Filed Pursuant to Rule 424(b)(3)
Registration No. 333-223895

PROSPECTUS SUPPLEMENT NO. 12
(To Prospectus Dated April 17, 2018)

SKYE BIOSCIENCE, INC.
Up to 140,694,163 Shares of Common Stock

This prospectus supplement no. 12 supplements the prospectus dated April 17, 2018, relating to the resale by the selling shareholders identified in such prospectus of up to 140,694,163 shares of common stock of Skye Bioscience, Inc. (formerly, Emerald Bioscience, Inc.), $0.001 par value (the "Common Stock"), including (i) 32,500,000 shares of Common Stock and 44,200,000 shares of Common Stock issuable upon exercise of warrants, which we sold to investors in a private placement on January 19, 2018 and February 16, 2018, (ii) 9,000,000 shares of Common Stock issued upon conversion of a secured promissory note for a convertible loan on January 19, 2018, (iii) 20,000,000 shares of Common Stock, which equals the number of shares of Common Stock issued upon the conversion of shares of our Series F Convertible Preferred Stock, par value $0.001 per share ("Series F Preferred Stock"), (iv) 2,000,000 shares of Common Stock, which equals the number of shares of Common Stock issued upon the conversion of shares of our Series D Convertible Preferred Stock, par value $0.001 per share ("Series D Preferred Stock"), (v) 28,335,000 shares of Common Stock issued upon the conversion of shares of our Series B Convertible Preferred Stock, par value $0.001 per share ("Series B Preferred Stock"), 1,781,250 shares of Common Stock issued upon the exercise of the warrants which we sold to investors in a private placement on August 20, 2015 and 1,843,750 shares of Common Stock issuable upon exercise of the warrants which we sold to investors in a private placement on August 20, 2015, (vi) 241,663 shares of Common Stock which we sold to investors in a private placement on January 7, 2015 and (vii) 792,500 shares of Common Stock issuable upon exercise of warrants issued to our placement agents.

This prospectus supplement incorporates into our prospectus the information contained in our attached Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 1, 2021.

You should read this prospectus supplement in conjunction with the prospectus, including any supplements and amendments thereto. This prospectus supplement is qualified by reference to the prospectus except to the extent that the information in the prospectus supplement supersedes the information contained in the prospectus.

This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any supplements and amendments thereto.

You should carefully consider matters discussed under the caption "Risk Factors" beginning on page 8 of the prospectus. Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is March 1, 2021.

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

FORM 10-K

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

For the fiscal year ended **December 31, 2020**

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

For the transition period from _____ to _____

Commission File Number: **000-55136**

Skye Bioscience, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**45-0692882**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5910 Pacific Center Blvd. Suite 320, San Diego, CA	**92121**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(949) 480-9051**

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

Title of each class:	Name of each exchange on which registered:
None	**None**

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

Common Stock, Par Value $0.001
(Title of Class)

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was approximately $29,109,240 as of June 30, 2020, based upon the closing price of $0.16 per share of the registrant's common stock on the OTCQB on June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter.

As of February 23, 2021, there were 350,007,749 shares of the registrant's common stock issued and outstanding.

TABLE OF CONTENTS

PART I

As used in this report, unless otherwise indicated, the terms "we," "us," "our," "Company" and "Skye Bioscience" refer to Skye Bioscience, Inc., a Nevada corporation formerly known as Emerald Bioscience, Inc., together with its wholly owned subsidiaries, Nemus, a California corporation, and EMBI Australia Pty Ltd, an Australian proprietary limited company.

Item 1. Business.

History

We were incorporated in the State of Nevada on March 16, 2011 in the transportation and logistics business. We are presently a biopharmaceutical company focused on the discovery, development and commercialization of cannabinoid-based therapeutics.

Effective March 25, 2019, we changed our name from Nemus Bioscience, Inc. to Emerald Bioscience, Inc. and effective January 19, 2021, we changed our name to Skye Bioscience, Inc.

In August 2019, we formed a new subsidiary in Australia, EMBI Australia Pty Ltd. in order to qualify for the Australian government's research and development tax credit for research and development dollars spent in Australia. The primary purpose of EMBI Australia Pty Ltd. is to conduct clinical trials for our product candidates.

As of December 31, 2020, we have devoted substantially all of our efforts to securing product licenses, carrying out research and development activities, planning clinical development, building infrastructure and raising capital. We have not yet realized revenue from our planned principal operations and is a number of years away from potentially being able to do so.

Business Overview

We are a biopharmaceutical company targeting the discovery, development and commercialization of cannabinoid-based therapeutics through a number of license agreements with the University of Mississippi ("UM"). We continue to be a development and commercialization partner of UM working to bring UM's proprietary cannabinoid molecules through the development process.

UM 5050 Prodrug Agreements and UM 8930 Analog Agreements

In July 2018, we renewed our ocular licenses for UM 5050, related to the prodrug formulation of tetrahydrocannabinol ("THC"), and UM 8930, related to an analog formulation of cannabidiol ("CBD"). On May 24, 2019, the ocular delivery licenses were replaced by "all fields of use" licenses for both UM 5050 and UM 8930 (collectively, the "License Agreements"). Pursuant to the License Agreements, UM granted us an exclusive, perpetual license, including, with the prior written consent of UM, the right to sublicense, the intellectual property related to UM 5050 and UM 8930 for all fields of use.

The License Agreements contain certain milestone payments, annual maintenance, royalty and sublicensing fees payable by us, as defined therein. The royalty obligations apply by country and by licensed product, and end upon the later of the date that no valid claim of a licensed patent covers a licensed product in a given country, or ten years after the first commercial sale of such licensed product in such country.

Each License Agreement continues, unless earlier terminated, until the later of the expiration of the last to expire of the patents or patent applications within the licensed technology or the expiration of our payment obligations under the License Agreements. UM may early terminate each License Agreement, by giving written notice of termination, upon our material breach of the License Agreements, including failure to make material payments without cure, material breach of covenants, representations or warranties without cure, material noncompliance of the license grant, a bankruptcy event, our dissolution or cessation of operations, our failure to make reasonable efforts to commercialize at least one product or failure to keep at least one product on the market after the first commercial sale for a continuous period of one year, other than for reasons outside our control, or our failure to meet certain pre-established development milestones. We may terminate each License Agreement upon 60 days' written notice to UM.

UM 5070 License Agreement

In January 2017, we entered into a license agreement with UM pursuant to which UM granted us an exclusive, perpetual license, including the right to sublicense, the intellectual property related to a platform of cannabinoid-based molecules ("UM 5070"), to research, develop and commercialize products for the treatment of infectious diseases.

The License Agreement contains certain milestone payments, annual maintenance, royalty and sublicensing fees payable by us, as defined therein. The royalty obligations apply by country and by licensed product, and end upon the later of the date that no valid claim of a licensed patent covers a licensed product in a given country, or ten years after the first commercial sale of such licensed product in such country.

The License Agreement continues, unless earlier terminated, until the later of the expiration of the last to expire of the patents or patent applications within the licensed technology or the expiration of our payment obligations under the License Agreement. UM may early terminate each License Agreement, by giving written notice of termination, upon our material breach of the License Agreement, including failure to make material payments without cure, material breach of covenants, representations or warranties without cure, material noncompliance of the license grant, a bankruptcy event, our dissolution or cessation of operations, our failure to make reasonable efforts to commercialize at least one product or failure to keep at least one product on the market after the first commercial sale for a continuous period of one year, other than for reasons outside our control, or our failure to meet certain pre-established development milestones. We may terminate the License Agreement upon 60 days' written notice to UM.

Our Product Candidates

Cannabinoids are a class of chemically diverse compounds that are mainly found in extracts from the cannabis plant. These compounds express their physiological response by binding to cannabinoid (CB1 and CB2) and certain other receptors found throughout the human body. Some cannabinoids have been observed to exert multiple effects on the human body, including, but not limited to impacting the immune response, nervous system function and repair, gastrointestinal maintenance and motility, motor function in muscles, pancreatic functionality, tissue repair, blood sugar regulation, and integrity of function in the eye (including the optic nerve). Cannabis and specific cannabinoids have been studied widely and the results suggest that there may be a potential for these compounds to be used in treating many disorders or alleviating disease-associated symptoms.

We are focused on the development of proprietary, synthetic cannabinoid-derived molecules that have been bioengineered to improve solubility, bioavailability and pharmacology of natural cannabinoids, while also providing the Company with strong intellectual property protection. The following table summarizes certain information regarding our cannabinoid product candidates:

Product Candidate	Indication	Development Status
THCVHS	Glaucoma	Preclinical
CBDVHS	Multiple Targets	Preclinical
Cannabinoid Cocktail	Anti-infective	Research

THCVHS

Our lead compound initially being developed to treat ocular disease is THCVHS, a prodrug of THC. A prodrug is a medication or compound, that after administration is metabolized into a pharmacological active drug. The molecule has been designed to make the usually lipophilic THC more hydrophilic to allow for improved transport across the membranes of the eye. In 2013 and 2014, UM conducted studies of the formulation in the rabbit ocular model which showed that THCVHS was able to penetrate all chambers of the eye which could potentially broaden the proposed therapeutic indications of interest for THCVHS to diseases of the eye that affect the retina and the optic nerve, such as glaucoma, macular degeneration or diabetic retinopathy. These studies also revealed that THCVHS was able to achieve potentially therapeutic concentrations in the anterior compartment, vitreous humor, and posterior compartment of the normal rabbit eye, which is very similar to the human eye in anatomy and physiology.

Glaucoma is an ocular neuropathy associated with the initiation of programmed cell death, known as apoptosis, of the retinal ganglion cells ("RGCs") of the optic nerve, resulting in the progressive and irreversible loss of vision. Intraocular pressure ("IOP") has been identified as an important risk factor in the pathogenesis of this disease. Elevated IOP can lead to damage of RGC axons through vascular ischemia by compromising blood flow to the cells, and physical crush injury as the elevated ocular pressure compresses these delicate cells. Cannabinoid receptors are highly concentrated in the eye, especially in the anterior compartment that helps regulate IOP, and the posterior compartment in the area of the retina and optic nerve. Stimulation of cannabinoid receptors by THC has been previously shown to lower IOP in both animal and human studies.

Additional studies using an alpha-chymotrypsin induced glaucoma model in rabbits were performed by UM in 2013 and 2014 under a grant from the National Institutes of Health (the "NIH"). Those studies showed that THCVHS was able to reduce IOP by 45% to 50%. Reduction in IOP was successful in an almost linear dose-responsive manner, with greater decline in IOP associated with higher dosage concentration. The decline in IOP observed in the rabbit model correlated to historical human data when patients were exposed to systemically administered THC via inhalational methods. The human studies were conducted by the NIH and the U.S. Army in the 1970's where glaucoma patients for the NIH study and normal volunteers for the U.S. Army study were exposed to THC by smoking marijuana. Patients tested by the NIH exhibited a decline in IOP ranging from 35% to as high as 65%, correlated to the amount of THC in the plasma. Normal volunteers in the U.S. Army study also showed a decrease in IOP of approximately 10% to 20% in a setting of normotension. While THC from smoking marijuana was able to reduce IOP in humans, the effect was short lived given the short half-life of the THC molecule. The half-life of the THCVHS used in the rabbit glaucoma model was considerably longer; however, we intend to formulate THCVHS in order to lengthen the half-life to the degree that it would be effective when dosed once a day.

We examined the THCVHS in further testing using a nanoparticle delivery system to prolong the drug's half-life in late 2015 and 2016. The studies were conducted by UM and placed THCVHS into a solid lipid-nanoparticle system ("SLN") to deliver the drug to the eye using topical drop administration. The SLN delivery of THCVHS was administered to rabbits that underwent elevated IOP inducement using the alpha-chymotrypsin model.

Data from that experiment confirmed previous studies that showed administration of THCVHS resulted in a 45% reduction in IOP from baseline with a half-life consistent with five to six-times per day dosing. When THCVHS was administered via SLN delivery in normotensive animals, a lower concentration of THCVHS (0.4% equivalent THC) exhibited a decrease in IOP of approximately 20% while a higher concentration of THCVHS (0.6% equivalent THC) lowered IOP up to 38%. The use of SLN technology lengthened the half-life of THCVHS equivalent to dosing the drug two to three times a day. The formulation we are developing for human studies will encapsulate THCVHS in a nanoemulsion including the emulsifier, Carbopol, to increase the residence time of the drug in the eye. Testing of this formulation in a normotensive animal models revealed statistically significant lowering of the IOP when compared to both latanoprost and timolol, the current standard-of-care in the treatment of IOP, as well as extended pharmacologic activity time that could support once daily dosing.

Further animal experimentation conducted in 2016-2017 examined both the penetration and concentration of THCVHS in key organs of the eye. The data revealed that IOP declined in a concentration-time dependent manner and could be correlated to the concentration of THC in organs regulating IOP, such as the trabecular meshwork in the anterior compartment and the retina-choroid in the posterior compartment. The data was important for demonstrating a direct causal relationship between the penetration and concentration of THC with IOP-lowering capability and the presence of THC in multiple compartments of the eye. Additionally, neither free-THC nor 11-hydroxy-THC (the main active metabolite of THC) was detected in the peripheral circulation of the test animals, indicating that the topical dosage of the test compound remained restricted to the eye, an enclosed organ.

In 2019, UM completed experiments showing that THCVHS was statistically superior in lowering IOP compared to the prostaglandin-based therapy, latanoprost, the current standard-of-care for treating glaucoma. Significance was reached across multiple timepoints during a seven-day course of dosing using a validated rabbit normotensive ocular model and THCVHS exerted pharmacologic activity consistent with once-daily to twice-daily dosing.

Additionally, we worked with Glauconix Biosciences Inc. ("Glauconix") to complete a pilot study to research the mechanism of action and IOP-lowering ability of THC when administered into an ex vivo model of a 3D-human trabecular meshwork using both healthy and glaucomatous-derived tissues. The Glauconix study validated the mechanism of action of THCVHS in lowering IOP, a defining disease process of hypertensive glaucoma. Moreover, biomarkers associated with inflammation and fibrosis in both normal and tissues affected by glaucoma were significantly decreased, pointing to anti-inflammatory and anti-fibrotic activities that are often associated with the cannabinoid class of molecules in other disease-states; and data revealed that biomarkers associated with neovascularization, a disease process of new blood vessel formation that can damage the retina in a variety of ocular diseases, was also inhibited by THC, prompting further study for the utility of this drug in diseases of the retina.

The rabbit ocular model is an accepted animal model for regulatory agencies when considering a candidate drug for human testing and this data will be submitted as part of our investigational new drug application ("IND") to the Food and Drug Administration ("FDA"). The manufacturing of the active pharmaceutical ingredient THCVHS is conducted in the United States. Formulation of the eye drop for testing is also performed in the United States but may utilize regulatory-accepted excipients sourced from countries outside the United States, such as China. The recent COVID-19 pandemic may impact our ability to source specific materials that are part of the eye drop formulation and could possibly impact volunteer and/or patient recruitment in Australia for our Phase I clinical studies of THCVHS. The pandemic has resulted in a shift of our first in-human studies, from the second half of 2020 to the third quarter of 2021. Our first-in-human studies are to be conducted in healthy volunteers and patients with glaucoma and ocular hypertension in Australia (the "THCVHS Clinical Trial"). Initially, we plan to conduct a Phase 1, first-in-human, randomized, double-blind, placebo-controlled, single-ascending dose ("SAD") and multiple-ascending dose ("MAD") study to establish a safe and tolerable dosing window of THCVHS in humans that can be used in the design of subsequent clinical trials.

Subsequently, we may advance THCVHS into a Phase 2 clinical trial provided that data from the Phase 1 clinical trial demonstrates that the topical delivery of THCVHS is safe and well-tolerated, and IOP is markedly different between THCVHS and the placebo. Design of a subsequent Phase 2 clinical trial will be dependent upon the advice of our Advisory Board, the FDA and other regulatory bodies.

CBDVHS

We have embarked on research exploring the utility of different formulations of CBDVHS, our proprietary CBD analog. Early studies of CBDVHS demonstrated analgesic, anti-inflammation, anti-fibrotic, anti-seizure properties, including the potential treatment and management of several eye diseases, such as uveitis, dry eye syndrome, macular degeneration and diabetic retinopathy. Data we presented at the American Association of Pharmaceutical Scientists ("AAPS") meeting held in November 2017, revealed that an ocular formulation of CBDVHS was able to penetrate multiple compartments of the eye, including reaching the retina and the optic nerve. Further testing will need to be conducted to further evaluate the possible utility of this compound as a therapeutic agent and we continue to advance our research studies related to CBDVHS to explore different therapeutic applications.

Cannabinoid Cocktail

Cannabinoid molecules have been shown in in vitro studies conducted by third parties to possess anti-infective activity against a variety of bacterial strains. We entered into a research agreement with UM to explore this area in 2015 and have tested a variety of cannabinoids in various strengths, combinations, and delivery systems against a variety of bacterial species found in community, healthcare, and institutional settings such as nursing homes, correctional facilities, and military quarters. As discussed above in "UM 5070 License Agreement," in January 2017, we entered into a license agreement with UM pursuant to which UM granted us an exclusive, perpetual license, including the right to sublicense, intellectual property related to UM 5070, a platform of cannabinoid-based molecules to research, develop and commercialize products for the treatment of infectious diseases.

Other Potential Products

We continue to work with UM to explore other potential indications and associated routes of administration based on the expanded UM 5050 and UM 8930 all fields licenses. Our decision to advance another potential therapeutic candidate will be influenced by a number of criteria, including but not limited to research, preclinical data, synthesis and formulation capability as well as prevailing market conditions.

Our Competitive Strengths

Cannabis is subject to strict regulation in the United States. Cannabis and cannabis extracts are classified by the U.S. Drug Enforcement Administration (the "DEA"), as a Schedule I substance, which means that, under federal law, it has no established medicinal use and may not be marketed or sold in the United States. In addition, the United States is a party to the Single Convention on Narcotic Drugs, which imposes certain requirements and restrictions on member parties with respect to the cultivation and wholesale trade in cannabis. Since 1968, UM has held the only contract with the Federal Government to cultivate cannabis on its behalf for research purposes and holds the requisite DEA registrations authorizing it to engage in that activity. The contract, which is open for competitive bidding at periodic intervals, is administered by the National Institute on Drug Abuse ("NIDA"), an agency within the NIH. UM's current contract was awarded in 2015 and runs for a base year of one year with four one-year options. As the sole contract holder since 1968, UM has developed significant expertise in the extraction, separation, processing and manufacture of cannabinoids. UM has also engaged in the cultivation of cannabis and the extraction of cannabinoids for purposes of developing drug product candidates apart from its role as NIDA contractor. We have entered into several research and license agreements with UM and view this collaborative association as a significant strategic advantage in the marketplace.

The only cannabinoid products that are currently approved as drugs in the United States and, to our knowledge, all cannabinoid products in late-stage development, are predominantly orally delivered products. Cannabinoids, when ingested orally, are subject to significant first pass metabolism by the liver and potential drug-drug interactions, resulting in very high inter-patient and intra-patient variation in bioavailability which can potentially compromise both efficacy and safety. This has been published in the literature and in product labeling by regulatory agencies worldwide. These independent assessments correlate with highly variable response rates and safety profiles which, in some cases, have been deemed to have marginal clinical utility. We have licensed from UM the rights to THCVHS, a pro-drug formulation of THC. Data from UM supports the delivery of the pro-drug through absorptive routes other than the gastrointestinal tract, which we believe has the potential to mitigate the issue of first-pass metabolism by the liver, potentially enhancing drug bioavailability and predictive pharmacokinetics. We are also working with UM and other parties on methods to formulate and deliver CBDVHS and a variety of other pharmaceutical-grade cannabinoids to better manage symptoms and/or treat diseases.

Our Business Strategy

Our goal is to become a premier developer of synthetic cannabinoid-derived medicines for global markets to treat significant unmet medical needs. Our current operating strategy includes:

- selection and licensing of potential clinical targets based on internal and external published data, access to appropriate cannabinoids, and the impact of both developmental and market conditions;
- prioritization of product candidates based on the potential clinical utility and market of associated target indications;
- development and execution of an intellectual property strategy;
- Clinical development and advancement of our current product pipeline;
- outsourcing services, such as use of Clinical Research Organizations ("CROs") and contract manufacturers for the active pharmaceutical ingredient, where possible and cost effective;
- obtaining regulatory direction and approval from the FDA, European Medicines Agency ("EMA"), and other regulatory agencies for our product candidates;
- research and development of additional indications for our product candidates; and
- partnering, out-licensing, or selling our product candidates to pharmaceutical companies to maximize profits and to bring our state-of-the-art therapeutics to patients in need.

Sales and Marketing

We have not established a sales, marketing or product distribution infrastructure because our lead product candidates are still in research, discovery or preclinical development stages. If and when we obtain approval to market any of our product candidates, we will evaluate what we believe to be the optimal commercialization path for the Company, the respective product candidate, and patients. Commercialization paths may include licensing, selling, or partnering with other commercial partners. We may also choose to build a commercial sales and marketing team for some or all of our product candidates.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for final manufacture. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture of any products that we may commercialize.

For all of our future product candidates, we aim to identify and qualify manufacturers to provide the API and fill-and-finish services prior to submission of a New Drug Application ("NDA") to the FDA. We expect to continue to develop drug candidates that can be produced cost-effectively at contract manufacturing facilities.

Intellectual Property

The success of most of our product candidates will depend in large part on our ability to:

- obtain and maintain patent and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute our patent applications and defend any issued patents we obtain;
- preserve the confidentiality of our trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

We intend to continue to seek patent protection for certain of our product candidates, drug delivery systems, molecular modifications, as well as other proprietary technologies and their uses by filing patent applications in the United States and other selected global territories. We intend for these patent applications to cover, where possible, claims for composition of matter, medical uses, processes for isolation and preparation, processes for delivery and formulations.

As of the date of this Annual Report, we have licensed from UM three inventions, which include U.S. patents as well as a number of foreign counterparts, including the European Union, Japan, Canada and Australia. The patents that we license, cover composition of matter and preparation of prodrug of THC, analog of cannabidiol, and platform of cannabinoids for the treatment of infectious diseases, and their methods of use. These patents are expected to expire in 2039. Additionally, in March 2020, we were notified by the United States Patent and Trademark Office, that a notice of allowance has been issued for the proprietary analog of cannabidiol, CBDVHS. The official issuance date for the CBDVHS US patent was July 2020. The expiration date of the US patent for CBDVHS is January 2037. Under our license agreements, UM retains ownership over the licensed patents and control over the maintenance and prosecution of the licensed patents and patent applications. We also rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees and selected consultants, scientific advisors and collaborators. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, such as pharmaceutical companies, including generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions. Many of our potential competitors may have substantially greater financial, scientific, technical, intellectual property, regulatory and human resources than we do, and greater experience than we do commercializing products and developing product candidates, including obtaining FDA and other regulatory approvals for product candidates. Consequently, our competitors may develop products for indications we pursue that are more effective, better tolerated, more widely prescribed or accepted, more useful and less costly, and they may also be more successful in manufacturing and marketing their products. We also face competition from third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients for clinical trials and in identifying and acquiring or in-licensing new products and product candidates.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. A failure to comply with such laws and regulations or prevail in any enforcement action or litigation related to noncompliance could have a material adverse impact on our business, financial condition and results of operations and could cause the market value of our common stock to decline.

Regulation of Cannabis and Cannabinoids

DEA Regulation

Cannabis, cannabis extracts and some cannabinoids are regulated as "controlled substances" as defined in the Controlled Substances Act (the "CSA"), which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, of controlled substances in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Cannabis, cannabis extracts and some cannabinoids are listed by the DEA as Schedule I controlled substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use are subject to a high degree of regulation. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. The registered entity must maintain records for the handling of all controlled substances and must make periodic reports to the DEA. These include, for example, distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. The registered entity must also report thefts or losses of any controlled substance and obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. In the event of non-compliance, the DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

The DEA has conducted a scientific review of the chemical structure of CBDVHS and determined that CBDVHS is not a regulated chemical nor controlled substance under the CSA. This decision by the DEA should help the Company expand the network of clinical testing sites, permit a greater cross-section of patients to participate in studies of this drug, as well as speed the initiation of clinical trials. THCVHS remains a Schedule I, controlled substance, pending a request to re-schedule THCVHS after a drug approval by the FDA.

U.S. Food and Drug Administration

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDA regulates drugs under the Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject us to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with good laboratory practice ("GLP") regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an institutional review board ("IRB") at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice ("GCP") requirements to establish the safety and efficacy of the proposed drug for each indication;
- submission of an NDA to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA unless, before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND does not always result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of reviewing and responding to a submission within ten months from the date of "filing" of a standard NDA for a new molecular entity. This review typically takes at least twelve months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision. However, if issues arise during the review, the FDA may request additional information and the review period may be extended to permit the applicant to provide and the FDA to review that information, which may significantly extend this time period.

In addition, under the Pediatric Research Equity Act of 2003 ("PREA"), as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that is adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of REMS plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept a NDA for filing. In this event, the application must be resubmitted with the additional information requested. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

The testing and approval process for a NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. For some products, such as our product candidates, an additional step of DEA review and scheduling is required.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of a NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program.

Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Exclusivity and Approval of Competing Products

Hatch Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

Hatch Waxman Patent Exclusivity

In seeking approval for a drug through a NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

The ANDA or 505(b)(2) NDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except when the ANDA or 505(b)(2) NDA applicant challenges a listed drug. A certification that the proposed product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of notice of the Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

Hatch Waxman Non-Patent Exclusivity

In addition to patent issues, market and data exclusivity provisions under the FDCA can delay the submission or the approval of certain applications for competing products. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that references the previously approved drug. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a Paragraph IV certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA, or supplement to an existing NDA or 505(b)(2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant, are deemed by the FDA to be essential to the approval of the application or supplement. Three-year exclusivity may be awarded for changes to a previously approved drug product, such as new indications, dosages, strengths or dosage forms of an existing drug.

