we will likely control minimally certain aspects of their activities.

We intend to rely on Third Parties to conduct and oversee our clinical trials. If these Third Parties do not meet our deadlines or otherwise conduct the trials as required, we may not be able to obtain regulatory approval for or commercialize our drug candidates when expected or at all.

We may also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's good clinical practice regulations and DEA and state regulations governing the handling, storage, security and recordkeeping for controlled substances. These Third Parties are anticipated to play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We intend to rely heavily on these parties for the execution of our clinical and preclinical studies, and control only certain aspects of their activities.

If any of our clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with their services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We may conduct clinical trials for our drug candidates outside the United States, and the FDA may not accept data from such trials.

We may choose to conduct one or more of our clinical trials outside the United States. 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 study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws, and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States, as much of the criteria is evaluated in the discretion of the FDA. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

If we rely on Third Parties, our internal capacity to perform these functions will be 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 Parties requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Though we will carefully manage our relationships with these Third Parties, there can be no assurance that challenges or delays in the future will not have a material adverse impact on our business, financial condition and prospects.

If a Third Party terminates or fails to perform its obligations under an agreement with us, the prospects of regulatory approval of our drugs candidates could be delayed or terminated.

At present, we are not party to any collaborative arrangement with a Third Party, although we may pursue such arrangements before commencing any preclinical studies or clinical trials for our drug candidates. If we enter into future collaborative arrangements for the research and development of any drug and any Third Party does not devote sufficient time and resources to our drug candidates, we may not realize the potential commercial benefits of the collaborative agreement, and our results of operations may be materially adversely affected. In addition, if any such future Third Party were to breach or terminate its arrangements with us, the development of any drug candidate could be delayed or terminated.

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our drug 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 drug candidates. We will 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 are seeking to protect our proprietary positions by filing patent applications in the United States and abroad related to our novel technologies and drugs that are important to our business.

We do not know whether any of the pending patent applications for any of our drug candidates will result in the issuance of patents. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have often been the subject of litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any of our potential future patents are highly uncertain. The steps we will take 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. Patent examination processes 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 the patents are granted. The rights to be granted under future patents issued to us may not provide us with the proprietary protection or competitive advantages we seek. If we are unable to obtain and maintain patent protection for our technology and drugs, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and drugs similar or superior to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

The issuance of a patent may not always be 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 drugs, or limit the duration of the patent protection for our technology and drugs.

Costly litigation may be necessary to protect our intellectual property rights and we may be subject to claims alleging the violation of the intellectual property rights of others.

We may face significant expense and liability due to litigation or other proceedings relating to patents and other intellectual property rights of others. If another party has also filed a patent application or been issued a patent relating to an invention or technology claimed by us in pending applications, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome were favorable to us. We, or our licensors, also could be required to participate in interference proceedings involving issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology or to license rights from prevailing third parties.

The cost to us of any patent application or patent litigation, even if resolved in our favor, could be substantial. Our ability to enforce our patent protection could be limited by our financial resources, and may be subject to lengthy delays.

A third party may claim that we use inventions claimed by their patents and may go to court to stop us from engaging in research, development and/or the sale of any of our future drugs. Such lawsuits are expensive and would consume time and other resources. There is a risk that the court will decide that we are infringing on the third party's patents and will order us to stop the activities claimed by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed their patents.

Moreover, there is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license, if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may in the future, assert other intellectual property infringement claims against us with respect to our drug candidates, technologies or other matters.

We will rely on confidentiality agreements that could be breached and may be difficult to enforce, which could result in third parties using our intellectual property to compete against us.

We will take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. These agreements may be difficult and costly to enforce. Although we will seek to obtain these types of agreements from these Third Parties, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with our drug candidates. If a dispute arises, a court may determine that the right belongs to a third party. Enforcement of our rights can be costly and unpredictable. Despite the protective measures we intent to employ, we will still face the risk that:

- these agreements may be breached;

- these agreements may not provide adequate remedies for the applicable type of breach;
- our trade secrets or proprietary know-how will otherwise become known; or
- our competitors will independently develop similar technology or proprietary information.

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

The degree of future protection afforded by our intellectual property rights may be uncertain because intellectual property rights have limitations, and may not adequately protect us to enable us to maintain any competitive advantage. The following factors may weaken our protection:

- compounds may be made by others that are the same or similar to our drug candidates, but are not covered by our patent claims;
- inventions covered by our future patents or pending patent may have been discovered by others previously;
- independently developed similar or alternative technologies may duplicate any of our technologies without infringing our intellectual property rights;
- pending patents may not lead to issued patents;
- our future issued patents 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
- the patents of others may have an adverse effect on our business.

Sales Strategies and Licensing Opportunities

We currently do not have sales, distribution or marketing capabilities. If we are unable to establish a sales and marketing capability or collaborate with a partner to do so, it can be expected that little if any sales of the drugs that we may develop, if ever approved for marketing, would occur. Prospective investors in our securities must be aware that given the early stage of our efforts, no reliable estimates of revenues derived from sales of any drugs that we succeed in developing can be made. Further, no estimate of operating or net profits that could be derived from any drug sales can be made.

There is no guarantee that marketing approval for any drug candidate will lead to sales or profits. For example, the commercial success of our drug candidates, for which marketing approval is obtained from the FDA or other regulatory authorities, will depend upon the acceptance of these drugs by the medical community and reimbursement for them by third-party payors, including government payors. The degree of market acceptance of any approved drugs will depend on a number of factors, including but not limited to: convenience and ease of administration; limitations or warnings contained in a product's FDA approved labeling; pricing and cost effectiveness; effectiveness of our or our collaborators' sales and marketing strategies; and our ability to obtain sufficient third-party coverage or reimbursement.

Our desire is to have the drugs we may develop gain acceptance in foreign countries. We do not expect that we will have the personnel, resources, or desire to directly market any pharmaceutical product in any foreign country in the foreseeable future and cannot guarantee that any suitable marketing partner will be found for any drug.

Risks Related to Our Common Stock

There can be no assurance of a liquid public trading market for our Common Stock or whether investors will be able to readily be able to sell their shares of Common Stock.

At present, our Common Stock is subject to quotation on the OTCQB under the symbol "NXEN". There is only a limited and non-liquid public trading market for our Common Stock and there can be no assurance that a more liquid market will ever develop or be sustained. Market liquidity will depend on the perception of our business and any steps that our management might take to bring public awareness of our business to the investing public within the parameters of the federal securities laws. We can provide no assurance that there will be any awareness generated or sustained. Consequently, investors may not be able to liquidate their investment or liquidate it at a price paid by investors equal to or greater than their initial investment in our Common Stock. As a result, holders of our Common Stock may not find purchasers for their shares should they to decide to sell the Common Stock held by them at any specific time, if ever. Consequently, our Common Stock should be purchased only by investors who have no immediate need for liquidity from their investment and who can hold our Common Stock potentially for a prolonged period of time.

In the event an active trading market develops for our Common Stock, the market price may, from time-to-time, be volatile.

In the event an active trading market develops for our Common Stock, the market price of our Common Stock may be highly volatile. Some of the factors that may materially affect the market price of our Common Stock are beyond our control, such as changes in conditions or trends in the industry in which we operate, general market and economic conditions both in the United States and globally, as well as the number of our shares of Common Stock being purchased and sold at any particular time. These factors may materially adversely affect the market price of our Common Stock, regardless of our historic business performance or future business prospects. In addition, the public stock markets have experienced and may be expected to experience extreme price and trading volume volatility. These market fluctuations may adversely affect the market price of our Common Stock.

A large number of additional shares will be available for resale into the public market pursuant to Rule 144, which may cause the market price of our Common Stock to decline significantly.

Sales of a substantial number of shares of our Common Stock in the public market will become available pursuant to Rule 144 promulgated by the SEC under the Act, and could adversely affect the market price of our Common Stock. As of September 25, 2019, we have 53,984,004 shares of Common Stock outstanding, of which 44,314,220 are restricted due to applicable federal securities laws. As restrictions on the resale of shares of Common Stock expire, pursuant to the provisions of Rule 144 or otherwise, the market price could drop significantly if the holders of these restricted shares sell them or are perceived by the market as intending to sell them at any given date or over any particular period of time.

If holders of restricted securities sell a large number of shares pursuant to Rule 144, they could adversely affect the market price for our Common Stock, over which we will likely have no control.

You may experience dilution of your ownership interest because of the potential of future issuance of additional shares of our Common Stock or our preferred stock.

In the future, we may issue our authorized but previously unissued equity securities, including shares of our Common Stock, resulting in the dilution of the ownership interests of our present stockholders. We are authorized to issue an aggregate of 200,000,000 shares of Common Stock, par value $0.0001 per share, of which 53,984,004 shares of Common Stock are outstanding as of September 25, 2019.

We may also issue additional shares of our Common Stock, warrants or other securities that are convertible into or exercisable for the purchase of shares of our Common Stock in connection with hiring and/or retaining employees or consultants, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of our Common Stock or other securities, for any reason including those stated above, may have a negative impact on the market price of our Common Stock. There can be no assurance that the issuance of any additional shares of Common Stock, warrants or other convertible securities may not be at a price (or exercise prices) below the then prevailing price at which shares of our Common Stock will be quoted in the U.S. over-the-counter market.

We may never pay any dividends to our stockholders.

We currently intend to retain any future earnings for use in the operation and expansion of our business. Accordingly, we do not expect to pay any dividends in the foreseeable future, but will review this policy as circumstances dictate. The declaration and payment of all future dividends, if any, will be at the sole discretion of our board of directors, which retains the right to change our dividend policy at any time. Consequently, stockholders must rely on sales of their Common Stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

Insiders will continue to have substantial control over us and will be able to influence corporate matters.

Our directors and executive officers and present stockholders holding more than 5% of our Common Stock will own of record and beneficially, in the aggregate, approximately 73% of our outstanding Common Stock. As a result, if these stockholders were to choose to act together, they would be able to exercise considerable influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our Company or all or a significant percentage of our assets. This concentration of ownership could limit your ability to influence corporate matters and may have the effect of delaying or preventing a third party from acquiring control over us. For information regarding the ownership of our outstanding stock by our executive officers and directors and their affiliates, see the disclosure under Item 12 - "*Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."*

We cannot assure you that the interests of our management and affiliated persons will coincide with the interests of other stockholders. As long as our management and affiliated persons collectively control a substantial portion of our Common Stock, these individuals and/or entities controlled by them, including Kanativa USA Inc., will continue to collectively be able to strongly influence or effectively control our decisions.

Our Common Stock is thinly traded, so stockholders may be unable to sell at or near ask prices, or at all, if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our Common Stock is "thinly-traded," meaning that the number of persons interested in purchasing our Common Stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours, or purchase or recommend the purchase of our shares until such time as we become more seasoned and viable. As a consequence, there may be periods of several days or longer when trading activity in our Common Stock is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on its share price. We cannot give stockholders any assurance that a broader or more active public trading market for our Common Stock will develop or be sustained, or that current trading levels will be sustained.

Anti-takeover provisions of the Delaware General Corporation Law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could reduce our stock price.

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

State Blue Sky registration and potential limitations on resale of our Common Stock.

The holders of our shares of Common Stock and those persons who desire to purchase our Common Stock in any trading market, should be aware that there may be state blue-sky law restrictions upon the ability of investors to resell our securities. Accordingly, investors should consider the secondary market our securities to be a limited one.

It is the present intention of management to seek coverage and publication of information regarding the Company in an accepted publication manual, which will result in a "manual exemption." The manual exemption permits a security to be distributed in a specific state without being registered, if the registrant issuing the security has a listing for that security in a securities manual recognized by the state.

However, it is not enough for the security to be listed in a recognized manual. The listing entry must contain (1) the names of issuer's officers, and directors, (2) an issuer's balance sheet, and (3) a profit and loss statement for either the fiscal year preceding the balance sheet or for the most recent fiscal year of operations. Furthermore, the manual exemption is a non-issuer exemption restricted to secondary trading transactions, making it unavailable for issuers selling newly issued securities.

Most of the accepted manuals include Mergent/Moody's Manuals, Fitch's Investment Service, and Best's Insurance Reports, and many states expressly recognize these manuals. A smaller number of states declare that they "recognize securities manuals" but do not specify the recognized manuals.

Our Common Stock is considered a Penny Stock, which may be subject to restrictions on marketability, so you may not be able to sell your shares.

We may be subject now and in the future to the Penny Stock rules if our shares of Common Stock sell below $5.00 per share. Penny stocks generally are equity securities with a price of less than $5.00. The penny stock rules require broker-dealers to deliver a standardized risk disclosure document prepared by the SEC which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information must be given to the customer orally or in writing prior to completing the transaction and must be given to the customer in writing before or with the customer's confirmation.

In addition, the penny stock rules require that prior to a transaction, the broker dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. The penny stock rules are burdensome and may reduce purchases of any offerings and reduce the trading activity for shares of our Common Stock. As long as our shares of Common Stock are subject to the penny stock rules, the holders of such shares of Common Stock may find it more difficult to sell their securities.

The control deficiencies in our internal control over financial reporting may until remedied cause errors in our financial statements or cause our filings with the SEC to not be timely.

There may be errors in our financial statements that could require a restatement, or our filings may not be timely made with the SEC. Based on the work undertaken and performed by us, however, we believe the financial statements contained in our reports filed with the SEC are fairly stated in all material respects in accordance with generally accepted accounting principles ("GAAP") for each of the periods presented.

At present, our internal control over financial reporting or disclosure controls and procedures are not effective. We identified material weaknesses including lack of sufficient internal accounting personnel in order to ensure complete documentation of complex transactions and adequate financial reporting during the years ended June 30, 2019 and 2018.

We intend to implement additional corporate governance and control measures to strengthen our control environment as we are able, but we may not achieve our desired objectives. We may identify material weaknesses and control deficiencies in our internal control over financial reporting in the future that may require remediation and could lead investors losing confidence in our reported financial information, which could lead to a decline in our stock price.

Reporting requirements under the Exchange Act and compliance with the Sarbanes-Oxley Act of 2002 (SOX), including establishing and maintaining acceptable internal controls over financial reporting, are costly and may increase substantially.

