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, 2022

☐ **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.)
11250 El Camino Real, Suite 100, San Diego, CA	**92130**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(858) 410-0266**

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 $17,357,379 as of June 30, 2022, based upon the closing price of $0.035 per share of the registrant's common stock on the OTCQB on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter.

As of March 29, 2023, there were 971,549,608 shares of the registrant's common stock issued and outstanding.

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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, (i) Nemus, a California corporation, (ii) SKYE Bioscience Pty Ltd ("SKYE Bioscience Australia"), an Australian proprietary limited company formerly known as EMBI Australia Pty Ltd, (iii) Emerald Health Therapeutics, Inc. ("EHT") a corporation governed by the Business Corporations Act (British Columbia), (iv) Verdélite Sciences, Inc. ("VDL"), a corporation governed under the Canada Business Corporation Act and (v) Avalite Sciences, Inc. ("AVI"), a corporation governed by the Business Corporations Act (British Columbia).

FORWARD-LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K contain forward-looking statements that are based on management's current expectations and assumptions and information currently available to management 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 timing, progress and results of our clinical studies for SBI-100 Ophthalmic Emulsion (SBI-100 OE) and our estimates regarding the market opportunity for SBI-100 OE if approved;
- the early stage of our product candidates presently under development;
- our near term 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, including global supply chain disruptions;
- 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 residual impacts of the novel coronavirus ("COVID-19") pandemic, or responses to a future pandemic on our business, clinical trials or personnel;
- regulatory developments in the United States and foreign countries;
- current pending litigation matters, including the Cunning Lawsuit; and
- estimates of the costs and expenses associated with the wind-down of EHT's former business and the estimated value to be received by the Company with respect to the potential sale of any remaining EHT's assets.

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, including the residual impacts of the COVID-19 pandemic, the current global economic environment, including the impacts of the high inflationary environment, and associated business disruptions such as delayed clinical trials, laboratory resources and supply chain limitations, 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 1. Business.

About Skye Bioscience, Inc.

We were incorporated in the State of Nevada on March 16, 2011. We are a clinical stage pharmaceutical company focused on the discovery, development and commercialization of a novel class of cannabinoid derivatives to modulate the endocannabinoid system, which has been shown to play a vital role in overall human health and, notably, in multiple ocular indications. We are developing novel cannabinoid derivatives through our own directed research efforts and multiple license agreements. We have retained Novotech as our contract research organization ("CRO") in Australia and commenced our Phase 1 trial in December 2022. We have also filed our IND for SBI-100 OE in the United States in anticipation of the start of our Phase 2 clinical trial in 2023, which we expect to commence in mid 2023.

Effective January 19, 2021, we changed our name from Emerald Bioscience, Inc. to Skye Bioscience, Inc. Our common stock is quoted on the OTCQB, under the symbol "SKYE". Previously, it traded under the symbol EMBI.

In August 2019, we formed a new subsidiary in Australia, SKYE Bioscience 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 SKYE Bioscience Australia is to conduct clinical trials for our drug product candidates. SKYE Bioscience Australia is currently conducting our Phase 1 clinical study in Australia. We expect to report final data from this study in the fourth quarter of 2023.

As described in more detail in the section below titled "*Liquidity and Going Concern*", without additional funding during the second quarter of 2023, management believes that the Company will not have enough funds to meet its obligations and continue pre-clinical and clinical studies beyond the one year date the consolidated financial statements are issued. If we do not receive additional funding during of the second quarter of 2023, we likely cannot continue operations.

EHT Acquisition

On May 11, 2022, we entered into an Arrangement Agreement (as amended, the "Arrangement Agreement") with EHT, pursuant to which we agreed to acquire all of the issued and outstanding common shares of EHT pursuant to a plan of arrangement under the Business Corporations Act (British Columbia) (the "Acquisition"). The Acquisition was consummated on November 10, 2022. Under the terms of the Arrangement Agreement and the Plan of Arrangement, on November 10, 2022, each share of EHT common stock ("EHT Shares") outstanding immediately prior to the effective time of the Acquisition (the "Effective Time") was transferred to the Company in exchange for 1.95 shares (the "Exchange Ratio") of Company common stock. The cash and assets of EHT and its subsidiaries acquired in the Acquisition are being used to fund our Phase 1 and Phase 2 clinical trials. EHT and its subsidiaries are currently in the final stages of its realization process to wind down all prior operations and liquidate substantially all of its remaining assets.

As of the date of this Annual Report on Form 10K, we have divested both of EHT's former operating subsidiaries, VDL and Emerald Health Therapeutics Canada, Inc., and are in the process of resolving EHT's legacy tax matters with the Canadian tax authorities. In February 2023, the closing payment from the sale of VDL provided the Company with $5,547,000. This Acquisition has been a pivotal financing event for our business, allowing us to extend our cash runway into the second quarter of 2023 and will provide us with future funding as we collect the remaining receivables. In addition, EHT has a vacant lab facility which we are currently evaluating to determine whether it is practical to bring certain aspects of our research and development activities in house or to divest to generate additional corporate funding.

Our Product Candidates and Significant Contracts.

UM 5050 and UM 8930 License Agreements

We have license agreements with University of Mississippi ("UM") for UM 5050 and UM 8930 for "all fields of use" (each, a "License Agreement" and, collectively, the “License Agreements”). Pursuant to the License Agreements, UM granted us an exclusive license including, with the prior written consent of UM, the right to sublicense the intellectual property related to UM 5050 (referred to by Skye as SBI-100) and UM 8930 (referred to by Skye as SBI-200) for all fields of use. All fields of use means no restrictions on use of the underlying inventions, including developing UM 5050 and UM 8930 to treat any disease through any form of delivery under the License Agreements.

The exclusive license for our lead molecule, SBI-100, a cannabinoid receptor type 1 ("CBR1") agonist, under the License Agreement for UM 5050 is expected to allow us to explore related uses for the active moiety of SBI-100. Independent in vitro and in vivo studies have demonstrated the potential use of SBI-100 in a variety of potential indications based on the ability of CBR1 agonists 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. While earlier third party research validated the utility of a cannabinoid to provide therapeutic utility against diseases such as glaucoma, available methods of administration were burdened with their own side effects and limitations. Notably, it is difficult to topically deliver a natural cannabinoid molecule into the eye due to its lipophilic nature. SBI-100 is a natural cannabinoid that has been chemically modified to reduce the lipophilic nature of the original molecule and enhance the ability to administer the molecule on and through the eye. It is designed such that after it is introduced into the body, enzymes convert it back to its original active ingredient and enable its beneficial mechanisms of action to be unlocked. The Company's development team is also considering various routes of administration for SBI-100 into the body for different potential disease applications.

The exclusive license of SBI-200, a novel cannabinoid receptor ("CBR") modulator, under the License Agreement for UM 8930, allows us to explore uses in ophthalmic disorders as well as expanded research and development into organ systems outside of ophthalmology. Potential therapeutic areas beyond ophthalmic indications for SBI-200 may include the central nervous system, gastrointestinal tract, endocrine/metabolic system, reproductive system, or as yet unrecognized opportunities. We have developed strategic collaborations to identify and advance these applications.

SBI-100 OE

Our lead product, SBI-100 OE, is initially being developed to treat glaucoma and ocular hypertension. SBI-100 OE is comprised of the molecule licensed from UM, SBI-100, plus a proprietary nanoemulsion formulation. The first-in-human Phase 1 trial of SBI-100 OE is currently being conducted in healthy volunteers in Australia to evaluate this drug candidate's safety, tolerability, pharmacokinetics and pharmacodynamics. 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. The Company is currently eligible for a 48.5% refundable tax offset as long as it has aggregate turnover of less than $20 million per annum.

SBI-100 OE targets the CB1 receptor, which plays a key role in managing intraocular pressure associated with glaucoma. Glaucoma is an ocular neuropathy associated with the initiation of programmed cell death, known as apoptosis, of retinal ganglion cells ("RGCs") of the optic nerve, resulting in 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 CBR1 has been previously shown to lower IOP in both animal and human studies.

In 2019, UM completed experiments showing that SBI-100 was statistically superior in lowering IOP compared to the prostaglandin-based therapy latanoprost, the current standard-of-care for treating glaucoma. Statistical significance was reached across multiple time points during a seven-day course of dosing using a validated rabbit normotensive ocular model and SBI-100 exerted pharmacologic activity consistent with once-daily to twice-daily dosing. Skye has since completed the development of a proprietary nanoemulsion formulation to optimize the amount of SBI-100 that can be delivered to the eye in a single drop while also improving the duration of activity. Importantly, this formulation can be sterilized by filtration without impacting the attributes of SBI-100. This final formulation of the API, known as SBI-100 Ophthalmic Emulsion, significantly reduced IOP compared to other commercially available ophthalmic solutions and is now being evaluated in clinical trials.

We evaluated the mechanism of action and IOP-lowering ability of the active moiety of SBI-100 when administered into an ex vivo model of a 3D-human trabecular meshwork using both healthy and glaucomatous-induced tissues. The trabecular meshwork plays a key role in removing a vital functional liquid in the eye, called aqueous humor, in order to maintain a healthy balance of pressure in the eye (an imbalance can lead to a detrimental increase in IOP). This study validated the mechanism of action of SBI-100 in lowering IOP, a defining disease process of hypertensive glaucoma. Moreover, biomarkers associated with inflammation and fibrosis in both normal tissue and tissues affected by glaucoma were significantly decreased, pointing to anti-inflammatory and anti-fibrotic activities often associated with cannabinoids in other disease states. Data also 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 the active moiety, prompting further study for the utility of this drug in diseases of the retina.

Manufacturing of SBI-100 OE has been conducted in the United States. We completed the manufacture of the clinical trial material for our Phase 1 clinical trial in September 2022. We rely on compendial excipients that can be sourced from countries outside the United States, such as China.

In June 2022, we received approval from Belberry Limited, a certified Australian Human Research Ethics Committee, to begin our Phase 1 clinical trial for the study of our lead product candidate, SBI-100 OE. We subsequently notified the Australian Therapeutics Goods Administration of our intent to initiate our Phase 1 clinical trial through the Clinical Trial Notification scheme. In connection with this marketing approval to initiate the first-in-human trial for SBI-100 OE, we triggered the first milestone payment under our License Agreement for UM 5050 with UM. We commenced enrollment and dosing of the Phase 1 in November and December 2022. We expect our Phase 1 study to complete enrollment in the first half of 2023. The Company has announced that the safety review committee ("SRC") for this study reviewed safety data from the first and second cohorts of the single ascending dose arm of the Phase 1 and recommended advancing to the next cohort. After the review of the second cohort of safety data, the SRC also provided its recommendation that the study progress to the second arm of the Phase 1 study.

During the third and fourth quarter of 2022, we manufactured the active pharmaceutical ingredient to be used in our Phase 2 clinical trial. The formulation and packaging of SBI-100 OE for its planned Phase 2 trial will be conducted by NextPharma Oy at its Finnish facility. NextPharma is a contract manufacturing organization with strong capabilities in preservative-free multi-dose and blow-fill-seal packaging of eye drop dispensers.

In December 2022 we obtained FDA clearance of our Investigational New Drug application to conduct clinical studies in the US, clearing the path to commence our Phase 2 trial in the United States without having to first complete our Phase 1 study. We expect to begin our Phase 2 trial in the middle of 2023. The Phase 2 study will be a randomized, controlled, double-masked clinical trial in patients with glaucoma or ocular hypertension to obtain additional data to determine whether the topical delivery of SBI-100 OE is safe and well-tolerated, and whether the IOP is markedly different between SBI-100 OE and the placebo.

In January 2023, our Phase 2 clinical trial protocol received study level approval from a central institutional review board (“IRB”). Additionally, in February 2023 we announced an agreement with Lexitas Pharma Services, Inc. (“Lexitas”), a leading full-service ophthalmic-focused contract research organization (“CRO”), to conduct our Phase 2a study for glaucoma and ocular hypertension.

SBI-200

We have initiated research activities to explore the utility of SBI-200. Early studies of SBI-200 demonstrated analgesic, anti-inflammation, anti-fibrotic and 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 early ocular formulation of SBI-200 was able to penetrate multiple compartments of the eye, including reaching the retina and the optic nerve. We are further evaluating the possible utility and development of this compound as a therapeutic agent.

Cannabinoid Pharmaceutical Innovation Program (CPIP)

We are focused on the development of proprietary, synthetic cannabinoid derivatives that have been designed to improve the solubility, bioavailability and pharmacology of cannabinoids, with the goal of providing therapeutic benefits to fulfill unmet needs, while also providing the Company with strong intellectual property protection. At the end of 2021, we announced that the Company would establish the Cannabinoid Pharmaceutical Innovation Program, or CPIP, to focus on targeting important signaling pathways in the endocannabinoid system ("ECS") which are relevant to various ocular pathologies and to identify possible new drug candidates to add to our development pipeline. Moreover, new research continues to demonstrate that this cell signaling network can impact fundamental processes including synaptic plasticity, pain control, metabolism and immunity, highlighting that the ECS may be central to a wide range of diseases settings. Thus, while our pipeline remains grounded in ophthalmology, the company may additionally explore ECS-modulating therapeutics to address pathologies beyond ocular disease.

The CPIP reflects the Company's continued commitment to expand its leadership in cannabinoid-based science and cutting-edge research that can be commercialized through new and existing technologies. It leverages R&D initiatives with key opinion leaders with specialized research centers in the US and internationally, such as UM, University of Cordoba and University of Eastern Piedmont. As a first step in building the CPIP in October 2021, we announced the establishment of a new Exclusive Sponsored Research Agreement ("ESRA") with VivaCell Biotechnology España, S.L.U ("VivaCell"), (formerly known as Emerald Health Biotechnology España, S.L.U), focused on developing and characterizing novel molecules that can affect the ECS for therapeutic benefit. This agreement deepens the commitment of Dr. Eduardo Munoz, Professor of Immunology, Department of Cell Biology, Physiology and Immunology of the University of Córdoba, Spain, and Director of the inflammation and cancer research group at the Institute Maimonides for Biomedical Research Córdoba, and Dr. Giovanni Appendino, Professor of Organic Chemistry, Department of Pharmaceutical Sciences at the University of Eastern Piedmont, Novara, Italy, who are the principal investigators and continue to lead our scientific advisory board. Under the terms of the ESRA the Company will approve and fund designated projects and have exclusive rights to all data and products, and any intellectual property resulting from this research collaboration will be owned by the Company. Vivacell will receive a single digit royalty on all licensing revenue or other consideration paid to the Company by a third-party licensee, assignee or purchaser related to any product commercialized as part of designated projects. Through the CPIP the Company intends to expand its relationships with other investigators and institutions who are leaders in the field of cannabinoid research.

Our Competitive Strengths

We are developing novel, proprietary cannabinoid derivatives that have the potential to treat ophthalmic disorders and other diseases with unmet needs. Our lead product candidate, SBI-100 OE, is being developed for the treatment of glaucoma and ocular hypertension. Currently, most approved drugs for glaucoma target similar molecular receptors and have similar mechanisms of action. As a result there is a significant unmet medical need to develop new drugs that target different receptors using novel mechanisms of action. SBI-100 OE has the potential to meet these needs. The eye is rich in cannabinoid receptors, including CBR1, which is the main target for SBI-100 OE. Our studies, along with multiple studies from other institutions, have demonstrated that activation of CBR1 can not only result in reduction of IOP, but also have anti-inflammatory, anti-fibrotic and anti-neovascular effects, which may offer potential benefits in other eye diseases beyond glaucoma. As a novel agent for the potential treatment of glaucoma and ocular hypertension, SBI-100 OE may represent a new treatment opportunity for physicians and patients and we are leading the field in this area of research.

With the implementation of the CPIP, we intend to leverage the potential success of SBI-100 OE to discover and develop additional novel cannabinoid derivatives capable of targeting multiple cannabinoid receptors in the eye for the treatment of ocular diseases. The combined experience of our board of directors, management team, scientific and clinical advisors provides a significant strategic capability as we work to define and build our competitive advantage.

Our Business Strategy

Our goal is to become a premier developer of synthetic cannabinoid derivatives 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 their potential clinical utility and the market and competitive dynamics of the associated target indications;
- development and execution of an intellectual property strategy;
- clinical development and advancement of our current product pipeline;
- outsourcing activities such as clinical trial management and drug manufacturing via clinical research organizations ("CROs") and contract manufacturers, 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;
- discovery, research and development of additional novel cannabinoid-based molecules for future product candidates; and
- partnering, out-licensing, or selling our product candidates to pharmaceutical companies to focus on core strengths, 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, pre-clinical or clinical development stages. We are evaluating what we believe to be the optimal commercialization path for the Company, our product candidates, and patients. Commercialization paths may include licensing/partnering with or selling assets to other commercial enterprises.

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 active pharmaceutical ingredient ("API"), formulation, 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 two inventions from UM 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 SBI-100 and other cannabinoid receptor modulators, and their methods of use. The US patent for SBI-100 is expected to expire in 2029. Additionally, in July 2020 the United States Patent and Trademark Office granted a patent for SBI-200. The expiration date of the US patent for SBI-200 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, 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 Controlled Substances

Drug Enforcement Administration (DEA) Regulation

Certain 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. Certain 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 SBI-200 and determined that SBI-200 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 for SBI-200. SBI-100 remains a Schedule I controlled substance, pending a request to re-schedule SBI-100 after marketing authorization by the FDA.

U.S. Food and Drug Administration (FDA)

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 legally marketed in the United States, generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with GLP regulations;
- submission of an Investigational New Drug application ("IND") to the FDA , which must be authorized as open before clinical trials may begin;
- approval and oversight of each study by an institutional review board ("IRB") before each clinical site may initiate the trial(s);
- conduct of adequate and well-controlled 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 development and completion of an FDA pre-approval 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;
- satisfactory development and completion of an FDA BioResearch Monitoring (BIMO) inspection of the clinical study sites which participated in the studies supporting the NDA application; 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 nonclinical testing may continue even after the IND is submitted. An IND generally 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 work to resolve any outstanding concerns before the hold can be lifted and 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 humans under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects/patients 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.

Before marketing authorization, 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.

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 or due to a business decision. 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 nonclinical 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 an 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 and/or first-in-class product 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 an NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from nonclinical 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 nonclinical 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 an 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 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. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. Additional state and federal healthcare reform measures

may 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 ("GAAP"), and 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 eleven 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 our technology and products. Information contained on our website is not incorporated by reference into, and should not be considered a part of, this Annual Report.

RISK FACTORS

Item 1A. Risk Factors.

Any investment in our securities 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 securities. Our business, financial condition or results of operations could be materially 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 on Form 10-K, there has been very limited trading of shares of our common stock. The trading price for shares of our common stock 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. We have organized the description of these risks into groupings in an effort to enhance readability, but many of the risks interrelate or could be grouped or ordered in other ways, so no special significance should be attributed to the groupings or order below. 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 on Form 10-K.

Risk Factor Summary

- We currently have no product revenues and no products approved for marketing and need substantial additional funding in the near term to continue our operations.
- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- UM is the owner of intellectual property related to SBI-100 and SBI-200.
- 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 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 conducted, and continue to conduct, clinical trials for our product candidates outside of the United States and we may do so for our other product candidates. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.
- 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.
- We expect to face intense competition, often from companies with greater resources and experience than we have.
- The current volatility of global financial conditions and inflation could negatively impact our business and financial condition.
- Adverse U.S. or international geopolitical or economic conditions could negatively affect our business, financial condition and results of operations.
- If we are not able to attract and retain highly qualified personnel, we may not be able to successfully implement our business strategy.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.
- If we are unable to prevent disclosure of our trade secrets or other confidential information to third parties, our competitive position may be impaired.
- We engage in transactions with related parties which present possible conflicts of interest that could have an adverse effect on us.
- Unpredictable business disruptions could seriously harm our future revenues and financial condition, increase our costs and expenses, and impact our ability to raise capital.
- The COVID-19 pandemic, related variants and other epidemic diseases has, and could continue to, adversely impact our business, including our drug manufacturing, nonclinical activities and clinical trials.
- Due to our limited resources, we may be forced to focus on a limited number of development candidates which may force us to pass on opportunities that could have a greater chance of clinical success.
- Our business and operations would be adversely affected in the event that our computer systems or those of our partners, contract research organizations, contractors, consultants or other third parties we work with were to suffer system failures, cyber-attacks, loss of data or other security incidents.
- Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could have a material adverse effect on our business, financial condition or results of operations.
- If we fail to enter and maintain successful collaborative arrangements or strategic alliances for our product candidates, we may have to reduce or delay our product candidate development or increase our expenditures.
- The Company is currently subject to lawsuits, and in the future may be subject to additional lawsuits, that could divert its resources and result in the payment of significant damages and other remedies.
- If we are unsuccessful in the resolution of the Cunning Lawsuit, our business may be materially harmed, and we may be required to take actions to reorganize, discontinue or liquidate part or all of our operations.
- If we are not able to favorably resolve our litigation with Ms. Cunning, we could potentially be required to seek relief through a filing under the U.S. Bankruptcy Code, either through plan of reorganization or under an alternative plan, which could include liquidation.
- Government authorities extensively regulate our activities.
- Some of the product candidates we are developing, including SBI-100, 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.
- Research restrictions, product shipment delays or prohibitions could have a material adverse effect on our business, results of operations and financial condition.
- 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.