This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and, as a general matter, does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for other versions of a drug. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a disease or condition that affects populations of fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting a NDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict business practices in the pharmaceutical industry. These laws include anti-kickback and false claims laws and regulations as well as data privacy and security laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exemptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. A violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-covered, uses. In addition, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal HIPAA also created federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Pharmaceutical companies are also subject to the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. The Patient Protection and Affordable Care Act, as amended by the ACA, signed into law on March 2010, created new federal requirements for reporting, by applicable manufacturers of covered drugs, payments and other transfers of value to physicians and teaching hospitals. Applicable manufacturers are also required to report annually to the government certain ownership and investment interests held by physicians and their immediate family members. In addition, certain states require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other health care professionals and entities.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH") and its implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

To the extent that any of our product candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third party payors. Third party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third party payor not to cover our products, if approved, could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. By way of example, in the United States, the ACA contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, reform government program reimbursement methodologies. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

Foreign Regulation

In order to market any product outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. While our management and many of our consultants are familiar with and have been responsible for gaining marketing approval in many countries, we have not reviewed the specific regulations in countries outside of the United States, as it pertains to cannabinoids.

Additional Regulation

We are a reporting company with the Securities and Exchange Commission (the "SEC"), and, therefore, subject to the information and reporting requirements of the Exchange Act of 1934, as amended (the "Exchange Act") and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"). In addition, our financial reporting is subject to United States generally accepted accounting principles ("U.S. GAAP"), and U.S. GAAP is subject to change over time.

We are also subject to federal, state and local laws and regulations applied to businesses generally. We believe that we are in conformity with all applicable laws in all relevant jurisdictions.

Employees

As of the date of this Annual Report, we have a total of six full-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages and we consider our relations with our employees to be good.

We anticipate that we will need to hire additional employees or independent contractors for our continued development efforts. We also intend to utilize independent contractors and outsourced services, such as CROs, and third party manufacturers, where possible and appropriate.

Website

Our Internet website, which is located at http://www.skyebioscience.com, describes our company and our management and provides information about cannabis-based therapeutics. Information contained on our website is not incorporated by reference into, and should not be considered a part of, this Annual Report.

FORWARD-LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition and stock price could be materially and negatively affected. In some cases, you can identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," "would" or the negative of these terms or other comparable terminology. Factors that could cause actual results to differ materially from those currently anticipated include those set forth in the section below titled "Risk Factors," including, without limitation, risks relating to:

- the results of our research and development activities, including uncertainties relating to the discovery of potential product candidates and the preclinical and clinical testing of our product candidates;
- the early stage of our product candidates presently under development;
- our need for substantial additional funds in order to continue our operations, and the uncertainty of whether we will be able to obtain the funding we need;
- our ability to obtain and, if obtained, maintain regulatory approval of our current product candidates, and any of our other future product candidates, and any related restrictions, limitations, and/or warnings in the label of any approved product candidate;
- our ability to retain or hire key scientific or management personnel;
- our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights;
- our dependence on University of Mississippi, third party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators;
- our ability to develop successful sales and marketing capabilities in the future as needed;
- the size and growth of the potential markets for any of our approved product candidates, and the rate and degree of market acceptance of any of our approved product candidates;
- competition in our industry;
- the duration and impact of the novel coronavirus ("COVID-19") pandemic; and
- regulatory developments in the United States and foreign countries.

We operate in a rapidly changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, such as the COVID-19 outbreak and associated business disruptions including delayed clinical trials and laboratory resources, nor can we assess the impact of all factors on our 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 statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. The forward-looking statements included in this report speak only as of the date hereof, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

Item 1A. Risk Factors.

Any investment in our common stock involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained in this Annual Report on Form 10-K before deciding whether to purchase our common stock. Our business, financial condition or results of operations could be materially and adversely affected by these risks if any of them actually occur. Our common stock is quoted on the OTCQB under the symbol "SKYE." This market is extremely limited, and the prices quoted are not a reliable indication of the value of our common stock. As of the date of this Annual Report, there has been very limited trading of shares of our common stock. If and when our common stock is traded, the trading price could decline due to any of these risks, and an investor may lose all or part of his or her investment. Some of these factors have affected our financial condition and operating results in the past or are currently affecting us. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks described below and elsewhere in this Annual report.

Risks Related to our Business and Capital Requirements

We currently have no product revenues and no products approved for marketing and need substantial additional funding to continue our operations.

We expect to need substantial additional funding to pursue the clinical development of our product candidates and launch and commercialize any product candidates for which we receive regulatory approval. We need to bring in additional capital in the near term and expect to incur additional costs associated with operating as a public company. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our capital needs. As noted in our audited financial statements for the years ended December 31, 2020 and 2019, the uncertainties surrounding our ability to fund our operations raise substantial doubt about our ability to continue as a going concern.

To date, we have financed our operations entirely through debt and equity financings. We may seek additional funds through public or private equity or debt financing, via strategic transactions or collaborative arrangements. Additional funding from those or other sources may not be available when or in the amounts needed, on acceptable terms, or at all.

There are no assurances that future funding will be available on favorable terms or at all. If additional funding is not obtained, we may need to reduce, defer or cancel preclinical and lab work, planned clinical trials, or overhead expenditures, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Any of these events could significantly harm our business, financial condition and prospects.

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

Our historical financial statements have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report on our audited financial statements for the years ended December 31, 2020 and 2019 that included an explanatory paragraph referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity financing or other capital, attain further operating efficiencies, reduce expenditures, and, ultimately, generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. However, if adequate funds are not available to us when we need it, we will be required to curtail our operations which would, in turn, further raise substantial doubt about our ability to continue as a going concern. The doubt regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all. Additionally, if we are unable to continue as a going concern, our stockholders may lose some or all of their investment in us.

We rely heavily on UM for our research and development programs, and UM is a joint owner of the intellectual property resulting from its preclinical research and development.

We rely heavily on our relationship with UM for our research and development programs. Under the terms of our agreements with UM, we are required to fund preclinical and clinical trials required for cannabinoid-based products developed by UM. If UM were to terminate one or more of our agreements, we may be required to return or destroy certain materials or data developed during our partnership that is confidential to UM and face substantial delays or possible termination of the affected program. In addition, the agreements provide that all intellectual property rights (including any patents and non-manufacturing related know-how) that are conceived by both UM and us during the course of the collaboration are to be jointly owned by UM and us, and we may need to seek UM's consent to pursue, use, license and/or enforce some of these intellectual property rights in the future. An unexpected deterioration in our relationship with UM may have a material adverse effect on our business, reputation, results of operations and financial condition.

We are heavily dependent on the success of our early-stage product candidates, which will require significant additional efforts to develop and may prove not to be viable for commercialization.

We have no products approved for sale and all of our product candidates are in preclinical development, including the development of cannabinoid-based formulations. Further preclinical testing is ongoing and if successful, will be part of a regulatory filing to satisfy Investigational New Drug ("IND") requirements that need to be met in order for the candidate compounds and routes of administration to enter testing in humans. Our business depends entirely on the successful development, clinical testing, and commercialization of these and any other product candidates we may seek to develop in the future, which may never occur. The success of our product candidates will depend on several factors, which we may not be able to successfully complete, such as:

- receipt of necessary controlled substance registrations from the DEA;
- successful completion of preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA and other applicable regulatory authorities;
- obtaining, maintaining and protecting our intellectual property portfolio;
- identifying, making arrangements and ensuring necessary registrations with third party manufacturers, or establishing commercial manufacturing capabilities for applicable product candidates;
- launching commercial sales of the products, if and when approved;
- acceptance of our products, if and when approved, by patients, the medical community and third party payors;
- obtaining and maintaining healthcare coverage and adequate reimbursement of our products; and
- maintaining a continued acceptable safety profile of our products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. We expect to conduct clinical trials for certain of our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We conduct certain research and development operations through our Australian wholly owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations could suffer.

In August 2019, we formed a wholly owned Australian subsidiary, EMBI Australia, to conduct various clinical activities for our product candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our lead product candidate in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals. In addition, current Australian tax regulations provide for a refundable R&D tax credit equal to 43.5% of qualified expenditures. If our subsidiary loses its ability to operate in Australia, or if we are ineligible or unable to receive the R&D tax credit, or the Australian government significantly reduces or eliminates the tax incentive program, our business and results of operation may be adversely affected.

We expect to face intense competition, often from companies with greater resources and experience than we have.

The highly competitive pharmaceutical industry continues to rapidly expand and evolve as an increasing number of competitors and potential competitors enter the market, many of which have substantially greater financial, technological, managerial and research and development resources and experience than we have. Our pipeline products, if successfully developed, will compete with product offerings from large and well-established companies that have greater marketing and sales experience and capabilities than we or our collaboration partners have. If we are unable to compete successfully, we may be unable to grow and sustain our revenue.

The current volatility of global financial conditions could negatively impact our business and financial condition.

Current global financial conditions and recent market events have been characterized by increased volatility and the resulting tightening of the credit and capital markets has reduced the amount of available liquidity and overall economic activity. We cannot guaranty that debt or equity financing, and the ability to borrow funds or cash generated by operations will be available or sufficient to meet or satisfy our initiatives, objectives, or requirements. Our inability to access sufficient amounts of capital on terms acceptable to us for our operations will negatively impact our business, prospects, liquidity and financial condition.

If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our success depends in large measure on our key personnel, including Mr. Punit Dhillon, our Chief Executive Officer. The loss of the services of Mr. Dhillon could significantly hinder our operations. We do not currently have key person insurance in effect for Mr. Dhillon. In addition, the competition for qualified personnel in the pharmaceutical industry is intense and there can be no assurance that we will be able to continue to attract and retain all personnel necessary for the development and operation of our business.

Breach of any of the license agreements with UM could result in the loss of such license rights that are important to our business and our operations could be materially harmed.

We licensed from UM the use, development and commercialization rights for our product candidates. As a result, our current business plans are dependent upon our maintenance of the license agreements and the rights we licensed under it. If we breach the terms of our license agreement with UM, or any future license agreement on which our business or product candidates are dependent, UM or other licensors may have the right to terminate the applicable agreement in whole or in part and thereby limit or terminate our rights to the licensed technology and intellectual property and/or any rights we have acquired to develop and commercialize certain product candidates. The loss of the rights licensed to us under our license agreement with UM, or any future license agreement that we may enter granting rights on which our business or product candidates are dependent, would harm, or even eliminate, our ability to further develop the applicable product candidates and would materially harm our business, prospects, financial condition and results of operations.

Our operating activities may be restricted as a result of covenants related to the outstanding indebtedness under our Credit Agreement.

We could default on the payment of our indebtedness under our Amended and Restated Multi-Draw Credit Agreement entered into with Emerald Health Sciences, Inc. ("Emerald Health Sciences"), a related party, on April 1, 2020 (the "Credit Agreement"), when it comes due which may result in acceleration of all amounts outstanding under our Credit Agreement. Additionally, our Credit Agreement restricts, among other things, our ability to incur debt and requires us to comply with certain covenants. We may not be able to comply with these restrictions and covenants in the future, which could result in an event of default under our Credit Agreement and result in the acceleration of the maturity of the indebtedness under the Credit Agreement. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In that case, we may be required to delay, limit, reduce or terminate our product candidate development or commercialization efforts or grant others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We engage in transactions with related parties which present possible conflicts of interest that could have an adverse effect on us.

We have entered, and may continue to enter, into transactions with Emerald Health Sciences and its affiliates and other related parties for financing, corporate, business development and operational services. Such transactions may not have been entered into on an arm's-length basis, and we may have achieved more or less favorable terms because such transactions were entered into with our related parties. We rely, and will continue to rely, on our related parties to maintain these services. If the pricing for these services changes, or if our related parties cease to provide these services, including by terminating agreements with us, we may be unable to obtain replacements for these services on the same terms without disruption to our business. This could have a material effect on our business, results of operations and financial condition. The details of certain of these transactions are set forth in "Certain Relationships and Related Party Transactions." Related party transactions create the possibility of conflicts of interest with regard to our management, we may enter into contracts between us, on the one hand, and related parties, on the other, that may not result in arm's-length transactions, including that:

- our executive officers and directors that hold positions of responsibility with related parties may be aware of certain business opportunities that are appropriate for presentation to us as well as to such other related parties and may present such business opportunities to such other parties; and

- our executive officers and directors that hold positions of responsibility with related parties may have significant duties with, and spend significant time serving, other entities and may have conflicts of interest in allocating time.

Such conflicts could cause an individual in our management to seek to advance his or her economic interests or the economic interests of certain related parties above ours. Further, the appearance of conflicts of interest created by related party transactions could impair the confidence of our investors. Our audit committee reviews these transactions. Notwithstanding this, it is possible that a conflict of interest could have a material adverse effect on our liquidity, results of operations and financial condition.

We are expecting delays to our THCVHS clinical trial because of the COVID-19 pandemic and unpredictable business disruptions could seriously harm our future revenues and financial condition, increase our costs and expenses, and impact our ability to raise capital.

Our operations could be subject to unpredictable events, such as earthquakes, power shortages, telecommunications failures, water shortages, medical epidemics such as the COVID-19 outbreak and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Notably, we rely on third party manufacturers to produce our product candidates. In connection with the recent COVID-19 pandemic, there could possibly be an impact on sourcing materials that are part of the eye drop formulation, as well as impacting volunteer and/or patient recruitment in Australia for clinical studies. Therefore, we have shifted our first-in-human studies of the lead drug candidate, THCVHS, from the second half of 2020 to the third quarter of 2021. Additionally, COVID-19 has caused significant disruptions to the global financial markets which could impact our ability to raise additional capital. The ultimate impact on us and our significant suppliers and manufacturers is unknown, but our operations and financial condition could suffer, and any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, results of operations, financial condition and cash flows from future prospects.

Risks Related to Controlled Substances

The product candidates we are developing will be subject to U.S. controlled substance laws and regulations, and failure to comply with or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, and our financial condition.

The product candidates we plan to develop will contain controlled substances as defined in the CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, 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. 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. While cannabis, cannabis extracts, and some cannabinoids are Schedule I controlled substances, products approved for medical use in the United States that contain cannabis, cannabis extracts or some cannabinoids must be placed on Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement.

If approved by the FDA, we expect the finished dosage forms of our cannabinoid-derived drug product 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. In addition, the scheduling process may take one or more years, thereby delaying the launch of the drug product in the United States. Furthermore, if the FDA, DEA, or any foreign regulatory authority determines that any of our drug product candidates may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate establishing whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of the drug product.

Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must 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. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining the necessary registrations may result in delay of the manufacturing, development, or distribution of our product candidates. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our 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. Individual states have also established controlled substance laws and regulations. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners or clinical sites must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

To conduct clinical trials with our product candidates in the United States prior to approval, each of our research sites must obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense the product candidate and to obtain the product. If the DEA delays or denies the grant of a research registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites.

Manufacturing of our product candidates is, and, if approved, our commercial products will be, subject to the DEA's annual manufacturing and procurement quota requirements, if classified as Schedule II. The annual quota allocated to us or our contract manufacturers for the controlled substances in our product candidates may not be sufficient to meet commercial demand or complete clinical trials. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and operations.

If, upon approval of any of our product candidates, the product is scheduled as Schedule II or III, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute the product to pharmacies and other health care providers. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program may make physicians less willing to prescribe, and pharmacies to dispense, our products, if approved.

Our ability to research, develop and commercialize our drug product candidates is dependent on our ability to obtain and maintain the necessary controlled substance registrations from the DEA.

In the United States, the DEA regulates activities relating to the cultivation, possession and supply of cannabis for medical research and/or commercial development, including the requirement to obtain annual registrations to manufacture or distribute pharmaceutical products derived from cannabis extracts. The National Institute on Drug Abuse ("NIDA") also plays a role in oversight of the cultivation of cannabis for medicinal research. We do not currently handle any controlled substances, but we plan to partner with third parties to engage in the research and development of cannabis-derived compounds for medical purposes.

The cultivation of cannabis is strictly regulated in the United States under a complex legal framework and our partners may be unable to obtain or maintain the necessary authorizations to cultivate cannabis for the research and development of cannabis-derived compounds.

We are partnering with UM to research and develop cannabis-derived drug products. Pursuant to that partnership, UM plans to cultivate cannabis and make extracts to conduct or enable our third party laboratories to conduct early investigations into proof-of-concept studies on the activity of these cannabinoids in various medical conditions. The regulation of cannabis is complex and subject to stringent controls. If UM cannot obtain or maintain the necessary regulatory authorizations that we anticipate will be required for the contemplated development program, our business may suffer, and we may not be able to pursue the discovery, research and development of cannabinoids. While UM conducts research using cannabinoids derived from the plant, all of the Company's candidate molecules are synthetic derivatives and therefore may not fall under the DEA's definition of a controlled substance.

Risks Related to Government Regulation

If we fail to demonstrate the safety and efficacy of any product candidate that we develop to the satisfaction of the regulatory authorities, we may incur additional costs or experience difficulty in completing, the development and commercialization of such product candidate.

We are not permitted to commercialize, market, promote, or sell any product candidate in the United States without obtaining marketing approval from the FDA or in other countries without obtaining approvals from comparable foreign regulatory authorities, such as the European Medicines Agency (the "EMA"), and we may never receive such approvals. To gain approval to market a drug product, we must complete extensive preclinical development and clinical trials that demonstrate the safety and efficacy of the product for the intended indication to the satisfaction of the FDA or other regulatory authority.

We have not previously submitted a new drug application ("NDA") to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. If we do not receive regulatory approval for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights.

The FDA or any foreign regulatory bodies could delay, limit or deny approval of our product candidates for many reasons, including our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that the product candidate is safe and effective for the requested indication, the regulatory agency's disagreement with the interpretation of data from preclinical studies or clinical trials, or our inability to demonstrate that the clinical and other benefits of the product candidate outweigh any safety or other perceived risks. The FDA or applicable regulatory body could also require additional preclinical or clinical studies, deny approval of the formulation, labeling or the specifications of the product candidate, or the manufacturing processes or facilities of third party manufacturers with which we contract. The policies of the applicable regulatory agencies could also significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of a NDA or foreign regulatory filing for a product candidate, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials. The FDA or the applicable foreign regulatory agency also may approve the product candidate for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve the labeling that we believe is necessary or desirable for the successful commercialization of the product. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of the product candidate and would materially adversely impact our business and prospects.

Preclinical and clinical drug development involves a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Clinical testing is expensive and can take several years to complete, and its outcome is inherently uncertain. Moreover, obtaining sufficient quantities of product for clinical testing is subject to regulation by DEA and, in some cases, NIDA. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or subsequently to commercialize our product candidates, including:

- FDA, DEA or NIDA may not authorize the use and distribution of sufficient quantities of product for clinical testing;
- regulators or independent institutional review boards (IRBs) may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Our pool of suitable patients may be smaller for some of our product candidates, which will impact our ability to enroll a sufficient number of suitable patients. In addition, some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is affected by other factors including the severity of the disease under investigation, the eligibility criteria for the study in question, the perceived risks and benefits of the product candidate, the patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, and the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether, which could result in increased development costs and cause the value of our company to decline and limit our ability to obtain additional financing.

Our development and commercialization strategy for THCVHS, may depend, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of dronabinol, based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.

The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act ("FDCA"), Section 505(b)(2) permits the filing of a NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving a NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an approved product. The FDA may also require companies to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the listed product's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions. Depending on guidance from the FDA, we may decide to submit a NDA for THCVHS under Section 505(b)(2) relying, in part, on the FDA's previous findings of safety and efficacy from investigations for the approved drug product Dronabinol for which we have not received a right of reference and published scientific literature. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval, the FDA may require us to perform additional clinical trials or measurements to support approval. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of our product candidates, including THCVHS.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved.

Once regulatory approval has been granted, the approved product and its manufacturer are subject to continual review by the FDA, DEA and/or non-U.S. regulatory authorities and such approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow-up studies or surveillance. In addition, we will be subject to extensive and ongoing regulatory requirements with regard to labeling, packaging, adverse event reporting, storage, distribution, advertising, promotion, recordkeeping and submission of safety and other post-market information. Manufacturers of our products and manufacturers' facilities are required to comply with current good manufacturing practice ("cGMP") regulations, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and to comply with requirements concerning advertising and promotion for our products. If we, any future collaboration partner or a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the collaboration partner, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

Any DEA registrations that we receive may also be subject to limitations such as the DEA's annual manufacturing and procurement quota requirements. The annual quota allocated to us or our contract manufacturers for the controlled substances in our product candidates may not be sufficient to meet commercial demand. Our facilities that handle controlled substances, and those of our third party contractors, will also be subject to registration requirements and periodic inspections. Additionally, if approved by the FDA, the finished dosage forms of our drug product candidates will be subject to the DEA's rescheduling process, which may delay product launch and impose additional regulatory burdens. Failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our 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. For additional information, see Risk Factor, "*The product candidates we are developing will be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during non-clinical and clinical development and post-approval, and our financial condition.*"

The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling and regulatory requirements. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and/or other non-U.S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions.

Widely publicized events concerning the safety risk of certain drug products have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the imposition by the FDA of risk evaluation and mitigation strategies ("REMS"), to ensure that the benefits of the drug outweigh its risks. In addition, widely publicized events concerning the safety risk of certain drug products have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the imposition by the FDA of REMS to ensure that the benefits of the drug outweigh its risks. In addition, because of the serious public health risks of high-profile adverse safety events with certain products, the FDA may require, as a condition of approval, costly REMS programs.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or in other countries. If we or any future collaboration partner are not able to maintain regulatory compliance, we or such collaboration partner, as applicable, will not be permitted to market our future products and our business will suffer.

Serious adverse events or undesirable side effects or other unexpected properties of any of our product candidates may be identified during development or after approval that could delay, prevent or cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, an IRB, or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label, the imposition of distribution or use restrictions or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause undesirable or unexpected side effects that prevented further development of the compound.

Undesirable side effects or other unexpected adverse events or properties of any of our other product candidates could arise or become known either during clinical development or, if approved, after the approved product has been marketed. If such an event occurs during development, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates. If such an event occurs after such product candidates are approved, a number of potentially significant negative consequences may result, including withdrawal of regulatory approval, requirements for additional warnings on the label, use or distribution restrictions, requirements to conduct post-market studies, requirements to create a medication guide outlining side effects, and liability for harm caused to patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

We expect to rely on third parties, such as CROs, to conduct some or all of our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize any of our product candidates.

We expect to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct our preclinical and clinical studies on our product candidates in compliance with applicable regulatory requirements. These third parties will not be our employees and, except for restrictions imposed by our contracts with such third parties, we will have limited ability to control the amount or timing of resources that they devote to our programs. Although we expect to rely on these third parties to conduct our preclinical studies and clinical trials, we will remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and the applicable legal, regulatory, and scientific standards, and our reliance on these third parties will not relieve us of our regulatory responsibilities. These entities must maintain and comply with valid DEA registrations and requirements. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as current good clinical practices ("cGCPs"), for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. If we or any of our third party contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, we are required to report certain financial interests of our third party investigators if these relationships exceed certain financial thresholds and meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by principal investigators who previously served or currently serve as scientific advisors or consultants to us from time to time and receive cash compensation in connection with such services. Our clinical trials must also generally be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of the third parties with whom we contract may also have relationships with other commercial entities, some of which may compete with us. If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties or obligations or comply with regulatory requirements, we may need to enter into new arrangements with alternative third parties. This could be costly, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, or to commercialize such product candidate being tested in such studies or trials. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third party contractors or to do so on commercially reasonable terms. Though we plan to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on, and expect to continue relying on, third party contract manufacturing organizations to manufacture and supply product candidates for us, as well as certain raw materials used in the production thereof. If one of our suppliers or manufacturers fails to perform adequately, we may be required to incur significant delays and costs to find new suppliers or manufacturers.

We currently have no experience in, and we do not own facilities for, manufacturing our product candidates. We rely on, and expect to continue relying upon, third party manufacturing organizations to manufacture and supply our product candidates and certain raw materials used in the production thereof. Some of our key components for the production of our product candidates may have a limited number of suppliers.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We expect that we will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements, for manufacture of our drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, DEA or others, they will not be able to secure and/or maintain DEA registrations and regulatory approval for their manufacturing facilities. In addition, we expect that we will have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, or if DEA does not register these facilities for the manufacture of controlled substances, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We do not have any commercial supply agreements with our suppliers. In the event that we and our suppliers cannot agree to the terms and conditions for them to provide clinical and commercial supply needs, we would not be able to manufacture our product or candidates until a qualified alternative supplier is identified, which could also delay the development of, and impair our ability to commercialize, our product candidates. The failure of third party manufacturers or suppliers to perform adequately or the termination of our arrangements with any of them may adversely affect our business.

Healthcare reform measures could hinder or prevent our products candidates' commercial success, if approved.

In the United States, there have been, and we anticipate there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell any of our products profitably if approved. In the United States, the Federal government passed the Patient Protection and Affordable Care Act in 2010, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"). The ACA:

- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires collection of rebates for drugs paid by Medicaid managed care organizations;
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

We expect that state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved, or additional pricing pressure. The implementation of cost containment measures or other healthcare reform initiatives may prevent us from being able to generate revenue, attain profitability, or commercialize any products for which we may obtain regulatory approval. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to make and implement healthcare reforms may adversely affect our ability to set a price we believe is fair for our products, to generate revenues and achieve or maintain profitability, to raise capital, and to obtain timely approval of our products.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;

- HIPAA, which created federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters, and as amended by the Health Information Technology and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the ACA, which require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members; and

- state law equivalents of each of the above federal laws, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may be subject to requests for access to our product candidates. Demand for compassionate use of our unapproved therapies could strain our resources, delay our drug development activities, negatively impact our regulatory approval or commercial activities, and result in losses.