The rules and regulations of the SEC require a public company to prepare and file periodic reports under *the Securities Exchange Act of 1934* (the "Exchange Act"), which will require that the Company engage legal, accounting, auditing and other professional service providers. The engagement of such services is costly and continuing. Additionally, SOX requires, among other things, that we design, implement and maintain adequate internal controls and procedures over financial reporting. The costs of complying with SOX and the limited technically qualified personnel we have may make it difficult for us to design, implement and maintain adequate internal controls over financial reporting. We expect these costs to be approximately $50,000 per year or perhaps more as our operations increase in scope and magnitude. If we fail to maintain an effective system of internal controls or discover material weaknesses in our internal controls, we may not be able to produce reliable financial reports and/or discover and report fraud, which may harm our overall financial condition and result in loss of investor confidence and a decline in our share price.

As a public company, we are subject to the reporting requirements of the Exchange Act, SOX, the *Dodd-Frank Act of 2010* and other applicable securities rules and regulations. Our legal and financial compliance costs related to these rules and regulations may increase, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual and quarterly, and, from time-to-time, current reports, with respect to our business and operating results.

We are working with our legal, independent accounting and financial advisors to identify those areas in which changes should or could be made to improve our financial and management control systems to manage our growth and our legal obligations as a public company. These areas include corporate governance, corporate and internal controls, disclosure controls and procedures and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas, if and when any perceived deficiencies are discovered. However, we anticipate that the expenses associated with being a reporting public company are expected to be both material and continuing. We estimate that the aggregate cost of legal services; accounting and audit functions; personnel, such as a chief financial officer familiar with the obligations of public company reporting; and consultants to design and implement internal controls could be material. In addition, if and when we retain additional independent directors and/or members of senior management, we may incur additional expenses related to director compensation and/or premiums for directors' and officers' liability insurance ("D&O Insurance"), the costs of which we cannot estimate at this time. We may also incur additional expenses associated with investor relations and similar functions, the costs for which we cannot estimate at this time. However, these additional expenses individually, or in the aggregate, may also be expected to be material.

In addition, being a public company could make it more difficult, or more costly for us to obtain certain types of insurance, including D&O Insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The increased costs associated with operating as a public company may decrease our net income or increase our net losses, and may cause us to reduce costs in other areas of our business or increase the prices of our drug to offset the effect of such increased costs. Additionally, if these requirements divert our management's attention from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations.

Our by-laws provide for indemnification of our directors and the purchase of D&O insurance at our expense and limit their potential or actual liability which may result in a significant cost to us and damage the interests of our stockholders.

The Company's By-Laws include provisions that eliminate the personal liability of the directors of the Company for monetary damages to the fullest extent possible under the laws of the State of Delaware as well as other applicable laws. These provisions eliminate the liability of directors to the Company and its stockholders for monetary damages arising out of any violation of a director of his fiduciary duty of due care. Under Delaware law, however, such provisions do not eliminate the personal liability of a director for: (i) breach of the director's duty of loyalty; (ii) acts or omissions not in good faith or involving intentional misconduct or knowing violation of law; (iii) payment of dividends or repurchases of stock other than from lawfully available funds; or (iv) any transaction from which the director derived an improper benefit. These provisions do not affect a director's liabilities under the federal securities laws or the recovery of damages by third parties.

Financial Industry Regulatory Authority, Inc. ("*FINRA*") *sales practice requirements may limit a stockholder's ability to buy and sell our Common Stock.*

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our Common Stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

If we fail to maintain effective internal controls over financial reporting, the price of our Common Stock may be adversely affected.

Our internal control over financial reporting may have weaknesses and conditions that could require correction or remediation, the disclosure of which may have an adverse impact on the price of our Common Stock. We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely affect our public disclosures regarding our business, prospects, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our Common Stock.

We are required to comply with certain provisions of Section 404 of SOX and if we fail to comply in a timely manner, our business could be harmed and our stock price could decline.

Rules adopted by the SEC pursuant to Section 404 of SOX require an annual assessment of internal controls over financial reporting, and for certain issuers an attestation of this assessment by the issuer's independent registered public accounting firm. The standards that must be met for management to assess the internal controls over financial reporting as effective are evolving and complex, and require significant documentation, testing, and possible remediation to meet the detailed standards. We expect to incur expenses and to devote resources to Section 404 compliance on an ongoing basis. It is difficult for us to predict how long it will take or costly it will be to complete the assessment of the effectiveness of our internal control over financial reporting for each year and to remediate any deficiencies in our internal control over financial reporting. As a result, we may not be able to complete the assessment and remediation process on a timely basis. In addition, although attestation requirements by our independent registered public accounting firm are not presently applicable to us, we could become subject to these requirements in the future and we may encounter problems or delays in completing the implementation of any resulting changes to internal controls over financial reporting. If our Chief Executive Officer or Chief Financial Officer determines that our internal controls over financial reporting are not effective as defined under Section 404, we cannot predict how the market prices of our shares will be affected; however, we believe that there is a risk that investor confidence and share value may be negatively affected.

Our share price could be volatile and our trading volume may fluctuate substantially.

The price of our common shares has been and may in the future continue to be extremely volatile, with the sale price fluctuating from a low of pennies per share to a high of $6.00 during the previous twelve-month period. Many factors could have a significant impact on the future price of our common shares, including:

- our inability to raise additional capital to fund our operations, whether through the issuance of equity securities or debt;
- our failure to successfully implement our business objectives and strategic growth plans;
- compliance with ongoing regulatory requirements;
- market acceptance of our drug candidates, once approved for sale;
- changes in government regulations;
- general economic conditions and other external factors; and
- actual or anticipated fluctuations in our quarterly financial and operating results; and
- the degree of trading liquidity in our common shares.

Our annual and quarterly results may fluctuate greatly, which may cause substantial fluctuations in our Common Stock price.

Our annual and quarterly operating results may in the future fluctuate significantly depending on a number of factors. Any unfavorable change in these or other factors could have a material adverse effect on our operating results for a particular quarter or year, which may cause downward pressure on our Common Stock price. We expect quarterly and annual fluctuations to continue for the foreseeable future.

Risks Related to the Regulation of Cannabis in the United States

While cannabis is legal in many U.S. state jurisdictions, it continues to be a controlled substance under the United States CSA.

In the United States, cannabis is largely regulated at the state level. To the Company's knowledge, there are to date a total of 29 states, plus the District of Columbia, Puerto Rico and Guam, that have legalized cannabis in some form. Notwithstanding the permissible regulatory environment of medical cannabis at the state level, cannabis continues to be categorized as a controlled substance under the CSA and as such, violates federal law in the United States.

The United States Congress has passed appropriations bills each of the last three years that have not appropriated funds for the prosecution of cannabis offenses of individuals who are in compliance with state medical cannabis laws. American courts have construed these appropriations bills to prevent the federal government from prosecuting individuals when those individuals comply with state law. However, because this conduct continues to violate federal law, American courts have observed that should Congress at any time choose to appropriate funds to fully prosecute the CSA, any individual or business – even those that have fully complied with state law – could be prosecuted for violations of federal law. And if Congress restores funding, the government will have the authority to prosecute individuals for violations of the law where before it lacked funding under the CSA's five-year statute of limitations.

Violations of federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges, including, but not limited to, disgorgement of profits, cessation of business activities or divestiture. This could have a material adverse effect on the Company, including its reputation and ability to conduct business, the listing of its securities on various stock exchanges, its financial position, operating results, profitability or liquidity or the market price of its publicly traded shares. In addition, it is difficult for the Company to estimate the time or resources that would be needed for the investigation of any such matters or its final resolution because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial.

Currently the Company does not intend to proceed with clinical trials using cannabis-derived cannabinoids in the U.S. If the Company decides to proceed with plant-derived cannabinoids, it could become subject to risks relating to the characterization of cannabis as a controlled substance.

The approach to the enforcement of cannabis laws may be subject to change or may not proceed as previously outlined.

As a result of the conflicting views between state legislatures and the federal government regarding cannabis, involvement in the cannabis industry in the United States is subject to inconsistent legislation and regulation. The response to this inconsistency was addressed in the Cole Memo addressed to all United States district attorneys acknowledging that notwithstanding the designation of cannabis as a controlled substance at the federal level in the United States, several U.S. states have enacted laws relating to cannabis.

The Cole Memo outlined certain priorities for the DOJ relating to the prosecution of cannabis offences. In particular, the Cole Memo noted that in jurisdictions that have enacted laws legalizing cannabis in some form and that have also implemented strong and effective regulatory systems to control the cultivation, distribution and possession of cannabis, conduct in compliance with those laws and regulations is less likely to be a priority at the federal level. Notably, however, the DOJ has never provided specific guidelines for what regulatory and enforcement systems it deems sufficient under the Cole Memo standard.

In light of limited investigative and prosecutorial resources, the Cole Memo concluded that the DOJ should be focused on addressing only the most significant threats related to cannabis. States where medical cannabis had been legalized were not characterized as a high priority. In March 2017, newly appointed Attorney General Jeff Sessions again noted limited federal resources and acknowledged that much of the Cole Memo had merit; however, he disagreed that it had been implemented effectively and, on January 4, 2018, Attorney General Jeff Sessions issued the Sessions Memo, which rescinded the Cole Memo. The Sessions Memo rescinded previous nationwide guidance specific to the prosecutorial authority of the United States Attorneys relative to cannabis enforcement on the basis that they are unnecessary, given the well-established principles governing federal prosecution that are already in place. Those principles are included in chapter 9.27.000 of the United States Attorneys' Manual and require federal prosecutors deciding which cases to prosecute to weigh 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.

As a result of the Sessions Memo, federal prosecutors will now be free to utilize their prosecutorial discretion to decide whether to prosecute cannabis activities despite the existence of state-level laws that may be inconsistent with federal prohibitions. No direction was given to federal prosecutors in the Sessions Memo as to the priority they should ascribe to such cannabis activities, and as a result it is uncertain how active federal prosecutors will be in relation to such activities. Further, the Sessions Memo did not discuss the treatment of medical cannabis by federal prosecutors.

Medical cannabis is currently protected against enforcement by enacted legislation in the United States Congress in the form of the Rohrabacher-Blumenauer Amendment (the "RBA") which similarly prevents federal prosecutors from using federal funds to impede the implementation of medical cannabis laws enacted at the state level, subject to Congress restoring such funding. Subsequent to the issuance of the Sessions Memo on January 4, 2018, the United States Congress passed its omnibus appropriations bill, SJ 1662, which for the fourth consecutive year contained the RBA language (referred to in 2018 as the Rohrabacher-Leahy Amendment) and continued the protections for the medical cannabis marketplace and its lawful participants from interference by the DOJ up and through the 2018 appropriations deadline of September 30, 2018. Due to the ambiguity of the Sessions Memo in relation to medical cannabis, there can be no assurance that the federal government will not seek to prosecute cases involving cannabis businesses that are otherwise compliant with state law.

Until September 2018, the DOJ is prohibited from expending any funds for the prosecution of medical cannabis businesses operating in compliance with state and local laws pursuant to the RBA. If the RBA or an equivalent thereof is not successfully amended to the next or any subsequent federal omnibus spending bill, the protection afforded thereby to U.S. medical cannabis businesses would lapse, and such businesses would be more at risk to prosecution under federal law. There is a possibility that all amendments may be banned from federal omnibus spending bills, and if this occurs and the substantive provisions of the RBA are not included in the base federal omnibus spending bill or other law, these protections would lapse. The Company regularly monitors the regulatory activities of Congress. Fully 62% of the combined House of Representatives and the Senate represent states with medical marijuana laws enacted or in process.

If we decide to proceed with clinical trials using plant-derived cannabinoids, and are conducting those trials in the United States, we could be subject to risks relating to the enforcement of cannabis laws.

The Company is operating at a regulatory frontier. The cannabis industry is a new industry that may not succeed.

Should the federal government in the U.S. change course and decide to prosecute those dealing in medical or other cannabis under applicable law, there may not be any market for the Company's products and services in the U.S.

Cannabis is a new industry subject to extensive regulation, and there can be no assurance that it will grow, flourish or continue to the extent necessary to permit the Company to succeed. The Company is treating the cannabis industry as a deregulating industry and to the extent that the Company decides to proceed with clinical trials using plant-derived cannabinoids, it will adjust its future operations, product and market strategy as the industry develops and matures.

Future operations in the United States cannabis market may become the subject of heightened scrutiny.

Any future operations in the United States cannabis market may become the subject of heightened scrutiny by regulators, stock exchanges, clearing agencies and other authorities in Canada. As a result, the Company may be subject to significant direct and indirect interaction with public officials. There can be no assurance that this heightened scrutiny will not in turn lead to the imposition of certain restrictions on the Company's ability to operate in the United States or any other jurisdiction, in addition to those described herein.

Regulatory scrutiny of the Company's industry may negatively impact its ability to raise additional capital.

The Company's business activities rely on newly established and/or developing laws and regulations in multiple jurisdictions. These laws and regulations are rapidly evolving and subject to change with minimal notice. Regulatory changes may adversely affect the Company's profitability or cause it to cease operations entirely. The cannabis industry may come under scrutiny by the U.S. FDA, the SEC, the DOJ, the Financial Industry Regulatory Authority or other federal or other applicable state or nongovernmental regulatory authorities or self-regulatory organizations that supervise or regulate the production, distribution, sale or use of cannabis for medical or non-medical purposes in the U.S. It is impossible to determine the extent of the impact of any new laws, regulations or initiatives that may be proposed, or whether any proposals will become law. The regulatory uncertainty surrounding the Company's industry may adversely affect the business and operations of the Company, including without limitation, the costs to remain compliant with applicable laws and the impairment of its ability to raise additional capital, create a public trading market in the U.S. or elsewhere for securities of the Company, which could reduce, delay or eliminate any return on investment in the Company.

State and local laws and regulations may heavily regulate brands and forms of cannabis products and there is no guarantee that the Company's proposed products and brands will be approved for sale and distribution in any state.

States generally only allow the manufacture, sale and distribution of cannabis products that are grown in that state and may require advance approval of such products. Certain states and local jurisdictions have promulgated certain requirements for approved cannabis products based on the form of the product and the concentration of the various cannabinoids in the product. If the Company produces products that are derived from plant-based (rather than synthetic) cannabinoids, the Company intends to follow the guidelines and regulations of each applicable state and local jurisdiction in preparing products for sale and distribution, there is no guarantee that such products will be approved to the extent necessary. If the products are approved, there is a risk that any state or local jurisdiction may revoke its approval for such products based on changes in laws or regulations or based on its discretion or otherwise.

We may have difficulties accessing the services of banks in the United States due to the nature of our business.