- Laws and regulations affecting therapeutic uses of cannabinoids are constantly evolving.
- Our product candidates may contain controlled substances, the use of which may generate public controversy.
- We may not be able to file investigational new drug applications to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner, or at all.
- 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.
- Nonclinical 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.
- 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.
- Our development and commercialization strategy for SBI-100 OE, 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.
- Even if we receive marketing 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.
- 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 marketing approval, limit the commercial potential, or result in significant negative consequences following marketing approval.
- We expect to rely on third parties, such as CROs, to conduct some or all of our nonclinical 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 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.
- Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.
- 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.
- 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 marketing approval or commercial activities, and result in losses.
- Our stock price may be volatile, which may result in losses to our stockholders.
- 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 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.
- We do not anticipate paying any cash dividends.
- Our common stock is subject to penny stock rules, which may make it more difficult for our stockholders to sell their common stock.
- We will need additional capital, and the sale of additional shares or other equity securities could result in additional dilution to our stockholders.
- Our principal stockholder owns a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.
- We have a substantial number of authorized common shares available for future issuance that could cause dilution to our Stockholders' interest and adversely impact the rights of the holders of our Shares.
- The issuance of shares upon exercise of outstanding warrants, convertible debt and options may cause immediate and substantial dilution to our existing stockholders.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.
- We may face risks related to the wind-down of EHT's operations.

Risks Related to our Business and Capital Requirement

We currently have no product revenues and no products approved for marketing and need substantial additional funding in the near term 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, 2022 and 2021, 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, equity financings and a strategic acquisition. 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, 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;
- enter into strategic alliances or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or on terms that are less favorable than might otherwise be available;
- dispose of technology assets, or relinquish or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves;
- pursue the sale of our company to a third party at a price that may result in a loss on investment for our stockholders; or
- file for bankruptcy or cease operations altogether.

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 current independent registered public accounting firm has issued a report on our audited financial statements for the years ended December 31, 2022 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 former independent registered public accounting firm has issued a report on our audited financial statements for the years ended December 31, 2021 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, among other things, the successful resolution of our litigation with Ms. Cunning, 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. We will require additional financing during the second quarter of 2023 to continue operations. The uncertainty as to the resolution of the Cunning Lawsuit could limit our ability to raise new capital from investors to operate our business. Additionally, the increased turmoil in the U.S. capital markets created a substantially more difficult business environment. Our ability to access the capital markets is expected to be extremely limited. If adequate funds are not available to us when we need it, we will be required to curtail or perhaps cease 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.

UM is the owner of intellectual property related to SBI-100 and SBI-200.

Intellectual property rights (including any patents, non-manufacturing related know-how and improvements) for both SBI-100 and SBI-200 are owned by UM, and in the future we may need to seek UM's consent to pursue, use, sub-license and/or enforce some of these intellectual property rights which we are entitled to use pursuant to the License Agreements. An unexpected deterioration in our relationship with UM may have a material adverse effect on our business, reputation, results of operations and financial condition.

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 license 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 license under them. If we breach the terms of our License Agreements 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 or cause us to have to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology. Moreover, disputes may arise regarding intellectual property subject to a license agreement such as our license agreements with UM, including: (i) the scope of the rights granted under the license agreement and other interpretation related issues, (ii) the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement, (iii) our diligence obligations under the license agreement and what activities satisfy those diligence obligations. The loss of the rights licensed to us under our License Agreements 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.

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 clinical and preclinical development. 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, any one of 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;
- approval from regulatory agencies such as the Food and Drug Administration (the "FDA") or an Institutional Review Board ("IRB"), to conduct our clinical trials;
- receipt of marketing approvals from the Food and Drug Administration (the "FDA") and other applicable regulatory authorities;
- obtaining, maintaining and protecting our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for our product candidates;
- 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, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- 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 have conducted, and continue to conduct, clinical trials for our product candidates outside of the United States and we may do so for our other product candidates. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We have conducted, and continue to conduct our initial Phase 1 clinical trial for SBI -100 OE in Australia. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or a comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the

application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Conducting trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

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, SKYE Bioscience 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 48.5% 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 and inflation could negatively impact our business and financial condition.

Current global financial conditions and recent market events have been characterized by increased volatility, inflation and the resulting tightening of the credit and capital markets has reduced the amount of available liquidity and overall economic activity. Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency rates may have a potential adverse effect of on revenues, expenses and resulting margins. We cannot guarantee 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.

Global markets have recently experienced increased rates of inflation. Inflation itself, as well as certain governmental efforts to combat inflation, may have significant negative effects on any economy which the Company does business. Past governmental efforts to curb inflation also involved other more drastic economic measures. Any future economic measures to curb inflation could be expected to have similar adverse effects on the level of economic activity in the market, which the Company does business and, in turn, on the operations of the Company. For example, the Federal Reserve recently raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending.

Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. Other policies and measures adopted by governments include interest rate adjustments, intervention in the currency markets or actions to adjust or fix the value of the local currency may adversely affect the Company's business and results of operations.

Adverse U.S. or international economic conditions could negatively affect our business, financial condition and results of operations. We face risks associated with U.S. and international economic conditions and are subject to events beyond our control including war, public health crises (such as the COVID-19 pandemic), trade disputes, economic sanctions, and their collateral impacts. Adverse U.S. or international economic conditions or periods of inflation or high energy prices may contribute to higher unemployment levels, decreased consumer spending, reduced credit availability and declining consumer confidence and demand, each of which poses a risk to our business. In February 2022, armed conflict escalated between Russia and Ukraine. The sanctions imposed by the U.S. and other countries against Russia, following Russia's invasion of Ukraine, to date include restrictions on selling or importing goods, services, or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business and financial organizations in Russia. The U.S. and other countries could impose wider sanctions and take other actions should the conflict further escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets, all of which could impact our business, financial condition and results of operations.

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 President and Chief Executive Officer, and Ms. Kaitlyn Arsenault, our Chief Financial Officer. The loss of the services of Mr. Dhillon and Ms. Arsenault could significantly hinder our operations. We do not currently have key person insurance in effect for Mr. Dhillon and Ms. Arsenault. 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. We also rely on, and have relied on in the past, consultants and advisors to assist us in formulating our strategy. Our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications, or other intellectual property rights, from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology and/or its use. There can be no assurance that any of our future patent applications or the patent applications of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents.

The patent prosecution process is also expensive and time-consuming, and we and our licensors, such as UM, may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, contract research organizations, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

If we are unable to prevent disclosure of our trade secrets or other confidential information to third parties, our competitive position may be impaired.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Our ability to stop third parties from obtaining the information or know-how necessary to make, use, sell, offer to sell or import our products or practice our technology is dependent in part upon the extent to which we prevent disclosure of the trade secrets that cover these activities. Trade secret rights can be lost through disclosure to third parties. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our trade secrets to third parties, resulting in loss of trade secret protection. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, which would not constitute a violation of our trade secret rights. Enforcing a claim that a third party is engaged in the unlawful use of our trade secrets is expensive, difficult and time consuming, and the outcome is unpredictable. In addition, recognition of rights in trade secrets and a willingness to enforce trade secrets differs in certain jurisdictions.

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 affiliates and other related parties for financing, corporate, business development and operational services. For example, we currently have a sponsored research agreement with VivaCell Biotechnology España, S.L.U ("VivaCell"). Emerald Health Sciences, Inc. ("Sciences"), which holds 17.44% of the outstanding shares of common stock of the Company, also owns a majority of the outstanding shares of VivaCell. 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.

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 man made 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, and such third party manufacturers ability to manufacture our products could be negatively affected by such events.

The COVID-19 pandemic, related variants and other epidemic diseases has, and could continue to, adversely impact our business, including our drug manufacturing, nonclinical activities and clinical trials.

The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce. For example, the COVID-19 pandemic has in the past negatively impacted our ability to source materials that are part of the eye drop formulation, as well as negatively impacted our patient recruitment in Australia for our clinical trials. The extent to which the COVID-19 pandemic may impact our business, including our preclinical studies, planned clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence. We continue to monitor COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of its employees and other third parties with whom the Company does business. In connection with the COVID-19 pandemic or an outbreak of another highly infectious or contagious disease or other health concern, we may continue to experience disruptions that could severely impact our business, drug manufacturing, nonclinical activities, and clinical trials.

Due to our limited resources, we may be forced to focus on a limited number of development candidates which may force us to pass on opportunities that could have a greater chance of clinical success.

Due to our limited resources and capabilities, we will have to decide to focus on developing a limited number of product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our business and operations would be adversely affected in the event that our computer systems or those of our partners, contract research organizations, contractors, consultants or other third parties we work with were to suffer system failures, cyber-attacks, loss of data or other security incidents.

Despite the implementation of security measures, our computer systems, as well as those of our partners, contract research organizations, contractors, consultants, law and accounting firms and other third parties we work with, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, ransomware attacks, denial-of-service attacks, cybercriminals, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on our partners and third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risks of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber-terrorists, have increased significantly and are becoming increasingly difficult to detect. If a failure, accident or security breach were to occur and cause interruptions in our operations, or the operations of our partners or third-party providers, it could result in a misappropriation of confidential information, including our intellectual property or financial information or clinical trial participant personal data, a material disruption or delay in our drug development programs, and/or significant monetary losses. For example, during the second quarter of 2022, we were indirectly impacted by a cyberattack on our Phase 1 clinical supply contract manufacturer which delayed our production timeline and the anticipated initiation of enrollment in our Phase 1 clinical studies for SBI-100 OE to the fourth quarter of 2022. The loss of preclinical or clinical trial data from completed, ongoing or planned trials, or chemistry, manufacturing and controls data for our product candidates, could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties under the privacy laws of the European Union or other countries as well as state and federal privacy laws in the United States. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems or the systems of our service providers.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could have a material adverse effect on our business, financial condition or results of operations.

Privacy and data security have become significant issues in the U.S., and in many other jurisdictions where we may in the future conduct our operations. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and may increase our compliance costs and exposure to liability. As we receive, collect, process, use and store personal and confidential data, we are or may be subject to diverse laws and regulations relating to data privacy and security. Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In the U.S., we may 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 for Economic and Clinical Health Act, and their implementing regulations, or collectively, HIPAA, impose, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information held by covered entities and their business associates. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, state laws govern the privacy and security of health-related and other personal 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. By way of example, California enacted the California Consumer Privacy Act, or CCPA, effective January 1, 2020, which gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with, data breach litigation. The CCPA may increase our compliance costs and potential liability. Further, the California Privacy Rights Act, or CPRA, generally went into effect on January 1, 2023, and significantly amends the CCPA. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Connecticut, Utah and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition

If we fail to enter and maintain successful collaborative arrangements or strategic alliances for our product candidates, we may have to reduce or delay our product candidate development or increase our expenditures.

An important element of our strategy for developing, manufacturing and commercializing our product candidates is entering into collaborative arrangements or strategic alliances with pharmaceutical companies, research institutions or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our research or development programs.

In addition, these kinds of collaborative arrangements and strategic alliances may place certain aspects of the development of our product candidates outside of our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances will subject us to several risks, including the risks that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the product candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay development and may increase the cost of developing our product candidates.

The Company is currently subject to lawsuits, and in the future may be subject to additional lawsuits, that could divert its resources and result in the payment of significant damages and other remedies.

From time to time, the Company may be subject to litigation claims through the ordinary course of its business operations or otherwise, regarding, among other things, intellectual property rights matters, employment matters and tax matters. Litigation to defend the Company against claims by third parties, or to enforce any rights that the Company may have against third parties, may be necessary, which could result in substantial costs and diversion of the Company's resources, causing a material adverse effect on its business, financial condition and results of operations. Given the nature of the Company's business, it is, and may from time to time in the future be, party to various, and at times numerous, legal, administrative and regulatory inquiries, investigations, proceedings and claims that arise in the ordinary course of business, as well as potential class action lawsuits. Because the outcome of such legal matters is inherently uncertain, if one or more of such legal matters were to be resolved against the Company for amounts in excess of management's expectations or any applicable insurance coverage or indemnification right, the Company's results of operations and financial condition could be materially adversely affected. Any litigation to which the Company is a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal, or in payments of substantial monetary damages or fines, the posting of bonds requiring significant collateral, letters of credit or similar instruments, or the Company may decide to settle lawsuits on similarly unfavorable terms. Moreover, the Company cannot be sure that the remedies available to it at law or under contract, will be sufficient in amount, scope or duration to fully or partially offset any such possible liabilities. Any of these factors, individually or in the aggregate, could have a material adverse effect on the Company's business, results of operations, cash flows or liquidity. For a description of certain currently pending legal and regulatory proceedings, see Item 3 "Consolidated Statements and Other Financial Information — Legal Proceedings" of this Annual Report and Item 3 (Legal Proceedings) of this Annual Report.

If we are unsuccessful in the resolution of the Cunning Lawsuit, our business may be materially harmed, and we may be required to take actions to reorganize, discontinue or liquidate part or all of our operations.

As described in more detail under the caption "Legal Proceedings – Cunning Lawsuit", on January 18, 2023, a jury rendered a verdict in favor of Ms. Cunning and awarded her $512,500 in economic damages (e.g., lost earnings, future earnings and interest), $840,960 in non-economic damages (e.g., emotional distress) and $3,500,000 in punitive damages. The plaintiff's counsel has also filed a motion for attorney fees claiming fees of $1,351,850 and a multiplier of 1.5, for a total of $2,027,775. The Company intends to vigorously challenge the verdict in the trial court and appeal and pursue reimbursement under its existing insurance policies. However, the outcome of the litigation and the amount recoverable under its existing insurance policies, if any, is inherently uncertain.

While we cannot currently determine the ultimate liability pursuant to this verdict, we recorded an estimate for a legal contingency of $6,205,310 related to the Cunning Lawsuit. If we are unable to reduce the verdict prior to the rendering of a final judgment by the court or to reach a reasonable settlement with Ms. Cunning, we would be liable to pay substantial damages in excess of our liquid assets. Any or all of the foregoing would materially harm our business, fundamentally change our business, and could result in our being required to take actions to discontinue operations, liquidate part or all of our operations or file a petition for bankruptcy in order to reorganize or liquidate.

If we are not able to favorably resolve our litigation with Ms. Cunning, we could potentially be required to seek relief through a filing under the U.S. Bankruptcy Code, either through plan of reorganization or under an alternative plan, which could include liquidation.

If we are not able to favorably resolve our litigation with Ms. Cunning, we could potentially be required to seek relief through a filing under the U.S. Bankruptcy Code. The announcement of a filing under the U.S. Bankruptcy Code could materially adversely affect the relationships between us and our employees, suppliers, third party contractors and consultants, and others.

Substantial risks would result from any such bankruptcy filing. For example:

- if we were not able to develop a successful plan for reorganization, we would be forced to liquidate; and
- the equity interests of our current stockholders and employees could be completely eliminated

Risks Related to Controlled Substances

Government authorities extensively regulate our activities.

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 shares to decline.

Some of the product candidates we are developing, including SBI-100, 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.

Some 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 certain cannabinoids may be classified as Schedule I controlled substances, products approved for medical use in the United States that contain certain cannabinoids must be placed on Schedules II-V, since approval by the FDA satisfies the “accepted medical use” requirement. The DEA has conducted a scientific review of the chemical structure of SBI-200 and determined that SBI-200 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 for SBI-200. SBI-100 remains a Schedule I controlled substance, pending a request to re-schedule SBI-100 after marketing authorization by the FDA.

If approved by the FDA, we expect the finished dosage forms of SBI-100 OE to be reevaluated by the DEA and no longer listed as a Schedule I drug. Consequently, SBI-100 OE's manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use may be subject to a significant degree of regulation by the DEA, if the finished dosage form is determined to be a Schedule II drug. 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 may also establish controlled substance laws and regulations that

may require additional regulatory approvals to conduct research and clinical trials in that state. As a result, we or our partners or clinical sites may also be required to obtain separate state registrations, permits or licenses in order to be able to receive, handle, and distribute controlled substances for clinical trials. Delay in obtaining these state registrations, permits or licenses may delay the start of our clinical trials. While some states automatically schedule a drug based on federal action, other states schedule drugs through rule making 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 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.

Research restrictions, product shipment delays or prohibitions could have a material adverse effect on our business, results of operations and financial condition.

Research on and the shipment, import and export of our product candidates and the API used in our product candidates will require research permits, import and export licenses by many different authorities. For instance, in the United States, the FDA, U.S. Customs and Border Protection, and the DEA; in Canada, the Canada Border Services Agency, and Health Canada; in Europe, the European Medicines Agency and the European Commission; in Australia and New Zealand, the Australian Customs and Border Protection Service, the Therapeutic Goods Administration, the New Zealand Medicines and Medical Device Safety Authority and the New Zealand Customs Service; and in other countries, similar regulatory authorities, regulate the research on and import and export of pharmaceutical products that contain controlled substances. Specifically, the import and export process requires the issuance of import and export licenses by the relevant controlled substance authority in both the importing and exporting country. We may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if we obtain the relevant licenses, shipments of API and our product candidates may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage the product shipment resulting in delays in clinical trials. Once shipment is complete, we or the research contractors we are working with may also suffer further delays or restrictions as a result of regulations governing research on controlled substances. A delay in a clinical trial or, upon commercialization, a partial or total loss of revenue from one or more shipments of API or our product candidates could have a material adverse effect on our business, results of operations and financial condition. The aforementioned examples and lists of various authorities that may currently, or in the future, affect our ability to conduct research on or import or export our product candidates and/or API, should not be construed as exhaustive or comprehensive in any way.

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 synthesis, possession and supply of controlled substances for medical research and/or commercial development.

We are partnering with multiple clinical research organizations and manufacturing organizations to research and develop our pharmaceutical drug products. The regulation of controlled substances is complex and subject to stringent controls. If our partners 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.

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

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

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

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

Risks Related to Government Regulation

We may not be able to file investigational new drug applications to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner, or at all.

Prior to commencing clinical trials in territories with a regulatory authority we must obtain the necessary approvals to commence the clinical studies. For example, before initiating a clinical trial in the United States for any of our product candidates, we may be required to have an IND in effect for each product candidate. Submission of an IND may not result in the FDA allowing clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Once an IND is submitted, the sponsor must wait 30 calendar days before initiating the clinical trial, during which FDA will review the IND and either provide comments or allow the trial to proceed. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a clinical trial application (the equivalent of an IND in foreign jurisdictions), these regulatory authorities may change their requirements in the future.

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, and we may never receive such approvals. To gain approval to market a drug product, we must complete extensive nonclinical 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 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.

Nonclinical 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 or other foreign equivalent authorities 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. Additionally, the COVID-19 pandemic may slow enrollment in our future clinical trials.

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 SBI-100 OE, 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 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 SBI-100 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 SBI-100.

Even if we receive marketing 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 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 or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, 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, 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 risk evaluation and mitigation strategies 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 risk evaluation and mitigation strategies 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 marketing 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 nonclinical 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 nonclinical and clinical studies on our product candidates in compliance with applicable regulatory requirements. For example, we are currently engaged with Novotech, a CRO in Australia, to conduct our Phase 1 clinical trial. 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, 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 current

good clinical practices, 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 current good manufacturing practice 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 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 current good manufacturing practice 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.

Although we have quality agreements governing our development of clinical supplies, 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.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. Among the provisions of the ACA of importance to our potential product candidates, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; expanded eligibility criteria for Medicaid programs; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; created a new Medicare Part D coverage gap discount program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at the Centers for Medicare and Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, or AMP, beginning January 1, 2024.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

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;

- the Health Insurance Portability and Accountability Act, 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 marketing 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.

Our common shares are quoted on the OTCQB and are thinly traded. We cannot predict whether, and 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 may 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 have been, and may continue to 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 can be characterized by significant price volatility when compared to other more well-known issuers, and we expect that our share price will continue to be more volatile than a well-known issuer for the indefinite future. The volatility in our share price is attributable to a number of factors. First, as noted above, our common shares have been, and may continue to 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. You should not invest in our common shares unless you have the ability to tolerate a thinly traded and volatile market for the shares.

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.

We have, and may in the future, consider actions that make us eligible to list our common shares on a stock exchange. For example, we previously applied to list our shares of common stock on the Canadian Stock Exchange ("CSE"), but after consideration, we have determined that we do not currently meet the applicable listing requirements. We have have decided not to continue with the CSE listing application process for now and we do not anticipate having our shares of common stock listed on the CSE in the foreseeable future. We may not be able 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. If we incur additional indebtedness it 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, Sciences, owns a significant percentage of our outstanding capital stock. As of March 29, 2023, Sciences owned 17.44% of our outstanding shares of common stock. As such, Sciences may be able to exert significant influence over 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 to our Stockholders' interest and adversely impact the rights of the holders of our Shares.

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 March 29, 2023, we have reserved; 41,677,750 shares for issuance upon the exercise of outstanding options, 2,680,000 shares for issuance upon the vesting of outstanding restricted stock units, 43,592,069 shares for issuance under our equity incentive plan, 28,000,000 shares for issuance under our 2022 employee stock purchase plan, and 197,134,632 shares for issuance upon the exercise of outstanding warrants. As of March 29, 2023, we had no outstanding preferred stock. As of March 29, 2023, we had 3,715,365,941 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, convertible debt 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 March 29, 2023, we had outstanding (i) warrants to purchase up to 197,134,632 shares of our common stock at exercise prices ranging from $0.02 to $5.00 per share, (ii) options to purchase up to 41,677,750 shares of our common stock at exercise prices ranging from $0.02 to $1.80 per share, (iii) 2,680,000 unreleased restricted stock units exchangeable for shares of our common stock upon vesting. 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.