We are developing product candidates to treat conditions for which there are currently limited therapeutic options. If we experience requests for access to unapproved drugs, we may experience significant disruption to our business which could result in losses. We are a small company with limited resources, and any unanticipated trials or access programs resulting from requests for access could deplete our drug supply, increase our capital expenditures, and otherwise divert our resources from our primary goals.

In addition, legislation referred to as "Right to Try" laws have been introduced at the local and national levels, which are intended to give patients access to unapproved therapies. Patients who receive access to unapproved drugs through compassionate use or expanded access programs have life-threatening illnesses and generally have exhausted all other available therapies. The risk for serious adverse events in this patient population is high and could have a negative impact on the safety profile of our product candidate, which could cause significant delays or an inability to successfully commercialize our product candidate and could materially harm our business. In addition, in order to perform the controlled clinical trials required for regulatory approval and successful commercialization of our product candidates, we may also need to restructure or pause any ongoing compassionate use and/or expanded access programs, which could prompt adverse publicity.

Risks Related to our Common Stock

Our stock price may be volatile, which may result in losses to our stockholders.

The stock markets have experienced significant price and trading volume fluctuations, and the market prices of companies quoted on the OTCQB, where our shares of common stock will be quoted, generally have been very volatile and have experienced sharp share-price and trading-volume changes. The trading price of our common stock is likely to be volatile and could fluctuate widely in response to factors which may be out of our control, such as variations in our operating results, changes in expectations of our future financial performance, changes in operating and stock price performance of other companies in our industry, additions or departures of key personnel, and future sales of our common stock.

Domestic and international stock markets often experience significant price and volume fluctuations. These fluctuations, as well as general economic and political conditions unrelated to our performance, may adversely affect the price of our common stock. In the past, following periods of volatility in the market price of a public company's securities, securities class action litigation has often been initiated.

Our common shares are thinly-traded, and in the future, may continue to be thinly-traded, and you may be unable to sell at or near ask prices or at all.

We cannot predict the extent to which an active public market for our common stock will develop or be sustained due 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 became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent. We cannot give you 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.

The market for our common shares may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. The potential volatility in our share price is attributable to a number of factors. First, as noted above, our common shares may be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. Secondly, an investment in us is a speculative or "risky" investment due to our lack of revenues or profits to date. As a consequence of this enhanced risk, more risk-averse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer.

We cannot assure you that our common stock will become eligible for listing or quotation on any exchange and the failure to do so may adversely affect your ability to dispose of our common stock in a timely fashion.

In order for our common stock to become eligible for listing or quotation on any exchange, reverse merger companies must have had their securities traded on an over-the-counter market for at least one year, maintained a certain minimum closing price for not less than 30 of the most recent 60 days prior to the filing of an initial listing application and prior to listing, and timely filed with the SEC all required reports since the consummation of the reverse merger, including one annual report containing audited consolidated financial statements for a full fiscal year commencing after the date of filing of the Current Report on Form 8-K which discloses the reverse merger. We may not be able to meet all of the filing requirements above and may not be able to satisfy the initial standards for listing or quotation on any exchange in the foreseeable future or at all. Even if we are able to become listed or quoted on an exchange, we may not be able to maintain a listing of the common stock on such stock exchange.

We do not anticipate paying any cash dividends.

We presently do not anticipate that we will pay any dividends on any of our capital stock in the foreseeable future. The payment of dividends, if any, would be contingent upon our revenues and earnings, if any, capital requirements, and general financial condition. The payment of any dividends will be within the discretion of our Board. We presently intend to retain all earnings, if any, to implement our business plan; accordingly, we do not anticipate the declaration of any dividends in the foreseeable future.

Our common stock is subject to penny stock rules, which may make it more difficult for our stockholders to sell their common stock.

Broker-dealer practices in connection with transactions in "penny stocks" are regulated by certain penny stock rules adopted by the SEC. Penny stocks generally are equity securities with a price of less than $5.00 per share. The penny stock rules require a broker-dealer, prior to a purchase or sale of a penny stock not otherwise exempt from the rules, to deliver to the customer a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that prior to a transaction in a penny stock the broker-dealer 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. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for a stock that becomes subject to the penny stock rules.

We will need additional capital, and the sale of additional shares or other equity securities could result in additional dilution to our stockholders.

We require additional capital for the development and commercialization of our product candidates and may require additional cash resources due to changed business conditions or other future developments, including any investments or acquisitions we may decide to pursue. If our resources are insufficient to satisfy our cash requirements, we will seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity securities could result in additional dilution to our stockholders. The incurrence of additional indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations. We cannot assure you that financing will be available in amounts or on terms acceptable to us, if at all.

Our principal stockholder owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our principal stockholder, Emerald Health Sciences, owns a significant percentage of our outstanding capital stock. As of February 23, 2021, Emerald Health Sciences owned 31.8% of our outstanding shares of common stock. As such, Emerald Health Sciences may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership may prevent or discourage unsolicited acquisition proposals or offers for our common stock that some of our stockholders may believe is in their best interest.

We have a substantial number of authorized common shares available for future issuance that could cause dilution of our stockholders' interest and adversely impact the rights of holders of our common stock.

We have a total of 5,000,000,000 shares of common stock authorized for issuance and up to 50,000,000 shares of preferred stock with the rights, preferences and privileges that our Board may determine from time to time. As of February 23, 2021, we have reserved; 22,050,000 shares for issuance upon the exercise of outstanding options, 18,984,109 shares for issuance under our 2014 equity incentive plan, 5,179,223 shares underlying the Amended Credit Agreement, and 95,580,001 shares for issuance upon the exercise of outstanding warrants. As of February 23, 2021, we had no outstanding preferred stock. As of February 23, 2021, we had 4,508,198,918 shares of common stock unreserved and available for issuance. We may seek financing that could result in the issuance of additional shares of our capital stock and/or rights to acquire additional shares of our capital stock. We may also make acquisitions that result in issuances of additional shares of our capital stock. Those additional issuances of capital stock would result in a significant reduction of your percentage interest in us. Furthermore, the book value per share of our common stock may be reduced. This reduction would occur if the exercise price of any issued warrants, the conversion price of any convertible notes is lower than the book value per share of our common stock at the time of such exercise or conversion.

The addition of a substantial number of shares of our common stock into the market or by the registration of any of our other securities under the Securities Act of 1933, as amended (the "Securities Act"), may significantly and negatively affect the prevailing market price for our common stock. The future sales of shares of our common stock issuable upon the exercise of outstanding warrants may have a depressive effect on the market price of our common stock, as such warrants would be more likely to be exercised at a time when the price of our common stock is greater than the exercise price.

The issuance of shares upon exercise of outstanding warrants and options may cause immediate and substantial dilution to our existing stockholders.

If the price per share of our common stock at the time of exercise of any warrants, options, or any other convertible securities is in excess of the various conversion or exercise prices of these convertible securities, conversion or exercise of these convertible securities would have a dilutive effect on our common stock. As of February 23, 2021, we had outstanding (i) warrants to purchase up to 95,580,001 shares of our common stock at exercise prices ranging from $0.06 to $5.00 per share, and (ii) options to purchase up to 22,050,000 shares of our common stock at exercise prices ranging from $0.045 to $0.31 per share. Further, any additional financing that we secure may require the granting of rights, preferences or privileges senior to those of our common stock and which result in additional dilution of the existing ownership interests of our common stockholders.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. In general, an "ownership change" occurs if the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. During 2018, pursuant to the Emerald Financing transaction, the Company underwent a significant ownership change which likely triggered a limitation under Section 382. If we experience ownership changes as a result of future transactions in our stock, our ability to use our net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to further limitations, which could potentially result in increased future tax liability to us.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our principal executive and corporate offices are located at 5910 Pacific Center Blvd. Suite 320, San Diego, CA 92121.

Item 3. Legal Proceedings.

Not applicable.

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 Information.

Our common stock has been quoted on the OTCQB, under the symbol "SKYE". Previously, it traded under the symbols "EMBI" until January 19, 2021 and prior to that it traded under the symbol "NMUS" until March 25, 2019. There can be infrequent trading volume, which precipitates wide spreads in the "bid" and "ask" quotes of our common stock, on any given day. On February 23, 2021, the last reported sale price of our common stock on the OTCQB was $0.12 per share.

The following table sets forth, for the quarters indicated, the high and low bid prices per share of our common stock on the OTCQB, reported by the Financial Industry Regulatory Authority Composite Feed or other qualified interdealer quotation medium. Such quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

Quarter Ended	High	Low
December 31, 2020	$ 0.06	$ 0.03
September 30, 2020	$ 0.16	$ 0.04
June 30, 2020	$ 0.20	$ 0.07
March 31, 2020	$ 0.20	$ 0.05
December 31, 2019	$ 0.49	$ 0.13
September 30, 2019	$ 0.45	$ 0.25
June 30, 2019	$ 1.17	$ 0.28
March 31, 2019	$ 0.90	$ 0.30
December 31, 2018	$ 0.60	$ 0.05
September 30, 2018	$ 0.39	$ 0.18
June 30, 2018	$ 0.34	$ 0.22
March 31, 2018	$ 0.48	$ 0.14

Holders. As of February 23, 2021, there were 63 stockholders of record. The number of stockholders of record does not include beneficial owners of our common stock, whose shares are held in the names of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividends. We have never declared or paid a cash dividend on our common stock. We do not expect to pay cash dividends on our common stock in the foreseeable future. We currently intend to retain our earnings, if any, for use in our business. Any dividends declared in the future will be at the discretion of our Board and subject to any restrictions that may be imposed by our lenders.

Recent Sales of Unregistered Securities. None.

Issuer Purchases of Equity Securities. None during the fiscal year ended December 31, 2020 covered by this Annual Report.

Penny Stock Regulation. Shares of our common stock will probably be subject to rules adopted by the SEC that regulate broker-dealer practices in connection with transactions in "penny stocks." Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in those securities is provided by the exchange or system). The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, deliver a standardized risk disclosure document prepared by the SEC, which contains the following:

- a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading;
- a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to violation to such duties or other requirements of securities' laws;
- a brief, clear, narrative description of a dealer market, including "bid" and "ask" prices for penny stocks and the significance of the spread between the "bid" and "ask" price;
- a toll-free telephone number for inquiries on disciplinary actions;
- definitions of significant terms in the disclosure document or in the conduct of trading in penny stocks; and
- such other information and is in such form (including language, type, size and format), as the SEC shall require by rule or regulation.

Prior to effecting any transaction in penny stock, the broker-dealer also must provide the customer the following:

- the bid and offer quotations for the penny stock;
- the compensation of the broker-dealer and its salesperson in the transaction;
- the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and
- monthly account statements showing the market value of each penny stock held in the customer's account.

In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules, 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 acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for a stock that becomes subject to the penny stock rules. Holders of shares of our common stock may have difficulty selling those shares because our common stock will probably be subject to the penny stock rules.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements for the years ended December 31, 2020 and 2019 together with notes thereto. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited, to those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Unless otherwise provided in this Annual Report, references to "we," "us," "our" and "Skye Bioscience" in this discussion and analysis refer to Skye Bioscience, Inc., a Nevada corporation formerly known as Emerald Bioscience, Inc., together with its wholly owned subsidiaries, Nemus, a California corporation, and EMBI Australia Pty Ltd., an Australian proprietary limited company.

Overview

We are a biopharmaceutical company targeting the discovery, development, and the commercialization of cannabinoid-based therapeutics, through a number of license agreements with the University of Mississippi ("UM").

Effective March 25, 2019, we changed our name from Nemus Bioscience, Inc. to Emerald Bioscience, Inc. and effective January 19, 2021, we changed our name to Skye Bioscience, Inc.

In August 2019, we formed a new subsidiary in Australia, EMBI Australia, in order to qualify for the Australian government's research and development tax credit for research and development dollars spent in Australia. The primary purpose of EMBI Australia is to conduct clinical trials for our product candidates.

Recent Events and Significant Contracts

Expansion of UM 5050 and UM 8930 Licenses from Ocular Delivery Only to All Fields of Use

On May 24, 2019, we executed two restated and amended license agreements with UM which expanded our use of UM 5050, a prodrug of tetrahydrocannabinol ("THC"), and UM 8930, an analog of cannabidiol ("CBD"), this expanded our scope of field of use from ocular delivery only to all fields of use. Pursuant to these license agreements, we have exclusive, perpetual, worldwide licenses related to UM 5050 and UM 8930. Additionally, with the prior written consent of UM, we have the right to sublicense the licensed intellectual property.

The exclusive license for tetrahydrocannabinol-valine-hemisuccinate ("THCVHS"), the proprietary prodrug of THC, is expected to allow us to explore related uses for the active moiety of the prodrug, namely THC. Independent *in vitro* and *in vivo* studies have demonstrated the potential use of THC in a variety of potential indications based on the ability of the cannabinoid to act as an anti-inflammatory, anti-fibrotic, and/or inhibitor of neovascularization. The Company has generated data related to these effects using an *ex vivo* human tissue model of the eye. The prodrug technology employed in THCVHS is designed to enhance the pharmacokinetic and pharmacodynamics of the active part of the molecule, once introduced into the body through various routes of administration being considered by the development team.

The exclusive license of cannabidiol-valine-hemisuccinate ("CBDVHS"), the analog of CBD, is expected to permit us to expand research and development into organ systems outside of the current ocular space. Potential disease targets over time could involve the central nervous system, the gastrointestinal tract, the endocrine/metabolic system, reproductive system diseases, or as yet unrecognized opportunities. This bioengineered version of CBD is expected to enlarge the disease target pool by virtue of new routes of administration into the body, thereby enhancing bioavailability. The determination by the DEA that CBDVHS is not a controlled substance permits us to enlarge the potential pool of clinical test sites and a more diverse patient pool in the study of disease. We expect to develop strategic collaborations to identify and advance these applications.

THCVHS

THCVHS, our lead ocular compound, is a prodrug of THC. We have delayed our first-in-human studies of THCVHS, from the second half of 2020 to the third quarter of 2021. The first-in-human Phase 1 trials are expected to be conducted in both normal subjects and patients with glaucoma or ocular hypertension in Australia (the "Clinical Trial"). We are eligible under the AusIndustry research and development tax incentive program to obtain a cash incentive from the Australian Taxation Office. The tax incentive is available to us based on specific criteria with which we must comply and is based on our eligible research and development spend in Australia. Prior to August 2020, we executed several agreements, and the work underlying those agreements was subsequently delayed. After August 2020, we have been focused on clinical enabling activities, notably:

- formulation and manufacturing of drug product to supply our GLP toxicology studies and first-in-human Phase 1 clinical trial;
- initiating and completing GLP toxicology studies to support our first-in-human Phase 1 clinical trial;
- initiating and completing validation of a pharmacokinetic assay for both animal and human samples to support our pre-clinical and clinical studies; and
- engaging our vendors and contractors to support the finalization of study-related materials for our Phase 1 study, including the finalization of the clinical study protocol.

The manufacturing of the active pharmaceutical ingredient of THCVHS is conducted in the United States. Formulation of the eye drop for testing is also performed in the United States but can rely on regulatory-accepted excipients that can be sourced from countries outside the United States, such as China. In connection with the recent pandemic of COVID-19 there could possibly be an impact on sourcing materials that are part of the eye drop formulation, as well as impacting volunteer and/or patient recruitment in Australia for clinical studies.

CBDVHS

CBDVHS is our proprietary CBD analog. We have embarked on studies with UM exploring the utility of our drug candidate CBDVHS as a topical formulation for the potential treatment and management of several ocular diseases, including but not limited to, uveitis, dry eye syndrome, macular degeneration and diabetic retinopathy.

In July 2019, we engaged Glauconix to conduct research as to whether CBD or CBDVHS is associated with an increase in IOP and, if so, what the potential mechanism of action would be by exposing the 3D-human trabecular meshwork tissue constructs to these molecules. In December 2019, we announced that data generated by Glauconix Biosciences, Inc. showed significant anti-inflammatory and anti-fibrotic activity in ocular tissue with CBDVHS when compared to CBD, indicating therapeutic potential as a neuroprotectant, especially in diseases of the retina. Additionally, CBD was associated with biomarkers related to the elevation of IOP while CBDVHS was not associated with elevating IOP at anti-fibrotic concentrations.

In the second quarter of 2019, UM also completed preclinical experiments showing that CBDVHS exhibited an ability to penetrate multiple chambers of the eye and reach the optic nerve. These findings support the therapeutic potential to provide ocular neuroprotection of retinal ganglion cells, an important goal in treating diseases that lead to vision loss. The data were published in the peer-reviewed Journal of Ocular Pharmacology and Therapeutics in a paper entitled, “Analog Derivatization of Cannabidiol for Improved Ocular Permeation” (2019; volume 35 (5): 1-10).

In July 2019, we engaged StemoniX to evaluate CBD and CBDVHS in a human*in vitro* neural model that has application for epilepsy. The series of experiments are designed to provide insight into how these cannabinoids stabilize neuronal cells. In November and December 2019, we also executed additional preclinical research agreements with StemoniX related to CBDVHS.

In February 2019, we entered into the Purisys Agreement to provide manufacturing and product development services for our analog formulation of CBD. We made an upfront payment and additional payments will be made upon Purisys’s shipment of the active pharmaceutical ingredient.

In December 2019, we announced data generated by StemoniX, that CBDVHS was both pharmacologically and therapeutically distinct from CBD when studied in an *in vitro* human neural tissue model mimicking chemically induced seizure-like hyperactivity. Additionally, CBDVHS was observed to gain potency in anti-seizure-like activity over the seven-day observation period, whereas the suppressive effect afforded by CBD dissipated by day three. In the assessment of safety parameters of CBDVHS, the molecule was not found to be toxic to the neurologic cells tested in multiple assays, both in acute and longer-term exposure.

We plan to continue to work with UM to explore other potential indications and associated routes of administration based on the expanded UM 8930 exclusive licenses. Our decision to advance a potential therapeutic candidate will be influenced by several criteria, including but not limited to, preclinical data, synthesis and formulation capability as well as prevailing market conditions.

Critical Accounting Policies and Estimates

Our Management’s Discussion and Analysis of Financial Condition and Results of Operations section discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments, including those related to accrued expenses, financing operations, and contingencies and litigation. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The most significant accounting estimates inherent in the preparation of our consolidated financial statements include estimates as to the appropriate carrying value of certain assets and liabilities which are not readily apparent from other sources. These accounting policies are described at relevant sections in this discussion and analysis and in the notes to the consolidated financial statements included in this Annual Report on Form 10-K. We believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our consolidated financial statements.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last is considered unobservable, is used to measure fair value:

Level 1: Valuations for assets and liabilities traded in active markets from readily available pricing sources such as quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of our financial instruments, with the exception of the Credit Agreement (as defined below) and derivative liabilities, including, cash, prepaid expenses, accounts payable, the PPP loan and other current liabilities approximate their fair value due to the short maturities of these financial instruments. The derivative liabilities are valued on a recurring basis utilizing Level 3 inputs.

As of December 31, 2019, the aggregate fair value of the advances under the Amended Credit Agreement was $1,877,938, the carrying amount of the liability on December 31, 2019 was $387,070 and is included in Convertible multi-draw credit agreement - related party, net of discount in our Consolidated Balance Sheets. As of December 31, 2020, we estimate that the fair value of the Amended Credit Agreement to be materially consistent with the fair value estimate as of December 31, 2019, plus the non-convertible advances made in 2020. This determination was based on the following considerations: (i) we have not experienced any significant change in our credit worthiness or operations year over year, (ii) there have been no repayments or convertible draws (iii) the facility is closer to maturity, and (iv) the embedded conversion feature on the convertible advances is out-of-the-money at the reporting date. Information pertinent to estimating the fair value of the Amended Credit Agreement includes valuing the embedded conversion feature and considering the discounted cash flows of the interest and principal payments through maturity.

Convertible Instruments

We account for hybrid contracts with embedded conversion features in accordance with GAAP. ASC 815,*Derivatives and Hedging Activities* (“ASC 815”) requires companies to bifurcate conversion options from their host instruments and account for them as free-standing derivative financial instruments according to certain criteria. The criteria includes circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

We account for convertible debt instruments with embedded conversion features in accordance with ASC 470-20,*Debt with Conversion and Other Options* (“ASC 470-20”) if it is determined that the conversion feature should not be bifurcated from their host instruments. Under ASC 470-20, we record, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the difference between the fair value of the underlying common stock at the commitment date and the embedded effective conversion price. When we determine that the embedded conversion option should be bifurcated from its host instrument, the embedded feature is accounted for in accordance with ASC 815. Under ASC 815, a portion of the proceeds received upon the issuance of the hybrid contract is allocated to the fair value of the derivative. The derivative is subsequently marked to market at each reporting date based on current fair value, with the changes in fair value reported in the results of operations.

We also follow ASC 480-10, *Distinguishing Liabilities from Equity* ("ASC 480-10") when evaluating the accounting for our hybrid instruments. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception (for example, a payable settled with a variable number of the issuer's equity shares); (b) variations in something other than the fair value of the issuer's equity shares (for example, a financial instrument indexed to the Standard and Poor's S&P 500 Index and settled with a variable number of the issuer's equity shares); or (c) variations inversely related to changes in the fair value of the issuer's equity shares (for example, a written put option that could be net share settled). Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date with a re-measurement reported in other expense (income) in the accompanying Consolidated Statements of Comprehensive (Loss) Income.

When determining the short-term vs. long-term classification of derivative liabilities, we first evaluate the instruments' exercise provisions. Generally, if a derivative is a liability and exercisable within one year, it will be classified as short-term. However, because of the unique provisions and circumstances that may impact the accounting for derivative instruments, we carefully evaluate all factors that could potentially restrict the instrument from being exercised or create a situation where exercise would be considered remote. We evaluate our derivative liabilities at each reporting period end and make updates for any changes in facts and circumstances that may impact classification.

Warrants Issued in Connection with Financings

We generally account for warrants issued in connection with debt and equity financings as a component of equity, unless the warrants include a conditional obligation to issue a variable number of shares or there is a deemed possibility that we may need to settle the warrants in cash. For warrants issued with a conditional obligation to issue a variable number of shares or the deemed possibility of a cash settlement, we record the fair value of the warrants as a liability at each balance sheet date and record changes in fair value in other expense (income) in the Consolidated Statements of Comprehensive (Loss) Income.

Stock-Based Compensation Expense

Stock-based compensation expense is estimated at the grant date based on the fair value of the award, and the cost is recognized as expense ratably over the vesting period with forfeitures accounted for as they occur. We use the Black-Scholes Merton option pricing model for estimating the grant date fair value of stock options using the following assumptions:

- Volatility - Stock price volatility is estimated over the expected term based on a blended rate of industry peers and our actual stock volatility adjusted for periods in which significant financial variability is identified.
- Expected term - The expected term is based on a simplified method which defines the life as the weighted average of the contractual term of the options and the vesting period for each award.
- Risk-free rate - The risk-free interest rate for the expected term of the option is based on the average market rate on U.S. Treasury securities in effect during the period in which the awards were granted.
- Dividends - The dividend yield assumption is based on our history and expectation of paying no dividends in the foreseeable future.

Net (Loss) Income Per Share of Common Stock

We apply FASB ASC No. 260, *Earnings per Share.* Basic net (loss) income per share of common stock is computed by dividing (loss) income available to common stockholders by the weighted-average number of shares of common stock outstanding for the period. The diluted net (loss) income per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock, restricted stock subject to vesting, warrants to purchase common stock and common shares underlying convertible debt instruments are considered to be common stock equivalents. In periods with a reported net loss, such common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is anti-dilutive.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to the accompanying Consolidated Financial Statements included in Part IV, Item 15 of this Annual Report on Form 10- K for information on recently issued accounting pronouncements and recently adopted accounting pronouncements. While we expect certain recently adopted accounting pronouncements to impact our estimates in future periods, the impact upon adoption was not significant to our current estimates and operations.

Results of Operations

For the years ended December 31, 2020 and 2019

Revenues. To date, we have not generated any revenues, and do not expect to generate any revenue from the sale of products in the near future.

Operating expenses. For the year ended December 31, 2020, our total operating expenses were $6,289,013 as compared to $6,632,578 for the year ended December 31, 2019.

Research and development. Research and development expenses for the year ended December 31, 2020 were $1,944,411, which consisted of salaries and benefits and consulting fees for the staff involved in our preclinical and clinical drug development activities, contract research and development fees paid to UM, fees related to contract manufacturing and formulation, a $200,000 license fee incurred under the UM 8930 Analog Agreement for the receipt for the first United States Patent and Trademark Office notice of allowance and the annual license maintenance fee for UM 5070.

Research and development expenses for the year ended December 31, 2019 were $2,237,956, which consisted of upfront payments for the all fields of use licenses for UM 5050 and UM 8930, the annual license maintenance fee for UM 5070, salaries and benefits and consulting fees for the staff involved in our preclinical and clinical drug development activities, contract research and development fees including fees for manufacturing and formulation, regulatory consulting fees, in preparation of the Clinical Trials.

For the year ended December 31, 2020, research and development expenses decreased by $293,545, as compared to the year ended December 31, 2019. The decrease is primarily due to an overall decline in contracted development costs as the Company moved its focus towards exploring new strategic initiatives in 2020. Contracted development costs were lower during 2020 as compared to 2019, due to a lack of cash on hand through the second quarter and the delay of our clinical trials due to COVID-19.

General and administrative. General and administrative expenses for the year ended December 31, 2020 were $4,344,602 which primarily consisted of salaries, consulting fees, stock-based compensation expense and professional fees associated with our costs of being a public company. General and administrative expenses for the year ended December 31, 2019 were $4,394,622, which primarily consisted of the same components. General and administrative expenses remained relatively constant year over year.