The use, sale, or possession of all forms of cannabis in the United States is illegal under federal law. As a Schedule I drug under the federal *Controlled Substances Act of 1970* , cannabis is considered to have "no accepted medical use" and have a high potential for abuse and physical or psychological dependence. As a result, historically many banks have not accepted for deposit funds from persons/entities that are engaged in cannabis-related businesses, including those engaged in developing drugs containing cannabinoids such as our Company. As described above, on February 14, 2014, the Financial Crimes Enforcement Network ("FinCEN") released guidance to banks "clarifying Bank Secrecy Act expectations for financial institutions seeking to provide services to cannabis-related businesses." In addition, U.S. Rep. Jared Polis (D-CO) has stated he will seek an amendment to banking regulations and laws in order to allow banks to transact business with state-authorized medical marijuana treatment programs. While these are positive developments, there can be no assurance this legislation will be successful, or that, even with the FinCEN guidance, banks will decide to do business with corporations that are in the business of developing drugs containing cannabinoids, or that, in the absence of actual legislation, state and federal banking regulators will not strictly enforce current prohibitions on banks handling funds generated from an activity that is illegal under federal law. While the Company has not, to date, experienced any difficulty in opening accounts and otherwise using the services of banks, any changes in this regard could materially harm our business.

Due to the classification of cannabis as a Schedule I controlled substance under the CSA, banks and other financial institutions which service the cannabis industry are at risk of violating certain financial laws, including anti-money laundering statutes.

Because the manufacture, distribution, and dispensation of cannabis remains illegal under the CSA, banks and other financial institutions providing services to cannabis-related businesses risk violation of federal anti-money laundering statutes (18 U.S.C. §§ 1956 and 1957), the unlicensed money-remitter statute (18 U.S.C. § 1960) and the *U.S. Bank Secrecy Act*. These statutes can impose criminal liability for engaging in certain financial and monetary transactions with the proceeds of a "specified unlawful activity" such as distributing controlled substances which are illegal under federal law, including cannabis, and for failing to identify or report financial transactions that involve the proceeds of cannabis-related violations of the CSA. The Company may also be exposed to the foregoing risks if it produces drugs derived from plant-based (rather than synthetic) cannabinoids.

Any re-classification of cannabis or changes in U.S. controlled substance laws and regulations may affect the Company's business.

If cannabis and/or CBD is re-categorized as a Schedule II or lower controlled substance, the ability to conduct research on the medical benefits of cannabis would most likely be simpler and more accessible; however, if cannabis is re-categorized as a Schedule II or other controlled substance, the resulting re-classification would result in the requirement for FDA approval if medical claims are made for any of the Company's products, such as medical cannabis. As a result, the manufacture, importation, exportation, domestic distribution, storage, sale and use of such products may be subject to a significant degree of regulation by the DEA. In that case, the Company may be required to be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. Obtaining the necessary registrations may result in delay of the manufacturing or distribution of the Company's anticipated products. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Failure to maintain compliance could have a material adverse effect on the Company's business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. Furthermore, if the FDA, DEA, or any other regulatory authority determines that the Company's products may have potential for abuse, it may require the Company to generate more clinical or other data than the Company currently anticipates establishing whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of that product.

CBD is classified as Schedule I controlled substance. The DEA recently published a final rule in the Federal Register creating a new drug code for "marijuana extracts".

In connection with the new drug code, the DEA has determined that all CBD products, regardless of origin, shall be considered Schedule I controlled substances. The Company is unable to determine what the impact of this will be on its business.

U.S. federal trademark and patent protection may not be available for the intellectual property of the Company due to the current classification of cannabis as a Schedule I controlled substance.

As long as cannabis remains illegal under U.S. federal law as a Schedule I controlled substance pursuant to the CSA, the benefit of certain federal laws and protections which may be available to most businesses, such as federal trademark and patent protection regarding the intellectual property of a business, may not be available to the Company if it determines to produce drugs using cannabis. As a result, the Company's intellectual property may never be adequately or sufficiently protected against the use or misappropriation by third-parties. In addition, since the regulatory framework of the cannabis industry is in a constant state of flux, the Company can provide no assurance that it will ever obtain any protection of its intellectual property, whether on a federal, state or local level.

The Company's contracts may not be legally enforceable in the United States.

If, in the future, the Company enters into contracts that involve cannabis and/or other activities that are not legal under U.S. federal law and in some jurisdictions, the Company may face difficulties in enforcing its contracts in U.S. federal and certain state courts.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not Applicable.

ITEM 2. PROPERTIES

Our principal office is located at 4340 East Kentucky Avenue, Suite 206, Glendale, Colorado 80246. Our telephone number is (303) 495-7583. Our offices consist of approximately 300 square feet of executive offices and we believe that these facilities will be sufficient for the next twelve months.

ITEM 3. LEGAL PROCEEDINGS.

There are no pending legal proceedings to which the Company is a party, and the Company's property is not the subject of any pending legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not Applicable.

PART II

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

Market Price Information

Our Common Stock is currently quoted on the OTCQB Market under the symbol NXEN. For the periods indicated, the following table sets forth the high and low bid prices per share of Common Stock. The below prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

	Price Range	
Period	High	Low
Year Ended June 30, 2018:		
First Quarter	$ 4.4999	$ 0.69
Second Quarter	$ 5.95	$ 0.792
Third Quarter	$ 6.00	$ 1.21
Fourth Quarter	$ 4.00	$ 1.52
Year Ended June 30, 2019:		
First Quarter	$ 3.95	$ 0.29
Second Quarter	$ 1.48	$ 0.15
Third Quarter	$ 0.21	$ 0.081
Fourth Quarter	$ 0.10	$ 0.031

As of September 25, 2019, the closing price for the Common Stock was $0.091 per share.

As of September 25, 2019, our shares of Common Stock were held by 738 stockholders of record. The transfer agent of our Common Stock is Standard Registrar and Transfer Company, Inc., whose telephone number is: (801) 571-8844.

Dividends

Holders of Common Stock are entitled to dividends when, as, and if declared by the Board of Directors, out of funds legally available therefor. We have never declared cash dividends on our Common Stock and our Board of Directors does not anticipate paying cash dividends in the foreseeable future as it intends to retain future earnings to finance the growth of our businesses. There are no restrictions in our certificate of incorporation or bylaws that restrict us from declaring dividends.

Securities Authorized for Issuance Under Equity Compensation Plans

On August 10, 2017, BioPharma adopted its 2017 Stock Incentive Plan under which the board of directors is authorized the grant up to 7,200,000 shares of its common stock. An aggregate of 6,400,000 shares of Common Stock to five officers and directors of the Company, valued at $800,000 ($0.125 per share) were granted. On July 25, 2018, the Company accelerated the vesting of 1,083,342 unvested shares of Common Stock previously granted to its former Chief Executive Officer and Chief Financial Officer. As of June 30, 2019, 150,000 of the shares issued (valued at $18,750) were subject to forfeiture until vesting occurred.

On March 30, 2018, the Company's board of directors approved and recommended for adoption by the stockholders of the Company a 2018 Equity Incentive Plan and reserved 8,000,000 shares of Common Stock for issuance under the terms of that Plan. The total number of shares reserved and available for grant and issuance under the 2018 Plan is 8,000,000 shares, plus any reserved shares not issued or subject to outstanding grants under the 2017 Stock Plan and shares that cease to be subject to awards under the 2017 Stock Plan because of forfeiture. In addition, the number of shares available for grant and issuance under the 2018 Plan will be increased on July 1 of each of the next ten calendar years by the lesser of (a) 15% of the number of shares issued during the most recently completed fiscal year or (b) such number of shares determined by the board of directors. The 2018 Plan permits the board to grant a variety of incentive awards: stock options, restricted stock awards, stock bonus awards, and stock appreciation rights. Stockholder approval was obtained on March 29, 2019. As of June 30, 2019, 3,032,500 stock options had been granted and were outstanding.

Recent Sales of Unregistered Securities

During the quarter ended June 30, 2019 we issued and sold the unregistered securities set forth in the table below.

Date	Persons or Class of Persons	Securities	Consideration
May 2019	Kotzker Consulting LLC	15,000 shares of Common Stock	Services valued at $1,500

We relied upon the exemption from registration contained in Section 4(a)(2) under the Securities Act, as the securities were sold only to one investor, sophisticated as to the business of the Company, without the use of general solicitation or advertising. No underwriters or placement agents were used and no commissions were paid in the above stock transaction. A restrictive legend was placed on the certificate evidencing the securities issued in the above transaction.

Issuer Purchases of Securities

None.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

Forward-Looking Statements

The following plan of operation provides information which management believes is relevant to an assessment and understanding of our results of operations and financial condition. The discussion should be read along with our financial statements and notes thereto. This section includes a number of forward-looking statements that reflect our current views with respect to future events and financial performance. Certain statements that the Company may make from time to time, including all statements contained in this report that are not statements of historical fact, constitute "forward-looking statements". Forward-looking statements may be identified by words such as "plans," "expects," "believes," "anticipates," "estimates," "projects," "will," "should," and other words of similar meaning used in conjunction with, among other things, discussions of future operations, financial performance, product development and new product launches, market position and expenditures. You should not place undue certainty on these forward-looking statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our predictions.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is intended to help you understand our historical results of operations during the periods presented and our financial condition for the years ended June 30, 2019 and 2018. This MD&A should be read in conjunction with our financial statements as of June 30, 2019 and 2018. See section entitled "*Forward-Looking Statements*" above.

Overview

We are engaged in pursuing pre-clinical and drug development activities for certain pharmaceutical formulations that include cannabinoids. Since March 2017, we have filed five of our own provisional patent applications, and acquired a license covering certain intellectual property related to a drug delivery system. In October 2018, we acquired all of the membership interest in CRx Bio Holdings LLC, which also engaged in the research and development of advanced cannabinoid formulations and drug delivery systems, by issuing 11,000,000 shares of our common stock. As part of the CRx acquisition, we also acquired three additional patent applications. CRx had an agreement with a major university to perform pre-clinical research related to the parenteral administration of cannabinoid formulations. As this research is common to both the CRx programs and the Nexien programs, we will be able to consolidate this research and maintain the original Nexien capital expenditure budget.

As a relatively new business engaged in start-up operations and activities, we will require substantial additional funding to successfully complete any of our drug development programs. At present, we cannot estimate the substantial capital requirements needed to secure regulatory approvals for our drug candidates. Nevertheless, we estimate that we will need to raise at a minimum $1.5 million during the next 12 months to continue our drug development and pre-clinical research programs and fund the operating costs related to being a public company. Determining a budget is subject to a number of factors. In general, this estimate may be higher if our research efforts prove to be successful, or lower if the research efforts produce results that warrant a decision to cease ongoing research and development efforts. Failure to obtain this necessary capital at acceptable terms, if at all, when needed, may force us to delay, limit, or terminate our drug development efforts to secure regulatory approvals and would adversely impact our planned research and development efforts in connection with the Company's future drugs, which may make it more difficult for us to attain profitability.

We are a start-up company with no revenues from operations. Notwithstanding our successful raise of $2,076,158, net of offering costs, in equity capital since inception to June 30, 2019, there is substantial doubt that we can continue as an on-going business for the next twelve months without the success of our business operations. We do not anticipate that Nexien BioPharma will generate revenues from its research and development activities related to its drug development projects in the near future, due to the protracted revenue model of pursuing pharmaceutical drug development in accordance with the pathway set forth by the FDA.

Results of Operations

Net loss for the year ended June 30, 2019 was $4,300,913 as compared to $1,283,197 for the year ended June 30, 2018, an increase of $3,017,716. As explained below, most of the loss is attributable to significant stock-based compensation costs, the fair value of common stock issued for the CRx acquisition, and the impairment charge related to license fees.

General and administrative costs of $3,668,841 incurred during the year ended June 30, 2019 includes $1,897,755 of non-cash stock-based compensation costs for: vesting of common shares previously issued to management valued at $210,418; the fair value of vested stock options granted of $1,531,403 and the fair value of warrants issued of $155,934. Also included in general and administrative expenses for 2019 is a non-cash charge of $1,484,042 for (i) the $727,700 fair value of the 957,500 vested shares issued for the acquisition of CRX Bio Holdings LLC and (ii) $756,342 for the vesting of shares issued to CRx subject to forfeiture. General and administrative costs of $773,437 for the year ended June 30, 2018 includes non-cash stock-based compensation costs for the period of $480,349, consisting of $424,999 as the value of shares issued to management, and $55,350 for common stock issued to two individuals under consulting agreements. Exclusive of stock-based compensation costs, general and administrative costs for the year ended June 30, 2019 were $287,044, a decrease of $6,044 from comparable costs for 2018 of $293,088.

During the year ended June 30, 2018, the Company granted an aggregate of 6,400,000 shares of BioPharma Common Stock to five officers and directors of the Company, subject to forfeiture restrictions. Restrictions lapsed as to one-third of each grant as of the initial date of grant, and restrictions as to one-twelfth of each grant will lapse quarterly for a two-year period commencing on the last day of each calendar quarter beginning on October 1, 2017. Stock-based compensation for the year ended June 30, 2018 of $480,349 includes $424,999 as the value of shares vested under the grant and $55,350 as the value of Common Stock issued to two individuals under consulting agreements. In March 2018, the Company cancelled 1,166,667 unvested shares previously issued to its former CEO.

During the year ended June 30, 2019, the Board of Directors granted options to purchase a total of 1,810,000 shares of Common Stock, exercisable for a period of seven years, to officers/directors/consultants of the Company at an exercise price of $0.54 per share; options to purchase a total of 150,000 shares of Common Stock, exercisable for a period of seven years, to two individuals, (i) a director and (ii) a consultant of the Company, at an exercise price of $0.38 per share; options to purchase 500,000 shares of Common Stock to an officer/director at an exercise price of $0.48 per share for a period of seven years; and options to purchase 800,000 shares of Common Stock to three officers/directors at an exercise price of $0.655 per share for a period of seven years.

Research and development costs decreased to $63,858 for the year ended June 30, 2019 as compared to $116,791 for the year ended June 30, 2018, which included $75,000 paid under an agreement with a contract manufacturer with significant expertise in pre-clinical and clinical trial development and regulatory approvals to develop an injectable formulation for our drug candidate (see "*Contractual Obligations and Commitments*" below). Research and development costs for the year ended June 30, 2019 were for continuation of activities under our agreement with the contract manufacturer and payment to a major university under a research agreement.