Risks Related to the EHT Acquisition

We may face risks related to the wind-down of EHT's operations.

On May 11, 2022, we entered into an Arrangement Agreement (as amended, the "Arrangement Agreement") with EHT pursuant to which we agreed to acquire all of the issued and outstanding common shares of EHT (the "EHT Shares") pursuant to a plan of arrangement under the Business Corporations Act (British Columbia) (the "Acquisition"). As previously mentioned, the Acquisition of EHT and its subsidiaries was consummated on November 10, 2022. As of the date of this Annual Report on Form 10-K, We intend to continue to continue to wind down the operations of EHT and its subsidiaries and focus on the business of SKYE we have divested both of EHT's former operating entities, VDL and EHTC, and are in the process of closing EHT's legacy tax matters with the Canadian tax authorities. The ability to realize the benefits of the Acquisition may depend in part on successfully winding down the operations of EHT, including, but not limited to: the sale of EHT's remaining facilities at terms favorable to us, the timely termination of obsolete contracts, the implementation of cost-cutting measures necessary to maximize the remaining asset balances, the effective management of the termination of remaining personnel and related severance payments, and the implementation of a successful transition plan, which includes the effective cessation of regulatory requirements related to operating in the cannabis industry.

Other risks resulting from the EHT assets and discontinued operations that could diminish the assets being acquired by us include unforeseen expenses, liabilities, or potential off-balance sheet liabilities, including litigation and tax related liabilities.

The difficulties that we encounter in the transition, integration and wind-down processes could have an adverse effect on the level of expenses, and operating results of our business. As a result of these factors, it is possible that any anticipated benefits from the Acquisition will not be realized.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Principal Offices

Our principal executive offices and corporate offices are located at 11250 El Camino Real Suite 100, San Diego, CA 92130.

Owned Real-estate

We own a 3,742 square foot research facility located at 9295 198 street, Unit 104, in Langley, British Columbia Canada. We acquired the former analytical testing laboratory as part of the acquisition of Emerald Health Therapeutics, Inc. The facility owned by AVI holds an active dealer's license pursuant to the Controlled Drugs and Substances Act ("CDSA") in Canada. The dealer's license permits the possession and conduct of research on certain controlled substances as may be approved under the license. AVI currently has no operations.

As of December 31, 2022, we owned a 88,478 square foot commercial property, located at 560 Industriel Boulevard, St-Eustache, Quebec. We acquired the former cannabis cultivation and production facility as part of the Emerald Health Therapeutics, Inc. Acquisition. The facility held an active cannabis cultivation and production license and was not operating as it was pending sale pursuant to a share purchase agreement entered on November 10, 2022. On February 9, 2023, the facility was sold pursuant to a share transfer agreement with C3 Souvenir Holdings, Inc. ("C3").

Item 3. Legal Proceedings.

Cunning Lawsuit

The Company is a party to a legal proceeding with a former employee alleging, among other things, wrongful termination, violation of whistleblower protections under the Sarbanes-Oxley Act of 2002 and retaliation under California law against the Company relating to certain actions and events that occurred with the Company's former management during the employee's employment term from March 2018 to July 2019. The case, entitled *Wendy Cunning vs Skye Bioscience, Inc.*, was filed in U.S. District Court for the Central District of California (the "Cunning Lawsuit"). On January 18, 2023, a jury rendered a verdict in favor of Ms. Cunning and awarded her $512,500 in economic damages (e.g., lost earnings, future earnings and interest), $840,960 in non-economic damages (e.g., emotional distress) and $3,500,000 in punitive damages. The plaintiff's counsel has also filed a motion for attorney fees claiming fees of $1,351,850 and a multiplier of 1.5, for a total of $2,042,775. The Company strongly believes that this case was incorrectly decided as to liability, the amount of compensatory damages, and the appropriateness and amount of punitive damages. The Company intends to vigorously challenge the verdict in the trial court

and appeal and pursue reimbursement under its existing insurance policies. However, the outcome of the litigation and the amount recoverable under its existing insurance policies, if any, is inherently uncertain. If we are unsuccessful in our defense of these claims or unable to settle the claims in a manner satisfactory to us, we may be faced with significant monetary damages that could exceed our resources and could have a material adverse effect on the Company and its financial position.

Proposed Class Action Lawsuit

In July 2020, Emerald Health Therapeutics, Inc., a subsidiary of the Company, was added as a defendant in a proposed class action commenced against a large number of Canadian license holders including Aurora Cannabis Inc.; Aurora Cannabis Enterprises Inc.; AuroraCo.; Aleafiaco; Aleafia Health Inc.; Canopy Growth Corporation; Emblem Cannabis Corp.; Hexo Corp.; HexoCo; Cronos Group Inc.; Cronosco; Tilray Canada Ltd.; Organigram Holdings Inc.; OrganigramCo; MediPharm Labs Corp.; MediPharmCo; CanopyCo; Aphria Inc.; Broken Coast Cannabis Ltd.; AphriaCo; Emerald Cannabis Corporation; and EmeraldCo. The proposed class action was commenced in the Alberta Court of Queen's Bench sitting at Calgary. The plaintiffs allege that the defendants, including Emerald Health Therapeutics, Inc., marketed and sold medicinal and recreational cannabis products with an advertised content of THC and CBD and that the amount of THC and/or CBD as contained on the label was wrong and outside the permissible variability limits. The claim alleges the following causes of action indiscriminately against all of the defendants: breach of contract and breach of consumer protection legislation, including the various Sale of Goods Acts and Consumer Protection Acts; common law and statutory misrepresentation; negligence in product labelling; breach of the duty to warn; unjust enrichment; waiver of tort. The claim seeks an aggregate of $505 million in damages as against all of the defendants) and $5,000,000 in punitive damages against each defendant plus an accounting of revenues from each defendant. The proceedings are still at an early stage. We are disputing the allegations and have been and will continue to vigorously defend against the claims.

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 symbol "EMBI" until January 19, 2021. 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 March 29, 2023, the last reported sale price of our common stock on the OTCQB was $0.02 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, 2022	$ 0.03	$ 0.01
September 30, 2022	0.04	0.02
June 30, 2022	0.06	0.03
March 31, 2022	0.06	0.03
December 31, 2021	0.11	0.05
September 30, 2021	0.18	0.08
June 30, 2021	0.26	0.08
March 31, 2021	0.25	0.04

Holders. As of March 29, 2023, there were 82 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, 2022 covered by this Annual Report.

Penny Stock Regulation. Shares of our common stock are 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 affecting 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, 2022 and 2021 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, SKYE Bioscience Pty Ltd ("SKYE Bioscience Australia"), an Australian proprietary limited company formerly known as EMBI Australia Pty Ltd., Emerald Health Therapeutics, Inc. (EHT), Verdélite Sciences, Inc. (VDL) and Avalite Sciences, Inc. (AVI).

About Skye Bioscience, Inc.

We were incorporated in the State of Nevada on March 16, 2011. We are a clinical stage pharmaceutical company focused on the discovery, development and commercialization of a novel class of cannabinoid derivatives to modulate the endocannabinoid system, which has been shown to play a vital role in overall human health and, notably, in multiple ocular indications. We are developing novel cannabinoid derivatives through our own directed research efforts and multiple license agreements. We have retained Novotech as our contract research organization ("CRO") in Australia and commenced our Phase 1 trial in December 2022. We have also filed our IND for SBI-100 OE in the United States in anticipation of the start of our Phase 2 clinical trial in 2023, which we expect to commence in mid 2023.

Effective January 19, 2021, we changed our name from Emerald Bioscience, Inc. to Skye Bioscience, Inc. Our common stock is quoted on the OTCQB, under the symbol "SKYE". Previously, it traded under the symbol EMBI.

In August 2019, we formed a new subsidiary in Australia, SKYE Bioscience 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 SKYE Bioscience Australia is to conduct clinical trials for our drug product candidates. SKYE Bioscience Australia is currently conducting our Phase 1 clinical study in Australia. We expect to report final data from this study in the fourth quarter of 2023.

As described in more detail in the section below titled "*Liquidity and Going Concern*", without additional funding during the second quarter of 2023, management believes that the Company will not have enough funds to meet its obligations and continue pre-clinical and clinical studies beyond the one year date the consolidated financial statements are issued. If we do not receive additional funding during of the second quarter of 2023, we likely cannot continue operations.

EHT Acquisition

On May 11, 2022, we entered into an Arrangement Agreement (as amended, the "Arrangement Agreement") with EHT, pursuant to which we agreed to acquire all of the issued and outstanding common shares of EHT pursuant to a plan of arrangement under the Business Corporations Act (British Columbia) (the "Acquisition"). The Acquisition was consummated

on November 10, 2022. Under the terms of the Arrangement Agreement and the Plan of Arrangement, on November 10, 2022, each share of EHT common stock (“EHT Shares”) outstanding immediately prior to the effective time of the Acquisition (the “Effective Time”) was transferred to the Company in exchange for 1.95 shares (the “Exchange Ratio”) of Company common stock. The cash and assets of EHT and its subsidiaries acquired in the Acquisition are being used to fund our Phase 1 and Phase 2 clinical trials. EHT and its subsidiaries are currently in the final stages of its realization process to wind down all prior operations and liquidate substantially all of its remaining assets.

As of the date of this Annual Report on Form 10K, we have divested both of EHT's former operating subsidiaries, VDL and Emerald Health Therapeutics Canada, Inc., and are in the process of resolving EHT's legacy tax matters with the Canadian tax authorities. In February 2023, the closing payment from the sale of VDL provided the Company with $5,547,000. This Acquisition has been a pivotal financing event for our business, allowing us to extend our cash runway into the second quarter of 2023 and will provide us with future funding as we collect the remaining receivables. In addition, EHT has a vacant lab facility which we are currently evaluating to determine whether it is practical to bring certain aspects of our research and development activities in house or to divest to generate additional corporate funding.

Our Product Candidates and Significant Contracts.

UM 5050 and UM 8930 License Agreements

We have license agreements with University of Mississippi ("UM") for UM 5050 and UM 8930 for "all fields of use" (each, a "License Agreement" and, collectively, the “License Agreements”). Pursuant to the License Agreements, UM granted us an exclusive license including, with the prior written consent of UM, the right to sublicense the intellectual property related to UM 5050 (referred to by Skye as SBI-100) and UM 8930 (referred to by Skye as SBI-200) for all fields of use. All fields of use means no restrictions on use of the underlying inventions, including developing UM 5050 and UM 8930 to treat any disease through any form of delivery under the License Agreements.

The exclusive license for our lead molecule, SBI-100, a cannabinoid receptor type 1 ("CBR1") agonist, under the License Agreement for UM 5050 is expected to allow us to explore related uses for the active moiety of SBI-100. Independent in vitro and in vivo studies have demonstrated the potential use of SBI-100 in a variety of potential indications based on the ability of CBR1 agonists 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. While earlier third party research validated the utility of a cannabinoid to provide therapeutic utility against diseases such as glaucoma, available methods of administration were burdened with their own side effects and limitations. Notably, it is difficult to topically deliver a natural cannabinoid molecule into the eye due to its lipophilic nature. SBI-100 is a natural cannabinoid that has been chemically modified to reduce the lipophilic nature of the original molecule and enhance the ability to administer the molecule on and through the eye. It is designed such that after it is introduced into the body, enzymes convert it back to its original active ingredient and enable its beneficial mechanisms of action to be unlocked. The Company's development team is also considering various routes of administration for SBI-100 into the body for different potential disease applications.

The exclusive license of SBI-200, a novel cannabinoid receptor ("CBR") modulator, under the License Agreement for UM 8930, allows us to explore uses in ophthalmic disorders as well as expanded research and development into organ systems outside of ophthalmology. Potential therapeutic areas beyond ophthalmic indications for SBI-200 may include the central nervous system, gastrointestinal tract, endocrine/metabolic system, reproductive system, or as yet unrecognized opportunities. We have developed strategic collaborations to identify and advance these applications.

SBI-100 OE

Our lead product, SBI-100 OE, is initially being developed to treat glaucoma and ocular hypertension. SBI-100 OE is comprised of the molecule licensed from UM, SBI-100, plus a proprietary nanoemulsion formulation. The first-in-human Phase 1 trial of SBI-100 OE is currently being conducted in healthy volunteers in Australia to evaluate this drug candidate's safety, tolerability, pharmacokinetics and pharmacodynamics. 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. The Company is currently eligible for a 48.5% refundable tax offset as long as it has aggregate turnover of less than $20 million per annum.

Manufacturing of SBI-100 OE has been conducted in the United States. We completed the manufacture of the clinical trial material for our Phase 1 clinical trial in September 2022. We rely on compendial excipients that can be sourced from countries outside the United States, such as China.

In June 2022, we received approval from Belberry Limited, a certified Australian Human Research Ethics Committee, to begin our Phase 1 clinical trial for the study of our lead product candidate, SBI-100 OE. We subsequently notified the Australian Therapeutics Goods Administration of our intent to initiate our Phase 1 clinical trial through the Clinical Trial Notification

scheme. In connection with this marketing approval to initiate the first-in-human trial for SBI-100 OE, we triggered the first milestone payment under our License Agreement for UM 5050 with UM. We commenced enrollment and dosing of the Phase 1 in November and December 2022. We expect our Phase 1 study to complete enrollment in the first half of 2023. The Company has announced that the safety review committee ("SRC") for this study reviewed safety data from the first and second cohorts of the single ascending dose arm of the Phase 1 and recommended advancing to the next cohort. After the review of the second cohort of safety data, the SRC also provided its recommendation that the study progress to the second arm of the Phase 1 study.

During the third and fourth quarter of 2022, we manufactured the active pharmaceutical ingredient to be used in our Phase 2 clinical trial. The formulation and packaging of SBI-100 OE for its planned Phase 2 trial will be conducted by NextPharma Oy at its Finnish facility. NextPharma is a contract manufacturing organization with strong capabilities in preservative-free multi-dose and blow-fill-seal packaging of eye drop dispensers.

In December 2022 we obtained FDA clearance of our Investigational New Drug application to conduct clinical studies in the US, clearing the path to commence our Phase 2 trial in the United States without having to first complete our Phase 1 study. We expect to begin our Phase 2 trial in the middle of 2023. The Phase 2 study will be a randomized, controlled, double-masked clinical trial in patients with glaucoma or ocular hypertension to obtain additional data to determine whether the topical delivery of SBI-100 OE is safe and well-tolerated, and whether the IOP is markedly different between SBI-100 OE and the placebo.

In January 2023, our Phase 2 clinical trial protocol received study level approval from a central institutional review board (“IRB”). Additionally, in February 2023 we announced an agreement with Lexitas Pharma Services, Inc. (“Lexitas”), a leading full-service ophthalmic-focused contract research organization (“CRO”), to conduct our Phase 2a study for glaucoma and ocular hypertension.

SBI-200

We have initiated research activities to explore the utility of SBI-200. Early studies of SBI-200 demonstrated analgesic, anti-inflammation, anti-fibrotic and 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 early ocular formulation of SBI-200 was able to penetrate multiple compartments of the eye, including reaching the retina and the optic nerve. We are further evaluating the possible utility and development of this compound as a therapeutic agent.

General Trends and Outlook

During the second quarter of 2022, we were indirectly impacted by a cyberattack on our Phase 1 clinical supply contract manufacturer. This disruption delayed our production timeline and the anticipated initiation of enrollment in our Phase 1 clinical studies for SBI-100 Ophthalmic Emulsion ("SBI-100 OE") to the fourth quarter of 2022. The overall potential delay in our drug product research and development from these types of incidents is unknown, but our operations and financial condition may continue to suffer in the event of continued business interruptions, supply chain issues, delayed clinical trials, production or a lack of laboratory resources due to the pandemic and other global conditions. It is possible that we may encounter other similar issues relating to the current situation that will need to be managed in the future. The factors to take into account in going concern judgements and financial projections include travel bans, restrictions, government assistance and potential sources of replacement financing, financial health of service providers and the general economy.

Financial Overview

We have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue development activities to support our product candidates through clinical trials. As a result, we expect to continue to incur operating losses and negative cash flows until our product candidates gain market acceptance and generate significant revenues.

Our net loss for the year ended December 31, 2022 was $19,481,602 as compared to a net loss of $8,522,182, for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $66,737,765 and negative cash flows from operations of $12,744,072. As of December 31, 2022, we had unrestricted cash of $1,244,527 as compared to $8,983,007 as of December 31, 2021.

On February 5, 2021, we increased our authorized shares of common and preferred stock to 5,000,000,000 and 50,000,000, respectively.

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, the percentage of completion as it relates to our clinical accruals, financing operations, contingencies, the fair value of assets acquired in the acquisition, 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 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 our financial instruments, with the exception of the derivative liabilities, approximate their fair value due to their short maturities. The derivative liabilities are valued on a recurring basis utilizing Level 3 inputs.

Convertible Instruments

We account for hybrid contracts with embedded conversion features in accordance with Accounting Standards Codification ("ASC") 815,*Derivatives and Hedging Activities* ("ASC 815") which 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 GAAP 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 recorded at fair value 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), net in the accompanying Consolidated Statements of Operations.

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 re-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), net in our Consolidated Statements of Operations.

Stock-Based Compensation Expense

Stock-based compensation expense is estimated at the grant date based on the fair value of the award, and the fair value is recognized as expense ratably over the vesting period with forfeitures accounted for as they occur. Upon the exercise of stock option awards, the Company's policy is to issue new shares of its common stock. The Company uses the Black-Scholes valuation method for estimating the grant date fair value of stock options using the following assumptions:

- Volatility - Expected volatility is estimated using the historical stock price performance over the expected term of the award.
- 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.

The Company accounts for liability-classified stock option awards ("liability options") under ASC 718 -*Compensation - Stock Compensation* ("ASC 718"), under which the Company accounts for its awards containing other conditions as liability classified instruments. Liability options are initially recognized at fair value in stock-compensation expense and subsequently re-measured to their fair values at each reporting date with changes in the fair value recognized in share-based compensation expense or additional paid-in capital upon settlement or cancellation.

Loss Per Common Share

We apply ASC No. 260, *Earnings per Share* in calculating its basic and diluted loss per common share. Basic loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of shares of common stock outstanding for the period. The diluted loss 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.

Commitments and Contingencies

We follow ASC 440 & ASC 450, subtopic 450-20 to report accounting for contingencies and commitments respectively. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to us, but which will only be resolved when one or more future events occur or fail to occur.

We assess such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against us or un-asserted claims that may result in such proceedings, we evaluate the perceived merits of any legal proceedings or un-asserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in our financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed. Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed. Based upon information available at this time, we believe that the current litigation matter related to the Cunning Lawsuit will have a material adverse effect on our consolidated financial position, results of operations and cash flows.

Asset Acquisition

We evaluate acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not we have acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Common stock issued as consideration in an asset acquisition is generally measured based on the acquisition date fair value of the equity interests issued. Direct transaction costs are recognized as part of the cost of an asset acquisition. We also evaluate which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. Consideration deposited into escrow accounts are evaluated to determine whether it should be included as part of the cost of an asset acquisition or accounted for as contingent consideration. Amounts held in escrow where we have legal title to such balances but where such accounts are not held in the our name, are recorded on a gross basis as an asset with a corresponding liability in our Consolidated Balance Sheets.

The cost of an asset acquisition, including transaction costs, are allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. However, as of the date of acquisition, if certain assets are carried at fair value under other applicable GAAP the consideration is first allocated to those assets with the remainder allocated to the non-monetary identifiable assets based on relative fair value basis.

Assets Held for Sale

Assets held for sale include the VDL real estate asset, Health Canada license and related intellectual property, that we plan to sell within the next year. Assets that meet the held for sale criteria are held for sale and reported at the lower of their carrying value or their fair value, less estimated costs to sell. Changes in fair value are recorded as a gain or loss in the results of operations but not to exceed original carrying value. An arrangement was in place to sell the assets of VDL at the time we completed the Acquisition of EHT, as such the VDL assets are considered held for sale and are presented within the Consolidated Balance Sheets. As of December 31, 2022 the VDL assets are held at carrying value less any costs to sell. The divestiture of VDL was completed after the balance sheet date on February 9, 2023.

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

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our clinical trials, our research and development efforts, variations in the level of expenditures related to investor relations and seeking new sources of capital, debt service obligations during any given period, and the uncertainty as to the extent and magnitude of the residual global impacts from the COVID-19 pandemic such as supply chain disruptions and inflation. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results.

For the years ended December 31, 2022 and 2021

Research and Development Expenses

Research and development expenses included the following:

- license fees;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party contract research organizations and investigative sites; and
- payments to third party manufacturing organizations and consultants.

We expect to incur future research and development expenditures to support our preclinical and clinical studies. Preclinical activities include, laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess safety and efficacy. Subject to the submission and approval by the FDA of our IND, clinical trials may commence and will involve the administration of the investigational new drug candidate to human subjects.