Other expense (income). For the year ended December 31, 2020, we had non-operating expense of $270,086, which was comprised primarily of the following:

- $436,270 of other income from the change in fair value of derivative liabilities which represents an overall decrease in the fair value of our derivative liabilities. The derivatives marked-to-market include the Series B and Emerald Health Sciences warrant liabilities and the derivative bifurcated from the Credit Agreement (as defined below). Several assumptions go into the valuations for each of these instruments however the decrease in our stock price, modification of the Credit Agreement and valuation assumptions were all contributing factors to the decrease in the fair value of these instruments during the year ended December 31, 2020;
- We incurred interest expense of $706,385 during the year ended December 31, 2020 due to the amortization of the debt discount and interest payments associated with the outstanding balance under the Credit Agreement. Interest expense declined by $294,328, when comparing the year ended December 31, 2020 and December 31, 2019, due to the partial pre-payment of amounts outstanding under the Credit Agreement, which resulted in a lower average outstanding balance during 2020 as compared to 2019.

For the year ended December 31, 2019, we had non-operating income of $7,686,003, which was comprised primarily of the following:

- $9,734,759 of other income from the change in fair value of derivative liabilities which represents an overall decrease in the fair value of our derivative liabilities. The derivatives marked-to-market include the Series B and Emerald Health Sciences warrant liabilities and the compound derivative bifurcated from the Credit Agreement (as defined below). Several assumptions go into the third party valuations for each of these instruments however the decrease in our stock price and valuation assumptions were all contributing factors to the decrease in the value of these instruments during the year ended December 31, 2019;
- $322,644 of other expense was related to drawdowns initiated under the Credit Agreement which required us to bifurcate compound embedded derivatives and record an additional charge for the fair value of such instruments in excess of proceeds;
- We incurred interest expense of $1,000,713 during the year ended December 31, 2019 due to the amortization of the debt discount and interest payments associated with the outstanding balance under the Credit Agreement which was entered into during the fourth quarter of 2018; and
- $725,425 loss on extinguishment related to the prepayment of the Credit Agreement.

Net (loss) income. For the year ended December 31, 2020, we had a net loss of $6,560,699 as compared to net income of $1,051,825 for the year ended December 31, 2019. The net income generated during 2019 was driven by other income primarily related to a non-cash adjustment in derivative liabilities from the decrease in our stock price. We expect to incur net losses for the foreseeable future.

Liquidity and Capital Resources

We have incurred operating losses and negative cash flows from operations since our inception and as of December 31, 2020, had an accumulated deficit of $38,733,981, stockholders' equity of $450,786 and working capital of $1,877,186. We anticipate that we will continue to incur net losses into the foreseeable future in order to advance and develop potential drug candidates into preclinical and clinical development activities and support our corporate infrastructure, which includes the costs associated with being a public company. We had unrestricted cash of $2,469,410 as of December 31, 2020, as compared to $1,829,977 as of December 31, 2019. The increase was primarily attributable to the proceeds received in the August 2020 Financing. Without additional funding, management believes that we will not have enough funds to meet our obligations beyond one year after the date the Consolidated Financial Statements are issued. These conditions give rise to substantial doubt as to our ability to continue as a going concern.

On October 5, 2018, we secured a Credit Agreement with Emerald Health Sciences (the "Credit Agreement"), providing us with a credit facility of up to $20,000,000. Under the Credit Agreement, we may draw a remaining amount of up to $13,550,000 in advances from Emerald Health Sciences from time to time. However, we do not consider the facility available until advance requests are approved, drawn down and funded. Through the third quarter of 2019, we effected three drawdowns under the Credit Agreement, each in the amount of $2,000,000, for an aggregate principal amount of $6,000,000 in advances, and issued Emerald Health Sciences warrants to purchase an aggregate of 7,500,000 shares of common stock at an exercise price of $0.50 per share. On December 20, 2019, we entered into a Warrant Exercise Agreement with Emerald Health Sciences, pursuant to which Emerald Health Sciences has exercised 40,800,000 of such warrants and paid the aggregate exercise price of approximately $4,080,000 for the related warrant shares in the form of a reduction of the corresponding amount of obligations outstanding under the Credit Agreement. Upon consummation of the transactions under the Warrant Exercise Agreement, the total outstanding principal amount excluding discounts under the Credit Agreement was $2,014,500.

On April 22, 2020, we entered into a Paycheck Protection Program Promissory Note in the principal amount of $116,700 (the "PPP Loan") from City National Bank. The PPP Loan was obtained pursuant to the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act administered by the U.S. Small Business Administration. We used the proceeds of the PPP loan for payment of payrolls and rent for our office space.

On April 29, 2020, we entered into an Amended and Restated Multi-Draw Credit Agreement with Emerald Health Sciences, which amends and restates the Credit Agreement, as reported in the current report on the Form 8-K filed with the SEC on April 29, 2020. The Amended Credit Agreement provides for a credit facility to us in the principal amount of up to $20,000,000, which includes, without limitation, the advances totaling $6,000,000 that were granted prior to the amendment. During the year ended December 31, 2020, we received the fourth and fifth advances of $150,000 and $300,000 pursuant to the Amended Credit Agreement. The advances bear interest at 7% per annum and mature on October 5, 2022.

On July 28, 2020, we filed a registration statement on Form S-1/A, which has been declared effective as of July 31, 2020, and on July 31, 2020, we filed a related registration statement on a Form S-1MEF that became effective under Rule 462(b). On July 31, 2020, we sold 56,333,334 common stock units each consisting of one share of common stock and one common stock warrant and 60,333,334 pre-funded units each consisting of one pre-funded warrant and one common stock warrant, which securities were registered under the foregoing registration statements under a securities purchase agreement, as reported in our current report on the Form 8-K filed with the SEC on August 5, 2020. The net proceeds from the transaction were $6,085,589. The common stock warrants and prefunded warrants have an exercise price of $0.06 and $0.001, respectively. The term of the common stock warrants is five years, and the pre-funded warrants are exercisable until all the pre-funded warrants have been exercised in full. We are using the net proceeds from the offering for general corporate purposes, including working capital.

During March 2020, we approved a plan to defer up to 50% of the members of senior management's compensation and 100% of the Board of Director and committee fees indefinitely. In August 2020, subsequent to closing the August 2020 Financing, our Board of Directors determined that we had been sufficiently financed and authorized us to pay the deferred compensation and fee balances together with a retention bonus of 10% of such balance.

From January 1, 2021 through February 23, 2021, we received $3,019,800 in proceeds from the exercise of warrants.

In December 2019, a novel strain of coronavirus ("COVID-19") emerged in Wuhan, China. Since then, it has spread to the United States and infections have been reported around the world. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread around the world and throughout the United States and Australia, where we have operations and conduct laboratory research and clinical studies. In response to the outbreak, federal and state authorities in the United States have introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, nonessential business closures, quarantines, self-isolations, shelters-in-place and social distancing. The COVID-19 outbreak and the response of governmental authorities to try to limit it are having a significant impact on the private sector and individuals, including unprecedented business, employment, and significant economic disruptions to the global financial markets. These disruptions could impact our ability to raise additional capital and obtain the necessary funds.

Notably, we rely on third party manufacturers to produce our product candidates. The manufacturing of the active pharmaceutical ingredient of THCVHS is conducted in the United States. Formulation of the eye drop for testing is also performed in the United States but can rely on regulatory-accepted excipients that can be sourced from countries outside the United States, such as China. In connection with the recent COVID-19 pandemic, there could possibly be an impact on sourcing materials that are part of the eye drop formulation, as well as impacting volunteer and/or patient recruitment in Australia for clinical studies. Therefore, we have shifted the expected start of our first-in-human studies of the lead drug candidate, THCVHS, from the second half of 2020 to the third quarter of 2021.

The ultimate impact on us and overall delay in our drug product research and development is unknown, but our operations and financial condition will suffer in the event of business interruptions, delayed clinical trials, production or a lack of laboratory resources due to the pandemic. As of the date of this filing, we are aware of the impact on our business as a result of COVID-19 but uncertain as to the extent of this impact on our consolidated financial statements. There is uncertainty as to the duration and hence the potential impact. As a result, we are unable to estimate the potential impact on our business as of the date of this filing.

Going Concern

Our independent registered public accounting firm has issued a report on our audited consolidated financial statements for the fiscal year ended December 31, 2020 that includes an explanatory paragraph referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. Our consolidated financial statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon our ability to generate profitable operations in the future and/or to obtain the necessary financing to meet our obligations and repay our liabilities arising from normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that we will be able to continue as a going concern. Our consolidated financial statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and the report of our independent registered public accounting firm are included in this report on pages F-1 through F-30.

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 maintain controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosures. Based upon their evaluation of those controls and procedures performed as of the end of the period covered by this report, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and dispositions of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the supervision and participation of our Chief Executive Officer and Interim Principal Accounting Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2020, based on criteria for effective internal control over financial reporting set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework - 2013 (COSO 2013 Framework).*

Based on their assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

As we are a smaller reporting company, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting during the fourth quarter ended December 31, 2020 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth certain information as of the date of this Annual Report, with respect to our directors, executive officers and significant employees.

Name	Age	Position
Punit Dhillon	40	Chief Executive Officer, Chairman, Director
Richard Janney	62	Interim Principal Accounting Officer
Margaret Dalesandro	74	Director
Jim Heppell	65	Director

Biographies of Directors, Executive Officers and Significant Employees

Punit Dhillon. Mr. Dhillon was appointed as a member of our Board in connection with the consummation of the investment in us by Emerald Health Sciences in 2018. On December 17, 2019, Mr. Dhillon was appointed as Chairman of our Board. Mr. Dhillon is currently a board member of Emerald Health Pharmaceuticals, Inc., Emerald Health Therapeutics, Inc. (EMH), a TSX Venture Exchange listed company, and Arch Therapeutics Inc. (OTCQB: ARTH). Mr. Dhillon is a Co-founder and Director of OncoSec Medical Incorporated (NASDAQ: ONCS) and was formerly the CEO through March 2018. Prior to OncoSec, Mr. Dhillon was the Vice President of Finance and Operations at Inovio Pharmaceuticals, Inc. (NASDAQ: INO) from September 2003 until March 2011. Mr. Dhillon has also previously been a consultant and board member for several TSX Venture Exchange listed early-stage life science companies, which matured through advances in their development pipelines and subsequent M&A transactions. Prior to joining Inovio, Mr. Dhillon worked for a corporate finance law firm as a law clerk and worked with MDS Capital Corp. (now Lumira Capital Corp.). Mr. Dhillon is an active member in his community and places great value on helping future leaders overcome challenges through mentorship and education and is a co-founder and board member of Young Entrepreneurship Leadership Launchpad (YELL), a not-for-profit and charity organization based in Canada. Mr. Dhillon has a Bachelor of Arts with honors in Political Science and a minor in Business Administration from Simon Fraser University. Mr. Dhillon's experience in the biotechnology and pharmaceutical industry, and his experience with publicly traded companies were the primary qualifications that the Board considered in appointing him as a director of the Company.

Jim Heppell. Mr. Heppell was the founder, CEO and director of BC Advantage Life Sciences I Fund, which won the Canadian Venture Capital Deal of the Year Award for having the highest realized return (23.4x its investment in Aspreva Pharmaceuticals) of any venture capital fund in Canada. Mr. Heppell has a Bachelor of Science degree in Microbiology and a law degree from the University of British Columbia. After being called to the Bar, he worked for six years with Fasken Martineau DuMoulin, during which time he was seconded to the BC Securities Commission for six months. Mr. Heppell then became President and Chief Executive Officer of Catalyst Corporate Finance Lawyers, a boutique corporate finance law firm that focused on building life science and technology companies. He is a past member of the Securities Policy Advisory Committee to the BCSC and is Past-Chairman of the Securities Section of the Canadian Bar Association (B.C. Branch). Mr. Heppell taught corporate finance and corporate governance courses at the University of British Columbia, Simon Fraser University and at a number of biotechnology conferences for numerous years. He is currently a director of a number of public and private life science companies, including Emerald Health Sciences. The Board considered Mr. Heppell's significant experience with life science and technology companies and the public markets in making the decision to appoint him as a director of the Company.

Dr. Margaret Dalesandro. Dr. Margaret Dalesandro currently serves on the board of OncoSec Medical Incorporated, a company listed on NASDAQ and a late-stage biotechnology company focused on designing, developing and commercializing innovative therapies and proprietary medical approaches to stimulate and guide an anti-tumor immune response for the treatment of cancer. In addition, Dr. Dalesandro is currently the President of Brecon Pharma Consulting LLC. Dr. Dalesandro has over twenty-five years of experience leading strategic product development in the pharmaceutical, biotechnology and diagnostics industries. She has previously served as a Business Director of Integrative Pharmacology at Corning, Incorporated, as a Vice President of Project, Portfolio and Alliance Management at ImClone Systems Inc., as an Executive Director of Project and Portfolio Management at GlaxoSmithKline, and as a Senior Consultant at Cambridge Pharma Consultancy over the course of her career. Dr. Dalesandro earned her Ph.D. in Biochemistry from Bryn Mawr College and completed a NIH Post-Doctoral Fellowship in Molecular Immunology at the Wake Forest University School of Medicine. The Board considered Dr. Dalesandro's significant experience with life science and technology companies in making the decision to appoint her as a director of the Company.

Richard Janney. Mr. Richard Janney currently is an independent contractor at RoseRyan, Inc. ("RoseRyan"), a professional services firm which provides accounting and financial advisory services to the Company on a regular basis. Mr. Janney currently serves as the acting Chief Financial Officer of Pinnacle Engines and Tempathic, Inc. on a part-time basis. Prior to Tempathic, Inc., Mr. Janney served as the Chief Financial Officer of Thinc, Inc. from September 2018 to August 2019, and as the Chief Executive Officer of AFFARI, LLC from 2011 to 2019. Mr. Janney also served as the principal accounting officer of several public and private companies, including Trident Microsystems, Inc., a NASDAQ listed company, and Asyst Technologies, Inc., a NASDAQ listed company. Mr. Janney's experience also includes being a manager at PricewaterhouseCoopers. Mr. Janney received a B.S. degree from California Polytechnic University San Luis Obispo in Business Administration with an emphasis in Finance and Accounting.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers, and any persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. SEC regulation requires executive officers, directors and greater than 10% stockholders to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, we believe that during the year ended December 31, 2020, our executive officers, directors, and greater than 10% stockholders complied with all applicable filing requirements on a timely basis, except that a Form 4 was filed late by Margaret Dalesandro, resulting in one transaction not being reported on a timely basis.

Family Relationships

There are no family relationships among our directors or executive officers.

Term of Office of Directors

Our directors are elected at each annual meeting of stockholders and serve until the next annual meeting of stockholders or until their successor has been duly elected and qualified, or until their earlier death, resignation or removal.

Directors and Officers Involvement in Certain Legal Proceedings

During the past ten years, our directors and executive officers have not been involved in any of the legal proceedings set forth in Item 401(f) of Regulation S-K promulgated by the SEC.

Board and Committee Meetings

During 2020, our Board met four times (including telephonic meetings) and took action by written consent 17 times. Each director attended at least 75% of the meetings held by the Board and by each committee on which she or he served while she or he was a director, either in person or by teleconference, during the year.

Director Attendance at Annual Meetings

Although we do not have a formal policy regarding attendance by members of our Board at each annual meeting of stockholders, we encourage all of our directors to attend. All of our directors attended our most recent annual general meeting of stockholders.

Audit Committee and Financial Expert

On February 23, 2015, our Board established an audit committee that operates under a written charter that has been approved by our Board. The members of our audit committee are Mr. Jim Heppell and Dr. Margaret Dalesandro. Mr. Jim Heppell serves as chairman of the audit committee and our Board has determined that he is an “audit committee financial expert” as defined by applicable SEC rules. The Board has determined that Mr. Jim Heppell and Dr. Margaret Dalesandro are independent directors as that term is defined in Rule 5605(a)(2) of the Nasdaq Listing Rules, and we have determined that both Mr. Jim Heppell and Dr. Margaret Dalesandro as audit committee members meet the more stringent requirements under Rule 5605(c)(2) of the Nasdaq Listing Rules. Our audit committee met two times (including telephonic meetings) and took action by written consent one time in 2020 as compensation matters were handled directly by our Board.

Our audit committee is responsible for: (1) selection and oversight of our independent accountant; (2) establishing procedures for the receipt, retention and treatment of complaints regarding accounting, internal controls and auditing matters; (3) establishing procedures for the confidential, anonymous submission by our employees of concerns regarding accounting and auditing matters; (4) engaging outside advisors; and, (5) approving fees for the independent auditor and any outside advisors engaged by the audit committee. The Audit Committee Charter is filed as Exhibit 99.1 to our Report on Form 8-K filed on February 27, 2015.

Compensation Committee

On May 31, 2015, our Board established a compensation and compliance committee which operated under a written charter that was approved by the Board. In 2018, the Board dissolved the former compensation and compliance committee and established a new compensation committee which operates under a written charter approved by the Board. The members of our compensation committee are Mr. Jim Heppell and Dr. Margaret Dalesandro. Mr. Jim Heppell serves as chairman of the compensation committee. Our compensation committee did not meet or take action by written consent during 2020.

Our compensation committee is responsible for the oversight of, and the annual and ongoing review of, the Chief Executive Officer, the compensation of the senior management team, and the bonus programs in place for employees, which includes: (1) reviewing the performance of the Chief Executive Officer and such other senior officers as the Board may request, and determining the bonus entitlement for such officer or officers on an annual basis and recommending the same to the Board for approval; (2) determining the proposed annual compensation of our executive officers for each fiscal year and recommending the same to the Board for approval; (3) reviewing and discussing the bonus plan proposed for our senior management team with the Chief Executive Officer; (4) reviewing and discussing the terms and conditions of proposed grants of stock options to directors, employees, consultants and advisors with the Chief Executive Officer; (5) reviewing and recommending to the Board the compensation of the Board and committee members; (6) reviewing and discussing with the Chief Executive Officer the standard forms of employment and consulting contracts used by us; (7) reviewing and discussing with the Chief Executive Officer the general benefit plans in place for employees; (8) engaging and setting the compensation for independent counsel and other advisors and consultants; and (9) reviewing and assessing the adequacy of its Charter and submitting any recommended changes to our Board for its consideration and approval.

Nomination and Corporate Governance Committee

In 2018, our Board established a nominating and corporate governance committee that operates under a written charter approved by the Board. The members of our nomination and corporate governance committee are Mr. Jim Heppell and Dr. Margaret Dalesandro. Dr. Margaret Dalesandro serves as chairman of the nomination and corporate governance committee. Our nomination and corporate governance committee met once during 2020 (including telephonic meetings) and took action by written consent one time.

Our nominating and corporate governance committee is responsible for assisting the Board in (1) identifying qualified individuals to become Board members, consistent with criteria approved by the Board, (2) determining the composition of the Board and its committees, (3) selecting the director nominees for the next annual meeting of shareholders, (4) monitoring a process to assess Board, committee and management effectiveness, (5) aiding and monitoring management succession planning and (6) developing, recommending to the Board, implementing and monitoring policies and processes related to our corporate governance guidelines.

Finance and Business Development Committee

In 2018, our Board established a finance and business development committee which operates under a written charter approved by the Board. The members of our finance and business development committee are Mr. Punit Dhillon and Mr. Jim Heppell. Mr. Punit Dhillon serves as chairman of the finance and business development committee. Our finance and business development committee did not meet but took action by written consent three times in 2020.

Our finance and business development committee is responsible for assisting the Board in (1) matters affecting our balance sheet, including capital structure strategies, debt and equity financings and working capital (2) analysis and assessment of financial and strategic aspects of major acquisitions and divestitures, collaborations and joint ventures, (3) formulating and recommending for approval to the Board our financial policies, including management of the financial affairs of the Company, (4) developing and maintaining relationships with investment banks, financial institutions and other investors and monitor developments in the capital markets and financing trends, and (5) evaluating and making recommendations to the Board concerning business development opportunities.

Nominations to the Board of Directors

We do not have any defined policy or procedural requirements for shareholders to submit recommendations or nominations for directors. Our Board believes that, given the stage of our development, a specific nominating policy would be premature and of little assistance until our business operations develop to a more advanced level. We do not currently have any specific or minimum criteria for the election of nominees to the Board. The Board, with the help of its nomination and corporate governance committee, will assess all candidates and make recommendations for election or appointment.

Stockholder Communications

We do not have a formal policy regarding stockholder communications with our Board. A shareholder who wishes to communicate with our Board may do so by directing a written request addressed to our Chief Executive Officer, at the address appearing on the first page of this filing.

Code of Ethics

On October 31, 2014, we adopted a formal code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, as well as our other officers, directors and employees. A copy of our code of ethics is available on our website at http://www.skyebioscience.com. We intend to disclose any future amendments to provisions of our code of ethics, or waivers of provisions required to be disclosed under the rules of the SEC, on a current report on Form 8-K or at the same location on our website identified in the preceding sentence. Any amendment or waiver disclosed on our website will remain available on our website for at least 12 months after the initial disclosure.

Item 11. Executive Compensation.

Summary Compensation Table

The following table sets forth information concerning the compensation earned for services rendered to us for the fiscal years ended December 31, 2020 and 2019 of our named executive officers as determined in accordance with SEC rules.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Richard Janney	2020	-	-	-	-	-	-	52,425	52,425
Interim PAO (2)	2019	-	-	-	-	-	-	-	-
Punit Dhillon	2020	160,000	-	-	387,000	-	-	-	547,000
CEO	2019	-	-	-	-	-	-	-	-
Dr. Brian S. Murphy, Former CEO/ CMO (3)	2020	247,026	6,750	-	-	-	-	195,000	448,776
	2019	390,000	-	-	-	-	-	-	390,000
Elena Traistaru, Former Interim PFA(4)	2020	-	-	-	41,000	-	-	130,571	171,571
	2019	-	-	-	-	-	-	-	-
Douglas Cesario,	2020	95,192	-	-	-	-	-	125,000	220,192
Former CFO(5)	2019	250,000	-	-	-	-	-	-	250,000
Dr. Dennis Kim,	2020	308,404	5,712	-	164,000	-	-	-	478,116
Former CMO(6)	2019	119,812	-	-	164,985	-	-	-	284,797
Dr. Avtar Dhillon, Former Executive Chairman (7)	2020	-	-	-	120,000	-	-	127,387	247,387
	2019	-	-	-	-	-	-	117,890	117,890

(1) Amounts reflect the full grant date fair value of stock options and awards, computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual.

(2) For the year ended December 31, 2020, other compensation consists of consulting fees charged to the Company by RoseRyan, Inc. for Mr. Richard Janney's services.

(3) Dr. Brian Murphy separated from us, effective August 7, 2020, pursuant to a Separation and Release Agreement between us and Dr. Murphy. For the year ended December 31, 2020, other compensation consists of severance payable under Mr. Murphy's Separation and Release Agreement.

(4) Ms. Elena Traistaru resigned as Interim Principal Accounting Officer, effective September 25, 2020. For the year ended December 31, 2020, other compensation consists of consulting fees charged to the Company by Ms. Traistaru's consulting company.

(5) Mr. Douglas Cesario separated from us, effective May 15, 2020, pursuant to a Separation and Release Agreement between us and Mr. Cesario. For the year ended December 31, 2020, other compensation consists of severance payable under the Separation and Release Agreement.

(6) Dr. Dennis Kim resigned as Chief Medical Officer, effective November 6, 2020.

(7) Dr. Avtar Dhillon resigned as Chairman and member of our Board of Directors, effective December 17, 2019. For the year 2020, other compensation consists of consulting fees earned under the Independent Contractor Agreement (defined below). See "Director Compensation" below. For the year 2019, other compensation represents fees earned for services rendered as a member of our Board of Directors.

Employment and Severance Arrangements

Employment Agreement

On August 7, 2020, we entered into an employment agreement with Mr. Punit Dhillon, our Chief Executive Officer. The agreement provides for an annual base salary of $400,000 per year and an annual discretionary bonus up to fifty percent (50%) of his base salary based on Mr. Punit Dhillon's achievement of annual corporate milestones agreed to by the Board. Mr. Punit Dhillon will also receive the normal benefits available to other similarly situated executives and will be entitled to severance pay under the circumstances described below.

Mr. Punit Dhillon's employment with the Company is at-will. Except for termination of Mr. Punit Dhillon's employment for "Cause," "By Death" or "By Disability" (as such terms are defined in his employment agreement), Mr. Punit Dhillon will be entitled to a minimum six months' severance if he is terminated by the Company without cause. Under his employment agreement, Mr. Punit Dhillon will be eligible to receive a 12-months' severance if he is employed by the Company for at least 12 months commencing on August 10, 2020, or a 24 months' severance if he is employed by the Company for at least 24 months commencing on August 10, 2020.

In connection with his appointment, the Company granted Mr. Punit Dhillon options to purchase 9,000,000 shares of the Company's common stock at an exercise price of $0.045 per share (the then market price of the Company's shares), with 10% of such options vested immediately upon grant and the remaining 90% vesting equally on each six-month anniversary of the grant date over four and a half years.

The foregoing description of the employment agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the employment agreements attached hereto as an exhibit and incorporated by reference herein.

Severance Arrangements

In February 2015, we adopted a change in control severance plan, in which our named executive officers participate, that provides for the payment of severance benefits if the executive's service is terminated within twelve months following a change in control, either due to a termination without cause or upon resignation for a good reason (as each term is defined in the plan).

In either such event, and provided the executive timely executes and does not revoke a general release of claims against us, he or she will be entitled to receive: (i) a lump sum cash payment equal to at least six months' of the executive's monthly compensation, plus an additional month for each full year of service over six years, (ii) Company-paid premiums for continued health insurance for a period equal to the length of the cash severance period or, if earlier, when executive becomes covered under a subsequent employer's healthcare plan, and (iii) full vesting of all then-outstanding unvested stock options and restricted stock awards.

On April 29, 2020, we entered into a Separation and Release Agreement with Mr. Douglas Cesario. Mr. Cesario's separation was effective May 15, 2020. Pursuant to the Separation and Release Agreement, Mr. Cesario agreed to certain ongoing cooperation obligations and to provide certain releases and waivers as contained in the Separation and Release Agreement. As consideration, we agreed to provide Mr. Cesario compensation and benefits in accordance with his Employment Agreement as follows: (i) through the Separation Date, an annualized base salary at the rate in effect for him as of the date of the Separation and Release Agreement; (ii) a gross payment of $125,000 in consideration for the restrictive covenants contained in the Separation and Release Agreement; and (iii) a continuation of health insurance benefits for reimbursement for a period of six months following the Separation Date.