Professional fees of $200,299 for the year ended June 30, 2019 decreased by $192,670 from $392,969 for the year ended June 30, 2018. Fees for the 2019 year consisted of legal fees to external counsels and our chief operating officer for patent and FDA related regulatory matters, legal fees for securities related matters, and fees for annual audit and other required regulatory filings. During the year ended June 30, 2018, the Company's efforts were focused on equity private placement financing activities, consummation of the Share Exchange Transaction, and filings with the U.S. Patent Office and the FDA. The decrease is due, in part, to a reduction in legal fees to external counsel for patent and FDA related regulatory matters subsequent to the CRx transaction wherein external counsel expenditures were now being performed by in-house counsel, and no longer incurring fees paid to our chief operating officer.

The Company has estimated that it may not be able to recover the $302,915 carrying value of costs capitalized under the Kotzker License Agreement, or the $65,000 of costs capitalized under the worldwide exclusive license with respect to a proprietary delivery system for cannabinoid-based medications with Accu-Break, and has recognized an impairment of $367,915 for both licenses for the year ended June 30, 2019. Although the Company has recognized an impairment under Generally Accepted Accounting Principles, this accounting action does not negatively impact the Company's rights under both of these license agreements, and it intends to monetize these assets to the extent that it can in light of its currently limited financial and personnel resources.

Liquidity and Capital Resources

At June 30, 2019, we had working capital or $265,920 and cash of $146,356, as compared to working capital of $745,954, and cash of $819,739 at June 30, 2018. The decrease in both working capital and cash was due primarily to the Company's utilization of existing funds for operating activities. We used $673,383 of cash for operating and investing activities, with no increase in liquidity from financing activities during the year ended June 30, 2019. While operating and investing activities used cash of $923,242 during fiscal 2018, $1,500,203 was provided through sales of Common Stock.

While management of the Company believes that the Company will be successful in its current and planned activities, there can be no assurance that the Company will be successful in its drug development activities, and raise sufficient equity, debt capital or strategic relationships to sustain the operations of the Company.

Our ability to create sufficient working capital to sustain us over the next twelve-month period, and beyond, is dependent on our raising additional equity or debt capital, or entering into strategic arrangements with one or more third parties.

There can be no assurance that sufficient capital will be available to us. We currently have no agreements, arrangements or understandings with any person to obtain funds through bank loans, lines of credit or any other sources.

Availability of Additional Capital

Notwithstanding our success in raising gross proceeds of $2.1 million from the private sale of equity securities through June 30, 2019, there can be no assurance that we will continue to be successful in raising equity capital and have adequate capital resources to fund our operations or that any additional funds will be available to us on favorable terms or in amounts required by us. We estimate we will need to raise at a minimum $1.5 million during the next 12 months to commence our drug development projects and fund the operating costs related to being a public company. Determining a budget is subject to a number of factors. In general, this estimate may higher if our research efforts prove to be successful or lower if the research efforts produce results that warrant a decision to cease ongoing research and development efforts. If we determine that it is necessary to raise additional funds, we may choose to do so through public or private equity or debt financing, a bank line of credit, or other arrangements. If we are unable to obtain adequate capital resources to fund operations, we may be required to delay, scale back or eliminate some or all of our plan of operations, which may have a material adverse effect on our business, results of operations and ability to operate as a going concern.

Any additional equity financing may be dilutive to our stockholders, new equity securities may have rights, preferences or privileges senior to those of existing holders of our shares of Common Stock. Debt or equity financing may subject us to restrictive covenants and significant interest costs.

Capital Expenditure Plan During the Next Twelve Months

As the result of the acquisition of CRx Bio ("CRx"), we were able to eliminate the salary of one officer of the Company. All other officers, including the new management team from CRx, are not being paid any cash compensation. In addition, by bringing on an in-house legal counsel with extensive patent experience, we were able to bring all Intellectual Property ("IP") legal expenses in house. This has substantially reduced most legal expenses, which is a significant percentage of cash expenses. Finally, as CRx had been exploring similar research for alternative delivery systems as Nexien, we will be able to consolidate this research and maintain the original Nexien capital expenditure budget.

To date, we raised approximately $2.1 million, in equity capital (including exercised warrants) and we may be expected to require up to an additional $1.5 million in capital during the next 12 months to fully implement our business plan and fund our operations. Determining a budget is subject to a number of factors. In general, this estimate may higher if our research efforts prove to be successful or lower if the research efforts are not fruitful. Our plan is to utilize the capital that we raise to fund our ongoing research efforts, as well as the costs incurred by being a public reporting company. However, there can be no assurance that we will continue to be successful in raising capital in sufficient amounts and/or at terms and conditions satisfactory to the Company. Our revenues are expected to come from our drug development projects. As a result, we will continue to incur operating losses unless and until we have obtained regulatory approval with respect to one of our drug development projects and commence to generate sufficient cash flow to meet our operating expenses. There can be no assurance that we will obtain regulatory approval and the market will adopt our future drugs. In the event that we are not able to successfully: (i) raise equity capital and/or debt financing; or (ii) market our drugs after obtaining regulatory approval, our financial condition and results of operations will be materially and adversely affected.

Going Concern Consideration

Our registered independent auditors have issued an opinion on our financial statements as of June 30, 2019 which includes a statement describing our going concern status. This means that there is substantial doubt that we can continue as an on-going business for the next twelve months unless we obtain additional capital to pay our bills and meet our other financial obligations. This is because we have not generated any revenues and no revenues are anticipated until we begin marketing any drugs that we successfully develop. Accordingly, we must raise capital from sources other than the actual sale from any drugs that we develop. We must raise capital to continue our drug development activities and stay in business.

Off-Balance Sheet Arrangements

As of June 30, 2019 and 2018, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated under the Securities Act of 1934.

Contractual Obligations and Commitments

On September 19, 2017, we entered into an agreement with a contract manufacturer with significant expertise in pre-clinical and clinical trial development and regulatory approvals to develop an injectable formulation for our drug candidate in the Kotzker Development Project with the objective of applying for FDA approval. It is anticipated that the drug candidate will be developed utilizing the new drug application 505(b)(2) regulatory pathway for use in the treatment during and immediately following exposure to organophosphorus nerve agents. The formulation of the drug candidate will be based on one or more synthetic cannabinoids. We paid $75,000 to the contract manufacturer upon signing the contract, which further provides that we pay an additional $20,000 upon completion of the drug formulation and $20,000 upon completion of Phase 1 development. No payment schedule has yet been agreed to upon completion of Phase 2 and Phase 3 development stage and the contract may be terminated by either party.

On February 28, 2018, we obtained a worldwide exclusive license with respect to a proprietary delivery system for cannabinoid-based medications. Upon execution of the agreement, as amended September 18, 2018, $35,000 was paid to the licensor. An additional $10,000 was paid on November 1, 2018, $20,000 was paid on February 28, 2019 and a final payment, in cash or stock at the option of the Company, of $35,000, due August 31, 2019, was paid in shares of our common stock. We are required to pay milestone payments upon obtaining regulatory approval of pharmaceutical licensed products and royalties based upon sales of licensed products. We may grant sublicenses under the terms of the agreement.

On October 26, 2018, we entered into a Limited Liability Company Interest Purchase Agreement (the “Purchase Agreement”) with the members of CRx Bio Holdings LLC, a Delaware limited liability company (“CRx”), to acquire all of the membership interest in CRx in exchange for 11,000,000 restricted shares of our common stock (the “Acquisition”). CRx is engaged in the research and development of advanced cannabinoid formulations and drug delivery systems with a focus on bioavailability and related pharmacokinetics and pharmacodynamics (PK/PD) enhancement. The Acquisition transaction was consummated on October 26, 2018. By acquiring CRx as a wholly-owned subsidiary, we acquired all of its assets, which consist primarily of three U.S. provisional patent applications relating to cannabinoid formulations to treat convulsive disorders, chronic traumatic encephalopathy, and neuropathic pain. At the closing, we issued to the six members of CRx (the “Sellers”) 1,100,000 shares not subject to any forfeiture restrictions and 9,900,000 shares which shall be released from forfeiture restrictions according to the following vesting schedule:

- 30% shall be fully vested 12 months following the Closing (October 26, 2019);
- 30% shall be fully vested 24 months following the Closing (October 26, 2020); and
- 30% shall be fully vested 36 months following the Closing (October 26, 2021).

Any Seller who is not then providing services to us or any of our subsidiaries on any vesting date, whether through voluntary termination or termination "for cause," will forfeit his unvested shares, which will be cancelled.

Effective December 31, 2018, one of the Sellers resigned from the Company and forfeited 1,732,500 unvested shares previously issued. In May 2019, the Seller who resigned returned to the Company an additional 142,500 vested shares issued in accordance with the Purchase Agreement.

Immediately after closing, Alex Wasyl, the CEO of CRx, was elected to serve as a director and our CEO. Alain Bankier, who had been serving as our interim CEO, was elected to serve as our Executive Chairman of the Board of Directors and Chief Strategy Officer. Richard Greenberg resigned his position as Chairman of the Board, but continues to serve on the Board. As of April 1, 2019, Mr. Bankier resigned as an officer and director of the Company.

Critical Accounting Policies

Our significant accounting policies are described in the notes to our financial statements as of June 30, 2019 and 2018 and are included elsewhere in this report.

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

As a "smaller reporting company", we are not required to provide this information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Consolidated Financial Statements
Nexien BioPharma, Inc.
For the years ended June 30, 2019 and 2018

Table of contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Nexien BioPharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nexien BioPharma, Inc. (the Company) as of June 30, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended June 30, 2019, and the related notes and schedules (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended June 30, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

The accompanying financial statements have been prepared assuming that the Company will continues as a going concern. As discussed in Note 1 to the financial statements, the Company suffered a net loss from operations and has a net capital deficiency, which raises substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ M&K CPAS, PLLC.

We have served as the Company's auditor since 2017.

Houston, TX

September 30, 2019

Nexien BioPharma, Inc.
Consolidated Balance Sheets
June 30, 2019 and 2018

	2019	2018
Assets		
Current Assets		
Cash	$ 146,356	$ 819,739
Prepaids-related	99,667	-
other	64,647	-
Due from related party	-	15,000
Total current assets	310,670	834,739
Due from related party - non-current	-	99,667
License	-	337,915
Total Assets	$ 310,670	$ 1,272,321
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued expenses	$ 44,750	$ 88,785
Total current liabilities	44,750	88,785
Commitments and Contingencies		
Stockholders' Equity		
Preferred stock, $.0001 par value; 10,000,000 authorized; none issued	-	-
Common stock-$.0001 par value; 200,000,000 shares authorized; 53,510,718 shares issued and outstanding -June 30, 2019; and 44,448,496 shares- June 30, 2018	5,351	4,445
Additional paid in capital	11,505,819	2,882,888
Common stock subject to forfeiture	(5,469,708)	(229,168)
Accumulated deficit	(5,775,542)	(1,474,629)
Total Stockholders' Equity	265,920	1,183,536
Total Liabilities and Stockholders' Equity	$ 310,670	$ 1,272,321

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

Nexien BioPharma, Inc.
Consolidated Statements of Operations
Years Ended June 30, 2019 and 2018

	2019	2018
Revenue	$ -	$ -
Operating expenses		
Professional fees	200,299	392,969
Research and development	63,858	116,791
General and administrative	3,668,841	773,437
Impairment of license fees	367,915	-
Total operating expenses	4,300,913	1,283,197
Net loss	$ (4,300,913)	$ (1,283,197)
Loss per share - basic and diluted	$ (0.08)	$ (0.03)
Weighted average shares outstanding - basic and diluted	51,033,855	42,668,066

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

Nexien BioPharma, Inc.
Consolidated Statement of Stockholders' Equity
Years ended June 30, 2018 and 2019

	Shares	Common Stock	Additional Paid in Capital	Comon Stock Subject to Forfeiture	Subscription Receivable	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 2017	32,615,112	$ 3,262	$ 1,235,457	$ -	$ (484,000)	$ (191,432)	$ 563,287
Proceeds from subscription receivable	-	-	-	-	484,000	-	484,000
Stock issued for cash at $0.125 per share	3,380,000	338	422,162	-	-	-	422,500
Issuance of shares to management at $0.125 per share	6,400,000	640	799,360	(533,334)	-	-	266,666
Issuance of stock for consulting services at $0.125 per share	442,800	44	55,306	-	-	-	55,350
Stock issued for cash at $0.25 per share	100,000	10	24,990	-	-	-	25,000
Share issuance costs	-	-	(4,917)	-	-	-	(4,917)
Recapitalization of Kinder Holder	852,051	85	(99,655)	-	-	-	(99,570)
Vesting of management shares subject to forfeiture	-	-	-	158,333	-	-	158,333
Cancellation of management shares	(1,166,667)	(116)	(145,717)	145,833	-	-	-
Stock issued for cash at $1.05 per share	24,000	2	25,198	-	-	-	25,200
Issuance of stock for warrant exercise							
at $0.25 per share	960,400	96	240,004	-	-	-	240,100
at $0.38 per share	746,800	75	283,709	-	-	-	283,784
at $0.50 per share	94,000	9	46,991	-	-	-	47,000
Net loss	-	-	-	-	-	(1,283,197)	(1,283,197)
Balance, June 30, 2018	44,448,496	4,445	2,882,888	(229,168)	-	(1,474,629)	1,183,536
Issuance of shares for acquisition of CRx at $0.76 per share	11,000,000	1,100	8,358,900	(7,524,000)	-	-	836,000
Cancellation of unvested CRx shares	(1,732,500)	(173)	(1,316,527)	1,316,700	-	-	-
Cancellation of vested CRx shares	(142,500)	(14)	(108,286)	-	-	-	(108,300)
Issuance of stock for accounts payable at $0.10 per share	15,000	1	1,499	-	-	-	1,500
Cancellation of shares	(77,778)	(8)	8	-	-	-	-
Vesting of management shares subject to forfeiture	-	-	-	210,418	-	-	210,418
Amortization of CRx shares	-	-	-	756,342	-	-	756,342
Fair value of options and warrants issued for services	-	-	1,531,403	-	-	-	1,531,403
Fair value of warrants issued	-	-	155,934	-	-	-	155,934
Net loss	-	-	-	-	-	(4,300,913)	(4,300,913)
Balance, June 30, 2019	53,510,718	$ 5,351	$ 11,505,819	$ (5,469,708)	$ -	$ (5,775,542)	$ 265,920

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

Nexien BioPharma, Inc.
Consolidated Statements of Cash Flows
Years Ended June 30, 2019 and 2018

	2019	2018
Cash flows from operating activities		
Net loss	$ (4,300,913)	$ (1,283,197)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock based compensation	1,897,755	480,349
Fair value of shares issued for CRx Acquisition	1,484,042	-
Impairment of license fee	367,915	-
Changes is assets and liabilities		
(Increase) in prepaids	(64,647)	-
Decrease (increase) in due from related party	15,000	26,662
(Decrease) increase in accounts payable and accrued expenses	(42,535)	(99,156)
Cash used in operating activities	(643,383)	(875,342)
Cash flows from investing activities		
Cash paid for license	(30,000)	(35,000)
Cash paid for acquisition deposit	-	(12,900)
Cash used in investing activities	(30,000)	(47,900)
Cash flows from financing activities		
Cash proceeds from issuance of common stock	-	1,527,583
Payment of offering costs	-	(27,380)
Cash provided by financing activities	-	1,500,203
Net increase in cash and cash equivalents	(673,383)	576,961
Cash and cash equivalents, beginning of period	819,739	242,778
Cash and cash equivalents, end of period	$ 146,356	$ 819,739
Supplemental disclosure of non-cash investing and financing activities		
Shares issued for Kinder Exchange	$ -	$ 99,570
Shares issued for settlement of accounts payable	$ 1,500	$ -
Cancellation of common shares	$ 181	$ -

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

Note 1 – Nature of Business and Basis of Presentation

The Company was incorporated on November 10, 1952 in Michigan as Gantos, Inc. On July 21, 2008, the Company completed its change in domicile to Delaware and subsequently changed its name to Kinder Holding Corp. (the "Company"). As of October 13, 2017, the Company completed a reverse acquisition of Intiva BioPharma Inc., a Colorado corporation ("BioPharma") through an exchange of shares (the "Share Exchange Transaction"). In connection with the Share Exchange Transaction, the Company changed its name to Intiva BioPharma Inc. on November 8, 2017 and, in September 2018, the Company changed its name to Nexien BioPharma, Inc.