Below is a summary of our research and development expenses during the years ended December 31, 2022 and2021:

	Year Ended December 31,			
	2022	2021	$ Change 2022 vs. 2021	% Change 2022 vs. 2021
Research and development expenses	$ 6,011,805	$ 2,931,437	$ 3,080,368	105 %

Research and development expenses for the year ended December 31, 2022 increased by $3,080,368 when compared to the year ended December 31, 2021. The increase in research and development expenses was primarily due to an increase in contract research and development activities, including $2,348,534 for the manufacturing of our Phase 1 clinical trial material for SBI-100 OE, the manufacture of API for our Phase 2 study and contracted site initiation costs for our Phase 1 clinical study. In addition, we incurred an increase of $77,601 in expense for the use of specialized consultants, had increased costs related to lab supplies and materials of $36,105, an increase in compensation cost of $493,281 due to bonus expense and additional headcount from the addition of regulatory and development personnel, an increase in software of $24,956 and an increase in license fees of $86,979 from meeting the first milestone under our license agreement with UM which was offset by the cancellation of UM5070.

General and Administrative Expenses

Below is a summary of general and administrative expenses during the years ended December 31, 2022 and 2021:

	Year Ended December 31,			
	2022	2021	$ Change 2022 vs. 2021	% Change 2022 vs. 2021
General and administrative expenses	$ 6,094,617	$ 4,916,277	$ 1,178,340	24 %

General and administrative expenses for the year ended December 31, 2022 increased by $1,178,340 as compared to the year ended December 31, 2021. The increase in general and administrative expenses was primarily due to an increase in employee wages and board fees of $746,952 related to the hiring of our chief financial officer, the addition of two board members and the special transaction bonus for executives and board members related to the Acquisition. Additionally, there were increases in professional and legal fees of $732,529 related primarily to preliminary diligence costs associated with the Acquisition which were expensed as incurred during the first quarter and other general legal costs from litigation and the roll out of our employee stock purchase plan and the amendment to our equity incentive plan. We also had increases in software expense of $169,183 from the implementation of new systems, an increase in facilities and rent expense of $23,290 and increases in travel and

insurance costs totaling $96,210. The aggregate increase was offset by decreases of $278,224, $202,834 and $119,205 in investor relations expenses, consulting and marketing and other general business expenses, respectively.

Estimated legal contingency

Below is a summary of the estimated legal contingency during the years ended December 31, 2022 and 2021:

	Year Ended December 31,			
	2022	2021	$ Change 2022 vs. 2021	% Change 2022 vs. 2021
Estimated legal contingency	$ 6,205,310	$ —	$ 6,205,310	N/A

For the year ended December 31, 2022, we recorded an estimated for a legal contingency of $6,205,310 related to the Cunning Lawsuit. The estimate reflects the full amount of the judgement plus an estimate for the plaintiff's legal fees.

Other Expense

Below is a summary of other expense during the years ended December 31, 2022 and 2021:

	Year Ended December 31,			
	2022	2021	$ Change 2022 vs. 2021	% Change 2022 vs. 2021
Change in fair value of derivative liability	$ (59,729)	$ 21,165	$ (80,894)	(382)%
Gain on forgiveness of PPP loan	—	(117,953)	117,953	(100)%
Interest expense	665,133	769,159	(104,026)	(14)%
Interest income	(19,011)	(3)	(19,008)	633600 %
Finance charge	120,228	—	120,228	N/A
Wind-down costs	456,508	—	456,508	N/A
Total other expense, net	**$ 1,163,129**	**$ 672,368**	**$ 490,761**	**73 %**

For the year ended December 31, 2022, we had net other expense of $1,163,129 primarily related to interest expense and wind down costs associated with the Acquisition. In addition, we recognized a finance charge of $120,228 from the repricing of the Sciences warrants. The increase was offset by decreases in interest expense of $104,026 due to a lower average outstanding principal balance outstanding during the year on the Amended Credit Agreement, a decrease in the fair value of the derivative liabilities of $80,894 and interest income of $19,008. Other expenses were offset by the gain on debt forgiveness realized from the PPP Loan that was realized during the period ended December 31, 2021.

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our clinical trials, our research and development efforts, variations in the level of expenditures related to investor relations and seeking new sources of capital. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. In particular, to the extent our medical affairs personnel and clinical trial subjects are subject to varying levels of restriction on accessing clinical trial sites due to constraints on the global supply chain, we expect our progress towards executing our clinical trials to be adversely affected.

Liquidity, Going Concern and Capital Resources

Liquidity and Going Concern

We have incurred operating losses and negative cash flows from operations since our inception. We expect to continue to incur significant losses and negative cash flows from operations through 2023 and into the foreseeable future. We anticipate that we will continue to incur net losses 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. Historically, we have funded our operations primarily through issuance of equity securities, borrowings from a related party and strategic transactions.

As of December 31, 2022, we had an accumulated deficit of $66,737,765, stockholders' deficit of $3,008,054 and a working capital deficit of $3,175,408. We had unrestricted cash of $1,244,527 as of December 31, 2022, as compared to $8,983,007 as of December 31, 2021. The decrease in our cash balance was primarily attributable to increased research and development expenses related to manufacturing SBI-100 in anticipation of the start of our Phase 2 clinical trial and prepayments to our CRO for our Phase 1 clinical trial, which commenced in the fourth quarter of 2022. The Company expects to continue to incur significant losses and negative cash flows from operations through 2023 and expects to incur significant losses and negative cash flows from operations in the future. During 2022, we also expended significant legal and professional resources on the Acquisition and general litigation, including litigation associated with the Cunning Lawsuit, as described in more detail above under the caption "Legal Proceedings - Cunning Lawsuit". The various Acquisition related transactional delays resulted in the further extension of the outside date to close the Acquisition. Due to these delays, in October 2022 the Company entered into a working capital loan from EHT to provide funds to continue operations through the date of closing of the Acquisition. Upon closing the Acquisition, we acquired net assets with an estimated fair value of $15,045,412, upon closing the Acquisition we received $6,784,057 in cash and upon the closing of the Verdélite SPA we received a closing payment of $5,547,000 on February 10, 2023. We expect to collect the remainder of the value from the divestiture of EHT's assets over a four year period. However, there are significant risks and uncertainties around the timing of these payments and ultimate realization of these assets.

On October 5, 2018, we secured a Credit Agreement with Sciences, that provided us with a credit facility of up to $20,000,000. On April 29, 2020, we entered into the first amendment to the Credit Agreement with Sciences, which amended and restated the Credit Agreement. On March 29, 2021, we entered the second amendment to the Amended Credit Agreement to defer interest payments until the earlier of maturity or prepayment of the principal balance. Effective September 15, 2021, the disbursement line under the credit facility was closed. As of December 31, 2022, we had an outstanding principal balance of $1,848,375 under the Amended Credit Agreement. The outstanding advances plus accrued interest under the Amended Credit Agreement were due on October 5, 2022 and on November 17, 2022, we executed an extension of the maturity date to December 30, 2022 in exchange for the repricing of Sciences warrants and the repayment of 25% of the outstanding principal balance plus accrued interest. On December 30, 2022, we negotiated an additional extension of the maturity date to the earlier of February 28, 2023 or the closing Verdélite SPA. On February 16, 2023, Sciences exercised all of its outstanding warrants and converted the remaining balance of the Amended Credit Agreement plus accrued interest which extended our cash runway. Pursuant to the February 16, 2023 Master Transaction Agreement with Sciences, Sciences agreed to use its best efforts to distribute the shares of Skye held by Sciences to the individual shareholders of Sciences upon Skye's listing to a nationally recognized exchange.

As described more fully above under the caption, "Legal Proceedings – Cunning Lawsuit", on January 18, 2023, a jury rendered a verdict in favor of Ms. Cunning and awarded her $512,500 in economic damages (e.g., lost earnings, future earnings and interest), $840,960 in non-economic damages (e.g., emotional distress) and $3,500,000 in punitive damages. The plaintiff's counsel has also filed a motion for attorney fees claiming fees of $1,351,850 and a multiplier of 1.5, for a total of $2,027,775. This jury verdict resulted in the recognition of an estimated legal contingency of $6,205,310, this judgement and the trial preparation also increased our overall legal costs for the year ended December 31, 2022. We strongly believe that this case was incorrectly decided as to liability, the amount of compensatory damages, and the appropriateness and amount of punitive damages. We intend to vigorously challenge the verdict in the trial court and appeal and pursue reimbursement under our existing insurance policies. However, the outcome of the litigation and the amount recoverable under its existing insurance policies, if any, is inherently uncertain.

We expect that the potential expected cash outflows required to pursue legal appeals or other strategies may limit our ability to pursue all of our plans for our business. Furthermore, the uncertainty as to the resolution of the litigation could limit our ability to raise new capital from investors to operate our business. Additionally, the increased turmoil in the U.S. capital markets created a substantially more difficult business environment. Our ability to access the capital markets is expected to be extremely limited.

Without additional funding during the second quarter of 2023, management believes that the Company will not have enough funds to meet its obligations and continue pre-clinical and clinical studies beyond one year after the date the consolidated financial statements are issued. If we do not receive additional funding during the second quarter of 2023, we likely cannot continue operations. These conditions indicate it is probable that there is substantial doubt as to our ability to continue as a going concern, unless we are able to raise sufficient capital to continue our operations.

Our independent registered public accounting firm has issued a report on our audited consolidated financial statements as of and for the year ended December 31, 2022 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 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, among other things, the successful resolution of our litigation with Ms. Cunning, 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.

Cash Flows

The following is a summary of our cash flows for the periods indicated and has been derived from our consolidated financial statements which are included elsewhere in this Form 10-K:

	Year Ended December 31,	
	2022	**2021**
Net cash, case equivalents and restricted cash provided by (used in):		
Operating activities	$ (12,744,072)	$ (6,474,888)
Investing activities	5,214,395	(90,866)
Financing activities	(208,794)	13,079,356
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (7,738,471)	$ 6,513,602

Cash Flows from Operating Activities

The primary use of cash for our operating activities during these periods was to fund research development activities for our clinical product candidate, SBI-100 OE, and general and administrative activities. Our cash used in operating activities also reflected changes in our working capital, net of adjustments for non-cash charges, such as a finance charge from the repricing of the Sciences warrants in connection with the extension of the Amended Credit Agreement, stock-based compensation expense, non-cash interest expense related to the amortization of our debt discounts on our related party Amended Credit Agreement, fair value adjustments related to our warrant liability and an estimated legal contingency related to the Cunning Lawsuit.

Cash used in operating activities of $12,744,072 during the year ended December 31, 2022, reflected a net loss from operations of $19,481,602, the losses were adjusted by aggregate non-cash charges of $7,499,434 and included a $761,904 decrease in our operating assets and liabilities. Non-cash charges included $629,032 for stock-based compensation expense, $489,595 non-cash interest expense from the amortization of the debt discount on the Amended Credit Agreement, a $59,729 gain from the decrease in fair value of our warrant liability, depreciation and amortization of $114,998, a finance charge of $120,228 due to the Sciences warrant repricing, and a loss of $6,205,310 due to the estimated legal contingency associated with the Cunning Lawsuit. The net change in our operating assets and liabilities included a $109,943 increase in our prepaid expense and other current assets, an increase in accounts payable of $799,740, and a $1,671,587 decrease in our accrued expense and other current liabilities.

Cash used in operating activities of $6,474,888 during the year ended December 31, 2021, reflected a net loss of $8,522,182, partially offset by aggregate non-cash charges of $1,400,351 and included a $646,943 net change in our operating assets and liabilities. Non-cash charges included $869,206 for stock-based compensation expense, $593,802 non-cash interest expense from the amortization of the debt discount on the Amended Credit Agreement, a $21,165 loss from the increase in fair value of our warrant liability, depreciation and amortization of $34,131, and a $117,953 gain from the forgiveness of the PPP Loan. The net change in our operating assets and liabilities included a $434,110 increase in our prepaid expense and other current assets, an increase in accounts payable of $518,638, and a $580,258 increase in our accrued expense and other current liabilities.

Cash Flows from Investing Activities

Cash provided by continued investing activities of $5,214,395 during the year ended December 31, 2022 consisted of our capital expenditures in relation to the purchase of property plant and equipment of $28,060, cash divested net of proceeds received from the sale of an asset of $66,458 and cash proceeds received from the Acquisition of $5,308,913. During the year ended December 31, 2021, the Company purchased $90,866 of machinery and office equipment.

Cash Flows from Financing Activities

During the year ended December 31, 2022, cash used in financing activities included $1,967 in proceeds received in connection with pre-funded warrants and $680,901 in proceeds from the EHT bridge financing, offset by $275,537 in repayments on our insurance premium financing, and $616,125 in prepayments on the Amended Credit Agreement.

During the year ended December 31, 2021 cash provided by financing activities included $7,011,799 in proceeds received in connection with the exercise of warrants, $6,062,774 in net proceeds from the issuance of common stock and warrants and $4,783 received from employee stock option exercises in 2021.

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 F38

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 GAAP 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 GAAP, 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 Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2022, 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, 2022, 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, 2022 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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	42	Chief Executive Officer, Chairman, Director
Kaitlyn Arsenault	36	Chief Financial Officer
Margaret Dalesandro	76	Director
Deborah Charych	58	Director
Praveen Tyle	63	Director
Keith Ward	53	Director

Biographies of Directors, Executive Officers and Significant Employees

Punit Dhillon. Mr. Dhillon currently serves as the Chair of the Board of Directors and as the Company's President and Chief Executive Officer. Mr. Dhillon was appointed as a member of the Board of Directors in 2018. In December 2019, Mr. Dhillon was appointed as the Chairman of the Board of Directors. In August 2020, Mr. Dhillon was appointed as the Company's Chief Executive Officer. Mr. Dhillon is currently a board member of Arch Therapeutics Inc., a US-based biotechnology company developing a novel approach to stop bleeding (hemostasis), control leaking (sealant), and manage wounds during surgery, trauma, and interventional care (OTCQB: ARTH). Mr. Dhillon was the co-founder and former President & CEO of OncoSec Medical Incorporated (NASDAQ: ONCS), a leading biopharmaceutical company developing cancer immunotherapies for the treatment of solid tumors, where he served as an executive until March 2018 and as a director until February 2020. Prior to that, from September 2003 to March 2011, Mr. Dhillon served as Vice President of Finance and Operations at Inovio Pharmaceuticals, Inc. (NASDAQ: INO), a DNA vaccine development company. Collectively, Mr. Dhillon has led and assisted in raising over $500 million through financings and mergers and acquisitions deals, as well as several licensing and development transactions with large pharmaceutical companies including Merck & Co., Inc. (NYSE: MRK), Bristol Myers Squibb Co (NYSE: BMY), and Pfizer Inc. (NYSE: PFE). Mr. Dhillon also co-founded and is the director of YELL Canada, a registered Canadian charity that partners with schools to support entrepreneurial learning. Mr. Dhillon received his Bachelor of Arts Honors degree in Political Science with 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 give him the qualifications necessary to serve as an officer and director of the Company.

Kaitlyn Arsenault, CPA. Ms. Arsenault was appointed as the Company's Chief Financial Officer in October 2021. From 2014 to 2021, Ms. Arsenault previously served as the President of KA Consulting, Inc., a registered public accounting firm in San Francisco, CA, providing independent technical accounting consulting services for emerging public and private companies in the pharmaceutical, life sciences, technology, and FinTech industries. From September 2016 to October 2021, she served as the Company's Head of Financial Reporting and Technical Accounting. Ms. Arsenault's experience includes addressing complex technical accounting issues related to equity financings, derivatives, debt instruments, stock-based compensation, revenue recognition, and mergers and acquisitions, among other subjects. Prior to becoming an independent financial consultant, Ms. Arsenault spent seven years in public accounting as an assurance manager in the SEC practice of Friedman LLP (now Marcum LLP), gaining public and private audit engagement experience across multiple industries. Ms. Arsenault received her Bachelor of Science degree in Accounting from Ramapo College of New Jersey and is a Certified Public Accountant in California (active) and New Jersey (inactive). Ms. Arsenault's prior track record with the Company, extensive experience with pharmaceutical, life science, and technology companies, and vast exposure to different accounting and financial issues in the public markets give her the qualifications and skills necessary to serve as an officer of the Company.

Dr. Margaret Dalesandro. Dr. Margaret Dalesandro is currently a member of the Board and has served as a member since August 2020. From 2019 to 2021, Dr. Dalesandro served on the board of OncoSec Medical Incorporated (NASDAQ: ONCS), 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, she served as Chair of the OncoSec Medical Incorporated Board from early 2020 through 2021. Since 2021, Dr Dalesandro has served on the board of Seelos Therapeutics, a company focusing on the development of treatments for central nervous system diseases (NASDAQ: SEEL). Since 2012, Dr. Dalesandro has been the President of Brecon Pharma Consulting LLC., a full-service pharma/biotech consultancy focusing on identifying and obtaining critical information early in product development. Dr. Dalesandro has over thirty-five years of experience leading strategic product development in the pharmaceutical, biotechnology, and diagnostics industries. From 2009 to 2012, she served as the Business Director of Integrative Pharmacology in the Life Sciences (Corning Integrated Pharmacology - CIP) division at Corning Incorporated, leading all aspects of the CIP business including commercial, technical, P&L, competitive assessment, strategy, and talent management; from 2002 to 2009, as Vice President of Project, Portfolio and Alliance Management at ImClone Systems Incorporated, which was a biopharmaceutical company dedicated to developing biologic medicines in the area of oncology; from 2000 to 2002, as Executive Director of Project and Portfolio Management at GlaxoSmithKline, a global pharmaceutical company producing treatments for respiratory illnesses, HIV, immuno-inflammation, and oncology (among others) (NYSE: GSK); and from 1998 to 2000, as Senior Consultant at Cambridge Pharma Consultancy, Europe's largest pharmaceutical R&D strategy consulting firm. During her tenure from 1989 to 1998 at Centocor Incorporated, a biotechnology company forming a part of the Johnson & Johnson group of companies and specializing in the production of treatments for infectious, cardiovascular, and autoimmune

diseases and cancer, Dr. Dalesandro developed and presently holds the patents on a diagnostic test for acute coronary syndrome based on the detection of platelet surface integrins. Dr. Dalesandro received her Ph.D. in Biochemistry from Bryn Mawr College and completed an NIH Post-Doctoral Fellowship in Molecular Immunology at Wake Forest University School of Medicine. Dr. Dalesandro's significant experience with life science and technology companies give her the qualifications and skills necessary to serve as a director of the Company.

Dr. Deborah Charych. Dr. Deborah Charych is currently a member of the Board and has served as a member since February 2023. Since October 2018, Dr. Charych has served as the Co-Founder, Chief Technology Officer, and Advisor of RayzeBio, Inc, an oncology company focused on the targeted delivery of radionuclides. Dr. Charych conceived and led the scientific and operational R&D strategy for RayzeBio, leading a successful Series A financing and launch in August 2020, as well as subsequent Series B, C, and D rounds. Prior to launching RayzeBio, Dr. Charych held a number of scientific leadership positions in biotech focused on translational drug development. From 2017 to 2019, she founded Third Rock Ventures, creating new biotech companies based on strong science, co-founding Maze Therapeutics, which focuses on harnessing the power of human genetics, functional genomics, and data science to advance our understanding of how to more effectively treat patients with severe rare and common diseases. From 2010 to 2018, Dr. Charych served as Executive Director of Preclinical and Translational Research at Nektar Therapeutics, conceiving of and leading the pre-clinical and early clinical development of an immuno-oncology pipeline with NKTR-214 and NKTR-358, next-generation IL-2 receptor agonists, which are currently in Phase 3 oncology and Phase 2 autoimmune clinical trials. At FivePrime Therapeutics from 2007 to 2010, Dr. Charych was the Director of Biologics Process Development/CMC/Protein Chemistry, leading a team that contributed to the clinical development of novel biologics for pan-FGF and CSF1 antagonist antibodies for oncology and immunology diseases. From 1998 to 2006, while at Chiron Corporation, she initiated and led a large proteomics effort to guide oncology target discovery, including the discovery of peptide-mimetic binders ('peptoids'). During her time at Lawrence Berkeley National Laboratory from 1993 to 1998, she assumed an academic leadership role as a tenured Principal Investigator, focusing on new biomaterials. Dr. Charych earned a PhD in Physical Chemistry from the University of California in Berkeley, CA and a B.S. in Chemistry from Carnegie-Mellon University in Pittsburgh, PA. Dr. Charych's education and significant experience with a wide variety of life science companies give her the qualifications and skills necessary to serve as a director of the Company.