On August 7, 2020, we entered into a Separation and Release Agreement with Dr. Brian Murphy, pursuant to which, Dr. Murphy resigned as the Company's Chief Executive Officer and a member of the Board, effective August 7, 2020. Pursuant to the Separation and Release Agreement, Dr. Murphy has agreed to certain ongoing cooperation obligations and to provide certain releases and waivers as set out in the Separation and Release Agreement. As consideration, we have agreed to provide Dr. Murphy with certain compensation and benefits in accordance with his Employment Agreement as follows: (i) an aggregate gross sum of $195,000, less federal and state withholdings, as salary continuation over six months in accordance with the Company's standard biweekly payroll practice; and (ii) Company's healthcare benefits (for similarly situated executives as amended from time to time), for a period of six months from the Separation Date.

The foregoing descriptions of the separation and release agreements do not purport to be complete and are qualified in their entirety by reference to the full text of such separation and release agreements attached hereto as exhibits and incorporated by reference herein.

Outstanding Equity Awards at Fiscal Year-end

As of December 31, 2020, our named executive officers held the following outstanding Company equity awards.

	Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Un-exercisable	Option Exercise Price	Option Expiration Date	Number of Shares of Stock Not Vested (#)	Market Value of Shares Not Vested ($)[1]
Punit Dhillon,	[2]10/10/2018	200,000	-	$ 0.305	10/10/2028		
CEO/Chairman	[3]8/7/2020	900,000	8,100,000	$ 0.045	8/7/2030		

(1) The market value of shares that have not vested is calculated based on the per share closing price of our common stock on December 31, 2020.

(2) The options specified above vest as follows: 1/12 each month on the anniversary of the grant date.

(3) The options specified above vest as follows: 10% of total vests on the grant date and 1/10 vests semi-annually on the anniversary of the grant date thereafter.

Exercises of Options

There were no exercises of stock options by our named executive officers during the year ended December 31, 2020.

Director Compensation

Since October 2018, our policy for the compensation of our non-employee directors has been as follows:

Each non-employee director receives a cash retainer of $40,000 on an annual basis, and an executive chair of the Board, if one is appointed as such and is a non-employee director, receives an additional $40,000 retainer annually.

Upon election to the Board, non-employee directors receive a one-time award of 200,000 stock options which vest in twelve equal monthly installments. In subsequent annual periods, each non-employee director receives a grant of 100,000 common stock options which vest in twelve equal monthly installments.

Non-employee directors who serve as members of special committees of the Board receive additional compensation as follows:

- Audit Committee: $5,000 per year ($20,000 for the chair)
- Compensation Committee: $2,500 per year ($10,000 for the chair)
- Nominating and Corporate Governance Committee: $1,000 per year ($5,000 for the chair)
- Finance and Business Development Special Committee: $40,000 per year for a non-employee member (no compensation for employee members)

Our directors received the following compensation for their service as our directors during the fiscal year ended December 31, 2020.

DIRECTOR COMPENSATION [1]

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($) [2]	Option Awards ($) [2]	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Punit Dhillon	68,082	-	-	-	-	-	68,082
Jim Heppell	83,527	-	40,000	-	-	-	123,527
Margaret Dalesandro	21,028	-	10,000	-	-	-	31,028

(1) Does not include compensation received for services provided as executive officers.

(2) Each non-employee director is entitled to an annual grant of 100,000 common stock options, all of which vest in twelve equal monthly installments. However, no annual option grants were approved by the Board of Directors in 2020. Amounts reflect the full grant date fair value of restricted stock awards and stock options, computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of restricted stock awards and options granted to our directors in Note 2 and 6 to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Securities Authorized for Issuance under Equity Compensation Plans

The table below includes the following information as of December 31, 2020 for the Company's 2014 Omnibus Incentive Plan. Shares available for issuance under the 2014 Omnibus Incentive Plan can be granted pursuant to stock options, stock appreciation rights, restricted stock, restricted stock unit awards, performance awards and other stock-based or cash-based awards, as selected by the plan administrator. For additional information about the 2014 Omnibus Incentive Plan, refer to Note 6 in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Equity Compensation Plan Information

Plan category	Number of shares of common stock to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of shares of common stock remaining available for future issuance under equity compensation plans (excluding shares of common stock reflected in column (a)) (c)
Equity compensation plans approved by security holders	22,050,000	$ 0.06	12,790,775
Total	**22,050,000**	**$ 0.06**	**12,790,775**

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to beneficial ownership of our common stock, by:

- each person known to be the beneficial owner of 5% or more of our outstanding common stock;
- each executive officer;
- each director; and
- all of the executive officers and directors as a group.

Beneficial ownership has been determined in accordance with Rule 13d-3 under the Exchange Act. Under this rule, certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire shares (for example, upon exercise of an option or warrant) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares is deemed to include the amount of shares beneficially owned by such person by reason of such acquisition rights. As a result, the percentage of outstanding shares of any person as shown in the following table does not necessarily reflect the person's actual voting power at any particular date.

The information set forth in the table below is based on 350,007,749 shares of our common stock issued and outstanding on February 23, 2021.

To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. Unless otherwise indicated, the address of each beneficial owner listed below is 5910 Pacific Center Blvd. Suite 320, San Diego, CA 92121.

Name and Address of Beneficial Owner	Beneficial Ownership	Percent of Class
Emerald Health Sciences, Inc. (1)	124,066,474 (2)	34.2%
Punit Dhillon	3,000,000 (3)	*%
Dr. Brian S. Murphy	1,275,000 (6)	*%
Richard Janney	-	*%
Elena Traistaru	- (9)	*%
Douglas Cesario	643,501 (7)	*%
Dr. Dennis Kim	- (10)	*%
Jim Heppell	1,025,000 (4)	*%
Dr. Margaret Dalesandro	81,250 (5)	*%
Dr. Avtar Dhillon	2,475,000 (8)	*%
All executive officers and directors as a group (9 persons)	8,499,751	2.4%

*Denotes less than 1% of our outstanding shares of common stock.

(1) The address of Emerald Health Sciences is 8262, The Landing, 200 - 375 Water St., Vancouver, British Columbia, Canada V6B 0M9.

(2) Includes (i) 111,387,251 shares of common stock, (ii) 7,500,000 shares issuable on exercise of warrants and (iii) 5,178,244 shares issuable upon the conversion of outstanding principal and accrued interest associated with the Amended Credit Agreement.

(3) Includes 2,000,000 shares of common stock underlying options that may be exercised within 60 days of February 23, 2021.

(4) Includes 525,000 shares of common stock underlying options that may be exercised within 60 days of February 23, 2021.

(5) Includes 81,250 shares of common stock underlying options that may be exercised within 60 days of February 23, 2021.

(6) Dr. Brian Murphy separated from us, effective August 7, 2020, pursuant to a Separation and Release Agreement between us and Dr. Murphy.

(7) Mr. Douglas Cesario separated from us, effective May 15, 2020, pursuant to a Separation and Release Agreement between us and Mr. Cesario.

(8) Includes 1,975,000 shares of common stock underlying options that may be exercised within 60 days of February 23, 2021. Dr. Avtar Dhillon resigned as Chairman and member of our Board of Directors, effective December 17, 2019.

(9) Ms. Elena Traistaru resigned as Interim Principal Accounting Officer, effective September 25, 2020.

(10) Dr. Dennis Kim resigned as Chief Medical Officer, effective November 6, 2020.

Changes in Control

Our management is not aware of any arrangements which may result in "changes in control" as that term is defined by the provisions of Item 403(c) of Regulation S-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Transactions with Related Persons

Except as specified below, there have been no other transactions with related persons in the last two fiscal years, or any currently proposed transaction, in which we were or are to be a participant and the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2020 and 2019, and in which any related person had or will have a direct or indirect material interest.

Emerald Health Sciences

In January 2018, we entered into a securities purchase agreement with Emerald Health Sciences, pursuant to which Emerald Health Sciences purchased a majority of the outstanding equity in us, resulting in a change in control of the Company. As part of the transaction, the members of Board of the Company, with the exception of Dr. Brian Murphy, our former CEO, tendered their resignation, and Emerald Health Sciences appointed two nominees to the Board.

In October 2018, the Board appointed Dr. Avtar Dhillon, the Chairman, CEO and President of Emerald Health Sciences, as the Executive Chairman of the Board. On December 17, 2019, the Board accepted the resignation of Dr. Avtar Dhillon, who offered his resignation as the Executive Chairman of the Board and the position of Chairman of the Finance and Business Development Committee of the Board. The Board also appointed Punit Dhillon, an existing member of the Board, as Chairman of the Board and as Chairman of the Finance and Business Development Committee of the Board, to fill the vacancies in such offices created by the resignation of Dr. Avtar Dhillon. On August 7, 2020, Mr. Punit Dhillon was appointed the CEO of the Company and tendered his resignation as Chairman of the Audit Committee and a member of the Compensation Committee and the Nomination and Corporate Governance Committee.

On February 1, 2018, we entered into an Independent Contractor Agreement (the "Independent Contractor Agreement") with Emerald Health Sciences, pursuant to which Emerald Health Sciences agreed to provide such services as are mutually agreed between the Company and Emerald Health Sciences, including reimbursements for reasonable expenses incurred in the performance of the Independent Contractor Agreement. These services may include, but are not limited to, corporate advisory services and technical expertise in the areas of business development, marketing, investor relations, information technology and product development. The Independent Contractor Agreement had an initial term of ten years and specified compensation to be agreed upon between the Company's chief executive officer and Emerald Health Sciences' CEO on a month-to-month basis. The fee due under this agreement was payable on a monthly basis; however, if we were unable to make payments due to insufficient funds, then interest on the outstanding balance is accrued at a rate of 12% per annum, calculated semi-annually. Under this agreement, the Company incurred expenses of $542,000 during the year ended December 31, 2019. As of December 31, 2019 and 2020, $7,032 remains unpaid. The Independent Contractor Agreement was terminated effective December 31, 2019.

On October 5, 2018, we entered into the Credit Agreement with Emerald Health Sciences. The Credit Agreement provides for a credit facility to us of up to $20,000,000 and is unsecured. Advances under the Credit Agreement bear interest at an annual rate of 7% (payable quarterly in arrears) and mature on October 5, 2022. At Emerald Health Sciences' election, advances and unpaid interest may be converted into Common Stock at a fixed conversion price of $0.40, subject to customary adjustments for stock splits, stock dividends, recapitalizations, etc. In connection with each advance under the Credit Agreement, we agreed, if requested by Emerald Health Sciences, to issue Emerald Health Sciences warrants to purchase shares of common stock in an amount equal to 50% of the number of shares of common stock that each advance may be converted into. The warrants have an exercise price of $0.50 per share, a term of five years and will be immediately exercisable upon issuance. The exercise price is subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events or upon any distributions of assets, including cash, stock or other property to our shareholders. On November 1, 2018, we affected an initial draw under the Credit Agreement in the amount of $2,000,000 and issued Emerald Health Sciences a warrant to purchase 2,500,000 shares of common stock at an exercise price of $0.50 per share, in accordance with the terms of the Credit Agreement. On February 1, 2019, we affected the second draw under the Credit Agreement in the amount of $2,000,000 and issued Emerald Health Sciences a warrant to purchase 2,500,000 shares of common stock at an exercise price of $0.50 per share, in accordance with the terms of the Credit Agreement. On March 29, 2019, we affected the third draw under the Credit Agreement in the amount of $2,000,000 and issued Emerald Health Sciences a warrant to purchase 2,500,000 shares of common stock at an exercise price of $0.50 per share, in accordance with the terms of the Credit Agreement. On December 20, 2019, we entered into a Warrant Exchange Agreement, pursuant to which Emerald Health Sciences exercised 40.8 million of such warrants and paid the aggregate exercise price of approximately $4.08 million for the related warrant shares in the form of a reduction of the corresponding amount of obligations outstanding under the Credit Agreement. Upon consummation of the transaction under the Warrant Exchange Agreement, the total outstanding principal amount excluding discounts under the Credit Agreement was $2,014,500. On April 29, 2020, we entered into an Amended and Restated Multi-Draw Credit Agreement with Emerald Health Sciences, which amends and restates the Credit Agreement, as reported in the current report on the Form 8-K filed with the SEC on April 29, 2020. The Amended Credit Agreement provides for a credit facility to us in the principal amount of up to $20,000,000, which includes, without limitation, the advances totaling $6,000,000 that were granted prior to the amendment. During the year ended December 31, 2020, we received the fourth and fifth advances of $150,000 and $300,000 pursuant to the Amended Credit Agreement. The advances bear interest at 7% per annum and mature on October 5, 2022. The Amended Credit Agreement is still in place; however, there is no guarantee of continued funding under the Amended Credit Agreement. A portion of the proceeds raised in this offering may be used to pay, in whole or in part, the principal and accrued interest on our Amended Credit Agreement. See "Use of Proceeds." The net proceeds of each advance shall be used for general corporate purposes.

On December 19, 2019, we entered into an Independent Contractor Services Agreement with Dr. Avtar Dhillon, pursuant to which Dr. Avtar Dhillon will provide ongoing corporate finance and strategic business advisory services to us. In exchange for his services, Dr. Dhillon initially received a monthly fee of $10,000, with (i) $5,000 paid each month and (ii) $5,000 accruing from the effective date and payable upon the Company's completion of a material financing. On March 30, 2020, we amended the Independent Contractor Services Agreement by agreeing to defer payment of 100% of Dr. Dhillon's consulting fees until the Board of Directors determined that we had been sufficiently financed to make such payments at which point we would pay Dr. Dhillon all his accrued consulting fees, and a bonus of 10% of his accrued consulting fees, less applicable tax and other withholdings. The deferral was paid concurrent with the August 2020 Financing. After the August 2020 Financing Dr. Dhillon continues to receive a monthly fee of $10,000 per month for his services. The Board reviews the monthly rate paid to Dr. Dhillon within 90 days of the end of each fiscal year. The Independent Contractor Services Agreement has an initial term of one year and automatically renews thereafter unless terminated earlier by either party. The Independent Contractor Services Agreement may be terminated by either party for cause upon written notice to the other party if the other party defaults in the performance of the agreement in any material respect or materially breaches the terms of the agreement, or without cause upon 30 days' prior written notice to the other party. Under this agreement, for the years ended December 31, 2020 and 2019, we incurred fees of $127,387 and $3,871, respectively. As of December 31, 2020, we have accrued $10,000 in expense related to the Independent Contractor Services Agreement.

On December 19, 2019, we entered into a Board Observer Agreement with Emerald Health Sciences, our largest shareholder. The Board Observer Agreement gives a right to Emerald Health Sciences to designate one observer to our Board for so long as Emerald Health Sciences maintains ownership of any securities in the Company. Under the Board Observer Agreement, the board observer will be permitted to attend all meetings (whether in person, telephonically or otherwise) of the Board in a non-voting, observer capacity. Emerald Health Sciences appointed Dr. Avtar Dhillon as its board observer. The Board Observer Agreement may be terminated by either party for cause upon written notice to the other party if the other party defaults in the performance of the agreement in any material respect or materially breaches the terms of the agreement, or without cause upon 30 days' prior written notice to the other party.

Emerald Health Biotechnology España, S.L.U.

In January 2021, we entered into a Collaborative Research Agreement with Emerald Health Biotechnology España, S.L.U, a subsidiary of Emerald Health Research, Inc. which is 100% owned by Emerald Health Sciences. Under the agreement, Emerald Health Biotechnology España, S.L. will provide research and development services pursuant to an agreed upon project plan for the research and development of CBDVHS. The term of the agreement is initially for a one-year period. The agreement will terminate upon delivery and acceptance of the final deliverable under the project plan or if either party is in breach of the terms of the contract and such breach remains uncured for 45 days. Payment for services rendered will be based on time and materials billable at reasonable market rates.

Douglas Cesario

In April 2020, we entered into a Separation and Release Agreement with Mr. Douglas Cesario, our former Chief Financial Officer. Mr. Cesario's separation was effective May 15, 2020. Pursuant to the agreement, Mr. Cesario agreed to certain ongoing cooperation obligations and to provide certain releases and waivers to us as set out in the agreement. As consideration, we agreed to provide Mr. Cesario compensation and benefits in accordance with his Employment Agreement as follows: (i) through May 15, 2020, an annualized base salary at the rate in effect for him as of the date of the agreement; (ii) a gross payment of $125,000 in consideration for the restrictive covenants contained in the agreement; and (iii) a continuation of health insurance benefits for a period of six months following May 15, 2020. In addition, 325,929 unvested stock options granted to Mr. Cesario were cancelled on May 15, 2020.

Dr. Brian Murphy

On August 7, 2020, we entered into a Separation and Release Agreement with Dr. Brian Murphy, pursuant to which, Dr. Murphy resigned as the Company's Chief Executive Officer and a member of the Board, effective August 7, 2020. Pursuant to the Separation and Release Agreement, Dr. Murphy agreed to certain ongoing cooperation obligations and to provide certain releases and waivers to us as set out in the Separation and Release Agreement. As consideration, we have agreed to provide Dr. Murphy with certain compensation and benefits as follows: (i) an aggregate gross sum of $195,000, less federal and state withholdings, as salary continuation over six months in accordance with our standard biweekly payroll practice; and (ii) a continuation of health insurance benefits (for similarly situated executives as amended from time to time), for a period of six months from the Separation Date.

Review, Approval and Ratification of Related Party Transactions

Given our small size and limited financial resources, we have not adopted formal policies and procedures for the review, approval or ratification of transactions, such as those described above, with our executive officers, directors and significant stockholders, other than all related party transactions must be approved by directors independent of the parties involved. However, all of the transactions described above were approved and ratified by the independent members of our Board. In connection with the approval of the transactions described above, our Board took into account several factors, including their fiduciary duties to the Company, the relationships of the related parties described above to the Company, the material facts underlying each transaction, the anticipated benefits to the Company and related costs associated with such benefits, whether comparable products or services were available, and the terms we could receive from an unrelated third party.

We intend to establish formal policies and procedures in the future, once we have sufficient resources and have appointed additional directors so that such transactions will be subject to the review, approval or ratification of our Board, or an appropriate committee thereof. On a moving forward basis, our Board will continue to approve any related party transaction based on the criteria set forth above.

Conflicts Related to Other Business Activities

The persons serving as our officers and directors have existing responsibilities and, in the future, may have additional responsibilities, to provide management and services to other entities in addition to us. As a result, conflicts of interest between us and the other activities of those persons may occur from time to time.

We will attempt to resolve any such conflicts of interest in our favor. Our officers and directors are accountable to our shareholders and us as fiduciaries, which requires that such officers and directors exercise good faith and integrity in handling our affairs. A shareholder may be able to institute legal action on our behalf or on behalf of that shareholder and all other similarly situated shareholders to recover damages or for other relief in cases of the resolution of conflicts in any manner prejudicial to us.

Director Independence

We have determined that Jim Heppell and Dr. Margaret Dalesandro are independent members of our Board, as that term is defined in Rule 5605(a)(2) of the Nasdaq Listing Rules.

Insider Trading Policy

On October 31, 2014, our Board adopted an Insider Trading Policy applicable to all directors and officers. Insider trading generally refers to the buying or selling of a security in breach of a fiduciary duty or other relationship of trust and confidence while in possession of material, non-public information about the security. Insider trading violations may also include 'tipping' such information, securities trading by the person 'tipped,' and securities trading by those who misappropriate such information. The scope of insider trading violations can be wide reaching. As such, our Board has adopted an Insider Trading Policy that outlines the definitions of insider trading, the penalties and sanctions determined, and what constitutes material, non-public information. Illegal insider trading is against our policy as such trading can cause significant harm to the reputation for integrity and ethical conduct of our company. Individuals who fail to comply with the requirements of the policy are subject to disciplinary action, at our sole discretion, including dismissal for cause. All members of our Board and all executive officers are required to ratify the terms of this policy on an annual basis. Our Insider Trading Policy is available on our website at http://www.skyebioscience.com.

Item 14. Principal Accounting Fees and Services.

Audit Fees

The aggregate fees billed in each of the fiscal years ended December 31, 2020 and 2019, for professional services rendered by Mayer Hoffman McCann P.C. for the audit of our annual consolidated financial statements included in our Annual Report on Form 10-K and quarterly reviews of the unaudited interim condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for 2020 and 2019 were $392,402 and $328,514, respectively. Substantially all MHM's personnel, who work under the control of MHM shareholders, are employees of wholly owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure.

Tax Fees

None.

All Other Fees

None.

Pre-Approval Policies and Procedures

Prior to engaging Mayer Hoffman McCann P.C. to perform a particular service, our Board obtains an estimate for the service to be performed. All of the services described above were approved by the members of the Audit Committee of the Board in accordance with its procedures.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Financial Statements. The following consolidated financial statements of Skye Bioscience, Inc., together with the report thereon of Mayer Hoffman McCann P.C., an independent registered public accounting firm, are included in this Annual Report on Form 10-K:

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Skye Bioscience, Inc. and Subsidiaries:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Skye Bioscience, Inc., formerly known as Emerald Bioscience, Inc., and Subsidiaries ("Company") as of December 31, 2020 and 2019, and the related consolidated statements of comprehensive (loss) income, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring operating losses and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 1 to the financial statements. The 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 outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2014.

Irvine, California
March 1, 2021

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
ASSETS	**2020**	**2019**
Current assets		
Cash	$ 2,469,410	$ 1,829,977
Restricted cash	4,566	4,538
Prepaid expenses	190,134	152,695
Other current assets	275	7,550
Total current assets	2,664,385	1,994,760
Property and equipment, net	7,341	1,983
Total assets	$ 2,671,726	$ 1,996,743
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 364,340	$ 129,809
Accounts payable - related party	17,032	10,000
Accrued interest - related party	44,087	-
Other current liabilities	259,111	420,406
Derivative liabilities	38,567	410,603
PPP loan current	64,062	-
Total current liabilities	787,199	970,818
Noncurrent liabilities		
PPP loan non-current	52,638	-
Multi-draw credit agreement - related party	450,000	-
Convertible multi-draw credit agreement - related party, net of discount	931,103	387,070
Derivative liabilities, non-current	-	90,797
Total liabilities	2,220,940	1,448,685
Stockholders' equity		
Preferred stock, $0.001 par value; 20,000,000 shares authorized; no shares issued and outstanding at December 31, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value; 500,000,000 shares authorized; 288,074,415 and 182,895,247 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	288,074	182,895
Additional paid-in-capital	38,896,693	32,538,445
Accumulated deficit	(38,733,981)	(32,173,282)
Total stockholders' equity	450,786	548,058
Total liabilities and stockholders' equity	$ 2,671,726	$ 1,996,743

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

	Year Ended December 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 1,944,411	$ 2,237,956
General and administrative	4,344,602	4,394,622
Total operating expenses	6,289,013	6,632,578
Operating loss	(6,289,013)	(6,632,578)
Other expense (income)		
Change in fair value of derivative liabilities	(436,270)	(9,734,759)
Fair value of derivative liabilities in excess of proceeds	-	322,644
Loss on extinguishment of debt - related party	-	725,425
Interest expense	706,385	1,000,713
Interest income	(29)	(26)
Total other expense (income), net	270,086	(7,686,003)
(Loss) income before income taxes	(6,559,099)	1,053,425
Provision for income taxes	1,600	1,600
Net (loss) income and comprehensive (loss) income	$ (6,560,699)	$ 1,051,825
(Loss) earnings per common share:		
Basic	$ (0.03)	$ 0.01
Diluted	$ (0.03)	$ (0.05)
Weighted average shares of common stock outstanding used to compute (loss) earnings per share:		
Basic	230,746,878	135,154,931
Diluted	231,420,973	169,560,265

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net (loss) income	$ (6,560,699)	$ 1,051,825
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation	1,872	1,462
Stock-based compensation expense	302,742	680,455
Change in fair value of derivative liabilities	(436,270)	(9,734,759)
Fair value of derivative liabilities in excess of proceeds	-	322,644
Loss on extinguishment of debt - related party	-	725,425
Amortization of debt discount	544,033	629,293
Changes in assets and liabilities:		
Prepaid expenses	(37,439)	(59,502)
Other current assets	7,275	(4,941)
Accounts payable	234,531	124,212
Accounts payable – related party	7,032	10,000
Accrued interest – related party	44,087	-
Other current liabilities	(161,295)	225,945
Net cash used in operating activities	(6,054,131)	(6,027,941)
Cash flows from investing activities:		
Purchases of property and equipment	(7,230)	-
Net cash used in investing activities	(7,230)	-
Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants - net of $854,078 and $80,628 of issuance costs in 2020 and 2019, respectively	6,085,589	1,919,372
Proceeds from warrant exercises	48,533	4,080,000
Proceeds from PPP loan	116,700	-
Proceeds from multi-draw credit agreement - related party, net of $0 and $9,301 issuance costs in 2020 and 2019, respectively	450,000	3,990,699
Prepayment of convertible multi-draw credit agreement - related party	-	(3,985,500)
Net cash provided by financing activities	6,700,822	6,004,571
Net increase (decrease) in cash and restricted cash	639,461	(23,370)
Cash and restricted cash, beginning of year	$ 1,834,515	$ 1,857,885
Cash and restricted cash, end of year	$ 2,473,976	$ 1,834,515
Supplemental disclosures of cash-flow information:		
Reconciliation of cash and restricted cash:		
Cash	$ 2,469,410	$ 1,829,977
Restricted cash	4,566	4,538
Total cash and restricted cash shown in the consolidated statements of cash flows	$ 2,473,976	$ 1,834,515
Cash paid during the year for:		
Interest	$ 117,459	$ 371,420
Income taxes	1,600	1,600
Supplemental disclosures of non-cash financing activities:		
Beneficial conversion feature on convertible multi-draw credit agreement	$ -	$ 1,584,850
Proceeds allocated to equity classified warrants issued with convertible multi-draw credit agreement	-	716,110
Fair value of compound derivative liability bifurcated from convertible multi-draw credit agreement	-	193,414
Reclassification of warrant liabilities to equity from exercise of warrants	26,250	6,077,698

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Stockholders' Equity				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts			
Balance, December 31, 2018	**133,907,747**	**$ 133,908**	**$ 17,528,947**	**$ (33,225,107)**	**$ (15,562,252)**
Stock-based compensation expense	-	-	680,455	-	680,455
Issuance of common stock and warrants, net of issuance costs of $80,628	8,000,000	8,000	1,911,372	-	1,919,372
Warrants issued in connection with convertible multi-draw credit agreement, related party	-	-	716,110	-	716,110
Beneficial conversion feature in connection with convertible multi-draw credit agreement - related party	-	-	1,584,850	-	1,584,850
Series B warrant exercises	187,500	187	144,188	-	144,375
Exercise of Emerald financing warrants	40,800,000	40,800	9,972,523	-	10,013,323
Net income for the year ended December 31, 2019	-	-	-	1,051,825	1,051,825
Balance, December 31, 2019	**182,895,247**	**$ 182,895**	**$ 32,538,445**	**$ (32,173,282)**	**$ 548,058**
Stock-based compensation expense	-	-	302,742	-	302,742
Issuance of common stock and warrants, net of issuance costs of $854,078	56,333,334	56,333	6,029,256	-	6,085,589
Exercise of pre-funded warrants	48,533,334	48,533	-	-	48,533
Series B warrant exercises	312,500	313	26,250	-	26,563
Net loss for the year ended December 31, 2020	-	-	-	(6,560,699)	(6,560,699)
Balance, December 31, 2020	**288,074,415**	**$ 288,074**	**$ 38,896,693**	**$ (38,733,981)**	**$ 450,786**

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations and Business Activities

Nature of Operations

Skye Bioscience, Inc. (the "Company") was initially incorporated in Nevada on March 16, 2011 as Load Guard Logistics, Inc. On October 31, 2014, the Company closed a reverse merger transaction (the "Merger") pursuant to which Nemus, a California corporation ("Nemus Sub"), became the Company's wholly owned subsidiary, and the Company assumed the operations of Nemus Sub. Nemus Sub was incorporated in the State of California on July 17, 2012. On November 3, 2014, the Company changed its name to Nemus Bioscience, Inc. by merging with Nemus Sub to form a Nevada company.