As further described in Note 3, BioPharma became a wholly-owned subsidiary of the Company. Since this transaction resulted in the existing shareholders of BioPharma acquiring control of the Company, for financial reporting purposes, the business combination has been accounted for as an additional capitalization of the Company (a reverse acquisition with BioPharma as the accounting acquirer). The operations of BioPharma were the only continuing operations of the Company. The accompanying financial statements as of June 30, 2019 and 2018 and for the years then ended present the historical financial information of BioPharma.

BioPharma was incorporated under the laws of the State of Colorado on March 27, 2017 to pursue pre-clinical and drug development activities, in accordance with U.S. Food and Drug Administration ("FDA") protocols, for certain pharmaceutical formulations that include cannabinoids. It is pursuing the formulation and development of drugs containing cannabinoids for the treatment of various diseases, disorders and medical conditions, and owns a license covering certain intellectual property, including certain patent applications, and has filed five of its own provisional patent applications for other drugs that include cannabinoids and other substances, including terpenes, that are intended to be developed with the objective of treating certain medical conditions and disorders. It was formed as a corporate subsidiary of the Colorado corporation Kanativa USA Inc. (formerly Intiva USA Inc.) ("Kanativa USA"), which is a subsidiary of the Ontario, Canada corporation, Kanativa Inc.

All share and per share amounts have been adjusted in the footnotes and accompanying financial statements to give effect to the Share Exchange Transaction.

Principles of Consolidation

The accompanying consolidated financial statements include BioPharma and its wholly owned subsidiaries: Intiva BioPharma Inc. (a Colorado corporation), NexN Inc. ("NexN") and NexDM Inc.," and were prepared from the accounts of the Company in accordance with accounting principles generally accepted in the United States of America (US GAAP). All significant intercompany transactions and balances have been eliminated on consolidation.

Basis of Presentation/Going Concern Uncertainty

All share and per share amounts have been adjusted in the footnotes and accompanying financial statements to give effect to the Share Exchange Transaction. (See Note 3).

The accompanying financial statements have been prepared in conformity with US GAAP, which contemplates continuation of the Company as a going concern. The Company has not established any source of revenue to cover its operating costs, and as such, has incurred an operating loss since inception of $5,775,542. The development of pharmaceuticals with the objective of obtaining approval by the FDA and other international regulatory authorities is not a short-term endeavor for any specific drug candidate. It also requires extremely significant amounts of capital funding for clinical trials and other matters. At June 30, 2019, the Company had working capital of $265,920. The Company will require significant additional capital to fund the implementation and execution of its business plan. This capital, which likely will be millions of dollars for a single drug candidate, will be required for research, regulatory applications, and clinical trials. At the present time, the Company does not have any commitments or known sources for this level of funding. These and other factors raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

Note 2 – Summary of Significant Accounting Policies

Use of Estimates

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

Cash and Cash Equivalents

For financial statement presentation purposes, the Company considers those short-term, highly liquid investments with original maturities of three months or less to be cash or cash equivalents. There were no cash equivalents at June 30, 2019 and 2018.

Valuation of Long-Lived Assets

The Company reviews the recoverability of its long-lived assets including equipment, goodwill and other intangible assets, when events or changes in circumstances occur that indicate that the carrying value of the asset may not be recoverable. The assessment of possible impairment is based on the Company's ability to recover the carrying value of the asset from the expected future pre-tax cash flows (undiscounted and without interest charges) of the related operations. If these cash flows are less than the carrying value of such asset, an impairment loss is recognized for the difference between estimated fair value and carrying value. The Company's primary measure of fair value is based on discounted cash flows. The measurement of impairment requires management to make estimates of these cash flows related to long-lived assets, as well as other fair value determinations.

Fair Value of Financial Instruments

FASB ASC 825, "Financial Instruments," requires entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized on the balance sheet, for which it is practicable to estimate fair value. FASB ASC 825 defines fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties. At June 30, 2019 and 2018, the carrying value of certain financial instruments (cash and cash equivalents, accounts payable and accrued expenses.) approximates fair value due to the short-term nature of the instruments or interest rates, which are comparable with current rates.

Fair Value Measurements

The Company measures fair value under a framework that utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of inputs which prioritize the inputs used in measuring fair value are:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2: Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability;
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means.

Note 2 – Summary of Significant Accounting Policies (continued)

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3: Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The assets or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

When the Company changes its valuation inputs for measuring financial assets and liabilities at fair value, either due to changes in current market conditions or other factors, it may need to transfer those assets or liabilities to another level in the hierarchy based on the new inputs used. The Company recognizes these transfers at the end of the reporting period that the transfers occur. For the periods ended June 30, 2018 and 2017, there were no significant transfers of financial assets or financial liabilities between the hierarchy levels.

As of June 30, 2019, no assets or liabilities were required to be measured at fair value on a recurring basis.

Earnings per Common Share

The Company computes net income (loss) per share in accordance with ASC 260, Earning per Share. ASC 260 requires presentation of both basic and diluted earnings per share (EPS) on the face of the income statement. Basic EPS is computed by dividing net income (loss) available to common shareholders (numerator) by the weighted average number of shares outstanding (denominator) during the period. Diluted EPS gives effect to all dilutive potential common shares outstanding during the period using the treasury stock method and convertible preferred stock using the if-converted method. In computing Diluted EPS, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Diluted EPS excludes all dilutive potential shares if their effect is anti-dilutive.

Income Taxes

The Company has adopted ASC 740, Accounting for Income Taxes. Pursuant to ASC 740, the Company is required to compute tax asset benefits for net operating losses carried forward. The potential benefits of net operating losses have not been recognized in these financial statements because the Company cannot be assured it is more likely than not it will utilize the net operating losses carried forward in future years.

Certain estimates and judgments must be made in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities using the tax rates and laws in effect when the differences are expected to reverse. ASC 740 provides for the recognition of deferred tax assets if realization of such assets is more likely than not to occur. Realization of the Company's net deferred tax assets is dependent upon generating sufficient taxable income in future years in appropriate tax jurisdictions to realize benefit from the reversal of temporary differences and from net operating loss, or NOL, carryforwards. Management has determined it more likely than not that these timing differences will not materialize and has provided a valuation allowance against substantially all the Company's net deferred tax assets.

Management will continue to evaluate the realization of the deferred tax assets and its related valuation allowance. If assessment of the deferred tax assets or the corresponding valuation allowance were to change, the Company would record the related adjustment to income during the period in which the determination is made.

Note 2 – Summary of Significant Accounting Policies (continued)

In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. Liabilities for anticipated tax audit issues in the U.S. are recognized based on the estimate of whether, and to the extent to which, additional taxes will be due. If it is ultimately determined that payment of these amounts is unnecessary, the liability will be reversed and a tax benefit will be recognized during the period in which it is determined that the liability is no longer necessary. The Company will record an additional charge to the provision for taxes in the period in which it is determined that the recorded tax liability is less than the Company expects the ultimate assessment to be.

ASC 740 which requires recognition of estimated income taxes payable or refundable on income tax returns for the current year and for the estimated future tax effect attributable to temporary differences and carry-forwards. Measurement of deferred income tax is based on enacted tax laws including tax rates, with the measurement of deferred income tax assets being reduced by available tax benefits not expected to be realized.

Revenue Recognition

Effective July 1, 2018, the Company adopted ASC 606 — Revenue from Contracts with Customers. Under ASC 606, the Company recognizes revenue from the commercial sales of products, licensing agreements and contracts to perform pilot studies by applying the following steps: (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to each performance obligation in the contract; and (5) recognize revenue when each performance obligation is satisfied.

There was no impact on the Company's financial statements as a result of adopting Topic 606 for year ended June 30, 2019.

Research and Development Expenses

Research and development expenses are charged to operations as incurred.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are deposited with major banks in the United States of America. Management believes that such financial institutions are financially sound and, accordingly, minimal credit risk exists with respect to these financial instruments. The Company does not have any significant off-balance-sheet concentration of credit risk.

Stock-based compensation

Pursuant to FASB ASC 718, all share-based payments to employees, including grants of employee stock options, are recognized in the statement of operations based on their fair values.

Issuance of shares for non-cash consideration

The Company accounts for the issuance of equity instruments to acquire goods and/or services based on the fair value of the goods and services or the fair value of the equity instrument at the time of issuance, whichever is more reliably determinable. The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the provisions of the standards issued by the FASB. The measurement date for the fair value of the equity instruments issued is determined as the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is recognized over the term of the consulting agreement.

Note 2 – Summary of Significant Accounting Policies (continued)

Reclassifications

Certain amounts in the consolidated financial statements for prior year periods have been reclassified to conform with the current year periods presentation.

Recent Accounting Pronouncements

In August 2018, the FASB issued Accounting Standards Update ("ASU") 2018-13, "Fair Value Measurement (Topic 820)." The amendments in this Update modify certain disclosure requirements of fair value measurements and are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently unable to determine the impact on its consolidated financial statements of the adoption of this new accounting pronouncement.

Although there are several other new accounting pronouncements issued or proposed by the FASB, which the Company has adopted or will adopt, as applicable, the Company does not believe any of these accounting pronouncements has had or will have a material impact on its consolidated financial position or results of operations.

Note 3 – Share Exchange Agreement

On August 8, 2017, the Company entered into a Share Exchange Agreement, as amended and restated on October 13, 2017, (the "Agreement"), with BioPharma. Pursuant to the terms of the Agreement, the Company agreed to issue to the shareholders of BioPharma 42,642,712 post-reverse stock-split shares of the Company's common stock, par value $0.0001 ("Common Stock"), in exchange for all of the issued and outstanding shares of BioPharma capital stock, thereby making BioPharma a wholly-owned subsidiary of the Company. As part of the Closing of the Agreement, the 20,000,000 pre-reverse split shares of the Company's Common Stock previously purchased by Kanativa USA, effective on June 26, 2017 in a change in control transaction from the Company's control shareholders, were canceled. Since this transaction resulted in the existing shareholders of BioPharma acquiring control of the Company, for financial reporting purposes, the business combination has been accounted for as an additional capitalization of the Company (a reverse acquisition with BioPharma as the accounting acquirer).

Note 4- Prepaid Expenses

Prepaid expenses at June 30, 2019 and 2018 consist of:

	2019	2018
Kanativa USA (Note 7)	$ 99,667	$ -
Insurance and other	64,647	-
	$ 164,314	$ -

Note 5 – License Agreements

Kotzker License Agreement

In March 2017, NexN licensed certain intellectual property from Kotzker Consulting LLC ("Kotzker Consulting"), an unrelated entity. The licensed intellectual property includes patent applications relating to the use of cannabinoid receptor modulators and terpenes in the acute treatment during exposure to organophosphorus nerve agents and/or organophosphorus insecticides. Under terms of the agreement, NexN shall use its commercially reasonable efforts to develop and commercialize the licensed products, and, in particular, will be responsible for the design, manufacturing, preclinical, clinical, and regulatory development activities of the licensed products and shall bear the costs of such activities. As consideration for entering into the agreement, NexN agreed to: (i) pay Kotzker Consulting $180,000, (ii) pay patent prosecution costs incurred as of the date of the agreement of $15,000 and (iii) issue to Kotzker Consulting 31,550 shares of Kanativa Inc.'s common stock valued at $78,875 ($2.50 per share based on recent private placement to third parties of Kanativa Inc.'s common stock). The Company has capitalized legal fees of $29,040 incurred in conjunction with acquiring the license agreement, As of June 30, 2017, $65,000 was due under the license agreement, which amount was paid in August 2017. The license agreement terminates, on a country by country basis, upon the expiration of the licensed patent for the licensed intellectual property, or when a competitor generic product utilizing the licensed technology is marketed in the particular country.

NexN shall be responsible for development milestone payments for (i) licensed products for use as a preventative and therapeutic neuroprotective against nerve agents and pesticides and (ii) licensed products for treatment of diseases. Milestone payments for each of the foregoing will each be due in two payments, the first payment no later than thirty (30) days from acceptance of submission of the regulatory filing of the first licensed product and the second payment no later than thirty (30) days from approval of the first licensed product. Royalties will be due beginning with first commercial sale of developed products. The Company has completed and submitted a Pre-Investigational New Drug meeting request and amendment thereto with the FDA.

In September 2017, BioPharma entered into a contract with a contract manufacturing organization to develop an injectable formulation of a drug product to be submitted to the FDA. It is anticipated that the product will be developed utilizing the new drug application 505(b) (2) regulatory pathway for use in the treatment during and immediately following exposure to organophosphorous nerve agents. The drug product is to consist of a synthetic cannabinoid and a blend of terpenes in an injectable vehicle.