Dr. Praveen Tyle. Dr. Praveen Tyle is currently a member of the Board and has served as a member since July 2021. Since 2006, Dr. Tyle has served as a member of the board at Kiora Pharmaceuticals, a pharmaceutical company that develops therapies for the treatment of eye diseases (NASDAQ: KPRX) and since 2003, he has served as a member of the board at Orient Europharma Co., Ltd., a pharmaceutical company operating primarily in Asia and producing a wide range of prescription drugs and nutrition products. Since 2021, Dr. Tyle has served as President, Chief Executive Officer, and Director of Invectys, Inc., a clinical-stage biopharmaceutical company founded from the world-renowned Pasteur Institute and focused on the development of innovative immunotherapy approaches to treat cancers. From 2016 to 2021, he was Executive Vice President of Research and Development at Lexicon Pharmaceuticals, Inc., a pharmaceutical company whose genetic approach to drug development is based on Nobel Prize-winning technology (NASDAQ: LXRX). From 2013 to 2016, he served as President, Chief Executive Officer, and Director of Osmotica Holdings (Cyprus & Osmotica Pharmaceutical), a company focusing on central nervous system drug development. From 2011 to 2012, Dr. Tyle was the Executive Vice President and Chief Scientific Officer of United States Pharmacopeia, an independent scientific nonprofit organization focused on building trust in the supply of safe, quality medicines. From 2008 to 2010, Dr. Tyle served as Senior Vice President and Global Head of Business Development and Licensing and Global Head of Research and Development at Novartis OTC, a pharmaceutical company that produces both patented and generic product on a global scale (NYSE: NVS). Earlier in his career, from 2004 to 2008, he was Corporate Senior Vice President and Chief Scientific Officer at Bausch + Lomb Corporation, a company specializing in eye care and whose products and innovations range from pharmaceuticals, lenses, and diagnostic and surgical tools (NYSE: BLCO / TSX: BLCO). Since 2005, Dr. Tyle has served as an Adjunct Associate Professor of Ophthalmology at the University of Rochester Eye Institute Medical Center, among other current and past academic roles. He has coauthored over 100 peer-reviewed academic papers and presentations and is named on multiple patents, including those related to ophthalmic innovations, drug delivery, and glaucoma. Dr. Tyle earned his B.Pharm. from Banaras Hindu University in India and received his PhD in Pharmaceutics & Pharmaceutical Chemistry from Ohio State University. Dr. Tyle's significant contributions in the field of ophthalmology and extensive experience with life science companies give him the qualifications and skills necessary to serve as a director of the Company.

Dr. Keith Ward. Dr. Keith Ward is currently a member of the Board and has served as a member since December 2021. Dr. Ward is a life sciences executive with over twenty-five years of experience in the biotech and pharmaceutical industry. In 2022, Dr. Ward co-founded Kuria Therapeutics, a private pharmaceutical company developing novel ophthalmic and dermal therapeutics, where he currently serves as President and Chief Executive Officer. Since 2019, Dr. Ward has also served as President and Chief Executive Officer of InterveXion Therapeutics, a private clinical-stage biotech company developing immunotherapies for substance use disorders. Prior to joining InterveXion, Dr. Ward served as Executive Vice President and Chief Development Officer for Reata Pharmaceuticals, where he led research and development, clinical operations, regulatory affairs, manufacturing, and project management. Before that, Dr. Ward developed ophthalmic pharmaceuticals and medical devices as Global Vice President of Pharmaceutical R&D for Bausch + Lomb. Dr. Ward has also held positions of increasing responsibility within GlaxoSmithKline and SmithKline Beecham Pharmaceuticals. Dr. Ward earned a B.S. in Toxicology with a minor in Chemistry from Northeast Louisiana University and a Ph.D. in Toxicology from the University of North Carolina at Chapel Hill. Dr. Ward's significant experience in biotech and pharmaceutical companies give him the qualifications and skills necessary to serve as a director of the Company.

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, 2022, our executive officers, directors, and greater than 10% stockholders complied with all applicable filing requirements on a timely basis.

Family Relationships

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

Term of Office of Directors

Our directors 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 current 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 2022, our Board met six times (including telephonic meetings) and took action by written consent fifteen 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. During 2022, our Board met by special committee eleven times (including telephonic meetings) and took action by written consent two times as a result of the special committee meetings.

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 our directors - other than Dr. Charych, who was elected as director in 2023 - attended our most recent 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 Dr. Keith Ward, Dr. Margaret Dalesandro and Dr. Praveen Tyle. Dr. Ward 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 Dr. Ward, Dr. Dalesandro and Dr. Tyle are independent directors as that term is defined in Rule 5605(a)(2) of the Nasdaq Listing Rules, and we have determined that each of Dr. Ward, Dr. Dalesandro and Dr. Tyle, as audit committee members, meet the more stringent requirements under Rule 5605(c)(2) of the Nasdaq Listing Rules. Our audit committee met five times (including telephonic meetings) and acted by written consent two times in 2022.

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 Dr. Praveen Tyle, and Dr. Margaret Dalesandro. Dr. Praveen Tyle serves as chairman of the compensation committee. The Board has determined that Dr. Margaret Dalesandro and Dr. Praveen Tyle are independent directors as that term is defined in Rule 5605(a)(2) of the Nasdaq Listing Rules. Our compensation committee met three times (including telephonic meetings) during 2022 and took no action by written consent during 2022.

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 nomination and corporate governance committee that operates under a written charter approved by the Board. The members of our nomination and corporate governance committee are Dr. Margaret Dalesandro, Dr. Praveen Tyle and Dr. Keith Ward. Dr. Margaret Dalesandro serves as chairman of the nomination and corporate governance committee. The Board has determined that Dr. Margaret Dalesandro, Dr. Praveen Tyle, and Dr. Keith Ward are independent directors as that term is defined in Rule 5605(a)(2) of the Nasdaq Listing Rules. Our nomination and corporate governance committee met three times during 2022 (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.

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 and Insider Trading Policy

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.

We maintain an Insider Trading Compliance Policy that prohibits our officers, directors and employees from purchasing or selling any type of security while in possession of material, non-public information relating to the security, whether the issuer of such security is the Company or any other company. Additionally, no officer, director or employee shall purchase or sell any security of the Company during the period beginning on the 14th calendar day before the end of any fiscal quarter of the Company and ending upon completion of the second full trading day after the public release of earnings data for such fiscal quarter or during any other trading suspension period declared by the Company. It prohibits officers, directors, or employees from pledging our stock as collateral to secure loans and from engaging in hedging transactions, including zero-cost collars and forward sale contracts. It further prohibits margin purchases of our stock, short sales of our stock, and any transactions in puts, calls or other derivative securities involving our stock.

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, 2022 and 2021 of our named executive officers as determined in accordance with SEC rules.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary ($)	Bonus ($) (4)	Stock Awards ($) (1)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Kaitlyn Arsenault	2022	325,856	130,031	—	—	—	—	—	455,887
Chief Financial Officer (2)	2021	75,000	19,031	58,000	269,240	—	—	181,473	602,744
Punit Dhillon	2022	432,577	298,000	—	—	—	—	2,500	733,077
CEO (3)	2021	400,000	220,521	116,000	160,680	—	—	2,500	899,701

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

(2) For the year ended December 31, 2021, other compensation consists of consulting fees charged to the Company by KA Consulting, Inc. and RoseRyan, Inc. for Ms. Arsenault's services.

(3) For the years ended December 31, 2022 and 2021, other compensation consists of personal tax preparation fee reimbursements per the executives employment agreement.

(4) In connection with the Acquisition, the Board approved transaction bonuses to be paid to the CEO and CFO of $111,000 and $148,000, respectively, upon the closing of the Acquisition (see Note 5). As the Acquisition was completed on November 10, 2022, the amounts stated included the transaction bonuses.

Employment and Severance Arrangements

Employment Agreements and Equity Awards

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. Dhillon's achievement of annual corporate milestones agreed to by the Board. Effective June 1, 2022, Mr. Dhillon's annual base salary was increased to $450,000 per year and his annual discretionary bonus eligibility was increased to sixty percent (60%) of his base salary. Mr. 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. Dhillon's employment with the Company is at-will. Except for termination of Mr. Dhillon's employment for "Cause," "By Death", "By Disability" (as such terms are defined in his employment agreement), Mr. Dhillon will be entitled to a severance payment equal to twenty-four (24) months of his then current base salary, less applicable statutory deductions and withholdings if terminated by the Company.

In connection with his appointment, the Company granted Mr. 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 the following four and a half years from the grant date.

During the year ended December 31, 2021, Mr. Dhillon was granted 2,000,000 restricted stock units and 3,090,000 stock options. The restricted stock units vest in three equal annual installments commencing on the first anniversary of the grant date, which was December 14, 2021. The stock options vest 25% on the one year anniversary of the grant date and 1/48th monthly thereafter.

On October 4, 2021, we entered into an employment agreement with Ms. Kaitlyn Arsenault, our Chief Financial Officer. The agreement provides for an annual base salary of $300,000 per year and an annual discretionary bonus of up to thirty five percent (35%) of her base salary based in part on Ms. Arsenault's achievement of milestones agreed to by the Board. Effective June 1, 2022, Ms. Arsenault's annual base salary was increased to $340,000 per year and her annual discretionary bonus eligibility was increased to forty percent (40%) of her base salary. Ms. Arsenault will also receive the normal benefits available to other similarly situated executives and will be entitled to severance pay under the circumstances described below.

Ms. Arsenault's employment with the Company is at-will. Except for termination of Mr. Arsenault's employment for "Cause," "By Death" or "By Disability" (as such terms are defined in her employment agreement), Ms. Arsenault will be entitled to a severance payment equal to six (6) months of her then current base salary, less applicable statutory deductions and withholdings, if she is terminated by the Company.

In connection with her appointment, the Company granted Ms. Arsenault options to purchase 1,600,000 shares of the Company's common stock at an exercise price of $0.09 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 in semi-annual installments over four years from issuance.

During the year ended December 31, 2021, Ms. Arsenault was granted 1,000,000 restricted stock units and 1,770,000 stock options. The restricted stock units vest in three equal annual installments commencing on the first anniversary of the grant date, which was December 14, 2021. The stock options vest 25% on the one year anniversary of the grant date and 1/48th monthly thereafter.

On September 15, 2021, prior to Ms. Arsenault's appointment as CFO, Ms. Arsenault was granted 400,000 stock options in connection with her consulting arrangement with us. The stock options vest 10% on the grant date and 90% in equal annual installments thereafter over a period of four years.

The foregoing description of the employment agreements above 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.

The foregoing descriptions of the change of control severance plan does not purport to be complete and is qualified in its entirety by reference to the full text of such change of control severance plan attached hereto as an exhibit and incorporated by reference herein.

Outstanding Equity Awards at Fiscal Year-end

As of December 31, 2022, 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	4,500,000	4,500,000	0.045	8/7/2030		
	(4)12/14/2021	772,500	2,317,500	0.058	12/14/2031		
	(5)12/14/2021					1,333,333	21,333
Kaitlyn Arsenault	(6)9/15/2021	130,000	270,000	0.120	9/15/2031		
CFO	(7)10/4/2021	520,000	1,080,000	0.090	10/4/2031		
	(4)12/14/2021	442,500	1,327,500	0.058	12/14/2031		
	(5)12/14/2021					666,667	10,667

(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, 2022.

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

(3) The options specified above vest as follows: 10% vests on the grant date and 90% vests in equal semi-annually installments thereafter over four years.

(4) The options specified above vest as follows: 25% vests on the one year anniversary of the grant date and 1/48th vests monthly thereafter over three years following the one year anniversary of the grant date.

(5) The restricted stock units specified above vest as follows: 33% on each grant date anniversary over three years.

(6) The options specified above vest as follows: 10% vests on the grant date and 90% vests in equal annual installments thereafter over four years.

(7) The options specified above vest as follows: 10% vests on the grant date and 90% vests in equal semi-annually installments thereafter over four years.

Exercises of Options

There were no exercises of stock options by our named executive officers during the year ended December 31, 2022.

Director Compensation

As of December 31, 2022, our policy for the compensation of our non-employee directors is 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 250,000 stock options which vest in twelve equal monthly installments. In subsequent annual periods, each non-employee director receives a grant of 250,000 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)

The table below summarizes the compensation paid by us to our non-employee directors for the year ended December 31, 2022. Mr. Dhillon, our employee director, does not receive additional compensation for his services as a member of our Board:

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) [1]	All Other Compensation ($)[6]	Total ($)
Jim Heppell [2]	24,069	—	73,368	47,512	144,949
Margaret Dalesandro [3]	67,500	—	—	—	67,500
Praveen Tyle [4]	86,000	—	—	—	86,000
Keith Ward [5]	66,944	—	—	—	66,944
Bobby Rai	5,617	—	—	—	5,617

(1) As of December 31, 2022, each non-employee director is entitled to an annual grant of 250,000 common stock options, all of which vest in twelve equal monthly installments. The amounts reported under “Option Awards” in the above table reflect the grant date fair value of these awards as determined in accordance with the Financial Accounting Standards Board’s Accounting Standards Codification *Topic 718, Compensation - Stock Compensation*. The value of stock option awards was estimated using the Black-Scholes option pricing model. The valuation assumptions used in the valuation of options granted may be found in Note 7 to our financial statements included in this annual report on Form 10-K for the year ended December 31, 2022. The annual Board member grants for the year ended December 31, 2022, were approved in 2023.

(2) On May 18, 2022, Mr. Heppell resigned from our Board and concurrently entered into a consulting agreement with us pursuant to which Mr. Heppell would provide mutually agreed upon services related to the wind down of EHT. In connection with the consulting agreement, Mr. Heppell was granted options to purchase 4,000,000 shares of common stock. These options have an exercise price of $0.04, and were subject to certain performance vesting and other vesting conditions pursuant to the consulting agreement. The vesting conditions of the stock option award provided that 50% of the options were vested upon grant and the remaining 50% (the "Second Tranche") would vest upon the sale of a real estate asset held by EHT at an amount greater than or equal to an amount specified in the Arrangement Agreement (the " Vesting Condition"). On February 9, 2023, the closing date of the sale of the real estate asset held by EHT, the Second Tranche of stock options was cancelled as the Vesting Condition was not satisfied. The value of the stock option award was estimated using the Black-Scholes option pricing model. In addition, on September 14, 2021, Mr. Heppell was granted options to purchase 150,000 shares of common stock. These options have an exercise price of $0.12, vest monthly over one year and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $18,300. In addition, on August 7, 2020, Mr. Heppell was granted options to purchase 1,000,000 shares of common stock. These options have an exercise price of $0.05, vest 10% on the date of grant with the remaining 90% vesting semi-annually over two years and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $40,000. In addition, on October 10, 2018, Mr. Heppell was granted options to purchase 200,000 shares of common stock. These options have an exercise price of $0.31, are fully vested and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $45,000. The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2022 for Mr. Heppell was 5,350,000, of which 3,350,000 were fully vested.

(3) On September 14, 2021, Dr. Dalesandro was granted options to purchase 150,000 shares of common stock. These options have an exercise price of $0.12, vest monthly over one year and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $18,300. In addition, on August 7, 2020, Dr. Dalesandro was granted options to purchase 250,000 shares of common stock. These options have an exercise price of $0.05 and vest 10% on the date of grant with the remaining 90% vesting semi-annually over two years and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $10,000. The aggregate number of shares issuable

upon exercise of option awards outstanding at December 31, 2022 for Dr. Dalesandro was 400,000, of which 400,000 were fully vested.

(4) On September 14, 2021, Dr. Tyle was granted options to purchase 25,000 shares of common stock. These options have an exercise price of $0.12, vest monthly over one year and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $3,050. In addition, on July 22, 2021, Dr. Tyle was granted options to purchase 250,000 shares of common stock. These options have an exercise price of $0.14 and vest 10% on the date of grant with the remaining 90% vesting semi-annually over two years and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $34,750. The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2022 for Dr. Tyle was 275,000, of which 162,500 were fully vested.

(5) On December 14, 2021, Dr. Ward was granted options to purchase 250,000 shares of common stock. These options have an exercise price of $0.06, vest monthly over one year and have a term of 10 years from the grant date. The value of the stock option award was estimated using the Black-Scholes option pricing model and totaled $12,750. The aggregate number of shares issuable upon exercise of option awards outstanding at December 31, 2022 for Dr. Ward was 250,000, of which 250,000 were fully vested.

(6) Under the consulting agreement, Mr. Heppell is entitled to a monthly fee of $6,300, which was increased to $16,600 per month upon the closing of the Acquisition. The consulting agreement provides Mr. Heppell with a termination payment in an amount equal to the monthly fees through the then-remaining term of the agreement if Mr. Heppell's engagement is terminated by the Company without cause. The consulting contract has been accounted for as an in-substance severance arrangement and $139,615 is recognized in severance expense during the year ended December 31, 2022. The monthly fee for Mr. Heppell's consulting agreement was adjusted to include the increased fee payments when the Acquisition closed. As of December 31, 2022, $47,512 has been paid to Mr. Heppell and $16,600 is owed and recognized in accounts payable - related party. The remaining portion of the consulting contract of $75,503 is accrued for in other current liabilities - related party. The consulting agreement with Mr. Heppell was terminated on February 9, 2023.

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, 2022 for the Company's 2014 Amended and Restated Omnibus Incentive Plan (the "2014 Amended and Restated Plan"). Shares available for issuance under the 2014 Amended and Restated 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 Amended and Restated Plan, refer to Note 8 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			
2014 Amended and Restated Omnibus Incentive Plan	45,661,730	$ 0.17	42,274,757
2022 Employee Stock Purchase Plan	—	—	28,000,000
Total	**45,661,730**	**$ —**	**70,274,757**

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to beneficial ownership of our common stock as of March 29, 2023, 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 or vesting of an RSU) 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 971,549,608 shares of our common stock issued and outstanding on March 29, 2023.

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 11250 El Camino Real, Suite 100, San Diego, CA 92130.

Name and Address of Beneficial Owner	Beneficial Ownership	Percent of Class
Emerald Health Sciences, Inc. (1)	169,407,901 (2)	17.4 %
Punit Dhillon	13,914,336 (3)	1.4 %
Kaitlyn Arsenault	1,744,114 (4)	*%
Dr. Margaret Dalesandro	560,417 (5)	*%
Dr. Praveen Tyle	304,167 (6)	*%
Dr. Keith Ward	354,167 (7)	*%
Dr. Deborah Charych	62,500 (8)	*%
All executive officers and directors as a group (6 persons)	16,939,701 (9)	1.7 %

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

(1) The address of Sciences is 10th Floor, 595 Howe St., Vancouver, British Columbia, Canada V6B 1A1.

(2) Based on a Schedule 13DA filed with the Company on March 17, 2023.

(3) Includes (i) 2,335,721 shares of common stock held by a family trust of which Mr. Dhillon is the trustee, (ii) 3,073,209 shares of common stock held directly by Mr. Dhillon, (iii) 331,500 shares of common stock issuable upon exercise of warrants, (iv) 8,173,906 shares of common stock underlying options that may be exercised within 60 days of March 29, 2023.

(4) Includes 1,410,781 shares of common stock underlying options that may be exercised or RSUs that vest within 60 days of March 29, 2023.

(5) Includes 560,417 shares of common stock underlying options that may be exercised within 60 days of March 29, 2023.

(6) Includes 304,167 shares of common stock underlying options that may be exercised within 60 days of March 29, 2023.

(7) Includes 354,167 shares of common stock underlying options that may be exercised within 60 days of March 29, 2023.

(8) Includes 62,500 shares of common stock underlying options that may be exercised within 60 days of March 29, 2023.

(9) Consists of (i) 5,408,930 shares beneficially owned by our current executive officers and directors as of March 22, 2023 and (ii) 10,865,938 shares subject to options exercisable or RSUs that vest within 60 days of March 22, 2023, of which 10,865,938 are vested as of such date.

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, 2022 and 2021, 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, Inc. ("Sciences") pursuant to which Sciences purchased a majority of the equity interest us, resulting in a change in control transaction. Sciences holds a significant interest in our equity as of December 31, 2022 and has provided us with financing under the Amended Credit Agreement. Jim Heppell was the Chief Executive Officer and a member of the Board of Directors of EHS during the year ended December 31, 2022 and was also a member of the Board of Directors of the Company until May 2022.

On October 5, 2018, we entered into the Credit Agreement with Sciences. The Credit Agreement originally provided for an unsecured credit facility of up to $20,000,000. Advances under the Credit Agreement accumulated interest at an annual rate of 7% and the original maturity date of the facility was October 5, 2022.

From November 1, 2018 to March 2019, Sciences advanced us an aggregate of $6,000,000 under the Credit Agreement. In connection with the advances under the Credit Agreement, we issued Sciences 7,500,000 warrants with an original exercise price of $0.50 per share and a term of five years. The warrants were fully vested at issuance.

On December 20, 2019, we entered into a Warrant Exchange Agreement, pursuant to which Sciences exercised 40.8 million 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 remaining 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 Sciences (the "Amended Credit Agreement"), which amended and restated the Credit Agreement, as reported in the current report on the Form 8-K filed with the SEC on April 29, 2020. During the year ended December 31, 2020, we received non-convertible 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 net proceeds of each advance were used for general corporate purposes.

On March 29, 2021, we entered into amendment two to the Amended Credit Agreement to defer interest payments through the earlier of maturity or prepayment of the principal balance. On September 15, 2021, we further amended the Amended Credit Agreement to close our access to any further disbursements.

On November 17, 2022, we entered into an amendment to the Amended Credit Agreement, pursuant to which (i) the Company agreed to prepay 25% of the outstanding principal amount under the Amended Credit Agreement, equal to $616,125, plus all accrued interest of $328,737 (ii) the parties agreed to extend the maturity date to the earlier of December 30, 2022 or the Termination Date (as such term is defined in the Amended Credit Agreement), (iii) the parties agreed to amend the exercise price of the warrants to purchase Company common stock held by Sciences to $0.017 per share and (iv) the parties agreed to use good faith efforts to enter into a customary piggyback registration rights agreement. On December 14, 2022, the Company and Sciences entered into a piggyback registration rights agreement pursuant to which, among other things, the Company agreed to provide registration rights for the shares of common stock underlying the warrants to purchase Company common stock held by Sciences should the Company file a registration statement with the SEC for the purpose of effecting a public offering of common stock.