In January 2018, the Company entered into a securities purchase agreement with Emerald Health Sciences, Inc. ("Emerald Health Sciences"), pursuant to which Emerald Health Sciences purchased a majority of the equity interest in the Company, resulting in a change in control (the "Emerald Financing"). As part of the transaction, the Company's Board members, with the exception of Dr. Brian Murphy, the Company's former CEO/CMO, tendered their resignation and Emerald Health Sciences appointed two new nominees to the Board. Later, in October 2018, the Board appointed Dr. Avtar Dhillon, the Chairman, Chief Executive Officer and President of Emerald Health Sciences, as the Executive Chairman of the Company's Board. On August 7, 2020, Dr. Brian Murphy resigned and Punit Dhillon was appointed as the Chief Executive Officer of the Company.

Effective March 25, 2019, the Company changed its name from Nemus Bioscience, Inc. to Emerald Bioscience, Inc. Effective January 19, 2021, the Company changed its name from Emerald Bioscience, Inc. to Skye Bioscience, Inc.

In August 2019, the Company formed a new subsidiary in Australia, EMBI Australia Pty Ltd., an Australian proprietary limited company ("EMBI Australia"), in order to qualify for the Australian government's research and development tax credit for research and development dollars spent in Australia. The primary purpose of EMBI Australia is to conduct clinical trials for the Company's product candidates.

On December 17, 2019, Dr. Avtar Dhillon resigned as the Chairman of the Company's Board and the Company entered into a Board Observer Agreement with Emerald Health Sciences. Refer to Note 11 - Related Party Matters for additional information.

The Company is a biopharmaceutical company located in San Diego, California that plans to research, develop and commercialize therapeutics derived from cannabinoids through several license agreements with the University of Mississippi ("UM"). UM is the only entity federally permitted and licensed to cultivate cannabis for research purposes in the United States.

As of December 31, 2020, the Company has devoted substantially all its efforts to securing product licenses, carrying out research and development, building infrastructure and raising capital. The Company has not yet realized revenue from its planned principal operations and is a number of years away from potentially being able to do so.

Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows from operations since inception and as of December 31, 2020, had an accumulated deficit of $38,733,981. The Company anticipates that it will continue to incur operating losses into the foreseeable future in order to advance and develop a number of potential drug candidates into preclinical and clinical development activities and support its corporate infrastructure which includes the costs associated with being a public company. As of December 31, 2020, the Company had unrestricted cash in the amount of $2,469,410. From January 1, 2021 through February 23, 2021, the Company received $3,019,800 in proceeds from the exercise of warrants (Note 13).

The Company's continued existence is dependent on its ability to raise sufficient additional funding to cover operating expenses and to carry out its research and development activities. As the Company approaches its first clinical trial, it expects to ramp up research and development spending and to increase cash used in operating activities. However, based on the Company's expected cash requirements, without obtaining additional funding by the second half of 2021, management believes that the Company will not have enough funds to commence clinical studies. These conditions give rise to substantial doubt as to the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying Consolidated Financial Statements do not include any adjustments that might result from the outcome of this uncertainty.

On October 5, 2018, the Company entered into a Multi-Draw Credit Agreement (the "Credit Agreement") with Emerald Health Sciences (See Note 4). On April 29, 2020, the Company entered into an Amended and Restated Multi-Draw Credit Agreement (the "Amended Credit Agreement") with Emerald Health Sciences, which amends and restates the Credit Agreement. The Amended Credit Agreement provides for a credit facility in the principal amount of up to $20,000,000, which includes, without limitation, the advances totaling $6,000,000 that were granted prior to the amendment.

Prior to the date of the Amended Credit Agreement, the Company had made three drawdowns in an aggregate principal amount of $6,000,000 and had issued to Emerald Health Sciences warrants to purchase an aggregate of 7,500,000 shares of common stock of the Company at an exercise price of $0.50 per share of the Company's common stock, in accordance with the terms of the Credit Agreement.

During the year ended December 31, 2020, the Company effected the fourth and fifth advances under the Amended Credit Agreement in the amounts of $150,000 and $300,000, respectively. Emerald Health Sciences elected that the fourth and fifth advances are not convertible into shares of Common Stock and no warrants were issued with the advances. The Company used the proceeds from the advances for general corporate and working capital purposes. As of December 31, 2020, the Company may draw down up to the remaining amount under the Amended Credit Agreement. However, the Company does not consider the facility available until advance requests are approved, drawn down and funded. The Amended Credit Agreement is still in place, however, there is no guarantee of continued funding.

On April 22, 2020, the Company entered into a Paycheck Protection Program Promissory Note in the principal amount of $116,700 (the "PPP Loan") from City National Bank (the "PPP Loan Lender"). The PPP Loan was obtained pursuant to the Paycheck Protection Program (the "PPP") of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") administered by the U.S. Small Business Administration ("SBA") (Note 4).

On July 31, 2020, the Company entered into the August 2020 Financing (Note 5), pursuant to which the Company sold 56,333,334 common stock units each consisting of one share of common stock and one common stock warrant and 60,333,334 pre-funded units each consisting of one pre-funded warrant and one common stock warrant in a registered public offering. The net proceeds from the transaction were $6,085,589. The common stock warrants and prefunded warrants have an exercise price of $0.06 and $0.001, respectively. The term of the common stock warrants is five years, and the pre-funded warrants are exercisable until all the pre-funded warrants have been exercised in full. The Company is using the net proceeds of the offering for general corporate purposes, including working capital.

During March 2020, the Company approved a plan to defer up to 50% of the members of senior management's compensation and 100% of the Board of Director and committee fees indefinitely. Upon the closing of the August 2020 Financing, the Company's Board of Directors determined that the Company had been sufficiently financed to pay the deferred salaries and fees, including a 10% retention bonus, to management and the Board in the aggregate amount of $293,078.

The Company plans to continue to pursue funding through public or private equity or debt financings, licensing arrangements, asset sales, government grants or other arrangements. However, the Company cannot provide any assurances that such additional funds will be available on reasonable terms, or at all. If the Company raises additional funds by issuing equity securities, substantial dilution to existing stockholders would result.

In December 2019, a novel strain of coronavirus ("COVID-19") emerged in Wuhan, China. Since then, it has spread to the United States and infections have been reported around the world. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread around the world and throughout the United States and Australia, where the Company has operations and conducts laboratory research and clinical studies. In response to the outbreak, federal and state authorities in the United States have introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, nonessential business closures, quarantines, self-isolations, shelters-in-place and social distancing. The COVID-19 outbreak and the response of governmental authorities to try to limit it are having a significant impact on the private sector and individuals, including unprecedented business, employment and significant economic disruptions to the global financial markets. These disruptions are likely to impact the Company's ability to raise additional capital and obtain the necessary funds.

Notably, the Company relies on third party manufacturers to produce its product candidates. The manufacturing of the active pharmaceutical ingredient of THCVHS is conducted in the United States. Formulation of the eye drop for testing is also performed in the United States but can rely on regulatory-accepted excipients that can be sourced from countries outside the United States, such as China. In connection with the recent pandemic of a COVID-19, there could possibly be an impact on sourcing materials that are part of the eye drop formulation, as well as impacting volunteer and/or patient recruitment in Australia for clinical studies. The location of the proposed clinical trial is Melbourne, Australia and since the COVID-19 outbreak in that country, the city has experienced multiple health emergency lockdowns which have had a negative impact on the conduct and timelines of clinical studies. Therefore, the Company has shifted its first-in-human studies of THCVHS from the second half of 2020 to the third quarter of 2021.

After considering the plans to alleviate substantial doubt, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the Consolidated Financial Statements and the accompanying notes. Actual results could differ from those estimates.

Use of Estimates

The preparation of the Consolidated Financial Statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of income and expense during the reporting period. Actual results could differ from those estimates. The most significant accounting estimates inherent in the preparation of the Company's financial statements include estimates as to the appropriate carrying value of certain assets and liabilities, which are not readily apparent from other sources. Such estimates and judgments are utilized for stock-based compensation expense, equity securities, derivative liabilities, and debt with embedded features.

Risks and Uncertainties

The Company's operations are subject to a number of risks and uncertainties, including but not limited to, changes in the general economy, the size and growth of the potential markets for any of the Company's product candidates, results of research and development activities, uncertainties surrounding regulatory developments in the United States and Australia, and the Company's ability to attract new funding.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The carrying values of those investments approximate their fair value due to their short maturity and liquidity. Cash includes cash on hand and amounts on deposit with financial institutions, which amounts may at times exceed federally insured limits. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk. As of December 31, 2020, and 2019, the Company has no cash equivalents.

Restricted cash on the balance sheet represents a certificate of deposit held by the Company's bank as collateral for the Company's credit cards.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (the "exit price") in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable, and the last is considered unobservable, is used to measure fair value:

Level 1: Valuations for assets and liabilities traded in active markets from readily available pricing sources such as quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's financial instruments, with the exception of the Amended Credit Agreement and derivative liabilities, including, cash, prepaid expenses, accounts payable, the PPP loan and other current liabilities approximate their fair value due to the short maturities of these financial instruments. The derivative liabilities are valued on a recurring basis utilizing Level 3 inputs (Note 3).

As of December 31, 2019, the fair value of the advances under the Amended Credit Agreement was $1,877,938, the carrying amount of the liability on December 31, 2019 was $387,070 and is included in Convertible multi-draw credit agreement - related party, net of discount in the Company's Consolidated Balance Sheets. As of December 31, 2020, the Company estimates the fair value of the Amended Credit Agreement to be materially consistent with the fair value estimate as of December 31, 2019, plus the non-convertible advances made in 2020. This determination was based on the following considerations: (i) the Company has not experienced any significant change in its credit worthiness or operations year over year, (ii) there have been no repayments or convertible draws, (iii) the facility is closer to maturity, and (iv) the embedded conversion feature on the convertible advances is out-of-the-money at the reporting date. Information pertinent to estimating the fair value of the Amended Credit Agreement includes valuing the embedded conversion feature and considering the discounted cash flows of the interest and principal payments through maturity (Note 4).

Income Taxes

The Company accounts for deferred income tax assets and liabilities based on differences between the financial reporting and tax bases of assets and liabilities, net operating loss carryforwards (the "NOLs") and other tax credit carryforwards. These items are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date. Any interest or penalties would be recorded in the Company's Consolidated Statements of Comprehensive (Loss) Income in the period incurred. When necessary, the Company recognizes interest and penalties related to income tax matters in income tax expense.

The Company records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion or all of the deferred tax assets will not be realized. In making such determinations, management considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial operations. Due to the substantial doubt related to the Company's ability to utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at December 31, 2020 and 2019. As a result of this valuation allowance, there are no income tax benefits reflected in the accompanying Consolidated Statements of Comprehensive (Loss) Income to offset pre-tax losses.

The Company recognizes a tax benefit from uncertain tax positions when it is more likely than not (50%) that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position.

Convertible Instruments

The Company accounts for hybrid contracts with embedded conversion features in accordance with GAAP. ASC 815,*Derivatives and Hedging Activities* ("ASC 815") requires companies to bifurcate conversion options from their host instruments and account for them as free-standing derivative financial instruments according to certain criteria. The criteria includes circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible debt instruments with embedded conversion features in accordance with ASC 470-20*Debt with Conversion and Other Options* ("ASC 470-20") if it is determined that the conversion feature should not be bifurcated from their host instruments. Under ASC 470-20, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the difference between the fair value of the underlying common stock at the commitment date and the embedded effective conversion price. When the Company determines that the embedded conversion option should be bifurcated from its host instrument, the embedded feature is accounted for in accordance with ASC 815. Under ASC 815, a portion of the proceeds received upon the issuance of the hybrid contract is allocated to the fair value of the derivative. The derivative is subsequently marked to market at each reporting date based on current fair value, with the changes in fair value reported in the results of operations.

The Company also follows ASC 480-10, *Distinguishing Liabilities from Equity* ("ASC 480-10") when evaluating the accounting for its hybrid instruments. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception (for example, a payable settled with a variable number of the issuer's equity shares); (b) variations in something other than the fair value of the issuer's equity shares (for example, a financial instrument indexed to the Standard and Poor's S&P 500 Index and settled with a variable number of the issuer's equity shares); or (c) variations inversely related to changes in the fair value of the issuer's equity shares (for example, a written put option that could be net share settled). Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date with a re-measurement reported in other expense (income) in the accompanying Consolidated Statements of Comprehensive (Loss) Income.

When determining the short-term vs. long-term classification of derivative liabilities, the Company first evaluates the instruments' exercise provisions. Generally, if a derivative is a liability and exercisable within one year, it will be classified as short-term. However, because of the unique provisions and circumstances that may impact the accounting for derivative instruments, the Company carefully evaluates all factors that could potentially restrict the instrument from being exercised or create a situation where exercise would be considered remote. The Company re-evaluates its derivative liabilities at each reporting period end and makes updates for any changes in facts and circumstances that may impact classification.

Warrants Issued in Connection with Financings

The Company generally accounts for warrants issued in connection with debt and equity financings as a component of equity, unless the warrants include a conditional obligation to issue a variable number of shares or there is a deemed possibility that the Company may need to settle the warrants in cash. For warrants issued with a conditional obligation to issue a variable number of shares or the deemed possibility of a cash settlement, the Company records the fair value of the warrants as a liability at each balance sheet date and records changes in fair value in other expense (income) in the Consolidated Statements of Comprehensive (Loss) Income.

Debt Issuance Costs and Interest

Discounts related to bifurcated derivatives, freestanding instruments issued in bundled transactions, and issuance costs are recorded as a reduction to the carrying value of the debt and amortized over the life of the debt using the effective interest method. The Company makes changes to the effective interest rate, as necessary, on a prospective basis. For debt facilities that provide for multiple advances, the Company initially defers any issuance costs until the first advance is made and then amortizes the costs over the life of the facility.

Research and Development Expenses and Licensed Technology

Research and development costs are expensed when incurred. These costs may consist of external research and development expenses incurred under agreements with third party contract research organizations and investigative sites, third party manufacturing organizations and consultants; license fees; employee-related expenses, which include salaries and benefits for the personnel involved in the Company's preclinical and clinical drug development activities; facilities expense, and other expenses; and equipment and laboratory supplies.

Costs incurred for the rights to use licensed technologies in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where the Company has not identified an alternative future use for the acquired rights, and are capitalized in situations where there is an identified alternative future use. No cost associated with the use of licensed technologies has been capitalized to date.

Stock-Based Compensation Expense

Stock-based compensation expense is estimated at the grant date based on the fair value of the award, and the cost is recognized as expense ratably over the vesting period with forfeitures accounted for as they occur. The Company uses the Black-Scholes Merton option pricing model for estimating the grant date fair value of stock options using the following assumptions:

- Volatility - Stock price volatility is estimated over the expected term based on a blended rate of industry peers and the Company's actual stock volatility adjusted for periods in which significant financial variability was identified.
- Expected term - The expected term is based on a simplified method which defines the life as the weighted average of the contractual term of the options and the vesting period for each award.
- Risk-free rate - The risk-free interest rate for the expected term of the option is based on the average market rate on U.S. Treasury securities in effect during the period in which the awards were granted.
- Dividends - The dividend yield assumption is based on the Company's history and expectation of paying no dividends in the foreseeable future.

Comprehensive (Loss) Income

Comprehensive (loss) income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. ASC 220 *Comprehensive Income* requires that an entity records all components of comprehensive (loss) income, net of their related tax effects, in its financial statements in the period in which they are recognized. For the years ended December 31, 2020 and 2019, the comprehensive (loss) income was equal to net (loss) income.

Net (Loss) Income Per Share of Common Stock

The Company applies FASB ASC No. 260, *Earnings per Share* in calculating its basic and diluted net (loss) income per share. Basic net (loss) income per share of common stock is computed by dividing net (loss) income available to common stockholders by the weighted-average number of shares of common stock outstanding for the period. The diluted net (loss) income per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock, restricted stock subject to vesting, warrants to purchase common stock and common shares underlying convertible debt instruments were considered to be common stock equivalents. In periods with a reported net loss, such common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is anti-dilutive. For additional information regarding the net (loss) income per share, see Note 7 "Net (Loss) Income per Share of Common Stock."

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in fiscal periods ending after December 15, 2020. Upon implementation, the Company may use either a modified retrospective or full retrospective method of adoption. The adoption of ASU 2020-06 will likely impact the way the Company calculates its (loss) earnings per share, result in expanded disclosures around convertible instruments and remove the requirement to assess and record beneficial conversion features. The impact from adoption will depend on whether the Company elects to early adopt this ASU. The Company currently plans to adopt the provisions of this ASU on the effective date. However, it reserves the right to early adopt these provisions.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740)*: *Simplifying the Accounting for Income Taxes*. The Board issued this update as part of its Simplification Initiative to improve areas of GAAP and reduce cost and complexity while maintaining usefulness of the financial statements. The main provisions remove certain exceptions, including the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. In addition, the amendments simplify income tax accounting in the areas such as income-based franchise taxes, eliminating the requirements to allocate consolidated current and deferred tax expense in certain instances and a requirement that an entity reflects the effect of enacted changes in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. For public companies, the standard is effective for fiscal years beginning after December 15, 2020, and interim periods therein, with early adoption permitted. The Company plans to adopt this ASU on the effective date of January 1, 2021. The amendments in the update related to foreign subsidiaries will be applied on a modified retrospective basis, the amendments to franchise taxes will be applied on either a retrospective or modified retrospective basis and all other amendments will be applied on a prospective basis. Because the Company's deferred tax assets and liabilities are fully reserved, it does not expect a material impact from the adoption of this standard.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13 Fair Value Measurement (Topic 820) intended to improve the effectiveness of disclosures around fair value measurements in the notes to financial statements. The ASU affects all entities that are required to make disclosures about recurring or nonrecurring fair value measurements. The amendments in this Update modify the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The Company early adopted certain provisions of this ASU upon issuance during the third quarter of 2018 and revised its disclosures to omit the disclosures removed by this ASU on a retrospective basis. As provided by the ASU, the Company elected to delay adoption of the additional disclosures until January 1, 2020, which include the range and weighed average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty until their effective date. Upon the effective date, the additional disclosures have been included on a prospective basis in the Company's financial statements, as applicable. Because much of this information was disclosed prior to adoption this guidance did not have a substantial impact to the Company's disclosures in the notes to its financial statements and had no impact on the Company's consolidated financial statements.

3. Warrants and Derivative Liabilities

Warrants

There are significant judgments and estimates inherent in the determination of the fair value of the Company's warrants. These judgments and estimates include assumptions regarding the Company's future operating performance, the time to completing a liquidity event and the determination of the appropriate valuation methods. If the Company had made different assumptions, the fair value of the warrants could have been significantly different (See Note 2).

Warrants vested and outstanding as of December 31, 2020 are summarized as follows:

Source	Exercise Price	Term (Years)	Number of Warrants Vested and Outstanding
Pre 2015 Common Stock Warrants	$ 1.00	6-10	1,110,000
2015 Common Stock Warrants	$ 5.00	5-10	100,000
2016 Common Stock Warrants to Service Providers	$ 1.15	10	40,000
2016 Series C Common Stock Warrants to Placement Agent	$ 0.40	5	125,000
2017 Series D Common Stock Warrants to Placement Agent	$ 0.25	5	480,000
2017 Common Stock Warrants to Service Provider	$ 0.41	5	125,000
2018 Emerald Financing Warrants	$ 0.10	5	3,400,000
Emerald Multi-Draw Credit Agreement Warrants	$ 0.50	5	7,500,000
2019 Common Stock Warrants	$ 0.35	5	8,000,000
2020 Common Stock Warrants	$ 0.06	5	116,666,668
2020 Common Stock Warrants to Placement Agent	$ 0.075	4.99	8,166,667
2020 Pre-Funded Warrants	$ 0.001	Indefinite	11,800,000
Total warrants vested and outstanding as of December 31, 2020			**157,513,335**

August 2020 Financing Warrants

In connection with the August 2020 Financing (Note 5), the Company issued 116,666,668 common stock warrants, 8,166,667 common stock warrants to the placement agent and 60,333,334 pre-funded warrants. The warrants were equity classified at issuance and of the $6,939,667 in gross proceeds, the Company allocated $2,767,767 and $2,146,997 of the gross proceeds to the common stock warrants and pre-funded warrants on a relative fair value basis, respectively. The remaining $2,024,903 was allocated to the common stock. The warrants issued to the placement agent were valued at $261,333 and recorded as equity issuance costs within equity. The warrants vested immediately and were valued utilizing the Black-Scholes option pricing model with the following assumptions:

	Common Stock Warrants	Pre-funded Warrants	Placement Agent Warrants
Dividend yield	0.00%	0.00%	0.00%
Volatility factor	91.64%	93.86%	91.64%
Risk-free interest rate	0.19%	0.52%	0.19%
Expected term (years)	5.0	10	4.99
Underlying common stock price	$ 0.05	$ 0.05	$ 0.05

2019 Common Stock Warrants

During the year ended December 31, 2019, the Company issued 8,000,000 fully vested common stock warrants to investors, in conjunction with the November 2019 Common Stock Offering discussed below (See Note 5). The warrants are equity classified at issuance and the Company allocated an aggregate of $722,208 of the gross proceeds to the warrants on a relative fair value basis. The warrants vested immediately and had an estimated aggregate fair value of $1,130,400 utilizing the Black-Scholes option pricing model with the following assumptions:

	At Issuance
Dividend yield	0.00%
Volatility factor	93.08%
Risk-free interest rate	1.62%
Expected term (years)	5.0
Underlying common stock price	$ 0.22

Emerald Multi-Draw Credit Agreement Warrants

During the year ended December 31, 2019, the Company issued 5,000,000 fully vested common stock warrants to Emerald Health Sciences, in conjunction with advances under the Credit Agreement discussed below (See Note 4). The warrants are equity classified at issuance and the Company allocated an aggregate of $716,110 of the gross proceeds to the warrants on a relative fair value basis. The proceeds allocated to the warrants were recorded as discounts to each advance and are being amortized over the term of the debt. The warrants vested immediately and had an estimated aggregate fair value of $1,830,573 utilizing the Black-Scholes option pricing model with the following assumptions:

	At Issuance
Dividend yield	0.00%
Volatility factor	91.6-92.1%
Risk-free interest rate	2.23-2.51%
Expected term (years)	5.0
Underlying common stock price	$0.33-0.69

Derivative Liabilities

The following tables summarize the activity of derivative liabilities for the periods indicated:

	Year Ended December 31, 2020				
	December 31, 2019, Fair Value of Derivative Liabilities	**Fair Value of Derivative Liabilities Issued**	**Change in Fair value of Liabilities**	**Reclassification of Derivatives to Equity**	**December 31, 2020, Fair Value of Derivative Liabilities**
Emerald Multi-Draw Credit Agreement - compound derivative liability [1]	$ 90,797	$ -	$ (90,797)	$ -	$ -
Emerald Financing - warrant liability [2]	276,024	-	(237,457)	-	38,567
Series B - warrant liability [3]	134,579	-	(108,016)	(26,563)	-
Total derivative liabilities	**$ 501,400**	**$ -**	**$ (436,270)**	**$ (26,563)**	**$ 38,567**
Less, noncurrent portion of derivative liabilities	(90,797)				-
Current balance of derivative liabilities	**$ 410,603**				**$ 38,567**

	Year Ended December 31, 2019				
	December 31, 2018, Fair Value of Derivative Liabilities	Fair Value of Derivative Liabilities Issued	Change in Fair value of Liabilities	Reclassification of Derivatives to Equity or Extinguishment	December 31, 2019, Fair Value of Derivative Liabilities
Emerald Multi-Draw Credit Agreement - compound derivative liability [1]	$ 219,453	$ 516,058	$ (484,147)	$ (160,567)*	$ 90,797
Emerald Financing - warrant liability [2]	15,251,413	-	(9,042,066)	(5,933,323)	276,024
Series B - warrant liability [3]	487,500	-	(208,546)	(144,375)	134,579
Total derivative liabilities	**$ 15,958,366**	**$ 516,058**	**$ (9,734,759)**	**$ (6,238,265)**	**$ 501,400**
Less, noncurrent portion of derivative liabilities	(219,453)				(90,797)
Current balance of derivative liabilities	**$ 15,738,913**				**$ 410,603**

**This amount has been included in the calculation of the extinguishment loss recorded in connection with the prepayment of the Emerald Credit Agreement as described in Note 4 below.*

Emerald Multi-Draw Credit Agreement Compound Derivative Liability (1)

In connection with the advances under the Credit Agreement (See Note 4), the Company bifurcated a compound derivative liability related to a contingent interest feature and acceleration upon default provision (contingent put option) provided to Emerald Health Sciences. The Company's estimate of fair value of the compound derivative liability was determined by using a differential cash flows valuation model, wherein the fair value of the underlying debt facility and its conversion right are estimated both with and without the presence of the contingent interest feature, holding all other assumptions constant. The resulting difference between the estimated fair values in both scenarios is the estimated fair value of the compound derivative. The fair value of the underlying debt facility was estimated by calculating the expected cash flows with consideration of the estimated probability of a change in control transaction, defined as an event of default by the agreement, and applying the expected default interest rate from the date of such default through maturity. The expected cash flows are then discounted back to the reporting date using a benchmark market yield. The conversion right component of the compound derivative was measured using a standard Black-Scholes Option Pricing model for each payment period.