Accu-Break License Agreement

On February 28, 2018, the Company obtained a worldwide exclusive license with respect to a proprietary delivery system for cannabinoid-based medications from Accu-Break Pharmaceuticals, Inc. ("Accu-Break"). Upon execution of the agreement, as amended September 18, 2018, $35,000 was paid to the licensor. An additional $10,000 was paid on November 1, 2018, $20,000 was paid on February 28, 2019 and a final payment of $35,000 was paid effective August 31, 2019 in common stock of the Company. The Company is required to pay milestone payments upon obtaining regulatory approval of pharmaceutical licensed products and royalties based upon sales of licensed products. The Company may grant sublicenses under the terms of the agreement.

The Company has estimated that it may not be able to recover the $302,915 carrying value of costs capitalized under the Kotzker License Agreement, nor the $65,000 of costs capitalized under the Accu-Break License Agreement, and has recognized an impairment of $367,915 for both licenses at June 30, 2019. Although the Company has recognized an impairment under Generally Accepted Accounting Principles, it retains its rights under both of these license agreements.

Note 6 – Stockholders' Equity

Common stock

In May 2017, BioPharma commenced a private placement of 1,116,400 units of Common Stock and Warrants at a price of $1.25 per unit. Each unit consisted of ten shares of Common Stock, one Class A Warrant to purchase one share of Common Stock at $0.25 per share, one Class B Warrant to purchase one share of Common Stock at $0.38 per share and one Class C Warrant to purchase one share of Common Stock at $0.50 per share. As of June 30, 2017, 778,400 units (representing 7,784,00 common shares) had been sold, for total gross proceeds of $973,000, including 387,200 units which were subscribed but for which funds had not been received. The 3,872,000 shares underlying the subscribed units in the amount of $484,000 were included as issued and outstanding shares at June 30, 2017, and the related $484,000 subscription receivable was recorded as a component of stockholders' equity as of June 30, 2017. Subsequent to June 30, 2017, the Company received proceeds of $484,000 for the subscribed shares. In July and August 2017, BioPharma sold an additional 338,000 units (representing 3,380,000 common shares) for gross proceeds of $422,500.

On August 25, 2017, BioPharma entered into consulting agreements with two unrelated individuals for (i) developing and maintaining social media portals and (ii) identifying and developing potential strategic partners for the Company's various drug development activities. The agreements were each for a three-month term, payable monthly in shares of the Company's Common Stock, valued at $0.125 per share, of an aggregate 304,800 shares and 138,000 shares, respectively. The Company issued an aggregate 442,800 shares of Common Stock to the two individuals, valued at $55,350, representing all amounts due pursuant to the consulting agreements.

On September 1, 2017, BioPharma completed a private placement sale of its common stock at $0.25 per share. The Company sold 100,000 shares for gross proceeds of $25,000, before offering costs of $4,917.

In January 2018, BioPharma completed a unit private placement of Common Stock and Warrants at a price of $2.10 per unit. Each Unit consisted of two shares of Common Stock and one Warrant to purchase an additional share of common stock at a price of $2.90 per share for a term of six months commencing with the date of acceptance of the underlying subscription agreement. The Company received proceeds of $25,200 from the sale of 12,000 units (24,000 shares).

During the year ended June 30, 2018, the Company issued 1,801,200 shares of Common Stock from the exercise of warrants from the May 2017 private placement of units as follows:

	Number	Exercise Price	Gross Proceeds
Class A	960,400	$ 0.25	$ 240,100
Class B	746,800	$ 0.38	$ 283,784
Class C	94,000	$ 0.50	$ 47,000

During the year ended June 30, 2019, the Company issued 15,000 shares of its common stock, valued at $0.10 per share, as settlement for accounts payable.

In May 2019, 77,778 shares of common stock, previously issued to the founders of Kinder Holding Corp. prior the reverse acquisition transaction in October 2017, were returned to the Company and cancelled as settlement under a contract dispute between the individuals and the Company.

Note 6 – Stockholders' Equity (continued)

CRX Limited Liability Company Interest Purchase Agreement

On October 26, 2018, Company entered into a Limited Liability Company Interest Purchase Agreement (the "Purchase Agreement") with the members of CRX Bio Holdings LLC, a Delaware limited liability company ("CRX"), to acquire all of the membership interest in CRX in exchange for 11,000,000 restricted shares of the Company's common stock (the "Acquisition"), valued at $0.76 per share. The transaction has been accounted for as an asset acquisition, and not a business combination, and has been valued at the fair value of the common stock issued by the Company, as CRX's cost basis was $0 in the assets. CRX is engaged in the research and development of advanced cannabinoid formulations and drug delivery systems with a focus on bioavailability and related pharmacokinetics and pharmacodynamics (PK/PD) enhancement. The Acquisition transaction was consummated on October 26, 2018. By acquiring CRX as a wholly-owned subsidiary, the Company acquired all of its assets, which consist primarily of three U.S. provisional patent applications relating to cannabinoid formulations to treat convulsive disorders, chronic traumatic encephalopathy, and neuropathic pain. At the closing, the Company issued to the six members of CRX (the "Sellers") 1,100,000 shares not subject to any forfeiture restrictions and 9,900,000 shares which shall be released from forfeiture restrictions according to the following vesting schedule:

- 30% shall be fully vested 12 months following the Closing (October 26, 2019);
- 30% shall be fully vested 24 months following the Closing (October 26, 2020);
- 30% shall be fully vested 36 months following the Closing (October 26, 2021).

Any Seller who is not then providing services to the Company or any of its subsidiaries on any vesting date, whether through voluntary termination or termination "for cause," will forfeit his unvested shares, which will be cancelled.

The transaction has been valued at $8,360,000, based on the fair value of the 11,000,000 shares issued of $0.76 per share, as per the closing market price of the Company's common stock on the date of the agreement. The $836,000 fair value of the 1,100,000 shares issued not subject to any forfeiture restrictions was charged to operations during the six months ended December 31, 2018. The $7,524,000 fair value of the 9,900,000 shares subject to forfeiture has been charged to stockholders' equity as a contra equity account, and is being amortized over the vesting periods. The net amount charged to stockholder's equity was $0 on the date of the acquisition. As of June 30, 2019, $1,484,042 has been charged to operations for the value of vested shares issued and the amortization of the unvested CRX shares issued.

Effective December 31, 2018, one of the sellers resigned from the Company and forfeited 1,732,500 unvested shares, valued at $1,316,699 ($0.76 per share); and in May 2019, that seller returned to the Company and additional 142,500 vested shares issued in accordance with the Purchase Agreement. The $108,300 fair value of the returned shares was credited to operations as of June 30, 2019.

Warrants

The Company had issued warrants to investors in a series of subscription agreements in equity financings.

On July 27, 2018, Company extended the expiration date of its Class C Warrants, from July 27, 2018, to August 8, 2018, and also offered holders of the Class C Warrants who did not wish to exercise their warrants the opportunity to exchange their Class C Warrants for new warrants. Each new warrant, denominated as Class D, was exercisable through November 30, 2018 to purchase one unit for $1.00, each unit consisting of one share of Common Stock and a warrant to purchase one share of Common Stock at a price of $2.00 per share through January 31, 2019. Holders of 944,400 Class C warrants were issued Class D warrants. All of the Class D warrants expired unexercised.

On September 12, 2018, the Company authorized the issuance of 94,000 Class E warrants to those shareholders who exercised their Class C warrants and did not exchange them for Class D warrants. Each Class E warrant was exercisable to purchase one share of common stock at a price of $2.00 per share through January 31, 2019. All of the Class E warrants expired unexercised.

Note 6 – Stockholders' Equity (continued)

The relative fair value of each warrant issuance was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants under the fixed option plan:

Average risk-free interest rates	2.0% - 2.16%
Average expected life (in years)	.35 to .39
Volatility	175% to 296%

The relative fair value attached to the Class D warrants is $151,467 and the relative fair value attached to the Class E warrants is $4,467 as of the grant date.

A summary of warrant activity during the years ended June 30, 2018 and 2019 is presented below:

	Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Outstanding and exercisable – June 30, 2017	2,335,200	$	.38	.53
Granted	1,026,000	$	.41	
Exercised	(1,801,200)	$	.32	
Expired	(525,600)	$	.34	
Outstanding and exercisable – June 30, 2018	1,034,400	$	.53	.1
Granted	1,038,400	$	1.09	
Exercised	-			
Expired	(2,072,800)	$	.75	
Outstanding and exercisable – June 30, 2019	-			

2017 Stock Incentive Plan

On August 10, 2017, BioPharma adopted its 2017 Stock Incentive Plan and granted an aggregate of 6,400,000 shares of Common Stock to five officers and directors of the Company, valued at $800,000 ($0.125 per share). In March 2018, 1,666,667 unvested shares (valued at $145,833) previously issued to the Company's former Chief Executive Officer were canceled. On July 25, 2018, the Company accelerated the vesting of 1,083,342 unvested shares of Common Stock previously granted to its former Chief Executive Officer and Chief Financial Officer. As of June 30, 2019, 5,083,333 shares issued (valued at $635,417) have been vested and 150,000 of the shares issued (valued at $18,750) are subject to forfeiture until vesting occurs.

2018 Equity Incentive Plan

(i) On March 30, 2018, the Company's board of directors approved and recommended for adoption by the stockholders of the Company a 2018 Equity Incentive Plan and has reserved 8,000,000 shares of Common Stock for issuance under the terms of that Plan.

In July 2018, the Board of Directors granted options to purchase a total of 1,810,000 shares of Common Stock, exercisable for a period of seven years, to officers/directors/consultants of the Company at an exercise price of $0.54 per share.

In August 2018, the Board of Directors granted options to purchase a total of 150,000 shares of Common Stock, exercisable for a period of seven years, to two individuals, (i) a director and (ii) a consultant of the Company, at an exercise price of $0.38 per share.

Note 6 – Stockholders' Equity (continued)

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants under the fixed option plan:

Average risk-free interest rates	2.3% - 2.8%
Average expected life (in years)	4.0 to 7.0
Volatility	160% to 296%

The fair value of the options granted is $867,715. Amortization of the vested portion of the options charged to operations was $727,406 during the year ended June 30, 2019, and $66,254 is unamortized at June 30, 2019.

(ii) On October 17, 2018, the Board of Directors granted options to purchase an aggregate 800,000 shares of Common Stock, exercisable for a period of seven years, to officers/directors of the Company at an exercise price of $0.655 per share and confirmed a grant of options made as of October 1, 2018, to purchase 500,000 shares of Common Stock, exercisable for a period of seven years, to an officer and director of the Company at an exercise price $0.48. All of the options were fully vested as of the date of grant

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants under the fixed option plan:

Average risk-free interest rates	2.88% - 2.93%
Average expected life (in years)	4.0
Volatility	171% to 172%

The fair value of the fully vested options granted of $803,997 was charged to operations during the year ended June 30, 2019.

A summary of option activity during the year ended June 30, 2019 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
Outstanding and exercisable – June 30, 2018	-		
Granted	3,260,000	$ 0.55	
Exercised	-		
Expired / Canceled	(227,500)	$ 0.50	
Outstanding– June 30, 2019	3,032,500	$ 0.56	6.2
Exercisable – June 30, 2019	2,895,000		

Note 7 – Related Party Transactions

BioPharma was formed as a subsidiary of Kanativa USA, which is a subsidiary of Kanativa Inc.

Kanativa USA was issued 24,000,000 shares of BioPharma's common stock as consideration for its contribution of 100% of the ownership of NexN, and costs and expenses incurred on behalf of BioPharma and NexN in the amount of $201,228. Included in the consideration for the issuance of the common stock is $172,915 of capitalized license agreement costs comprised of (i) the value of Kanativa Inc. common stock issued to Kotzker Consulting of $78,875 and (ii) payments to Kotzker Consulting and legal costs in the aggregate of $94,040 (See Note 5).

Note 7 – Related Party Transactions (continued)

At June 30, 2017, BioPharma was owed $141,329 from Kanativa USA for advances made by BioPharma on behalf of Kanativa USA in conjunction with the Share Exchange Agreement (See Note 3). During the years ended June 30, 2018 and 2019, $26,662 and $15,000, respectively, was repaid by Kanativa USA. The balance due from Kanativa USA at June 30, 2019 of $99,667, included in prepaid expenses, is being repaid at $1,500 per month with the remaining balance due on March 1, 2020.

On August 10, 2017, the Company granted an aggregate of 6,400,000 shares of Common Stock to five officers and directors of the Company, valued at $800,000 ($0.125 per share), under the Company's 2017 Stock Incentive Plan. One-third of each grant vested as of the initial date of grant (August 10, 2017), and 8-1/3% upon the end of each calendar quarter beginning December 31, 2017. In March 2018, the Company cancelled 1,166,667 unvested shares previously issued to its former CEO. As of June 30, 2019, 150,000 of the shares issued (valued at $18,750) are subject to forfeiture until vesting occurs.

In February 2018, the Company entered into an exclusive license agreement with Accu-Break whose President was an affiliate of the Company at the time of the agreement. See Note 5.

Certain of the members of the Company's Board of Directors and the Company's Chief Financial Officer are also directors and officers of Kanativa Inc., and other subsidiaries and affiliated entities of Kanativa Inc.

Note 8 – Income Taxes

The Company accounts for income taxes in accordance with standards of disclosure propounded by the FASB, and any related interpretations of those standards sanctioned by the FASB. Accordingly, deferred tax assets and liabilities are determined based on differences between the financial statement and tax bases of assets and liabilities, as well as a consideration of net operating loss and credit carry forwards, using enacted tax rates in effect for the period in which the differences are expected to impact taxable income. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount that is more likely than not to be realized. On December 22, 2017, the 2017 Tax Cuts and Jobs Act (the Tax Act) was enacted into law and the new legislation contains several key tax provisions that affected us, including a reduction of the corporate income tax rate to 21% effective January 1, 2018.

No provision for income taxes has been recorded due to the net operating loss carryforwards totaling approximately $1,954,000 as of June 30, 2019 that will be offset against future taxable income. The available net operating loss carry forwards expire in various years through 2039. No tax benefit has been reported in the financial statements because the Company believes there is a 50% or greater chance the carry forwards will expire unused. There were no uncertain tax positions taken by the Company.