On December 30, 2022, we entered into an amendment to the Amended Credit Agreement to extend the maturity date to the earlier of (a) five business days after the closing of the sale of VDL (b) February 28, 2023 or (c) the Termination Date (as such term is defined in the Amended Credit Agreement).

On May 18, 2022, Jim Heppell resigned from our board of directors and concurrently entered into a consulting agreement with us pursuant to which Mr. Heppell will provide mutually agreed upon services related to the wind down of EHT. The consulting agreement had an initial minimum term of one-year and will be automatically renewed for a one-year period on the anniversary of the contract unless terminated with 60 days' notice. Under the consulting agreement, Mr. Heppell was entitled to a monthly fee of $6,300, which was increased to $16,600 per month upon the closing of the Acquisition. The consulting agreement provides Mr. Heppell with a termination payment in an amount equal to the monthly fees through the then-remaining term of the agreement if Mr. Heppell's engagement is terminated by us without cause. In addition, Mr. Heppell was awarded 4,000,000 stock options which are subject to certain performance and other conditions. The Company has accounted for the consulting contract as an in-substance severance arrangement and recognized $139,615 in severance expense during the year ended December 31, 2022. The accrual for Mr. Heppell's severance was adjusted to include the increased fee payments when the Company closed the Acquisition. As of December 31, 2022, the Company recognized $16,600, in accounts payable - related party and $75,503 in other current liabilities - related party under this consulting agreement.

As of December 31, 2022, Mr. Heppell is also a board member and the CEO of Sciences. Mr. Heppell also served on VivaCell's board until he tendered his resignation on January 10, 2022.

In addition, the Board Observer Agreement in place with Sciences was amended in September 2021 to allow any board member or officer of Sciences to act as a representative of Sciences on a non-voting observer basis in meetings of the Board. On December 14, 2021, the Board Observer Agreement was terminated.

Effective February 16, 2023, the Company and Sciences entered into a master transaction agreement (the "MTA"). Under the MTA, (i) Sciences agreed to exercise 16,641,486 warrants to purchase common stock of the Company (the "Warrants") (ii) the parties agreed that the aggregate exercise price for the Warrants of $282,905 was to be paid through a reduction in the debt owed by the Company to Sciences (the "Credit Consideration") under the Amended Credit Agreement.

On February 22, 2023, the Company issued 16,641,486 shares of common stock to Sciences in connection with the exercise of the Warrants. Pursuant to the terms of the MTA, after the application of the Credit Consideration to the amounts owed under the Amended Credit Agreement, Sciences agreed to convert the remaining balance of $1,597,236 owed by the Company to Sciences under the Amended Credit Agreement into 41,379,164 shares of common stock of the Company at a conversion price of $0.0386, in accordance with an amendment to the Amended Credit Agreement set forth in the MTA.

Following the issuance of shares described above, the Amended Credit Agreement was terminated in its entirety per the terms of the MTA. Additionally, under the MTA, Sciences agreed to use its best efforts to transfer all of the common stock of the Company held by Sciences to its shareholders on a pro-rata basis at or immediately prior to the Company's listing to a nationally recognized stock exchange, subject to compliance with applicable securities laws.

VivaCell Biotechnology España, S.L.U (formerly known as Emerald Health Biotechnology España, S.L.U.)

In January 2021 and April 2021, we entered into two separate Collaborative Research Agreements with VivaCell Biotechnology Espana, S.L.U ("VicaCell"), a research and development entity with substantial expertise in cannabinoid science and a subsidiary of Emerald Health Research, Inc. which is 100% owned by Sciences. Under the agreements, VivaCell will provide research and development services pursuant to agreed upon project plans for the research and development of SBI-200 and the preclinical development services for novel derivatives. The term of each agreement is initially for a one-year period. The agreements will terminate upon delivery and acceptance of the final deliverables under the project plans or if either party is in breach of the terms of the contract and such breach remains uncured for 45 days. Payment for services are based on the negotiated amounts for the completion of agreed upon objectives as provided in the Collaborative Research Agreements. For the years ended December 31, 2022 and 2021, we incurred $87,927 and $220,418, respectively, in expenses under the Collaborative Research Agreements. As of December 31, 2021, the Company has recognized a prepaid asset in the amount of $8,056 to be offset against future research and development costs under the Collaborative Research Agreements. No amounts were due to or from VivaCell under these agreements for the year ended December 31, 2022. The foregoing summary of the Collaborative Research Agreements do not purport to be complete and are qualified in their entirety by the full text of such agreement, a copy of which is attached as an exhibit hereto and incorporated by reference herein.

On October 11, 2021, we entered into an Exclusive Sponsored Research Agreement (the “ESRA”) with VivaCell to fund certain research and development programs which are of mutual interest to both the Company and VivaCell. We will have the right to use all data, products, and information, including intellectual property which are generated in the performance of the research under each and all projects funded by the Company pursuant to the ESRA, and VivaCell assigns and agrees to assign, to us all rights to any intellectual property created or reduced-to-practice under, or as a part of, a project funded by us pursuant to the ESRA. The foregoing summary of the ESRA does not purport to be complete and is qualified in its entirety by the full text of such agreement, a copy of which is attached as an exhibit hereto and incorporated by reference herein.

We have agreed to pay to VivaCell a royalty based on any and all licensing revenue or other consideration paid to us by a third-party licensee, assignee or purchaser of intellectual property rights created under the ESRA. In addition, upon a change of control transaction we have agreed to pay an amount equal to the royalty percentage multiplied by the fair value of the intellectual property created under the ESRA. Pursuant to the ESRA, VivaCell will provide a budget to be approved by us for each project, and we will make payments in accordance with the approved budget and pay an annual retainer to VivaCell of $200,000 per year. The initial term of the agreement is one year, with automatic renewal for successive one-year terms unless either party terminates upon 60 days' prior written notice to the other party pursuant to the ESRA. For the years ended December 31, 2022 and 2021, we incurred $200,000 and $44,624 in expenses under the ESRA. As of December 31, 2022 and 2021, we recognized accounts payable of $50,000 and a prepaid asset in the amount of $5,376 to be offset against future research and development costs under the ESRA.

On March 1, 2022, we entered into a research project with VivaCell under the ESRA Agreement for the development of a screening platform for anteroposterior ocular diseases. The project budget is $190,500. For the year ended December 31, 2022, we incurred $167,000 of research and development expenses under the ESRA. As of December 31, 2022, we recognized $7,835, in other current liabilities - related parties related to the first research project. As of December 31, 2022, we recognized $47,001, in accounts payable - related parties under this agreement.

Review, Approval and Ratification of Related Party Transactions

It is the Company's policy that all related party transactions must be approved by directors independent of the parties involved. 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.

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 Dr. Margaret Dalesandro, Dr. Praveen Tyle, Dr. Keith Ward and Dr. Deborah Charych are independent members of our Board, as that term is defined in Rule 5605(a)(2) of the Nasdaq Listing Rules.

Item 14. Principal Accounting Fees and Services.

Audit Fees

The aggregate fees billed for each of the fiscal years ended December 31, 2022 and 2021, 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 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 the years ended December 31, 2022 and 2021 were $36,292 and $366,736, 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.

The aggregate fees billed for each of the fiscal years ended December 31, 2022 and 2021, for professional services rendered by Marcum LLP. 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 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 the years ended December 31, 2022 and 2021 were $125,861 and $—, respectively.

Audit Related Fees

None.

Tax Fees

None.

All Other Fees

None.

Pre-Approval Policies and Procedures

Prior to engaging Mayer Hoffman McCann P.C. and Marcum LLP to perform audit services, 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 Marcum LLP, an independent registered public accounting firm (PCAOB Firm No. 688), are included in this Annual Report on Form 10-K.

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 (PCAOB Firm No. 199), 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 Shareholders and Board of Directors of Skye Bioscience, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Skye Bioscience, Inc. (the "Company") as of December 31, 2022, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the year ended December 31, 2022, 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, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph - Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its 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 also described in Note 1. The consolidated financial statements do not include any adjustments that might 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 the Company's financial statements based on our audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, 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 audit 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 audit 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 audit provides 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 are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2022.

East Hanover, New Jersey
March 31, 2023

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 sheet of Skye Bioscience, Inc., formerly known as Emerald Bioscience, Inc., and Subsidiaries ("Company") as of December 31, 2021, and the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2021, 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, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, 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 audit 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 audit 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 audit provides 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 from 2014 to 2022.

Irvine, California
March 25, 2022

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31	
ASSETS	**2022**	**2021**
Current assets		
Cash and cash equivalents	$ 1,244,527	$ 8,983,007
Restricted cash	4,580	4,571
Prepaid expenses	850,377	554,217
Prepaid expenses - related party	—	13,432
Assets held for sale	6,432,216	—
Other current assets	412,018	56,870
Total current assets	8,943,718	9,612,097
Property, plant and equipment, net	87,854	87,710
Operating lease right-of-use asset, net	71,191	146,972
Other assets	8,309	8,309
Total assets	$ 9,111,072	$ 9,855,088
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities		
Accounts payable	$ 1,669,997	$ 897,880
Accounts payable - related parties	124,901	2,130
Accrued interest - related party	15,814	174,911
Accrued payroll liabilities	657,734	344,450
Other current liabilities	1,422,442	375,842
Other current liabilities - related parties	95,850	—
Derivative liability	3	59,732
Estimate for legal contingency	6,205,310	—
Multi-draw credit agreement - related party	—	450,000
Convertible multi-draw credit agreement - related party, net of $0 and $487,668 discount and $0 and $1,927 issuance costs, at December 31, 2022 and 2021, respectively	1,848,375	1,524,905
Operating lease liability, current portion	78,700	82,372
Total current liabilities	12,119,126	3,912,222
Non-current liabilities		
Operating lease liability, net of current portion	—	78,700
Total liabilities	12,119,126	3,990,922
Commitments and contingencies (Note 14)		
Stockholders' (deficit) equity		
Preferred stock, $0.001 par value; 50,000,000 shares authorized at December 31, 2022; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.001 par value; 5,000,000,000 shares authorized at December 31, 2022; 913,528,958 and 476,108,445 shares issued and outstanding at December 31, 2022 and 2021, respectively	913,528	476,108
Additional paid-in-capital	62,816,183	52,644,221
Accumulated deficit	(66,737,765)	(47,256,163)
Total stockholders' (deficit) equity	(3,008,054)	5,864,166
Total liabilities and stockholders' (deficit) equity	$ 9,111,072	$ 9,855,088

See accompanying notes to the consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31	
	2022	**2021**
Operating expenses		
Research and development	$ 6,011,805	$ 2,931,437
General and administrative	6,094,617	4,916,277
Estimated legal contingency	6,205,310	—
Total operating expenses	18,311,732	7,847,714
Operating loss	(18,311,732)	(7,847,714)
Other expense		
Change in fair value of derivative liability	(59,729)	21,165
Gain on forgiveness of PPP loan	—	(117,953)
Interest expense	665,133	769,159
Interest income	(19,011)	(3)
Finance charge	120,228	—
Wind-down costs	456,508	—
Total other expense, net	1,163,129	672,368
Loss before income taxes	(19,474,861)	(8,520,082)
Provision for income taxes	6,741	2,100
Net loss	$ (19,481,602)	$ (8,522,182)
Loss per common share		
Basic	$ (0.04)	$ (0.02)
Diluted	$ (0.04)	$ (0.02)
Weighted average shares of common stock outstanding used to compute loss per share:		
Basic	555,270,089	406,599,390
Diluted	555,270,089	406,599,390

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31	
	2022	**2021**
Cash flows from operating activities:		
Net loss	(19,481,602)	(8,522,182)
Adjustments to reconcile net loss to net cash used in operating activities:		
Finance charge from Sciences warrant modification	120,228	—
Depreciation and amortization	114,998	34,131
Stock-based compensation expense	629,032	869,206
Change in fair value of derivative liability	(59,729)	21,165
Amortization of debt discount - related party	489,595	593,802
Estimate for legal contingency	6,205,310	—
Gain on debt forgiveness	—	(117,953)
Changes in assets and liabilities:		
Prepaid expenses	(16,396)	(364,083)
Prepaid expenses - related party	13,432	(13,432)
Other current assets	112,907	(56,595)
Other asset	—	(8,309)
Accounts payable	688,269	533,540
Accounts payable – related parties	111,471	(14,902)
Accrued interest – related party	(159,097)	130,824
Accrued payroll liabilities	313,284	282,903
Other current liabilities	(1,839,252)	166,531
Other current liabilities - related parties	95,850	—
Operating lease liability	(82,372)	(9,534)
Net cash, cash equivalents and restricted cash used in operating activities	(12,744,072)	(6,474,888)
Cash flows from investing activities:		
Cash divested net of proceeds from the sale of an asset	(66,458)	—
Purchases of property and equipment	(28,060)	(90,866)
Cash from asset acquisition, net of transaction costs of $1,475,144 for the year ended December 31, 2022	5,308,913	—
Net cash, cash equivalents and restricted cash provided by (used in) investing activities	5,214,395	(90,866)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants - net of $0 and $935,260 of issuance costs in 2022 and 2021, respectively	—	6,062,774
Proceeds from warrant exercises	—	6,999,999
Proceeds from pre-funded warrant exercises	1,967	11,800
Proceeds from option exercises	—	4,783
Repayment of loan payable	(275,537)	—
Proceeds from EHT bridge financing	680,901	—
Repayment of Amended Credit Agreement	(616,125)	—
Net cash, cash equivalents and restricted cash (used in) provided by financing activities	(208,794)	13,079,356
Net (decrease) increase in cash, cash equivalents and restricted cash	(7,738,471)	6,513,602
Cash, cash equivalents and restricted cash, beginning of year	$ 8,987,578	$ 2,473,976
Cash, cash equivalents and restricted cash, end of year	$ 1,249,107	$ 8,987,578
Supplemental disclosures of cash-flow information:		
Reconciliation of cash and restricted cash:		
Cash and cash equivalents	$ 1,244,527	$ 8,983,007
Restricted cash	4,580	4,571
Total cash and restricted cash shown in the consolidated statements of cash flows	$ 1,249,107	$ 8,987,578

Cash paid during the year for:		
Interest	$ 333,547	$ 44,087
Income taxes	6,741	1,600
Supplemental disclosures of non-cash financing activities:		
Deferred issuance costs	$ 22,471	$ 170,606
Purchases of property and equipment in other current liabilities	11,300	—
Financing of D&O insurance premium	275,537	—
Release of share liability	13,000	—
Asset acquisition costs in other current liabilities and accounts payable	102,857	—
Stock issued for assets, net of equity issuance costs	3,074,098	—

See accompanying notes to the consolidated financial statements.

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

	Stockholders' (Deficit) Equity				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amounts			
Balance, December 31, 2020	**288,074,415**	**$ 288,074**	**$ 38,896,693**	**$ (38,733,981)**	**$ 450,786**
Stock-based compensation expense	1,350,000	1,350	854,856	—	856,206
Issuance of common stock and warrants, net of issuance costs of $935,260	58,111,112	58,111	6,004,663	—	6,062,774
Exercise of pre-funded warrants	11,800,000	11,800	—	—	11,800
Exercise of common stock warrants	116,666,668	116,666	6,883,333	—	6,999,999
Exercise of stock options	106,250	107	4,676	—	4,783
Net loss for the year ended December 31, 2021	—	—	—	(8,522,182)	(8,522,182)
Balance, December 31, 2021	**476,108,445**	**$ 476,108**	**$ 52,644,221**	**$ (47,256,163)**	**$ 5,864,166**
Stock-based compensation expense	1,483,332	1,483	627,549	—	629,032
Exercise of pre-funded warrants	19,666,667	19,667	(17,700)	—	1,967
Common stock, options and warrants issued for asset acquisition, net of issuance costs of $25,511	416,270,514	416,270	9,441,885	—	9,858,155
Finance charge from Sciences warrant modification	—	—	120,228	—	120,228
Net loss for the year ended December 31, 2022	—	—	—	(19,481,602)	(19,481,602)
Balance, December 31, 2022	**913,528,958**	**$ 913,528**	**$ 62,816,183**	**$ (66,737,765)**	**$ (3,008,054)**

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.

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, SKYE Bioscience Pty Ltd. (formerly "EMBI Australia Pty Ltd."), an Australian proprietary limited company ("SKYE Bioscience 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 SKYE Bioscience Australia is to conduct clinical trials for the Company's product candidates. The Company is a clinical stage pharmaceutical company located in San Diego, California that researches, develops and plans to commercialize cannabinoid derivatives through its own directed research efforts and through multiple license agreements with the University of Mississippi ("UM").

On May 11, 2022, the Company entered into an Arrangement Agreement, as amended on June 14, 2022, July 15, 2022 and October 14, 2022 (the "Arrangement Agreement") with Emerald Health Therapeutics, Inc., a corporation existing under the laws of the Province of British Columbia, Canada ("EHT"), pursuant to a plan of arrangement under the Business Corporations Act (British Columbia) (the "Acquisition") (Note 3). On November 10, 2022, the Company completed the Acquisition and each share of EHT common stock outstanding immediately prior to the effective time of the Acquisition was transferred to the Company in exchange for 1.95 shares of the Company's common stock (the "Exchange Ratio").

In addition, on November 10, 2022, EHT entered into a share purchase agreement with a third party for the sale of EHT's wholly owned subsidiary, Verdélite Sciences, Inc. for an aggregate purchase price of $9,385,064, subject to certain adjustments (the "Verdélite SPA"). The sale of this subsidiary will complete the divestiture of EHT's most significant former operating assets (Note 3).

As of December 31, 2022, the Company has devoted substantially all its efforts to securing product licenses, carrying out its own 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, 2022, had a working capital deficit of $3,175,408 and an accumulated deficit of $66,737,765. As of December 31, 2022, the Company had unrestricted cash in the amount of $1,244,527. For the years ended December 31, 2022 and 2021, the Company incurred losses from operations of $18,311,732 and $7,847,714, respectively. For the years ended December 31, 2022 and 2021, the Company incurred net losses of $19,481,602 and $8,522,182, respectively. The Company expects to continue to incur significant losses and negative cash flows from operations through 2023 and expects to incur significant losses and negative cash flows from operations in the future.

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 has recently begun its Phase 1 clinical trial in December 2022, it has increased research and development spending and increased cash used in operating activities. During the year ended December 31, 2022, the Company expended significant resources on the Acquisition and experienced various transactional delays which resulted in the further extension of the outside date to close the Acquisition. Due to these delays, in October 2022 the Company entered into a working capital loan from EHT to provide funds to continue operations through the date of closing of the Acquisition (Note 3). These two factors, among others, have resulted in an overall increase in cash used in operating activities for the year ended December 31, 2022. Based on the Company's expected cash requirements, management expects that the Company will be able to complete its Phase 1 clinical trial. However, if the Company cannot obtain additional funding by the second half of 2023, it will not have enough funds to continue 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.

On November 10, 2022, the Acquisition was completed and the Company acquired the cash and other assets of EHT (Note 3). Management expects that the Acquisition will provide funding for the Company into the second quarter of 2023, and that the Company expects to collect payments from the sale of VDL through 2026.

During the year ended December 31, 2022, the Company met its operational funding requirements during the pre-closing period by, among other things, laying off two employees and entering into a $700,000 working capital Loan Agreement with EHT (Note 3). In early 2023, the Company will continue with the liquidation of EHT's assets, including the closing of the Verdélite SPA, and explore additional financing options (Note 15). However, the Company cannot provide any assurances that the additional funding needed to will be available on reasonable terms, or at all. If the Company raises additional funds by issuing equity securities, dilution to existing stockholders would result.

Further, in January 2023, the Company was subject to an unfavorable outcome in a lawsuit with a former employee which resulted in the recognition of an estimated legal contingency of $6,205,310. The Company strongly believes that this case was incorrectly decided as to liability, the amount of compensatory damages, and the appropriateness and amount of punitive damages. The Company intends to vigorously challenge the verdict in the trial court and appeal and pursue reimbursement under its existing insurance policies. However, the outcome of the litigation and the amount recoverable under its existing insurance policies, if any, is inherently uncertain (Note 14).

On October 5, 2018, the Company entered into a Multi-Draw Credit Agreement (the "Credit Agreement") with Emerald Health Sciences ("Sciences"), a related party (See Note 13). On April 29, 2020, the Company entered into an Amended and Restated Multi-Draw Credit Agreement (the "Amended Credit Agreement") with Sciences. As of December 31, 2022, the Company had an outstanding principal balance of $1,848,375 under the Amended Credit Agreement. The outstanding advances plus accrued interest under the Amended Credit Agreement were due on October 5, 2022 and the Company executed an extension of the maturity date to December 30, 2022 in exchange for the repricing of Sciences warrants and the repayment of 25% of the outstanding principal balance plus accrued interest. The Company subsequently negotiated an additional extension of the maturity date to the earlier of February 28, 2023 or the closing Verdélite SPA. On February 16, 2023, Sciences exercised all of its outstanding warrants and converted the remaining balance of the Amended Credit Agreement (See Notes 5 & 15).