On April 29, 2020, the Company entered into the Amended Credit Agreement which removed the change in control provision as an event of default for advances before and after the amendment. As a result of the modification, the contingent interest feature component of the compound derivative is no longer required to be bifurcated as a derivative liability. During the year ended December 31, 2020, the liability has been reduced to $0 through an adjustment to the change in fair value of derivative liabilities.

Because Emerald Health Sciences would forgo the contingent interest if the contingent put option was exercised upon an event of default, the value ascribed to the contingent put option within the compound derivative is considered de minimis before and after the amendment to the Credit Agreement.

Emerald Financing Warrant Liability (2)

In January and February 2018, the Company issued 44,200,000 warrants to purchase common stock in conjunction with the Emerald Financing. The warrants vest immediately and have an exercise price of $0.10 per share with a term of five years and are exercisable in cash or through a cashless exercise provision. The warrants contained an anti-dilution protection feature that provided the investors with price protection if the Company subsequently issued or sold any shares of common stock, stock options, or convertible securities at a price less than the exercise price of $0.10. In connection with the August 2020 Financing, this provision was waived, and the exercise price was permanently set to $0.10. In addition, the warrants contain a contingent put option if the Company undergoes a subsequent financing that results in a change in control. The warrant holders also have the right to participate in subsequent financing transactions on an as-if converted basis.

In December 2019, Emerald Health Sciences paid the aggregate exercise price of $4,080,000 in the form of a reduction of the corresponding amount of obligations outstanding under the Credit Agreement to exercise 40,800,000 Emerald Financing Warrants. Under the Warrant Exercise Agreement between the Company and Emerald Health Sciences, the proceeds from the warrants were first applied directly to the accrued interest balance at the exercise date with the remainder applied to the oldest outstanding principal balances under the Credit Agreement. Immediately prior to exercise, the warrants were adjusted to fair value which considered the closing trading price on the exercise date (See Note 4).

The Company reviewed the warrants for liability or equity classification under the guidance of ASC 480-10, *Distinguishing Liabilities from Equity*, and concluded that the warrants should be classified as a liability and re-measured to fair value at the end of each reporting period. The Company also reviewed the warrants under ASC 815, *Derivatives and Hedging/Contracts in Entity's Own Equity*, and determined that the warrants also meet the definition of a derivative. With the assistance of a third party valuation specialist, the Company valued the warrant liabilities utilizing the Monte Carlo valuation method pursuant to the accounting guidance of ASC 820-10, *Fair Value Measurement*s.

The warrant liabilities were valued using Monte Carlo simulations conducted at the balance sheet dates using the following assumptions:

	As of December 31,	
	2020	**2019**
Dividend yield	0.00%	0.00%
Volatility factor	90.9%	79.5%
Risk-free interest rate	0.14%	1.62%
Expected term (years)	2.13	3.13
Underlying common stock price	$ 0.04	$ 0.13

Series B Warrant Liability (3)

In conjunction with the Redeemable Convertible Series B Preferred Stock financing, the Company issued the 2015 Series B Common Stock Warrants originally exercisable at a price of $1.15 per share. The warrants were exercisable in cash or through a cashless exercise provision and contain certain cash redemption rights. The Series B Common Stock Warrants also had a "down-round" protection feature if the Company subsequently issued or sold any shares of common stock, stock options, or convertible securities at a price less than the current exercise price. The down round provision was triggered and automatically adjusted down to $0.10 on December 28, 2017, after the Company entered into the Convertible Promissory Note (See Note 4) and the strike price was permanently reset to $0.00 on January 19, 2018, as a result of the Emerald Financing. However, because the remaining warrant holders still had certain cash redemption rights upon the occurrence of certain fundamental transactions, as defined in the Series B Common Stock Warrant agreements, the warrants continued to require liability classification. After the Emerald Financing repricing occurred, the warrants were valued using a Black Scholes Option Pricing Model.

To compute the fair value of the warrants, the Company utilized the following assumptions in the Black Scholes Merton Option Pricing Model:

	As of December 31, 2019
Dividend yield	0.00%
Volatility factor	79.2%
Risk-free interest rate	1.60%
Expected term (years)	0.64
Underlying common stock price	$ 0.13

During the year ended December 31, 2020, 312,500 Series B Common Stock Warrants with an intrinsic value of $26,563 were exercised for no consideration per share, which resulted in the issuance of 312,500 shares of common stock. Prior to exercise, these Series B Common Stock Warrants were adjusted to fair value using a Black Scholes Merton Option Pricing Model which considered the closing trading price on the exercise dates. Because the exercise price of these options was reset to $0.00, the fair value derived from the valuation model approximated the market value of the Company's common stock on the exercise dates.

As of December 31, 2020, the remaining Series B Common Stock Warrants expired unexercised.

4. Debt

Multi-Draw Credit Agreement- Related Party

The Company's Debt with Emerald Health Sciences consists of the following:

		As of December 31,	
	Conversion Price	2020	2019
Total principal value of convertible debt—related party	$ 0.40	$ 2,014,500	$ 2,014,500
Unamortized debt discount		(1,079,821)	(1,622,344)
Unamortized debt issuance costs		(3,576)	(5,086)
Carrying value of total convertible debt - related party		**931,103**	**387,070**
Total principal value of non-convertible debt—related party	n/a	450,000	-
Total carrying value of advances under the multi-draw credit agreement		**$ 1,381,103**	**$ 387,070**

On October 5, 2018, the Company entered into the Credit Agreement with Emerald Health Sciences, a related party (See Note 11). On April 29, 2020, the Company entered into the Amended Credit Agreement with Emerald Health Sciences, which amends and restates the Credit Agreement. For all pre-existing and new advances, the Amended Credit Agreement removed the change in control as an event of default (See Note 3) and defers the quarterly payment of interest until the Company completes a capital raise of at least $5,000,000. As of August 2020, interest is no longer being deferred as a result of the August 2020 Financing. The amendments to the pre-existing advances were accounted for as a modification. For all advances made after the Credit Agreement was amended, advances will be convertible at a reduced conversion price of $0.25 per share of Common Stock, unless Emerald Health Sciences provides notice that the advance will not be convertible.

For all outstanding advances, the Amended Credit Agreement provides for a credit facility to the Company of up to $20,000,000 and is unsecured. Advances under the Amended Credit Agreement bear interest at an annual rate of 7% and mature on October 5, 2022. At Emerald Health Sciences' election, convertible advances and unpaid interest may be converted into common stock at the fixed conversion price of the underlying advance, subject to customary adjustments for stock splits, stock dividends, recapitalizations, etc. As of December 31, 2020, the unused portion of the credit facility is $13,550,000. The Company does not consider the facility available until advance requests are approved, drawn down and funded. The Amended Credit Agreement is still in place; however, there is no guarantee of continued funding under the Amended Credit Agreement.

The Amended Credit Agreement provides for customary events of default which may result in the acceleration of the maturity of the advances in addition to, but not limited to, cross acceleration to certain other indebtedness of the Company. In the case of an event of default arising from specified events of bankruptcy or insolvency or reorganization, all outstanding advances will become due and payable immediately without further action or notice. If any other event of default under the Amended Credit Agreement occurs or is continuing, Emerald Health Sciences may, by written notice, terminate its commitment to make any advances and/or declare all the advances with any other amounts payable due immediately. If any amount under the Amended Credit Agreement is not paid when due, such overdue amount shall bear interest at an annual default interest rate of the applicable rate plus 10%, until such amount is paid in full.

In connection with each advance under the Amended Credit Agreement, the Company has agreed to issue to Emerald Health Sciences warrants to purchase shares of common stock in an amount equal to 50% of the number of shares of common stock that each advance may be converted into. The warrants have a term of five years that are immediately exercisable upon issuance. Under the Amended Credit Agreement, Emerald Health Sciences may issue notice that no warrants will be granted at the time of the advance request. The warrants issued under the Credit Agreement have an exercise price of $0.50 per share and any warrants issued under the Amended Credit Agreement will have a reduced exercise price of $0.35 per share. The exercise prices are subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events or upon any distributions of assets, including cash, stock or other property to the Company's stockholders (See Note 3).

In accounting for each advance and the warrants issued under the Amended Credit Agreement, the Company allocates the proceeds between the debt host and the freestanding warrants on a relative fair value basis for each advance. On the date of each advance, if the effective conversion rate of the debt is less than the market value of the Company's common stock, the Company records a beneficial conversion feature as a discount to the debt and an increase to additional paid-in capital. The debt discounts related to the warrants, beneficial conversion features and compound derivatives, if any, are being amortized over the term of the Amended Credit Agreement using the effective interest rate method. Amortization of the debt discount is recognized as non-cash interest expense and the compound derivatives related to the contingent interest feature and acceleration upon default provision were remeasured at fair value in subsequent periods in the Company's Consolidated Balance Sheets.

On November 1, 2018, an initial advance was made for $2,000,000 and the Company issued 2,500,000 warrants with an exercise price of $0.50 per share (See Note 3). In accounting for the convertible advance and warrants under the Credit Agreement, $1,684,920 of the proceeds was allocated to the debt and $315,080 was allocated to equity classified warrants. A beneficial conversion feature of $90,080 and a compound derivative liability of $204,102 were also recorded.

During the year ended December 31, 2019, the Company initiated two advances, each in the amount of $2,000,000, for an aggregate principal amount of $4,000,000, and the Company issued an aggregate of 5,000,000 warrants with an exercise price of $0.50 per share (See Note 3). In accounting for the convertible advances and warrants, an aggregate amount of $3,283,890 was allocated to the debt and $716,110 was allocated to equity classified warrants. A beneficial conversion feature of $1,584,850 and compound derivative liabilities of an aggregate of $516,058 were recorded (See Note 3). Of the $516,058 in compound derivatives, $322,644 was recorded as other expense in the Consolidated Statements of Comprehensive (Loss) Income for the year ended December 31, 2019, as the value of the beneficial conversion feature exceeded the proceeds allocated to the third draw.

During the year ended December 31, 2019, the Company used $3,985,500 in proceeds from the exercise of the 2018 Emerald Financing Warrants to prepay a portion of the outstanding principal balance. In connection with the prepayment, the Company recorded an extinguishment loss of $725,425 in the fourth quarter of 2019. The extinguishment loss was calculated as the difference between the fair value of the consideration paid to extinguish the debt and carrying value of the debt host plus the related compound derivative liability.

During the year ended December 31, 2020, the Company effected a fourth and fifth advances in the amounts of $150,000 and $300,000, respectively. Emerald Health Sciences has elected that the fourth and fifth advances will not be convertible into shares of the Company's common stock and gave notice to the Company that no warrants will be issued in connection with the advances.

Aggregate financing costs of $63,007 have been incurred and are recorded as a discount to the debt host and are being amortized using the effective interest rate method and recognized as non-cash interest expense over the term of the Amended Credit Agreement.

For the years ended December 31, 2020 and 2019, the effective interest rate related to the convertible portion of the Amended Credit Agreement was 98.01% and 32.05%, respectively. As of December 31, 2020, the unamortized debt discount on the convertible advances will be amortized over a remaining period of approximately 1.76 years. As of December 31, 2020, the fair value of the shares underlying the convertible advances under the Amended Credit agreement was $201,450. As of December 31, 2020, the if-converted value did not exceed the principal balance.

PPP Loan

On April 24, 2020, the Company received funding from the PPP Loan Lender pursuant to the PPP of the CARES Act administered by the SBA for a principal amount of $116,700. The PPP Loan matures on April 24, 2022 and bears interest at a rate of 1.00% per year. Interest and principal are payable monthly commencing on the date the amount of forgiveness determined under section 1106 of the CARES Act is remitted to the Company, but in no event ten months after the last day of the covered period if the Company fails to apply for loan forgiveness. The PPP Loan may be prepaid at any time prior to maturity with no prepayment penalties. Funds from the PPP Loan may only be used by the Company for payroll costs, costs for continuing group healthcare benefits, mortgage interest payments, rent, utility and interest on any other debt obligations that were incurred before October 9, 2020.

All or a portion of the principal from the PPP Loan may be forgiven by the SBA and the PPP Loan Lender upon application by the Company within 60 days but not later than 120 days after loan approval and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, and covered utilities during an eight-week period, or a longer period if elected by the Company, commencing on the date of loan approval. For purposes of the CARES Act, payroll costs exclude compensation of an individual employee in excess of $100,000, prorated annually. Not more than 40% of the forgiveness amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages of employees with salaries of $100,000 or less annually are reduced by more than 25%. After approval of the forgiveness amount and deferral period, the PPP Loan Lender will provide the Company with written notification of re-amortization of the PPP Loan and the remaining balance.

Interest Expense

The Company's interest expense consists of the following:

	Year Ended December 31,	
	2020	**2019**
Related party interest expense – stated rate	$ 161,546	$ 371,420
PPP loan interest expense – stated rate	806	-
Non-cash interest expense:		
Amortization of debt discount	542,523	616,383
Amortization of transaction costs	1,510	12,910
	$ 706,385	**$ 1,000,713**

5. Stockholders' Equity and Capitalization

Common Stock

August 2020 Financing

On July 31, 2020, the Company entered into a Securities Purchase Agreement with certain institutional investors for the issuance and sale of securities, with H.C. Wainwright & Co., LLC acting as the placement agent, pursuant to which the Company sold 56,333,334 common units, each consisting of one share of common stock and one warrant to purchase one share of common stock, and 60,333,334 pre-funded units, each consisting of one pre-funded warrant to purchase one share of common stock and one warrant to purchase one share of common stock, in a registered public offering which closed on August 4, 2020 (the "August 2020 Financing"). The common units and pre-funded units were sold at a price per unit of $0.06 and $0.059, respectively, for gross aggregate proceeds of $6,939,667. The common stock warrants and prefunded warrants have an exercise price of $0.06 and $0.001, respectively. The common stock warrants have a term of five years, and the pre-funded warrants are exercisable until all the pre-funded warrants have been exercised in full (Note 3).

In connection with the August 2020 Financing, the Company incurred issuance costs of $854,078, for net proceeds of $6,085,589. Additionally, the Company issued warrants to purchase 8,166,667 shares of common stock to the placement agent, which represent 7% of the total shares of common stock and pre-funded warrants sold in the offering. The placement agent warrants have an exercise price of $0.075 per share and a term of five years.

November 2019 Common Stock Offering

In November 2019, the Company sold in a registered direct offering an aggregate of 8,000,000 shares of its common stock, par value $0.001 per share, and warrants to purchase 8,000,000 shares of common stock (Note 3). The aggregate net proceeds of the transaction were $1,919,372.

Warrant Exercises

During the year ended December 31, 2020, the Pre-Funded Warrant holders exercised 48,533,334 warrants with an intrinsic value of $2,104,667, which resulted in the issuance of 48,533,334 shares of common stock.

During the year ended December 31, 2020, the Series B Warrant holders exercised 312,500 warrants with an intrinsic value of $26,563, which resulted in the issuance of 312,500 shares of common stock.

During the year ended December 31, 2019, Emerald Health Sciences exercised 40,800,000 2018 Emerald Financing Warrants with an intrinsic value of $4,284,000, which resulted in the issuance of 40,800,000 shares of common stock.

During the year ended December 31, 2019, the Series B Common Stock Warrant holders exercised 187,500 warrants with an intrinsic value of $144,375, which resulted in the issuance of 187,500 shares of common stock.

6. Stock-Based Compensation

Stock Incentive Plan

On October 31, 2014, after the closing of the Merger, the Board approved the Company's 2014 Omnibus Incentive Plan (the "2014 Plan"). The 2014 Plan initially reserved 3,200,000 shares for future grants. In October 2018, the Company increased the share reserve under the 2014 Plan to equal 10% of the number of issued and outstanding shares of common stock of the Company. In August 2020, the Company approved Amendment No. 2 to the 2014 Plan, which increased the share reserve by an additional 7,876,835 shares over the 10% of the number of issued and outstanding shares of common stock and removed certain restrictions on the number of shares of common stock and the amount of cash-based awards up to which participants of the 2014 Plan can receive in a calendar year. The 2014 Plan authorizes the issuance of awards including stock options, stock appreciation rights, restricted stock, stock units and performance units to employees, directors, and consultants of the Company. As of December 31, 2020, the shares available for future grant under the 2014 Plan are as follows:

	Shares Available for Grant
Available as of December 31, 2019	**13,128,381**
Share pool increase	18,394,752
Forfeited	1,837,407
Cancelled	5,830,235
Granted	(26,400,000)
Available as of December 31, 2020	**12,790,775**

Stock Options

Options granted under the 2014 Plan expire no later than ten years from the date of grant. Options granted under the 2014 Plan may be either incentive or non-qualified stock options. For incentive and non-qualified stock option grants, the option price shall be at least 100% of the fair value on the date of grants, as determined by the Company's Board of Directors. If at any time the Company grants an option, and the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant.

Options granted under the 2014 Plan may be immediately exercisable if permitted in the specific grant approved by the Board of Directors and, if exercised early may be subject to repurchase provisions. The shares issued generally vest over a period of one to five years from the date of grant.

The following is a summary of option activities under the Company's 2014 Plan for the year ended December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value*
Outstanding, December 31, 2019	**3,317,642**	**$ 0.33**	**8.34**	
Granted	26,400,000	0.05		
Cancelled	(5,830,235)	0.07		
Forfeited	(1,837,407)	0.26		
Outstanding, December 31, 2020	**22,050,000**	**$ 0.06**	**9.52**	**$ -**
Exercisable, December 31, 2020	**3,465,000**	**$ 0.15**	**8.88**	**$ -**
Vested and expected to vest, December 31, 2020	**22,050,000**	**$ 0.06**	**9.52**	**$ -**

**The aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company's stock exceeded the exercise price of the stock options at December 31, 2020 for those stock options for which the quoted market price was in excess of the exercise price ("in-the-money options").*

The weighted-average grant-date fair value of stock options granted for the years ended December 31, 2020 and 2019 was $0.04 and $0.22, respectively. The total fair value of the stock options that vested during the years ended December 31, 2020 and 2019 was $168,168 and $473,030, respectively.

The fair value of each stock option grant was estimated on the date of grant using the Black-Scholes option-pricing model under the following assumptions:

	Year Ended December 31,	
	2020	2019
Dividend yield	0.00%	0.00%
Risk-free interest rate	0.28-0.46%	1.49%
Expected term (years)	5.65-6.13	5.65
Volatility	92.51-107.87%	93.72%

Restricted Stock Awards

During the year ended December 30, 2020, 643,501 restricted stock awards ("RSAs") with a weighted average grant date fair value of $0.26 vested and were released from their service condition restriction. As of December 31, 2020, there are no unvested RSA awards outstanding under the 2014 Plan.

There was no restricted stock award ("RSA") activity under the Company's 2014 Plan during the year ended December 31, 2019.

Awards Granted Outside the 2014 Plan

Options

During the year ended December 31, 2020, 325,929 stock options with a weighted average exercise price of $0.25 were forfeited in connection with the separation and release of the Company's former CFO. As of December 31, 2020, an additional 869,144 options vested and outstanding with a weighted average exercise price of $0.25 were cancelled unexercised.

There was no option activity outside of the 2014 Plan during the year ended December 31, 2019.

The total fair value of stock options that vested during the years ended December 31, 2020 and 2019 were $18,252 and $54,756, respectively.

Restricted Stock Awards

The following is a summary of RSA activity outside of the Company's 2014 Plan during the year ended December 31, 2020:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2019	**450,000**	**$ 0.19**
Granted	-	-
Released	(450,000)	0.19
Unvested, December 31, 2020	**-**	**$ -**

Stock-Based Compensation Expense

The Company recognizes stock-based compensation expense using the straight-line method over the requisite service period. The Company recognized stock-based compensation expense, including compensation expense for RSAs discussed above, in its Consolidated Statements of Comprehensive (Loss) Income as follows:

	Year Ended December 31,	
	2020	2019
Research and development	$ 93,545	$ -
General and administrative	209,197	680,455
	$ 302,742	**$ 680,455**

The total amount of unrecognized compensation cost was $688,410 as of December 31, 2020. This amount will be recognized over a weighted-average period of 3.79 years.

7. Net (Loss) Income Per Share of Common Stock

The following tables are a reconciliation of the numerators and denominators used in the calculation of basic and diluted net (loss) income per share computations:

	For the Year Ended December 31, 2020		
	Loss (Numerator)	Shares (Denominator)	Per-Share Amount
Net loss	$ (6,560,699)		
Basic EPS			
Loss available to common stockholders	(6,560,699)	230,746,878	**$ (0.03)**
Effect of Dilutive Securities			
Warrants – liability classified	(345,473)	674,095	
Diluted EPS			
Loss available to common stockholders + assumed conversions	$ (6,906,172)	231,420,973	**$ (0.03)**

	For the Year Ended December 31, 2019		
	Income (Numerator)	Shares (Denominator)	Per-Share Amount
Net income	$ 1,051,825		
Basic EPS			
Income available to common stockholders	1,051,825	135,154,931	**$ 0.01**
Effect of Dilutive Securities			
Unvested restricted stock		858,856	
Options		392,784	
Warrants		447,431	
Warrants – liability classified	(9,250,612)	32,706,263	
Diluted EPS			
Loss available to common stockholders + assumed conversions	$ (8,198,787)	169,560,265	**$ (0.05)**

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been anti-dilutive:

	Year Ended December 31,	
	2020	2019
Stock options	22,050,000	4,119,931
Unvested restricted stock	-	234,645
Common shares underlying convertible debt	5,126,343	5,036,250
Warrants	145,039,240	20,712,000

8. Income Taxes

The components of (loss) income before the income tax provision consist of the following:

	Year Ended December 31,	
	2020	2019
United States	$ (6,556,280)	$ 1,120,521
Foreign	(2,819)	(67,096)
Pre-tax (loss) income from operations	**$ (6,559,099)**	**$ 1,053,425**

The Company is subject to taxation in the United States, California and Australia. The Company's tax years for 2017 (federal), 2016 (California) and 2019 (Australia) and forward are subject to examination by the United States, California and Australia tax authorities. However, to the extent allowed by law, the taxing authorities may have the right to examine periods where NOLs and credits were generated and carried forward and make adjustments up to the amount of the NOL and credit carryforwards. The Company is not currently under examination by any jurisdiction.

At December 31, 2020, the Company had federal and California NOLs aggregating $30,475,657 and $30,310,672, respectively. If not used, $13,213,037 of Federal NOLs and $30,310,672 of state NOLs will begin to expire in 2033. $17,262,620 of federal NOLs will carry forward indefinitely subject to an 80% limitation against taxable income. At December 31, 2020, the Company had Australia NOLs aggregating $43,349 which do not expire.

At December 31, 2020, the Company had federal and California research credit carryforwards of approximately $76,632 and $40,528, respectively. The federal research credit carry forwards will begin to expire in 2040, unless previously utilized and the California research credits will carry forward indefinitely. The Company's NOLs and research credit carryforwards are subject to a reserve.

Utilization of the domestic NOL will be subject to a substantial annual limitation due to ownership change limitations that may have occurred, or that could occur in the future, as required by Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOLs that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders.

Upon the occurrence of an ownership change under Section 382 as outlined above, utilization of the NOLs are subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL before utilization. While the Company has not performed a Section 382 study, multiple ownership changes may have already occurred as the Company raised capital through the issuance of stock. However, due to the existence of the valuation allowance for deferred tax assets, any potential change in ownership will not impact the Company's effective tax rate.