The deferred tax asset and valuation account is as follows at June 30:

	2019	2018
Deferred tax asset:		
Net operating loss carryforward (at the statutory rate of 21%-2019 and 34%-2018)	$ 470,228	$ 568,734
Valuation allowance	(470,228)	(568,734)
Total	$ -	$ -

Note 8 – Income Taxes (continued)

The components of income tax expense are as follows for the years ended June 30:

	2019	2018
Change in net operating loss benefit	$ 161,491	$ 497,789
Change in valuation allowance	(161,491)	(497,789)
Total	$ -	$ -

Note 9 - Commitments and Contingencies

At June 30, 2019, there were no legal proceedings against the Company.

Note 10 – Subsequent Events

Subsequent to June 30, 2019, the Company issued 473,286 shares of its common stock as follows:

- 16,667 shares, valued at $1,500 ($0.09 per share), as consideration for consulting services rendered.
- 75,000 shares, valued at $7,500 ($0.10 per share), as partial consideration for entering into an investor relations contract.
- 381,619 shares, valued at $35,000 ($0.092 per share), for final payment on the license agreement with respect to a proprietary delivery system for cannabinoid-based medications (See Note 5).

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of June 30, 2019. Based on such evaluation, we have concluded that, as of such date, our disclosure controls and procedures were not effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in applicable SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining internal control over financial reporting for our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over our financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that in reasonable detail accurately and fairy reflect our transactions.

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

All internal control systems, no matter how well designed, have inherent limitations, including the possibility of human error or circumvention through collusion of improper overriding of controls. Therefore, even those internal control systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time.

Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2019. In making its assessment of internal control over financial reporting, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal-Control-Integrated Framework - 2013* and implemented a process to monitor and assess both the design and operating effectiveness of our internal controls. Based on this assessment, management believes that as of June 30, 2019, our internal control over financial reporting was not effective.

As of June 30, 2019, we did not establish a formal written policy for the approval, identification, and authorization of related party transactions.

Changes in Internal Control Over Financial Reporting

Our management has evaluated, with the participation of our Chief Executive Officer/Chief Financial Officer, changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) during the fourth quarter of fiscal 2019. In connection with such evaluation, there have been no changes to our internal control over financial reporting that occurred during fiscal year ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting. While there have been no changes, we have assessed our internal controls as being deficient and will be taking steps beginning in 2019 to remedy such deficiencies.

ITEM 9B. OTHER INFORMATION.

There are no further disclosures.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our directors were elected to serve until the next annual meeting of shareholders and until their respective successors will have been elected and will have qualified. The following table sets forth the name, age and position held with respect to our present executive officers and directors:

Name	Age	Title
Alex Wasyl	30	Chief Financial Officer and Director
Evan Wasoff	72	Chief Financial Officer
Robert I. Goldfarb	64	Chief Operating Officer
Frank Manganella	53	Vice President of Corporate Development
Dr. Joseph Aceto	61	Vice President of Legal and Intellectual Property Counsel -
Richard Greenberg	70	Director
Lindy Snider	57	Director
Courtney Clark	53	Director

Alex Wasyl, 30, Chief Executive Officer and Director, was the co-founder of CRX Bio Holdings LLC. In addition, he has been the managing director of Elevated Life Sciences, a full-service life sciences research and product development company, which he founded in February 2009. Elevated Life Sciences specializes in full service product development, brand management, supply chain management and third-party quality control oversight and related services across the biotechnology, pharmaceuticals, green cleaning technology, as well as other industry sectors. Through his experience at Elevated Life Sciences, Alex has developed an in-depth knowledge of the development of cannabinoid formulations and therapeutics. He has a bachelor's degree in business administration from the College of New Jersey, having studied Marketing and Consumer Behavior Psychology, and has done further study in biology, biochemistry and physiology.

Evan Wasoff, 70, Chief Financial Officer, has over 40 years of experience as a certified public accountant. Mr. Wasoff also serves as CFO of Kanativa Inc. (formerly Intiva Inc.) From 2005 to 2012, Mr. Wasoff served as the Chief Financial Officer and compliance officer at Falcon Oil and Gas Ltd., a Canadian oil and gas exploration company with activities in Hungary, Australia, Canada and the United States. Since 2012, he has been the principal of AZCO Financial Management, LLC, located in Boulder Colorado, providing business advisory and consulting services and outsourced CFO and controllership services to publicly-reporting and private companies.

Mr. Wasoff holds a Certified Public Accounting license in Colorado. He received a B.S. degree in accounting from the State University of New York at Albany, and an MBA in Finance from the University of Colorado.

Robert Goldfarb, 64, Chief Operating Officer, has over 37 years of legal experience, with much of that focused on the pharmaceutical industry. Since 2007, Mr. Goldfarb has been President and general counsel for privately-held Accu-Break Pharmaceuticals, Inc. Since 2011, he has been a director of privately-held Sustained Nano Systems LLC. Mr. Goldfarb obtained his bachelor's degree from the University of Connecticut and his J.D. from the University of Florida. He is a member of the Florida Bar.

Frank Manganella, 53, Vice President of Corporate Development, has been the managing partner of portfolio management for CH3 Partners, a funds management, consultancy and financial advisory firm based in New York focused on the legal cannabis industry since October 2015. CH3 Partners specializes in assisting seed-stage to developed companies in the cannabis industry with business development, company due diligence and strategic planning for current and future growth. CH3 Partners works with companies specializing in media, marketing and licensing, legal services, financial services, cultivation and retail, delivery mechanisms, technology and life sciences, with a focus on the benefits of medicinal marijuana. From March 2011 to June 2014, Mr. Manganella was managing director and head of FIC Sales – Americas and global head of Hedge Fund Sales at Commerzbank AG. In his role, he was responsible for distribution and product development across multiple asset-classes geographical jurisdictions and products, including fixed income, currencies, commodities, emerging markets, credit and loans, ETFs and indices. Mr. Manganella received his MBA degree from Durham University in 2013.

Dr. Joseph Aceto, 61, Vice President of Legal and Intellectual Property Counsel , has been in the private practice of law since 2009, consulting on intellectual property matters, prosecuting, managing and advising clients on trademark and copyright matters, due diligence review, and intellectual property licensing. With a Ph.D. in pharmacology, he also works with clients in technology areas associated with new drugs, drug applications, nanotechnology, microfluidics, diagnostic assays, medical devices and several non-healthcare related disciplines. From 2002 to 2008, Dr. Aceto worked as internal counsel and director of intellectual property for Immunicon, Corp., a publicly traded, start-up biotech and medical device company with operations in the US and Europe. Dr. Aceto received his law degree from Widener University School of Law in 2000, his Ph.D. degree from Temple University in 1987, and an M.S. degree in biomedical engineering and science from Drexel University in 1983.

Richard Greenberg, 70, Director, since inception in March 2017. He has also served as Executive Vice President and a Director of Kanativa Inc. (formerly Intiva Inc). and Kanativa USA since their inception in February 2014 and August 2014, respectively. Mr. Greenberg has over 30 years of legal, consulting, and regulatory compliance experience. Mr. Greenberg has served as a Subcommittee Counsel for the U.S. House of Representatives, and as a Senior Enforcement Attorney for the U.S. Environmental Protection Agency.

Mr. Greenberg was a founder of TechLaw, Inc., a national consulting firm serving both the federal government and industry clients. Previous management roles include Director of Environmental Management Consulting Services for PricewaterhouseCoopers.

Mr. Greenberg received a B.A. degree from City University of New York – Queens College and a J.D. degree from Rutgers University School of Law.

Lindy Snider, 57, Director, is an active entrepreneur, philanthropist and advocate for the benefits of medical cannabis. In 2003, Ms. Snider founded and created the Pennsylvania-based Lindi Skin, the first-ever skincare collection dedicated to help relieve the often-debilitating skin side-effects of individuals undergoing cancer therapies including chemotherapy and radiation. Lindi Skin represents an entirely new niche in dermatology and oncology, providing cancer patients with skin care products that bring a sense of wellness and control as they deal with the side effects of their chemotherapy and radiation treatment, which include widely known conditions of hair loss and nausea, among other side-effects. Lindi Skin helps patients address the lesser known skin side-effects of sores, rashes, burns, flaky skin and loss of skin elasticity that often result.

Ms. Snider, as an active and dedicated philanthropist, is also an active board member of many Philadelphia and national charitable and other philanthropic organization, which include: Cancer Forward; PSPCA; National Museum of American Jewish History; Shoah Foundation's Next Generation Council; Philadelphia Orchestra; Fox Chase Cancer Foundation; and the Snider Foundation.

Ms. Snider is a founder and director of Athletes for Care, an organization dedicated to creating a community where former professional athlete can find support, opportunity and purpose in life after a career in sports. The organization is a strong advocate of the use of medical cannabis, as well as a director of Stem Holdings Inc., which owns and leases real estate to the marijuana industry. The common stock of Stem Holdings is registered under the Securities Exchange Act of 1934 and trades on the OTCQB under the symbol “STMH”.

Ms. Snider is chair of the Entrepreneurship and Social Impact Initiative of The Lambert Center for the Study of Medicinal Cannabis and Hemp at Thomas Jefferson University in Philadelphia and is also an associate fellow of the Institute of Emerging Health Professions, Thomas Jefferson University.

Courtney Clark, 53, Director, has more than 15 years of corporate finance expertise. She founded Aspen Peak Advisors, a marketing and investment banking firm in 2010 after having been an analyst and investment banker with TerraNova Capital Partners specializing in global emerging growth companies, primarily in the energy, technology, and medical device spaces. While at TerraNova she was Managing Director of the Public Capital Markets Group where she provided hands-on service and structuring through all stages of capital raising as well as after-market support for companies in the nascence of their corporate presence. Prior to investment banking, Ms. Clark was a Sales Director for First Resort Software (now owned by Gaylord Entertainment, GET:NYSE) where for five years she managed the sales and supported the implementation of integrated software solutions for companies involved in resort and hotel management.

Ms. Clark holds a BA from Georgetown University and an MBA from the University of Colorado Leeds School of Business. She is a mentor in the public school system and a hospice volunteer in her community.

There are no agreements with respect to the election of directors other than as provided in the Share Exchange Agreement.

Our directors, officers or affiliates have not, within the past five years, filed any bankruptcy petition, been convicted in or been the subject of any pending criminal proceedings, or is any such person the subject or any order, judgment or decree involving the violation of any state or federal securities laws.

Compensation Committee and Nominations Committee

We do not have any of the above-mentioned standing committees because our corporate financial affairs and corporate governance are simple in nature at this stage of development and each financial transaction is approved by our entire board of directors.

Audit Committee

Our Audit Committee members are Courtney Clark (Chair) and Lindy Snider. Both Courtney Clark and Lindy Snider are independent.

The Board of Directors has determined that Courtney Clark, who is independent, is the audit committee financial expert within the meaning of Item 407(d)(5) of Regulation S-K. In general, an “audit committee financial expert” is an individual member of the audit committee who (a) understands generally accepted accounting principles and financial statements, (b) is able to assess the general application of such principles in connection with accounting for estimates, accruals and reserves, (c) has experience preparing, auditing, analyzing or evaluating financial statements comparable to the breadth and complexity to our financial statements, (d) understands internal controls over financial reporting, and (e) understands audit committee functions.

Code of Ethics

We do not currently have a Code of Ethics applicable to our principal executive officers; however, the Company plans to implement such a code in the near future.

Potential Conflicts of Interest

Since we do not have a compensation committee comprised of independent Directors, the functions that would have been performed by such committee are performed by our Board of Directors. Thus, there is a potential conflict of interest in that our Directors have the authority to determine issues concerning management compensation, in essence their own. There is also a potential conflict in that Messrs. Greenberg and Wasoff are either officers and/or directors of Kanativa USA Inc., and its parent, Kanativa Inc. which owns approximately 35.2% of outstanding shares of the Company.

We are not aware of any other conflicts of interest with any of our Executives or Directors.

Board's Role in Risk Oversight

The Board assesses on an ongoing basis the risks faced by the Company. These risks include financial, technological, competitive, and operational risks. The Board's Audit Committee is responsible for the assessment and oversight of the Company's financial risk exposures.

Involvement in Certain Legal Proceedings

We are not aware of any material legal proceedings that have occurred within the past ten years concerning any Director or control person which involved a criminal conviction, a pending criminal proceeding, a pending or concluded administrative or civil proceeding limiting one's participation in the securities or banking industries, or a finding of securities or commodities law violations.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our Company's officers, directors and persons who beneficially own more than 10% of a registered class of our Company's equity securities to file reports of ownership and changes in ownership with the SEC, and to furnish to our Company copies of such reports.

Based solely on the review of Forms 3 and 4 received by our Company during the June 30, 2019 fiscal year, as required under Section 16(a)(2) of the Exchange Act, the following persons, although they reported all their transactions as required on either a Form 3 or Form 4, did not report on a timely basis: Alain Bankier, an officer and director, filed two Forms 4 late (relating to 2 transactions); Robert Goldfarb, an officer, filed one Form 4 late (relating to 1 transaction); Frank Manganella, an officer, filed one Form 4 late (relating to 1 transaction); and Lindy Snider, a director, filed one Form 4 late (relating to 1 transaction). Kanativa Inc. filed its Form 3 and one Form 4 late; and Kanativa USA and its beneficial owner, Jeffrey Friedland, each filed one Form 4 late (relating to 1 transaction).

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth information about the remuneration of our principal executive officer for services rendered during our fiscal years ended June 30, 2019 and 2018, and our other executive officers that had total compensation of $100,000 or more for our last completed full fiscal year (the "Named Officers"). Certain tables and columns have been omitted as no information was required to be disclosed under those tables or columns.

SUMMARY COMPENSATION TABLE

Name and principal position	Fiscal year	Salary ($)	Stock awards ($)	Option awards ($)(1)	All other compensation ($)	Total ($)
Alex Wasyl (Chief Executive Officer) (2)	2019	-0-	-0-	-0-	-0-	
	2018	-0-	-0-	-0-	-0-	-0-
Alain Bankier (former Interim Chief ExecutiveOfficer and Chief Strategy Officer) (3)	2019	-0-	-0-	418,843	-0-	418,843
	2018	-0-	200,000	-0-	-0-	200,000
Evan Wasoff (Chief Financial Officer	2019		-0-	209,422	-0-	209,422
	2018	20,000	125,000	-0-	-0-	145,000
Robert Goldfarb (Chief Operating Officer)	2019	55,000	-0-	-0-	-0-	55,000
	2018	132,000	125,000	-0-	-0-	257,000
Richard Greenberg (former Executive Vice President and Chairman)	2019	-0-	-0-	74,793	-0-	74,793
	2018	-0-	100,000	-0-	-0-	100,000

(1) The fair value was determined using the Black-Scholes option pricing model with the following assumptions: volatility at 296.73%; risk free interest rate of 2.78%; expected life of 4 years; and expected dividend rate of 0%.
(2) Mr. Wasyl has served in this capacity since October 26, 2018.
(3) Mr. Bankier has served in these capacities from March 8, 2018 to April 1, 2019.