On July 8, 2022, Sciences distributed its shareholdings in EHT to the individual shareholders of Sciences in the form of a return of capital. As a result, the common ownership interest by Sciences in both Skye and EHT was eliminated. On February 16, 2023, Sciences covenanted to use it best efforts to distribute its shareholdings in SKYE to the individual shareholders of Sciences upon Skye listing to a national exchange.

During the second quarter of 2022, the Company was indirectly impacted by a cyberattack on the contract manufacturer for its Phase 1 clinical trial material. This disruption delayed the Company's production timeline and the anticipated initiation of enrollment in the Company's Phase 1 clinical study for SBI-100 Ophthalmic Emulsion ("SBI-100 OE") to the fourth quarter of 2022.

It is possible that the Company may encounter other similar issues relating to supply chain issues, a lack of production or laboratory resources, global economic and political conditions, pandemics or cyberattacks that could cause business disruptions and clinical trial delays which will need to be managed in the future. The factors to take into account in going concern judgements and financial projections include travel bans, restrictions, government assistance and potential sources of replacement financing, financial health of service providers and the general economy.

The Company does not believe that inflation has had a material impact on its operating results during the periods presented. However, inflation, led by supply chain constraints, federal stimulus funding, increases to household savings, and the sudden macroeconomic shift in activity levels arising from the loosening or removal of many government restrictions and the broader availability of COVID-19 vaccines, has had, and may continue to have, an impact on general and administrative costs such as professional fees, employee costs and travel costs, and may in the future adversely affect the Company's operating results. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect the terms under which the Company can obtain, any potential additional funding.

Notably, the Company relies on third party manufacturers to produce its product candidates. The manufacturing of SBI-100 OE is conducted in the United States and Europe. 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. Since the COVID-19 pandemic, global supply chain disruptions have become more common and the Company may encounter future issues related to sourcing materials that are part of the eye drop formulation or manufacturing process, as well as impacting volunteer and/or patient recruitment in Australia for clinical studies. The location of the clinical trial site is in Australia and since the COVID-19 outbreak in that country, multiple cities have experienced health emergency lockdowns which have had a negative impact on the conduct and timelines of the clinical studies.

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. The accompanying Consolidated Financial Statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Assets Held for Sale

On November 10, 2022, the Company completed the Acquisition of EHT in accordance with the Arrangement Agreement. At the time of the Acquisition there were arrangements in place to sell the acquired assets and liabilities that comprised of two of EHT's subsidiaries, Emerald Health Therapeutics Canada, Inc. ("EHTC") and Verdélite Sciences, Inc. ("VDL"). As a result, EHTC and VDL were considered held for sale since the Acquisition and the Company has classified the associated assets of VDL as held for sale on the Consolidated Balance Sheets and the period costs related to both EHTC and VDL have been presented as wind-down costs in the Consolidated Statements of Operations. EHTC was divested on December 28, 2022 (see Note 3).

Assets that meet the held for sale criteria are held for sale and reported at the lower of their carrying value or their fair value, less estimated costs to sell. Changes in fair value are recorded as a gain or loss in the results of operations but not to exceed the original carrying value. The divestiture of VDL was completed after the balance sheet date on February 9, 2023, refer to Note 15 - Subsequent events for further detail.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries SKYE Bioscience Australia, EHT, Avalite Sciences, Inc. ("AVI"), VDL, EHTC and Nemus Sub. All intercompany accounts and transaction have been eliminated in consolidation.

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 and judgments as to the appropriate carrying values of equity instruments, debt with embedded features, estimates related to the Company's estimation of the percentage of completion under its research and development contracts, contingent legal liabilities, fair value of assets acquired in the Acquisition, and the valuation of stock based compensation awards, which are not readily apparent from other sources.

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, uncertainties related to the current global environment, including economic factors such as inflation, and risks related to the global supply chain disruptions (Note 1), risks related to operating primarily in a virtual environment, results of research and development activities, uncertainties surrounding regulatory developments in the United States, Canada, the European Union 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, 2022, and 2021, the Company has $25,842 and $— cash equivalents, respectively.

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.

Property, Plant and Equipment, net

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the estimated useful life of the improvements or the remaining lease term. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying Consolidated Balance Sheets.

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 derivative liabilities, approximate their fair value due to their short maturities. The derivative liabilities are valued on a recurring basis utilizing Level 3 inputs (Note 5).

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 Income (Loss) 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, 2022 and 2021. As a result of this valuation allowance, there are no income tax benefits reflected in the accompanying Consolidated Statements of Comprehensive Income (Loss) 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 ASC 815,*Derivatives and Hedging Activities* ("ASC 815") which 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 GAAP 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 recorded at fair value 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), net in the accompanying Consolidated Statements of Operations.

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), net in the Consolidated Statements of Operations.

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, 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. None of the costs 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 fair value is recognized as expense ratably over the vesting period with forfeitures accounted for as they occur. Upon the exercise of stock option awards, the Company's policy is to issue new shares of its common stock. The Company uses the Black-Scholes valuation method for estimating the grant date fair value of stock options using the following assumptions:

- Volatility - Expected volatility is estimated using the historical stock price performance over the expected term of the award.
- 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.

The Company accounts for liability-classified stock option awards ("liability options") under ASC 718 -*Compensation - Stock Compensation* ("ASC 718"), under which the Company accounts for its awards containing other conditions as liability classified instruments. Liability options are initially recognized at fair value in stock-compensation expense and subsequently re-measured to their fair values at each reporting date with changes in the fair value recognized in share-based compensation expense or additional paid-in capital upon settlement or cancellation.

Loss Per Common Share

The Company applies ASC No. 260, *Earnings per Share* in calculating its basic and diluted loss per common share. Basic loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of shares of common stock outstanding for the period. Diluted loss 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, restricted stock units, 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. For additional information regarding the loss per share (see Note 9).

Leases

In February 2016, the FASB issued Accounting Standards Update, or ASU, No. 2016-02,*Leases (Topic 842),* to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019.

At the inception of an arrangement, the Company determines whether the arrangement is, or contains, a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in the lease contract is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

Lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the Consolidated Balance Sheets as operating lease right-of-use assets, operating lease liability, current portion and operating lease liability, net of current portion.

Asset Acquisition

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Common stock, warrants and options issued as consideration in an asset acquisition are generally measured based on the acquisition date fair value of the equity interests issued. The Company refers to ASC 718 and utilizes a Black-Scholes Model to value the options and warrants issued is an asset acquisition and includes the fair value of such awards in the purchase consideration. Direct transaction costs are recognized as part of the cost of an asset acquisition. The Company also evaluates which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. Consideration deposited into escrow accounts are evaluated to determine whether it should be included as part of the cost of an asset acquisition or accounted for as contingent consideration. Amounts held in escrow where we have legal title to such balances but where such accounts are not held in the Company's name, are recorded on a gross basis as an asset with a corresponding liability in our consolidated balance sheet. The cost of an asset acquisition, including transaction costs, are allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. However, as of the date of acquisition, if certain assets are carried at fair value under other applicable GAAP the consideration is first allocated to those assets with the remainder allocated to the non-monetary identifiable assets based on a relative fair value basis.

Government Assistance

The Company adopted ASU 2021-10 *Government Assistance* on January 1, 2022. The Company accounts for the tax rebates received from the Australian Taxation Office ("ATO") under such guidance. The Company accounts for the rebates that it receives under the AusIndustry research and development tax incentive program under the income recognition model of IAS 20. Under this model, when there is reasonable assurance that the rebate will be received, the Company recognizes the income from the tax rebate as an offset to research and development expense during the period which the benefit applies to the research and development costs incurred. The total tax rebates received under the AusIndustry incentive program were $34,189 for the year ended December 31, 2022 related to incentives earned in the prior year and $— for the year ended December 31, 2021. As of December 31, 2022 and 2021, the Company has recognized $179,687 and $44,616, respectively, in other current assets in its Consolidated Balance Sheets.

Foreign Currency Translation

The Company's reporting currency and the functional currency of its foreign subsidiaries is the United States dollar. The local currencies of its foreign subsidiaries are the Canadian Dollar ("CAD") or Australian dollar ("AUD"). Assets and liabilities are translated based on the exchange rates at the balance sheet date (0.7384 for the CAD, 0.6792 for the AUD as of December 31, 2022 and 0.72610 for the AUD as of December 31, 2021), while expense accounts are translated at the weighted average exchange rate for the period (0.7361 for the CAD and 0.6748 for the AUD for the year ended December 31, 2022 and 0.71510 for the AUD as of December 31, 2021). Equity accounts are translated at historical exchange rates. The resulting translation adjustments are recognized in general and administrative expenses in the consolidated financial statements.

During the years ended December 31, 2022 and 2021, the Company recorded foreign currency translations of $63,717 and $6,684, respectively, which are reflected in general and administrative expenses in the accompanying Consolidated Statements of Operations.

Foreign currency gains and losses resulting from transactions denominated in foreign currencies are recorded in the Consolidated Statements of Operations. During the years ended December 31, 2022 and 2021, the Company recorded foreign currency transaction loss of $3,352 and gain of $2,238, respectively, which is reflected in the general and administrative expenses in the accompanying consolidated statement of operations.

Commitments and Contingencies

The Company follows ASC 440 & ASC 450, subtopic 450-20 to report accounting for contingencies and commitments respectively. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur.

The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or un-asserted claims that may result in such proceedings, the Company evaluates the perceived merits of any legal proceedings or un-asserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed. Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed. Based upon information available at this time, management believes that the current litigation matter related to the Cunning lawsuit will have a material adverse effect on the Company's consolidated financial position, results of operations and cash flows. Refer to Note 14 - Commitments and Contingencies for additional information.

Recent Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805), *Accounting for Contract Assets and Contract Liabilities from Contracts with Customers.* The aim of ASU 2021-08 is to improve the accounting for acquired revenue contracts with customers in a business combination by addressing diversity in practice and inconsistency related to (1) Recognition of an acquired contract liability, and (2) Payment terms and their effect on subsequent revenue recognized by the acquirer. The ASU will be effective for annual reporting periods after December 15, 2022, should be applied on a prospective basis and early adoption is permitted. The adoption of ASU 2021-08 does not currently impact the Company's financial statements. The Company plans to adopt the provisions of this ASU on the effective date.

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 Company currently plans to adopt the provisions of this ASU on the effective date. However, it reserves the right to early adopt these provisions.

Recently Adopted Accounting Pronouncements

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832), Disclosures by Business Entities about Government Assistance.* The aim of ASU 2021-10 is to increase the transparency of government assistance including the disclosure of (1) the types of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. Diversity currently exists in the recognition, measurement, presentation, and disclosure of government assistance received by business entities because of the lack of specific authoritative guidance in GAAP. The ASU will be effective for annual reporting periods after December 15, 2021, and early adoption is permitted. The Company adopted ASU 2021-10 *Government Assistance* on January 1, 2022 using the prospective adoption method as rebates from the ATO in prior periods have not been material to the Company's financial statements. The Company accounts for the tax rebates received from the ATO under such guidance. The Company accounts for the rebates that it receives under the AusIndustry research and development tax incentive program under the income recognition model of IAS 20. Under this model, when there is reasonable assurance that the rebate will be received, the Company recognizes the income from the tax rebate as an offset to research and development expense during the period which the benefit applies to the research and development costs incurred. Refer to disclosures under Government Assistance in Note 2 - the Summary of Significant Accounting Policies for additional information on the Company's treatment of tax rebates.

3. Acquisition of Emerald Health Therapeutics, Inc.

On May 11, 2022, the Company entered into the Arrangement Agreement, as amended on June 14, 2022, July 15, 2022 and October 14, 2022 with EHT, pursuant to a plan of arrangement under the Business Corporations Act (British Columbia). The Acquisition was consummated on November 10, 2022 (the "Closing Date").

The Company evaluated the accounting for the transaction and accounted for the Acquisition as an asset acquisition due to the wind-down state of EHT (Note 1). The primary purpose of the Acquisition was to utilize EHT's remaining cash and cash equivalents and liquidate the primary real estate asset owned by EHT in order to fund the Company's operations. To account for the Acquisition, the Company measured the equity interests issued on the Closing Date (including the value of the options and warrants rolled over) and accumulated the direct costs attributable to the Acquisition.

Upon closing the Acquisition, the Company acquired net assets with an estimated fair value of $15,045,412. The fair value of the consideration was allocated on a relative fair value basis to the "qualifying assets" in the Acquisition and any excess in the fair value of the assets initially reduced the value of the qualifying assets before reducing the value of the assets held for sale. The only qualifying asset identified in the Acquisition was AVI. The fair value of AVI at the time of Acquisition was $ 1,536,275 and the value attributable to AVI was fully eliminated in the Acquisition accounting. EHT is currently in the final stages of its realization process to wind down all prior operations and liquidate substantially all of its remaining assets. As of the date of this Annual Report on Form 10K we have divested both of EHT's former operating entities and are in the process of resolving legacy tax matters with the Canadian tax authorities. In addition, EHT's remaining subsidiary, AVI, owns a vacant laboratory facility that is fully-licensed to handle controlled substances under Canadian regulations, which the Company is currently evaluating for research, development and manufacturing activities. In negotiating the Exchange Ratio, the Company performed a review of EHT's assets and the costs expected to wind down operations. However, there are inherent risks and uncertainties around the ultimate liquidation value of EHT.

Upon the Closing Date of the Acquisition, the Company issued each EHT shareholder 1.95 shares of Skye common stock, for each share of EHT common stock outstanding as of the Closing Date. On November 10, 2022, the Company issued 416,270,514 shares of stock as consideration in the Acquisition and no fractional shares of Skye Common Stock were issued (Note 13). For U.S. and Canadian federal income tax purposes, the Acquisition constitutes a taxable exchange by the EHT shareholders. In addition, all outstanding stock options and warrants of EHT were exchanged for replacement options and warrants of Skye with identical terms, as adjusted in accordance with the Exchange Ratio.

On July 11, 2022, the Company and EHT entered into a consulting agreement pursuant to which representatives of the Company provided administrative assistance to EHT to assist EHT in satisfying its financial reporting, operational and regulatory obligations. EHT incurred $150 for each hour of services provided by the Company. The consulting agreement terminated on the date of the closing of the Acquisition (Note 13). The consulting agreement had an effective date of May 12, 2022 and as of December 31, 2022, the Company recorded a receivable of $22,542, which has been eliminated in consolidation at December 31, 2022.

Below is a summary of the total consideration, assets acquired and the liabilities assumed in connection with the Acquisition:

		November 10, 2022	
Purchase consideration			
Common stock	$	9,574,222	(a)
EHT rollover stock options		105,929	(b)
EHT rollover warrants		203,515	(c)
Transaction costs		1,552,490	(d)
Total consideration	**$**	**11,436,156**	
Assets acquired and liabilities assumed:			
Cash and cash equivalents	$	6,784,057	
Accounts receivable		14,375	
Prepaid Expenses		4,227	
Assets held for sale		6,610,662	(e)
Related party loan		680,901	(f)
Other current assets		356,961	(g)
Accounts payable		(909,048)	
Short term liability		(557,010)	(h)
Payroll liabilities		(577,421)	
Insurance premium loan payable		(89,851)	
Tax liabilities		(158,858)	
Other current liabilities		(722,839)	(i)
Total net assets acquired	**$**	**11,436,156**	

a. *Common Stock,* The Company issued 416,270,514 shares of common stock at $0.023 per share for an aggregate fair value of $9,574,222.

b. *EHT Rollover Stock Options,* The estimated fair value of options issued as consideration in the Acquisition was $105,929 and 8,282,626 SKYE options were issued after applying the Exchange Ratio. The assumptions to value these options were as follows (see Note 8):

	November 10, 2022
Dividend yield	0.00%
Volatility	76.61 - 126.45%
Risk-free interest rate	3.51 - 4.56%
Expected term (years)	0.02 - 4.83

c. *EHT Rollover Warrants,* The estimated fair value of warrants issued as consideration for the Acquisition was $203,515 60,947,407 SKYE warrants were issued after applying the Exchange Ratio.

The assumptions used to value these warrants are as follows:

	November 10, 2022
Dividend yield	0.00%
Volatility	102.9-114.6%
Risk-free interest rate	4.29-4.53%
Expected term (years)	0.56-2.27

d. *Transaction Costs,* The Company incurred aggregate transaction costs of $1,945,140 in connection with the Acquisition, of which $341,629 were expensed, $1,552,490 were considered part of the transaction consideration and $25,511, represented equity issuance costs, which were included as an offset to equity.

e. *Assets held for sale,* The Company acquired assets related to EHT and its subsidiaries which are considered held for held for sale in the amount of $6,610,662. This amount is primarily composed of the following balances:

i. The adjusted the fair value of the VDL assets held for sale of $8,540,732, net of direct liquidation costs of $390,241, which includes legal costs, advisory fees and other professional fees. In addition, the VDL assets were further reduced by $2,072,981 as a result of the relative fair value allocation. The resulting carrying value of the asset recorded by the Company is $6,467,751.

ii. The Company acquired deposits related to utilities for EHT's subsidiaries held for sale. The fair value of these deposits at the time of acquisition is $3,910.

iii. The Company has acquired the value of EHTC's Health Canada license which was transferred with the sale of EHTC (See *Divestiture of Emerald Health Therapeutics Canada, Inc.* below). The value of the license at the time of the acquisition was $91,700.

iv. The Company acquired prepaid expenses related to entities held for sale of $27,301.

f. *Related party loan*, on October 17, 2022, the Company and EHT entered into a loan agreement pursuant to which EHT loaned the Company $700,000 in accordance with the terms of a promissory note. Upon closing the Acquisition, the loan was offset by the balance due to Skye under the consulting agreement. The net related party loan balance was $680,901 as of the closing of the Acquisition. After the closing of the Acquisition, this balance eliminates in consolidation.

g. *Other current assets,* The Company acquired other current assets related to EHT and its subsidiaries which are considered held for held for sale in the amount of $356,961. This amount is primarily composed of the following balances:

i. The Company acquired deposits related to EHT's excise tax bonds of $252,418. As a condition of the EHTC and VDL stock purchase agreements it is expected that the cash value of these bonds will be received upon transfer of the Health Canada licenses to the purchasers of EHTC and VDL.

ii. The Company acquired an open receivables balance of $104,543 made up of a balance due from the buyer of VDL, a former customer of EHT's of $75,396. Additionally, this balance includes a property tax refund due of $29,147.

h. *Short-term liability* EHT received an upfront deposit of $557,010 for the sale of VDL,

i. *Other current liabilities,* The Company acquired liabilities related to EHT and its subsidiaries which are considered in the amount of $722,839. This amount is primarily composed of the following balances:

   i. The Company acquired an outstanding accrued liabilities balance of $587,139. The majority of the balance includes estimated late fees related to late tax filings.

   ii. In accordance with ASC 450, the Company has recorded a contingent liability related credits due to customers of EHT's former operations. At the time of the Acquisition, this liability was estimated at $135,700.

Wind-down costs consist primarily of employee payroll and benefits, legal fees related to divesting of EHT's assets and post closing Acquisition related fees, other professional fees for accounting and tax, tax payments, insurance, contract termination costs and operational costs through the cease operations date at each site.

The Company estimates that EHT will incur the following costs in the periods specified below to wind-down its operations:

Quarter ending:	**(USD)***
March 31, 2023	315,400
Thereafter	170,500
Total future estimated costs:	$ 485,900

**The timing and realization of the expected costs are based on management's estimates and are subject to change based on various factors, including but not limited to, the sale of EHT facilities at terms favorable to Skye, the timely termination of obsolete contracts, the implementation of cost-cutting measures necessary to maximize the remaining asset balance, the effective management of the termination of remaining personnel and related severance payments, the implementation of a successful transition plan, which includes the effective cessation of regulatory activities and the successful migration of historical data.*

Divestiture of Emerald Health Therapeutics Canada, Inc.

On December 28, 2022, approximately six weeks after the Acquisition, the Company entered into a Share Purchase Agreement ("SPA") with a third-party whereby the Company transferred all of its outstanding and fully paid, non-assessable 11,776,338 shares of common stock (the "EHTC Common Shares"), all of which were held by EHT with no par value, for the total purchase price of $110,759. The purchase price also includes the transfer of two licenses issued by Health Canada. EHTC was classified as an asset acquisition and did not meet the criteria of a business at the of Acquisition, and was considered held for sale at the time of Acquisition. Therefore, the sale of EHTC is determined to be treated as the sale of an asset to a third-party due to the discontinued state of the business at the date of divestment. No gain or loss related to the divestiture of EHTC was recorded.

Verdélite SPA

On November 10, 2022, EHT and C3, a third-party, entered into the Verdélite SPA effective November 8, 2022, pursuant to which C3 would acquire all of the outstanding shares of VDL, the holder of EHT's most significant real estate asset, for an aggregate purchase price of approximately $9,385,064, subject to certain adjustments. Prior to closing the Acquisition EHT received a $553,800 cash deposit.

Upon closing, the Company will receive cash proceeds of $5,547,000. The remainder of the purchase price will be paid as follows: (i) USD$369,200 will be payable in five (5) equal monthly installments payable on the last day of each month beginning on December 31, 2023 and ending April 30, 2024, with interest in accordance with the terms of the Verdélite SPA and (ii) USD$ 2,769,000 will be payable in three (3) equal installments on each of the 18-month, 30-month, and 42-month anniversaries of the VDL Closing Date, with interest in accordance with the terms of the Verdélite SPA. This transaction closed on February 9, 2023 (see Note 15).