The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred income tax assets are as follows:

	As of December 31,	
Current deferred tax assets/(liabilities):	**2020**	**2019**
State taxes	$ 336	$ 336
Amortization	180	-
Research and development credits	54,324	-
Other	83,056	112,222
Net operating loss	7,679,216	6,434,544
Gross deferred tax assets	**7,817,112**	**6,547,102**
Valuation allowance	(7,590,215)	(6,206,450)
Net deferred tax assets	**$ 226,897**	**$ 340,652**
Deferred tax liabilities		
Note discount	$ (226,897)	$ (340,652
Total deferred tax liabilities	**(226,897)**	**(340,652**
Net deferred tax assets	**$ -**	**$ -**

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2020 and 2019, due to the following:

	As of December 31,	
	2020	**2019**
Expected income tax benefit at federal statutory tax rate	$ (1,377,411)	$ 221,219
State income taxes, net of federal benefit	(415,249)	(434,881)
Change in fair value of warrants	(72,549)	(1,874,873)
Change in valuation allowance	1,383,765	1,469,187
Uncertain tax positions	470,838	436,145
Change in compound derivative	-	(101,671)
Loss on extinguishment of debt	33,925	117,198
Stock compensation	64,273	121,289
Rate adjustment	(108,649)	49,338
Other permanent difference	22,657	(1,351)
Provision for income taxes	**$ 1,600**	**$ 1,600**

The Company records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the substantial doubt related to the Company's ability to utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at December 31, 2020. As a result of this valuation allowance, there are no income tax benefits reflected in the accompanying statement of operations to offset pre-tax losses. During the year ended December 31, 2020, the valuation allowance increased by $1,383,765.

The Tax Cuts and Jobs Act of 2017 subjects a U.S. shareholder to tax on global intangible low-taxed income ("GILTI") earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company elects to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only.

On March 27, 2020, the CARES Act was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. Due to the Company's history of net operating losses, the CARES Act is not expected to have a material impact on the Company's financial statements.

On April 22, 2020, when the Company entered into the PPP Loan with the PPP Loan Lender (Note 4). In accordance with the Consolidated Appropriations Act, 2021 enacted on December 27, 2020, certain qualified expenses used with the funds of the PPP Loan are fully deductible for Federal income tax purposes. Additionally, should the Company receive forgiveness of the PPP loan in the future, the amount will not be considered taxable for Federal income tax purposes.

Under the FASB's accounting guidance related to income tax positions, among other things, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, the guidance provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

A reconciliation of the beginning and ending amounts of unrecognized tax positions are as follows:

	As of December 31,	
	2020	**2019**
Unrecognized tax positions, beginning of the year	$ 552,082	$ -
Gross increase - current period tax positions	585,812	552,082
Gross decrease – prior period tax positions	(3,721)	
Unrecognized tax positions, end of year	**$ 1,134,173**	**$ 552,082**

If recognized, none of the unrecognized tax positions would impact the Company's income tax benefit or effective tax rate as long as the Company's net deferred tax assets remain subject to a full valuation allowance. The Company does not expect any significant increases or decreases to the Company's unrecognized tax positions within the next twelve months.

The Company had no accrual for interest or penalties on the Company's Balance Sheets at December 31, 2020 and 2019 and has not recognized interest and/or penalties in the Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2020 and 2019.

9. Other Current Liabilities

Other current liabilities consist of the following:

	As of December 31,	
	2020	**2019**
Accrued payroll liabilities	61,547	43,830
Accrued research and development costs	93,888	148,006
Accrued legal expense	57,596	92,237
Accrued board fees	40,625	58,395
Total other accrued liabilities	5,455	77,938
	$ 259,111	**$ 420,406**

10. Significant Contracts - University of Mississippi

UM 5050 Prodrug and UM 8930 Analog Agreements

In July 2018, the Company renewed its ocular licenses for UM 5050, related to the prodrug formulation of tetrahydrocannabinol ("THC"), and UM 8930, related to an analog formulation of cannabidiol ("CBD"). On May 24, 2019, the ocular delivery licenses were replaced by "all fields of use" licenses for both UM 5050 and UM 8930 (collectively, the "License Agreements"). Pursuant to the License Agreements, UM granted the Company an exclusive, perpetual license, including, with the prior written consent of UM, the right to sublicense, the intellectual property related to UM 5050 and UM 8930 for all fields of use.

The License Agreements contain certain milestone payments, royalty and sublicensing fees payable by the Company, as defined therein. Each License Agreement provides for an annual maintenance fee of $75,000 payable on the anniversary of the effective date. The Company made upfront payments for UM 5050 and UM 8930 of $100,000 and $200,000, respectively. In addition, in March 2020, the Company was notified by the United States Patent and Trademark Office, that a notice of allowance was issued for the proprietary analog of cannabidiol, CBDVHS, under the UM 8930 License Agreement. As a result, the Company was required to pay UM a fee of $200,000. The milestone payments payable for each license are as follows:

i) $100,000 paid within 30 days following the submission of the first Investigational New Drug Application ("NDA") to the Food and Drug Administration or an equivalent application to a regulatory agency anywhere in the world, for a product;

ii) $200,000 paid within 30 days following the first submission of an NDA, or an equivalent application to a regulatory agency anywhere in the world, for each product that is administered in a different route of administration from that of the early submitted product(s); and

iii) $400,000 paid within 30 days following the approval of an NDA, or an equivalent application to a regulatory agency anywhere in the world, for each product that is administered in a different route of administration from that of the early approved product(s).

The royalty percentage due on net sales under each License Agreement is in the mid-single digits. The Company must also pay to UM a portion of all licensing fees received from any sublicensees, subject to a minimum royalty on net sales, and the Company is required to reimburse patent costs incurred by UM related to the licensed products. The royalty obligations apply by country and by licensed product, and end upon the later of the date that no valid claim of a licensed patent covers a licensed product in a given country, or ten years after the first commercial sale of such licensed product in such country.

Each License Agreement continues, unless terminated, until the later of the expiration of the last to expire of the patents or patent applications within the licensed technology or the expiration of the Company's payment obligations under such License Agreement. UM may terminate each License Agreement, by giving written notice of termination, upon the Company's material breach of such License Agreement, including failure to make payments or satisfy covenants, representations or warranties without cure, noncompliance, a bankruptcy event, the Company's dissolution or cessation of operations, the Company's failure to make reasonable efforts to commercialize at least one product or failure to keep at least one product on the market after the first commercial sale for a continuous period of one year, other than for reasons outside the Company's control, or the Company's failure to meet certain pre-established development milestones. The Company may terminate each License Agreement upon 60 days' written notice to UM.

As of December 31, 2020, with the exception of the fee due for the notice of allowance for CBDVHS, none of the other milestones under these license agreements have been met.

UM 5070 License Agreement

In January 2017, the Company entered into a license agreement with UM pursuant to which UM granted the Company an exclusive, perpetual license, including the right to sublicense, to intellectual property related to a platform of cannabinoid-based molecules ("UM 5070"), to research, develop and commercialize products for the treatment of infectious diseases.

The Company paid UM an upfront license fee of $65,000 under the license agreement. Under the license agreement, the Company is also responsible for annual maintenance fees of $25,000 that will be credited against any royalties incurred, contingent milestone payments upon achievement of development and regulatory milestones, and royalties on net sales of licensed products sold for commercial use. The aggregate milestone payments due under the license agreement if all the milestones are achieved is $700,000 and the royalty percentage due on net sales is in the mid-single digits. The Company must also pay to UM a percentage of all licensing fees we receive from any sublicensees, subject to a minimum royalty on net sales by such sublicensees. The Company's royalty obligations apply on a country by country and licensed product by licensed product basis, and end upon the later of the date that no valid claim of a licensed patent covers a licensed product in a given country, or ten years after first commercial sale of such licensed product in such country.

The license agreement continues, unless terminated, until the later of the expiration of the last to expire of the patents or patent applications within the licensed technology or expiration of the Company's payment obligations under the license. UM may terminate the license agreement, effective with the giving of notice, if: (a) the Company fails to pay any material amount payable to UM under the license agreement and do not cure such failure within 60 days after UM notifies us of such failure, (b) the Company materially breaches any covenant, representation or warranty in the license agreement and do not cure such breach within 60 days after UM notifies the Company of such breach, (c) the Company fails to comply in any material respect with the terms of the license and do not cure such noncompliance within 60 days after UM notifies us of such failure, (d) the Company is subject to a bankruptcy event, (e) the Company dissolves or ceases operations or (f) if after the first commercial sale of a product during the term of the license agreement, the Company materially fails to make reasonable efforts to commercialize at least one product or fail to keep at least one product on the market after the first commercial sale for a continuous period of one year, other than for reasons outside of the Company's control. The Company may terminate the license agreement upon 60 days' written notice to UM.

As of December 31, 2020, none of the milestones under this license agreement have been met.

11. Related Party Matters

Emerald Health Sciences

On February 1, 2018, the Company entered into an Independent Contractor Agreement with Emerald Health Sciences, pursuant to which Emerald Health Sciences agreed to provide such services as are mutually agreed between the Company and Emerald Health Sciences, including reimbursement for reasonable expenses incurred in the performance of the Independent Contractor Agreement. These services included, but were not limited to, corporate advisory services and technical expertise in the areas of business development, marketing, investor relations, information technology and product development. The Independent Contractor Agreement had an initial term of ten years and specified compensation to be agreed upon between the Company's Chief Executive Officer and Emerald Health Sciences' CEO on a month-to-month basis. The fee due under this agreement was payable on a monthly basis. Effective December 31, 2019, the Independent Contractor Agreement was terminated. As of December 31, 2020, and 2019, the Company has accrued $7,032 reimbursable expenses under the Independent Contractor Agreement which have yet to be paid. Under this agreement, no expenses were incurred for the year ended December 31, 2020. Under this agreement, for the year ended December 31, 2019, the Company incurred expenses of $542,000.

On December 17, 2019, Dr. Avtar Dhillon resigned as the Chairman of the Board and the position of Chairman of the Finance and Business Development Committee of the Board. Concurrently, the Company entered into a Board Observer Agreement with Emerald Health Sciences to allow Dr. Dhillon to continue as a representative of Emerald Health Sciences as a non-voting observer in future meetings of the Board.

On December 19, 2019, the Company entered into an Independent Contractor Services Agreement with Dr. Avtar Dhillon, pursuant to which Dr. Dhillon will provide ongoing corporate finance and strategic business advisory services to the Company. In exchange for his services, Dr. Dhillon initially received a monthly fee of $10,000, with (i) $5,000 paid each month and (ii) $5,000 accruing from the effective date and payable upon the Company's completion of a material financing. On March 30, 2020, the Company and Dr. Dhillon amended the Independent Contractor Services Agreement by agreeing to defer payment of 100% of Dr. Dhillon's consulting fees until the Board of Directors determined that the Company had been sufficiently financed to make such payments at which point the Company agreed to pay Dr. Dhillon all of his accrued consulting fees, and a bonus of 10% of his accrued consulting fees, less applicable tax and other withholdings. The deferral was paid concurrent with the August 2020 Financing. Subsequent to the August 2020 Financing Dr. Dhillon continues to receive a monthly fee of $10,000 per month for his services. The Board reviews the monthly rate paid to Dr. Dhillon within 90 days of the end of each fiscal year. The Independent Contractor Services Agreement has an initial term of one year and automatically renews thereafter unless terminated earlier by either party. The Independent Contractor Services Agreement may be terminated by either party for cause upon written notice to the other party if the other party defaults in the performance of the agreement in any material respect or materially breaches the terms of the agreement, or without cause upon 30 days' prior written notice to the other party. Under this agreement, for the years ended December 31, 2020 and 2019, the Company incurred fees of $127,387 and $3,871, respectively. As of December 31, 2020, the Company has accrued $10,000 in expense related to the Independent Contractor Services Agreement.

In addition, on August 10, 2020, Emerald Health Sciences, Inc. transferred to Dr. Avtar Dhillon 500,000 shares of the Company's common stock at a deemed price of $0.10 in exchange for the cancellation of $50,000 of debt.

As of December 31, 2020, Jim Heppell and Punit Dhillon are board members of the Company and Emerald Health Pharmaceuticals, a subsidiary of Emerald Health Sciences, Inc. As of December 31, 2020, Jim Heppell is also a board member of Emerald Health Sciences, Inc. The Company's CEO, Punit Dhillon also served as a board member of Emerald Health Sciences, Inc. until he tendered his resignation from such board on August 10, 2020.

The Company shares the same office location as Emerald Health Pharmaceuticals. However, the Company's workforce is remote, there is no written rental agreement with Emerald Health Pharmaceuticals, and no rent is being charged.

On August 10, 2020, Emerald Health Sciences, Inc. extinguished debt of $186,667 by transferring 1,566,666 shares of the Company's common stock at a deemed price of $0.10 per share to certain officers, employees and directors of the Company.

12. Contingencies

General Litigation and Disputes

From time to time, in the normal course of operations, the Company may be a party to litigation and other dispute matters and claims. Litigation can be expensive and disruptive to normal business operations. Moreover, the results of complex legal proceedings are difficult to predict. An unfavorable outcome to any legal matter, if material, could have a materially adverse effect on the Company's operations or financial position, liquidity or results of operations. As of December 31, 2020, there were no pending or threatened lawsuits or claims that could reasonably be expected to have a material effect on the Company's financial position or results of operations.

13. Subsequent Events

Emerald Health Biotechnology España, S.L.U

In January 2021, the Company entered into a Collaborative Research Agreement with Emerald Health Biotechnology España, S.L.U, a subsidiary of Emerald Health Research, Inc. which is 100% owned by Emerald Health Sciences. Under the agreement, Emerald Health Biotechnology España, S.L. will provide research and development services pursuant to an agreed upon project plan for the research and development of CBDVHS. The term of the agreement is initially for a one-year period. The agreement will terminate upon delivery and acceptance of the final deliverable under the project plan or if either party is in breach of the terms of the contract and such breach remains uncured for 45 days. Payment for services rendered will be based on time and materials billable at reasonable market rates.

Warrant Exercises

From January 1, 2021 through February 23, 2021 11,800,000 pre-funded warrants were exercised in exchange for 11,800,000 shares of common stock for gross proceeds of $11,800.

From January 1, 2021 through February 23, 2021 50,133,334 common stock warrants were exercised in exchange for 50,133,334 shares of common stock for gross proceeds of $3,008,000.

Increase to Authorized Shares of Capital Stock

On February 5, 2021, the Company increased its authorized shares of common and preferred stock to 5,000,000,000 and 50,000,000, respectively.

The following exhibits are filed with this Annual Report on Form 10-K.

Exhibit Number	Description of Exhibit
3.1 *	Articles of Incorporation of Registrant, as amended
3.2*	Amended and Restated Bylaws of Registrant
3.3	Certificate of Designation of the Relative Rights and Preferences of the Series B Preferred Stock filed with the Secretary of State of Nevada on August 19, 2015 (4)
4.1	Form of Warrants issued by Nemus to certain security holders to purchase an aggregate of 3,000,000 shares of commons stock(2)
4.2	Form of Warrants issued by Nemus to certain security holders to purchase an aggregate of 1,000,000 shares of commons stock(2)
4.3	Form of Common Stock Purchase Warrant to certain security holders to purchase shares of common stock(3)
4.4	Form of Warrant dated April 25, 2015 issued by Nemus Bioscience, Inc. to holder to purchase 100,000 shares of common stock(4)
4.5	Form of Warrant dated April 29, 2015 issued by Nemus Bioscience, Inc. to holder to purchase 90,000 shares of common stock(5)
4.6	Form of Warrant dated April 26, 2015 issued by Nemus Bioscience, Inc. to holder to purchase 6,000 shares of common stock(5)
4.7	Form of Warrant dated June 8, 2015 issued by Nemus Bioscience, Inc. to holder to purchase 10,000 shares of common stock(6)
4.8	Form of Warrant to certain security holders to purchase shares of common stock(4)
4.9	Registration Rights Agreement, dated January 7, 2015, by and between Nemus Bioscience, Inc. and certain investors(7)
4.10	Form of Warrant(30)
4.11	Form of Warrant (34)
4.12	Form of Common Warrant(38)
4.13	Form of Pre-Funded Warrant(38)
10.1†	Nemus Bioscience, Inc. 2014 Omnibus Incentive Plan(2)
10.2†	Form of Stock Option Agreement under 2014 Omnibus Incentive Plan(2)
10.3	Memorandum of Understanding, dated July 31, 2013, between Nemus and University of Mississippi, National Center for Natural Products Research (2)
10.9 **	License Agreement, dated September 29, 2014, between Nemus and the University of Mississippi, School of Pharmacy(2)
10.10 **	License Agreement, dated September 29, 2014, between Nemus and the University of Mississippi, School of Pharmacy(2)
10.11 **	License Agreement, dated September 29, 2014, between Nemus and the University of Mississippi, School of Pharmacy(2)
10.12	Lease Agreement dated September 1, 2014 between University of Mississippi Research Foundation, Inc. and Nemus(2)
10.13	Center Tower Lease dated October 13, 2014, by and between Nemus and Center Tower Associates LLC.(2)
10.17	Common Stock Purchase Agreement, dated January 7, 2015, by and between Nemus Bioscience, Inc. and certain investors(7)
10.19 †	Form of Indemnification Agreement (8)
10.20 †	Nemus Bioscience, Inc. Officer Change in Control Severance Plan(9)
10.21	Form of Registration Rights Agreement between Nemus Bioscience, Inc. and certain investors (4) 10.22† Form of Restricted Stock Award Agreement under 2014 Omnibus Incentive Plan (10)
10.23 **	License Agreement, dated December 14, 2015, between Nemus and the University of Mississippi, School of Pharmacy(11)
10.24 **	License Agreement, dated December 14, 2015, between Nemus and the University of Mississippi, School of Pharmacy(11)
10.25 **	Letter Agreement with Albany Molecular Research Inc. dated February 5, 2016(12)
10.26	Form of Securities Purchase Agreement between Nemus Bioscience, Inc. and certain investors(13)
10.27	Form of Registration Rights Agreement between Nemus Bioscience, Inc. and certain investors(13)

10.28	Form of Lock-up Agreement between Nemus Bioscience, Inc. and certain shareholders[14]
10.29	Form of Securities Purchase Agreement between Nemus Bioscience, Inc. and certain investors[15]
10.30	Form of Registration Rights Agreement between Nemus Bioscience, Inc. and certain investors[15]
10.31	Form of Lock-up Agreement between Nemus Bioscience, Inc. and certain shareholders[16]
10.32 **	License Agreement, dated January 10, 2017, between Nemus and the University of Mississippi, School of Pharmacy[17]
10.33	Securities Purchase Agreement, dated May 3, 2017, between Nemus Bioscience, Inc. and Schneider Finance LLC[18]
10.34	Financial Guarantee dated May 3, 2017[19]
10.35	Form of Securities Purchase Agreement[20]
10.36	Form of Registration Rights Agreement (20) 10.37† Form of Restricted Stock Agreement[21]
10.38	Securities Purchase Agreement[21]
10.39	Convertible Bridge Promissory Note[22]
10.40	Independent Contractor Termination Agreement and Release (23) 10.41* Independent Contractor Agreement[23]
10.42†	Employment Agreement, dated May 25, 2018, between Nemus Bioscience, Inc. and Douglas Cesario (24) 10.43† Stock Option Agreement, dated May 25, 2018, between Nemus Bioscience, Inc. and Douglas Cesario[24]
10.44 **	Letter Agreement, dated July 31, 2018, by and between Nemus Bioscience, Inc. and Albany Molecular Research Inc.[25]
10.45	Multi-Draw Credit Agreement, dated October 5, 2018, by and between Nemus Bioscience, Inc. and Emerald Health Sciences, Inc.[26]
10.46	Registration Rights Agreement, dated October 5, 2018, by and between Nemus Bioscience, Inc. and Emerald Health Sciences, Inc.[26]
10.47 †	Amendment No. 1 to 2014 Omnibus Incentive Plan[26]
10.48 **	Master Development and Clinical Supply Agreement, dated February 26, 2019, by and between Nemus Bioscience, Inc. and Noramco, Inc.[29]
10.49	Restated and Amended License Agreement, dated as of May 24, 2019, by and between the Company and University of Mississippi, School of Pharmacy[31]
10.50	Restated and Amended License Agreement, dated as of May 24, 2019, by and between the Company and University of Mississippi, School of Pharmacy[31]
10.51	First Amendment to Master Development and Clinical Supply Agreement, dated as of August 7, 2019, by and between the Company and Noramco, Inc.[32]
10.52	Start-Up Agreement, dated as of August 23, 2019, by and between the Company and Novotech[33]
10.53	Master Services Agreement, dated as of September 20, 2019, by and between EMBI Australia and Novotech (Australia) Pty Limited[34]
10.54	Form of Securities Purchase Agreement, dated as of November 20, 2019, between the Company and certain purchasers set forth in the signature page thereto[35]
10.55	Warrant Exercise Agreement, dated as of December 20, 2019, between the Company and Emerald Health Sciences[36]
10.56	Independent Contractor Services Agreement, dated as of December 19, 2019, between the Company and Dr. Avtar Dhillon.[36]
10.57	Amended and Restated Multi-Draw Credit Agreement, dated April 29, 2020, by and between Emerald Bioscience, Inc. and Emerald Health Sciences, Inc. Sciences, Inc.[37]
10.58	Separation and Release Agreement, dated April 29, 2020, between Emerald Bioscience, Inc. and Douglas Cesario[37]
10.59	Form of Securities Purchase Agreement, dated as of July 31, 2020, between the Company and certain purchasers set forth in the signature page thereto[38]
10.60	Separation and Release Agreement, dated August 7, 2020, by and between Emerald Bioscience, Inc. and Brian Murphy[39]
10.61	Employment Agreement, dated August 10, 2020, by and between Emerald Bioscience, Inc. and Punit Dhillon[39]
10.62	Amendment No. 2 to 2014 Omnibus Incentive Plan[39]
10.63*	Collaborative Research Agreement, dated January 2021, by and between Skye Bioscience, Inc. and Emerald Health Biotechnology España, S.L.,

21.1	Subsidiaries of the Registrant (2)
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer, pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934
31.2*	Certification of Principal Financial and Accounting Officer, pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934
32.1***	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2***	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.ins††	Instance Document
101.sch††	XBRL Taxonomy Schema Document
101.cal††	XBRL Taxonomy Calculation Linkbase Document 101.def†† XBRL Taxonomy Definition Linkbase Document 101.lab†† XBRL Taxonomy Label Linkbase Document
101.pre††	XBRL Taxonomy Presentation Linkbase Document

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(2) Included as exhibit to our Current Report on Form 8-K filed on November 3, 2014.
(3) Included as exhibit to our Current Report on Form 8-K filed April 7, 2015.
(4) Included as exhibit to our Current Report on Form 8-K filed August 20, 2015.
(5) Included as exhibit to our Quarterly Report on Form 10-Q filed May 13, 2015
(6) Included as exhibit to our Quarterly Report on Form 10-Q filed August 14, 2015
(7) Included as exhibit to our Current Report on Form 8-K filed on January 9, 2015.
(8) Included as exhibit to our Current Report on Form 8-K filed on January 12, 2015.
(9) Included as exhibit to our Current Report on Form 8-K filed on February 27, 2015.
(10) Included as exhibit to our Current Report on Form 8-K filed on October 22, 2015.
(11) Included as exhibit to our Current Report on Form 8-K filed on December 18, 2015.
(12) Included as exhibit to our Annual Report on Form 10-K filed on March 21, 2016.
(13) Included as exhibit to our Current Report on Form 8-K filed on October 26, 2016
(14) Included as exhibit to our Current Report on Form 8-K filed on October 27, 2016.
(15) Included as exhibit to our Current Report on Form 8-K filed on December 29, 2016.
(16) Included as exhibit to our Current Report on Form 8-K filed on January 10, 2017.
(17) Included as exhibit to our Current Report on Form 8-K/A filed on January 20, 2017.
(18) Included as exhibit to our Current Report on Form 8-K filed on May 4, 2017.
(19) Included as exhibit to our Current Report on Form 8-K filed on July 11, 2017.
(20) Included as exhibit to our Current Report on Form 8-K filed on November 2, 2017.
(21) Included as exhibit to our Current Report on Form 8-K filed on January 22, 2018.
(22) Included as exhibit to our Current Report on Form 8-K filed on January 3, 2018.
(23) Included as exhibit to our Annual Report on Form 10-K filed on March 19, 2018.
(24) Included as exhibit to our Current Report on Form 8-K filed on June 1, 2018.
(25) Included as exhibit to our Current Report on Form 8-K filed on August 1, 2018.
(26) Included as exhibit to our Current Report on Form 8-K filed on October 12, 2018.

(29) Included as exhibit to our Current Report on Form 8-K filed on March 4, 2019.
(30) Included as exhibit to our Annual Report on Form 10-K filed on March 14, 2019.
(31) Included as exhibit to our Current Report on Form 8-K filed on May 29, 2019.
(32) Included as exhibit to our Current Report on Form 8-K filed on August 8, 2019.
(33) Included as exhibit to our Current Report on Form 8-K filed on August 27, 2019.
(34) Included as exhibit to our Quarterly Report on Form 10-Q filed on September 30, 2019.
(35) Included as exhibit to our Current Report on Form 8-K filed on November 21, 2019.
(36) Included as exhibit to our Current Report on Form 8-K filed on December 20, 2019.
(37) Included as exhibit to our Current Report on Form 8-K filed on April 29, 2020.
(38) Included as exhibit to our Current Report on Form 8-K filed on August 5, 2020
(39) Included as exhibit to our Current Report on Form 8-K filed on August 12, 2020

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* Filed Herewith
** Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.
*** Furnished Herewith
† Management contract or compensatory plan or arrangement.
†† In accordance with Regulation S-T, XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, and is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not otherwise subject to liability under these sections.

Item 16. Form 10-K Summary.

None.

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.

Skye Bioscience, Inc.
a Nevada corporation

March 1, 2021

By: */s/ Punit Dhillon*
Punit Dhillon
Its: Chief Executive Officer, Chairman
(Principal Executive Officer)

March 1, 2021

By: */s/ Richard Janney*
Richard Janney
Its: Interim Principal Accounting Officer
(Principal Financial and Accounting 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.

By: */s/ Punit Dhillon* — March 1, 2021
Punit Dhillon
Its: Chief Executive Officer, Chairman
(Principal Executive Officer)

By: */s/ Richard Janney* — March 1, 2021
Richard Janney
Its: Interim Principal Accounting Officer
(Principal Financial and Accounting Officer)

By: */s/ Margaret Dalesandro* — March 1, 2021
Margaret Dalesandro
Its: Director

By: */s/ Jim Heppell* — March 1, 2021
Jim Heppell
Its: Director