The following table sets forth information with respect to stock awards for the Named Officers.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	Option Awards					Stock Awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexer-cisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
Alex Wasyl	-0-	-0-	-0-	—	—	-0-	-0-	-0-	-0-
Alain Bankier	762,500	-0-	-0-	0.54	7/25/2025	-0-(1)	-0-	-0-	-0-
	500,000	-0-	-0-	0.48	10/1/2025				
	500,000	-0-	-0-	0.655	10/26/2025				
Evan Wasoff	420,000	-0-	-0-	0.54	7/25/2025	-0-(1)	-0-	-0-	-0-
	200,000	-0-	-0-	0.655	10/26/2025				
Robert Goldfarb	-0-	-0-	-0-	—	—	83,333	7,500	-0-	-0-
Richard Greenberg	112,500	37,500	-0-	0.54	7/25/2025	66,667	6,000	-0-	-0-
	100,000	-0-	-0-	0.655	10/26/2025				

(1) On July 25, 2018, the Board approved the accelerated vesting of the shares granted to Messrs. Bankier and Wasoff.

Employment Contracts and Termination of Employment and Change-in-Control Arrangements

None of our executive officers or directors are parties to any employment contracts. No retirement, pension, profit sharing, or insurance programs or other similar programs have been adopted by the Company for the benefit of the Company's employees.

Director Compensation

We currently do not compensate our directors in cash for acting as such. We also reimburse our directors for reasonable expenses incurred in connection with their service as directors. Compensation for our directors serving in their capacities as such, was as follows for the fiscal year ended June 30, 2019:

DIRECTOR COMPENSATION

Name	Fees earned or paid in cash ($)	Option awards ($)	All other compensation ($)	Total ($)
Alain Bankier	-0-	49,862(1)	-0-	49,862
Courtney Clark	-0-	37,870(2)	-0-	37,870
Richard Greenberg	-0-	(3)	-0-	(3)
Lindy Snider	-0-	49,862(1)	-0-	49,862

(1) The fair value of these options was determined using the Black-Scholes option pricing model with the following assumptions: volatility at 296.73%; risk free interest rate of 2.78%; expected life of 4 years; and expected dividend rate of 0%.
(2) The fair value of these options was determined using the Black-Scholes option pricing model with the following assumptions: volatility at 290.95%; risk free interest rate of 2.78%; expected life of 4 years; and expected dividend rate of 0%.
(3) Mr. Greenberg's compensation is disclosed above in the Summary Compensation Table.

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

The following table sets forth information regarding the beneficial ownership of our shares of Common Stock as of September 25, 2019. The information in this table provides the ownership information for: each person known by us to be the beneficial owner of more than 5% of our common stock; each of our directors; each of our executive officers; and our executive officers and directors as a group.

Name of Beneficial Owner (1)	Common Stock Beneficially Owned (2)	Percentage of Common Stock Owned (2)
Alex Wasyl, Chief Executive Officer (3)	5,445,000	10.1%
Frank Manganella, VP Corporate Development (4)	2,420,000	4.5%
Evan Wasoff, Chief Financial Officer (5)	1,620,000	3.0%
Richard Greenberg, Director (6)	1,119,521	2.1%
Joseph Aceto, VP Legal (7)	1,045,000	2.0%
Robert Goldfarb, Chief Operating Officer	1,028,800	1.9%
Lindy Snider, Director (8)	567,500	1.1%
Courtney Clark, Director (9)	62,500	0.1%
Kanativa USA, Inc. (10)	19,000,000	35.2%
Kanativa Ventures Inc.	5,000,000	9.3%
Alain Bankier (11)	4,018,501	7.2%
All Officers and Directors (8 persons) (12)	13,308,051	*24.42%*

*less than 0.1%

(1) The address of each beneficial owner is 4340 E. Kentucky Avenue, Suite 206, Denver, Colorado 80246.
(2) Applicable percentage ownership is based on 53,984,004 Shares of Common Stock outstanding as of September 25, 2019. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Shares of common stock that are currently exercisable or exercisable within 60 days of September 25, 2019 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage of ownership of such person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.
(3) Includes 3,267,000 shares for which forfeiture restrictions have not yet lapsed.
(4) Includes 1,452,000 shares for which forfeiture restrictions have not yet lapsed.
(5) Includes 620,000 shares purchasable under immediately exercisable stock options.
(6) Includes 231,250 shares purchasable under immediately exercisable stock options.
(7) Includes 627,000 shares for which forfeiture restrictions have not yet lapsed.
(8) Includes 87,500 shares purchasable under immediately exercisable stock options.
(9) Includes 62,500 shares purchasable under immediately exercisable stock options.
(10) Kanativa USA, Inc. is a Colorado corporation that is a wholly-owned subsidiary of Kanativa Inc., a Canadian corporation.
(11) Includes 1,762,500 shares purchasable under immediately exercisable stock options.
(12) Includes 5,346,000 shares for which forfeiture restrictions have not yet lapsed and 1,001,250 shares purchasable under immediately exercisable stock options.

To the knowledge of the Company, there are no arrangements, the operation of which may at a subsequent date result in a change in control of the Company.

Securities Authorized for Issuance Under Equity Compensation Plans

As of June 30, 2019, we had the following equity securities authorized for issuance:

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted- average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	3,032,500	$ 0.56	8,293,500
Equity compensation plans not approved by security holders	-0-	$	—
Total	3,032,500		8,293,500

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

2017 Stock Incentive Plan

On August 10, 2017, BioPharma adopted the "2017 Stock Incentive Plan" under which the board of directors is authorized the grant up to 7,200,000 shares of its common stock. An aggregate of 6,400,000 shares of Common Stock to five officers and directors of the Company, valued at $800,000 ($0.125 per share) were granted. On July 25, 2018, the Company accelerated the vesting of 1,083,342 unvested shares of Common Stock previously granted to its former Chief Executive Officer and Chief Financial Officer. As of June 30, 2019, 150,000 of the shares issued (valued at $18,750) were subject to forfeiture until vesting occurred.

2018 Equity Incentive Plan

On March 30, 2018, the Company's board of directors approved and recommended for adoption by the stockholders of the Company a 2018 Equity Incentive Plan and reserved 8,000,000 shares of Common Stock for issuance under the terms of that Plan. The total number of shares reserved and available for grant and issuance under the 2018 Plan is 8,000,000 shares, plus any reserved shares not issued or subject to outstanding grants under the 2017 Stock Plan and shares that cease to be subject to awards under the 2017 Stock Plan because of forfeiture. In addition, the number of shares available for grant and issuance under the 2018 Plan will be increased on July 1 of each of the next ten calendar years by the lesser of (a) 15% of the number of shares issued during the most recently completed fiscal year or (b) such number of shares determined by the board of directors. The 2018 Plan permits the board to grant a variety of incentive awards: stock options, restricted stock awards, stock bonus awards, and stock appreciation rights. Stockholder approval was obtained on March 29, 2019. As of June 30, 2019, 3,032,500 stock options granted under the 2018 Plan are outstanding.

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

Certain Related Party Transactions

The Company's wholly-owned subsidiary, Intiva BioPharma Inc., a Colorado corporation ("Colorado BioPharma") was formed as a subsidiary of Kanativa USA, Inc. (formerly Intiva USA, Inc.) in March 2017. Kanativa USA, Inc. is a subsidiary of Kanativa Inc. (formerly Intiva Inc.), an Ontario, Canada corporation.

Three of our directors, Courtney Clark, Richard Greenberg and Lindy Snider, are three of Kanativa's six-person board of directors. Evan Wasoff, the Company's Chief Financial Officer, and Richard Greenberg are also officers of Kanativa and serve in similar positions with other subsidiaries and affiliated entities of Kanativa.

On August 10, 2017, Colorado BioPharma granted an aggregate of 6,400,000 shares of its restricted common stock to its executive officers and/or directors, subject to forfeiture. Forfeiture restrictions as to one-third of each grant lapsed as of the initial date of grant (August 10, 2017), and restrictions as to 8-1/3% of each grant will lapse at the end of each calendar quarter beginning December 31, 2017. In March 2018, the Company cancelled 1,166,667 unvested shares previously issued to its former CEO. On July 25, 2018, the Board of Directors approved the accelerated vesting of the shares granted to Alain Bankier and Evan Wasoff.

In September 2017, the Company entered into a Securities Services Agreement with Compliance Services Corp. pursuant to which the Company issued a total of 200,000 shares of the Registrant's common stock to each of Ivo Heiden and Securities Compliance Corp. and agreed to register such shares for resale. In response to the Company's request to return of a portion of the shares, 77,778 shares were returned for cancellation in May 2019.

Indebtedness of Management

No officer, director or security holder known to us to own of record or beneficially more than 5% of our Common Stock or any member of the immediate family or sharing the household (other than a tenant or employee) of any of the foregoing persons is indebted to us in the year 2019 and to date.

Director Independence

NASDAQ Rule 5605, which sets forth several tests to determine whether a director of a listed Company is independent, provides that a director would not be considered independent if the director or an immediate family member accepted any compensation from the listed Company in excess of $120,000 during any period of 12 consecutive months within the three years preceding the determination of independence (excluding compensation for board or board committee service, compensation paid to an immediate family member as a non-executive employee, benefits paid under a tax-qualified retirement plan and non-discretionary compensation).

In determining whether our directors are considered independent, the Company used the definition of independence as defined in NASDAQ Rule 4200. Based on that definition we believe that Lindy Snider and Courtney Clark are our independent directors.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table is a summary of the fees billed to us by M&K CPAS for professional services for the fiscal years as disclosed in the table below:

Fee Category	Fees Billed for Fiscal 2019	Fees Billed for Fiscal 2018
Audit Fees (1)	$ 18,350	$ 15,900
Audit-Related Fees (2)	-	6,150
Tax Fees	–	–
All Other Fees	–	–
Total Fees	$ 18,350	$ 22,050

(1) Includes audit of annual financial statements and review of unaudited quarterly financial statements.

(2) Includes review of our registration statement.

Audit Committee Pre-Approval Policies and Procedures

According to the Audit Committee Charter, the Audit Committee is to review and preapprove both audit and non-audit services to be provided by the independent auditor. The authority to grant preapprovals may be delegated to one or more designated members of the audit committee, whose decisions will be presented to the full audit committee at its next regularly scheduled meeting.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

The following exhibits are filed as part of this Form 10-K:

Exhibit Number	Description	Incorporated by Reference to:
2.1	Limited Liability Company Interest Purchase Agreement by and among the Members of CRX Bio Holdings LLC and Nexien BioPharma, Inc. dated October 26, 2018	Exhibit 2.1 to the registrant's current report on form 8-K filed October 30, 2018
3.1	Certificate of Incorporation	Exhibit 3.1 to the registrant's registration statement on Form 10 filed November 14, 2014
3.2	Certificate of Merger	Exhibit 3.1(i) to the registrant's registration statement on Form 10 filed November 14, 2014
3.3	Certificate of Amendment to Certificate of Incorporation	Exhibit 3.1(ii) to the registrant's registration statement on Form 10 filed November 14, 2014
3.4	Certificate of Amendment to Certificate of Incorporation	Exhibit 3.4 to the registrant's quarterly report on Form 10-Q filed May 15, 2018
3.5	Certificate of Amendment to Certificate of Incorporation	Exhibit 3.4 to the registrant's annual report on Form 10-K filed October 1, 2018
3.6	Bylaws	Exhibit 3.2 to the registrant's Form 10 registration statement filed November 14, 2014
10.1#	2017 Stock Incentive Plan	Exhibit 10.1 to the registrant's quarterly report on Form 10-Q filed May 15, 2018
10.2	Licensing Agreement between the Company and Kotzker Consulting LLC	Exhibit 10.2 to the registrant's quarterly report on Form 10-Q filed May 15, 2018
10.3	Exclusive License Agreement between the Company and Accu-Break Pharmaceuticals, Inc.	Exhibit 10.3 to the registrant's quarterly report on Form 10-Q filed May 15, 2018
10.4#	2018 Equity Incentive Plan	Exhibit 10.4 to the registrant's quarterly report on Form 10-Q filed May 15, 2018
10.5	First Amendment to Exclusive License Agreement between the Company and Accu-Break Pharmaceuticals, Inc. dated September 18, 2018	Exhibit 10.6 to the registrant's annual report on Form 10-K filed October 1, 2018
21.1	Subsidiaries of the Registrant	Exhibit 21.1 to the registration statement on Form S-1 (File No. 333-225477) filed June 7, 2018
31.1	Rule 13a-14(a) Certification of Alex Wasyl	
31.2	Rule 13a-14(a) Certification of Evan Wasoff	
32.1	Certification of Alex Wasyl Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
32.2	Certification of Evan Wasoff Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
101*	Financial statements from the Annual Report on Form 10-K of Nexien BioPharma, Inc. for the fiscal year ended June 30, 2019, formatted in XBRL: (i) the Balance Sheets; (ii) the Statements of Operations; (iii) the Statements of Stockholders' Deficit; (iv) the Statements of Cash Flows; and (v) the Notes to Financial Statements.	

# Indicates a management contract or compensatory plan or arrangement.

* In accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

ITEM 16. FORM 10-K SUMMARY.

Not applicable.

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.

NEXIEN BIOPHARMA, INC.

Dated: September 30, 2019

By: */s/ Alex Wasyl*
Alex Wasyl, Chief Executive Officer

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

Signature	Title	Date
/s/ Alex Wasyl Alex Wasyl	Chief Executive Officer (Principal Executive Officer) and Director	September 30, 2019
/s/ Evan Wasoff Evan Wasoff	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	September 30, 2019
/s/ Richard Greenberg Richard Greenberg	Director	September 30, 2019
/s/ Lindy Snider Lindy Snider	Director	September 30, 2019
/s/ Courtney Clark Courtney Clark	Director	September 30, 2019