4. Prepaid Expenses

Prepaid expenses consist of the following:

	As of December 31	
	2022	**2021**
Prepaid clinical expenses	$ 646,072	$ 470,286
Total other prepaid expenses	204,305	83,931
	$ 850,377	**$ 554,217**

5. Warrants and Derivative Liabilities

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

Warrants

Warrants vested and outstanding as of December 31, 2022 are summarized as follows:

Source	Exercise Price	Term (Years)	Number of Warrants Outstanding
Pre 2015 Common Stock Warrants	$ 1.00	10	1,110,000
2015 Common Stock Warrants	5.00	10	100,000
2016 Common Stock Warrants to Service Providers	1.15	10	40,000
2018 Emerald Financing Warrants	0.10	5	3,400,000
Emerald Multi-Draw Credit Agreement Warrants	0.02	5	7,500,000
2019 Common Stock Warrants	0.35	5	8,000,000
2020 Common Stock Warrants to Placement Agent	0.08	5	8,166,667
2021 Inducement Warrants	0.15	5	21,166,667
2021 Inducement Warrants to Placement Agent	0.19	5	1,481,667
2021 Common Stock Warrants	0.09	5	77,777,779
2021 Common Stock Warrants to Placement Agent	0.11	5	5,444,445
2022 Common Stock Warrants to Service Provider	0.04	2	2,000,000
November 2019 EHT Common Stock Warrants*	0.29	5	8,552,630
December 2019 EHT Common Stock Warrants*	0.02	5	9,141,486
December 2019 EHT Common Stock Warrants*	0.15	5	945,750
February 2020 EHT Common Stock Warrants*	0.15	5	20,172,409
June 2020 EHT Common Stock Warrants*	0.10	3	22,135,132
Total warrants outstanding as of December 31, 2022			**197,134,632**

**Replacement warrants issued on November 10, 2022 in conjunction with the Acquisition (see Note 3).*

As of December 31, 2022, all of the Company's warrants are fully vested with the exception of the*"2022 Common Stock Warrants to Service Provider."*

November 2022 Sciences Warrant Repricing

On November 17, 2022, the Company entered into an Amendment and Acknowledgement Agreement (the "Amendment Agreement") with Sciences. Under the terms of the Amendment Agreement, the exercise prices of all the outstanding Emerald Multi-Draw Credit Agreement Warrants and the December 2019 EHT Common Stock Warrants were repriced to $0.017. Refer to Note 6 for further information on the Amendment Agreement.

The Company accounted for the repricing of the warrants as a modification by comparing the fair value of the warrants immediately before and after the modification date to determine the incremental fair value of the repricing. The aggregate modified fair value of $150,851 resulted in an increase in fair value of $120,228. The Company recorded the incremental fair value as a financial charge to other expense in the Consolidated Statements of Operations for the year ended December 31, 2022. On the date of modification, the Company revalued the warrants with a Black-Scholes valuation method using the following assumptions as of the repricing date:

	November 17, 2022
Dividend yield	0.00%
Volatility factor	97.53 - 115.96%
Risk-free interest rate	4.40 - 4.67%
Expected term (years)	0.96 - 2.12
Underlying common stock price	$0.017

EHT Rollover Warrants

On November 10, 2022, the Company issued equity classified replacement warrants with a fair value of $203,515 in exchange for all outstanding warrants of EHT adjusted in accordance with the Exchange Ratio. The replacement warrants were exchanged with identical terms, including exercise prices, vest terms, and expiration dates (see Note 3).

2022 Common Stock Warrants Issued to a Service Provider

On April 1, 2022, the Company granted 2,000,000 equity classified warrants with a fair value of $35,688 to a service provider at an exercise price of $0.04 per share. The warrants vest monthly over one year and expire on April 1, 2024. Refer to Note 8 for the summary of stock-based compensation expense.

As of the date of grant, the Company valued the warrants with a Black-Scholes valuation method using the following assumptions:

	April 1, 2022 Date of Issuance
Dividend yield	0.00 %
Volatility factor	118.46 %
Risk-free interest rate	1.92 %
Expected term (years)	1.27
Underlying common stock price	$ 0.037

July 2021 Inducement Warrants and September 2021 Financing Warrants

In connection with the July 2021 Inducement (Note 7), the Company issued 21,166,667 common stock warrants and 1,481,667 warrants to the placement agent. The warrants were equity classified at issuance and the Company recorded the fair value of the common stock warrants and placement agent warrants of $2,790,884 and $192,224, respectively, as equity issuance costs related to the September 2021 Financing within equity.

The warrants were vested at issuance and were valued utilizing the Black-Scholes Merton option pricing model with the following assumptions:

	Common Stock Warrants	Placement Agent Warrants
Dividend yield	— %	— %
Volatility factor	137.87 %	137.87 %
Risk-free interest rate	0.73 %	0.73 %
Expected term (years)	5.0	5.0
Underlying common stock price	$ 0.15	$ 0.15

In connection with the September 2021 Financing (Note 7), the Company issued 77,777,779 common stock warrants, 19,666,667 pre-funded warrants, and 5,444,445 common stock warrants to the placement agent. The warrants were equity classified at issuance and the Company allocated $3,265,676 and $943,489 of the gross proceeds to the common stock warrants and pre-funded warrants on a relative fair value basis, respectively. The common stock warrants issued to the placement agent were valued at $421,522 and recorded as equity issuance costs within equity. The warrants vested immediately and were valued utilizing the Black-Scholes Merton option pricing model with the following assumptions:

	Common Stock Warrants	Pre-funded Warrants	Placement Agent Warrants
Dividend yield	— %	— %	— %
Volatility factor	136.02 %	135.06 %	136.02 %
Risk-free interest rate	1.01 %	1.55 %	1.01 %
Expected term (years)	5.0	10.0	5.00
Underlying common stock price	$ 0.09	$ 0.09	$ 0.09

Derivative Liability

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

	Year Ended December 31, 2022				
	December 31, 2021, Fair Value of Derivative Liability	Fair Value of Derivative Liability Issued	Change in Fair value of Liability	Reclassification of Derivative to Equity	December 31, 2022, Fair Value of Derivative Liability
Emerald Financing - warrant liability	59,732	—	(59,729)	—	3
Total derivative liability	**$ 59,732**	**$ —**	**$ (59,729)**	**$ —**	**$ 3**

	Year Ended December 31, 2021				
	December 31, 2020 , Fair Value of Derivative Liabilities	Fair Value of Derivative Liabilities Issued	Change in Fair value of Liabilities	Reclassification of Derivatives to Equity	December 31, 2021, Fair Value of Derivative Liabilities
Emerald Financing - warrant liability	38,567	—	21,165	—	59,732
Total derivative liability	**$ 38,567**	**$ —**	**$ 21,165**	**$ —**	**$ 59,732**

Emerald Financing Warrant Liability

The Emerald Financing Warrants were issued during 2018 in connection with the Emerald Financing, and originally contained a price protection feature. In connection with the August 2020 Financing, the exercise price was permanently set to $0.10. 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.

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 Measurements*. Beginning March 31, 2021, the Company changed its valuation model for the Emerald Financing Warrant Liability to a Black-Scholes valuation method, as it was determined that a more simplistic model such as the Black-Scholes valuation method yields a substantially similar result as a Monte Carlo simulation due to the Company's current assumptions.

The warrant liability is valued at the balance sheet dates using the following assumptions:

	As of December 31,	
	2022	2021
Dividend yield	— %	— %
Volatility factor	140.83 %	126.50 %
Risk-free interest rate	4.21 %	0.43 %
Expected term (years)	0.13	1.13
Underlying common stock price	$ 0.02	$ 0.05

The Emerald Financing Warrants expired exercised subsequent to year end.

6. Debt

Multi-Draw Credit Agreement - Related Party

The Company's debt with Sciences consists of the following:

	Conversion Price	As of December 31, 2022	As of December 31, 2021
Total principal value of convertible debt—related party	$ 0.40	$ 1,848,375	$ 2,014,500
Unamortized debt discount		—	(487,668)
Unamortized debt issuance costs		—	(1,927)
Carrying value of total convertible debt—related party		**1,848,375**	**1,524,905**
Total principal value of non-convertible debt—related party	n/a	—	450,000
Total carrying value of advances under the multi-draw credit agreement		**$ 1,848,375**	**$ 1,974,905**

On October 5, 2018, the Company entered into the Credit Agreement with Sciences, a related party (See Note 13). On April 29, 2020, the Company entered into the Amended Credit Agreement with 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 and deferred the quarterly payment of interest until the Company completed a capital raise of at least $5,000,000. As of August 2020, interest ceased being deferred as a result of the August 2020 Financing. The amendments to the pre-existing advances were accounted for as a modification.

On March 29, 2021, the Company amended the Amended Credit Agreement to defer interest payments through the earlier of maturity or prepayment of the principal balance. On September 15, 2021, the Company further amended the Amended Credit Agreement to close the disbursement line. The amendments were considered a modification for accounting purposes.

On November 17, 2022, the Company entered into Amendment No. 4 with Sciences. Under the terms of Amendment No. 4, the parties agreed that the Company would prepay25% of the outstanding principal amount equal to $616,125, plus all accrued interest of $328,737 through the date of the Amendment No. 4. In addition, the Amended Credit Agreement was amended to extend the maturity date to the earlier of December 30, 2022 or the Termination Date (as such term is defined in the Credit Agreement) and the parties agreed to use good faith efforts to enter into a customary piggyback registration rights agreement. In exchange for the extension, the Company agreed to reprice all of the outstanding Sciences warrants to $0.017 per share (Note 3).

On December 30, 2022, the Company entered into Amendment No. 5 to the Amended Credit Agreement to extend the maturity date to the earlier of (a) five business days after the closing of the sale of VDL (b) February 28, 2023 or (c) the Termination Date (as such term is defined in the Amended Credit Agreement).

Advances under the Amended Credit Agreement are unsecured and bear interest at an annual rate of7%. At 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.

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, 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 agreed to issue to 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 offive years that are immediately exercisable upon issuance. All of the warrants issued under the Credit Agreement had an initial exercise price of $0.50 per share which was reset to $0.017 per share in connection with Amendment No. 4. 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 the Company's stockholders (See Note 7).

In accounting for each advance and the warrants issued under the Amended Credit Agreement, the Company allocated 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 was less than the market value of the Company's common stock, the Company recorded 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.

From November 1, 2018 to March 2019, Sciences advanced the Company an aggregate of $6,000,000 under the Credit Agreement. In connection with the advances under the Credit Agreement, the Company issued Sciences 7,500,000 warrants with an original exercise price of $0.50 per share and a term of five years. The warrants were fully vested at issuance.

During the year ended December 31, 2019, the Company used $3,985,500 in proceeds from the exercise of the 2020 Emerald Financing Warrants to prepay a portion of the outstanding principal balance. After the prepayment, the total remaining principal amount excluding discounts under the Credit Agreement was $2,014,500.

On April 29, 2020, the Company entered into an Amended and Restated Multi-Draw Credit Agreement with Sciences (the "Amended Credit Agreement"), which amended and restated the Credit Agreement, as reported in the current report on the Form 8-K filed with the SEC on April 29, 2020. During the year ended December 31, 2020, the Company received non-convertible 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 net proceeds of each advance were used for general corporate purposes.

Aggregate financing costs of $63,007 have been incurred and are recorded as a discount to the debt host along with discounts recorded on the convertible advances were amortized through the original maturity date of October 5, 2022 using the effective interest rate method, interest expense related to the discounts was recognized as non-cash interest expense in Other expense within the Consolidated Statements of Operations.

For the years ended December 31, 2022 and 2021, the effective interest rate related to the convertible portion of the Amended Credit Agreement was 29.20% and 43.30%, respectively. As of December 31, 2022, the debt discount on the convertible advances was fully amortized. As of December 31, 2022, the fair value of the shares underlying the convertible advances under the Amended Credit agreement was $73,935. As of December 31, 2022, the if-converted value did not exceed the principal balance. Subsequent to year end, the Company entered into a Master Transaction Agreement with Sciences (the "MTA") that resulted in the conversion of the remaining principal balance of $ 1,848,375 plus accrued interest under the Amended Credit Agreement into 41,379,164 shares of common stock of the Company at a conversion price of $0.039. Refer to Note 15 - Subsequent Events for further information.

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 had an interest rate of 1.00% per year and funds from the PPP Loan could 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.

On April 5, 2021, the Company submitted an application for the full forgiveness of the PPP Loan to the PPP Loan Lender for the full amount of the loan. On May 20, 2021, the Company received notification that the application was accepted and that the full amount of the PPP Loan including accrued interest was forgiven. During the year ended December 31, 2021, the Company has recorded a gain on forgiveness of the PPP loan in an amount of $117,953.

Insurance premium loan payable

On February 28, 2022, the Company entered into an annual financing arrangement for a portion of its Directors and Officers Insurance Policy (the "D&O Insurance") with Marsh & McLennan in an amount of $275,537. The loan is payable in equal monthly installments of $31,149, matures on October 28, 2022 and bears interest at a rate 4.17% per annum. As of December 31, 2022, a total of $22,961 remains in prepaid expenses and the loan has been repaid.

Interest Expense

The Company's interest expense consists of the following:

	Year Ended December 31,	
	2022	2021
Related party interest expense – stated rate	$ 169,640	$ 174,911
Interest Expense - insurance premium loan payable	5,896	—
PPP loan interest expense – stated rate	—	446
Non-cash interest expense:		
Amortization of debt discount	488,238	592,154
Amortization of transaction costs	1,359	1,648
	$ 665,133	**$ 769,159**

7. Stockholders' Equity and Capitalization

The Company reserved shares of common stock, on an as-if converted basis, for issuance as follows:

	Year Ended December 31,	
	2022	2021
Options issued and outstanding	42,995,062	35,405,000
Awards available for grant under the 2014 Plan	42,274,757	14,132,929
Restricted stock unit awards issued and outstanding	2,666,667	4,000,000
Unreleased restricted stock awards issued to a service provider	—	150,000
Common stock underlying the Amended Credit Agreement	4,660,471	5,393,684
Warrants issued and outstanding	197,134,632	154,458,892
	289,731,589	**213,540,505**

Increase to Authorized Shares of Capital Stock

On February 5, 2021, the Company increased its authorized shares of common and preferred stock to5,000,000,000 and 50,000,000, respectively.

Common Stock

July 2021 Inducement and September 2021 Financing

On July 21, 2021, the Company entered into an Inducement Offer to Exercise Common Stock Purchase Warrants (the "July 2021 Inducement") with certain institutional investors and H.C. Wainwright & Co., LLC ("Wainwright") acting as the placement agent. As a result, on July 26, 2021, the investors exercised 21,166,667 warrants at their original exercise price of $0.06, for gross proceeds of $1,270,000. In exchange, the Company granted 21,166,667 new warrants with substantially the same terms and an exercise price of $0.15 per share (Notes 5).

On September 27, 2021, the Company entered into a Securities Purchase Agreement with certain institutional investors for the issuance and sale of securities, with Wainwright acting as the placement agent, pursuant to which the Company sold 58,111,112 shares of common stock and19,666,667 pre-funded warrants, and issued77,777,779 common stock warrants, in a registered public offering which closed on September 29, 2021 (the "September 2021 Financing"). The common stock and pre-funded warrants were sold at a price per share of $0.09 and $0.0899, respectively, for gross aggregate proceeds of $6,998,034. The common stock warrants and pre-funded warrants have an exercise price of $0.09 and $0.0001, respectively. The common stock warrants have a term offive years, and the pre-funded warrants are exercisable until all the pre-funded warrants have been exercised in full (Note 5).

In connection with the July 2021 Inducement and September 2021 Financing, the Company incurred cash issuance costs of $935,260, for net proceeds of $6,062,774. Additionally, the Company issued warrants to purchase 6,926,112 shares of common stock to the placement agent, which represent7% of the total shares of common stock and pre-funded warrants sold in the offering and 7% of the Inducement Warrants issued (Note 5).

Warrant Exercises

During the year ended December 31, 2022, 19,666,667 pre-funded warrants with an intrinsic value of $1,178,033 were exercised in exchange for 19,666,667 shares of common stock for proceeds of $1,967. As of December 31, 2022 all of the pre-funded warrants from the September 2021 Financing have been exercised.

During the year ended December 31, 2021, 11,800,000 pre-funded warrants with an intrinsic value of $460,200 were exercised in exchange for 11,800,000 shares of common stock for gross proceeds of $11,800. As of December 31, 2021 all of the pre-funded warrants from the August 2020 Financing have been exercised.

During the year ended December 31, 2021, 116,666,668 of the 2020 common stock warrants, including the warrants that were exercised in connection with the July 2021 Inducement discussed above, with an intrinsic value of $8,764,967 were exercised in exchange for 116,666,668 shares of common stock for gross proceeds of $6,999,999.

Common Stock Issuance

On March 2, 2022, the Company released 150,000 shares of common stock to a service provider (Note 8).

On November 10, 2022, the Company issued 416,270,514 shares of common stock to EHT shareholders at a 1.95 conversion rate as consideration in the Acquisition (Note 3).

Restricted Stock Units Released

On December 15, 2022, the Company released 1,333,333 restricted stock units that had vested to executives of the Company (Note 8).

8. Stock-Based Compensation

Stock Incentive Plan

On October 31, 2014, the Board approved the Company's 2014 Omnibus Incentive Plan (the "2014 Plan"). 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.

On June 14, 2022, in connection with the Acquisition, the Board approved the 2014 Amended and Restated Omnibus Incentive Plan (the "2014 Amended and Restated Plan") which replaced the 2014 Plan in its entirety. The 2014 Amended and Restated Plan, among other things, fixed the number of shares that can be issued under the plan to 91,219,570, provided that each January 1 beginning in 2023 and ending on (and including) January 1, 2032 the number of shares will increase by 5% of the outstanding shares of Common Stock as of the prior December 31, unless the Board of Directors of the Company decides to a lesser increase.

On September 30, 2022, the Amended and Restated 2014 Plan was approved by the shareholders. The 2014 Amended and Restated 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. The Company has reserved shares for issuance under our equity incentive plan upon share option exercise. As of December 31, 2022, the Company had 42,274,757 shares available for future grant under the 2014 Plan.

As of December 31, 2022, the shares available for future grant under the 2014 Amended and Restated Plan are as follows:

	Shares Available for Grant
Available as of December 31, 2021	**14,132,929**
Share pool increase	35,731,891
Forfeited	3,810,345
Cancelled	1,232,218
Granted	(12,632,626)
Available as of December 31, 2022	**42,274,757**

Stock Options

Options granted under the 2014 Amended and Restated Plan expire no later than ten years from the date of grant. Options granted under the 2014 Amended and Restated 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 Amended and Restated 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 four years from the date of grant.

The following is a summary of option activities under the Company's 2014 Amended and Restated Plan for the year ended December 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value*
Outstanding, December 31, 2021	**35,405,000**	**$ 0.07**	**9.08**	**$ 134,750**
Granted [1]	12,632,626	0.49		
Forfeited	(1,232,218)	0.47		
Cancelled	(3,810,346)	0.07		
Outstanding, December 31, 2022	**42,995,062**	**$ 0.18**	**7.14**	**$ —**
Exercisable, December 31, 2022	**25,441,484**	**$ 0.08**	**7.8**	**$ —**
Vested and expected to vest, December 31, 2022	**42,995,062**	**$ 0.18**	**7.14**	**$ —**

**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, 2022 for those stock options for which the quoted market price was in excess of the exercise price ("in-the-money options").*

[1] Includes 8,282,626 rollover options issued under the 2014 Plan related to the Acquisition. Upon the closing of the Acquisition, the entire fair value of the EHT rollover options was allocated to the purchase consideration. As a result the assumptions below exclude the EHT rollover options (See Note 3)

During the years ended December 31, 2022 and 2021, the Company received $— and $4,783 gross proceeds from the exercise of stock options.

The weighted-average grant-date fair value of stock options granted for the years ended December 31, 2022 and 2021, excluding EHT rollover options issued related to the Acquisition, was $0.04 and $0.07, respectively. The total fair value of the stock options that vested during the years ended December 31, 2022 and 2021 was $66,263 and $316,929, 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,	
	2022	2021
Dividend yield	0.00 %	0.00 %
Risk-free interest rate	2.89-3.60%	0.01-1.11%
Expected term (years)	5.00-6.08	5.27-6.13
Volatility	126.27-132.58%	119.10-138.00%

In connection with the termination of Dr. Avtar Dhillon's Independent Contractor Agreement on October 14, 2021 (Note 11), the Company modified Dr. Dhillon's option awards to accelerate the vesting of 1,650,000 unvested stock options and, extend the post-termination exercise period from 30 days to five years for all of his outstanding awards. The approval of the modification and receipt of notice to terminate the Independent Contractor Agreement on September 14, 2021, resulted in the recognition of $309,487 in stock compensation expense for the year ended December 31, 2021.

In connection with the Acquisition the Company issued a total of 8,282,626 stock options to EHT option holders on November 10, 2022 (Note 3). The exercise price and rollover option shares were adjusted by the Exchange Ratio at the Acquisition date and retain the vest periods as originally issued.

Stock Option Awards with Performance and Other Conditions

During the year ended December 31, 2022, the Company granted 4,000,000 stock options with an exercise price of $0.04 which include a combination of performance vesting conditions and other vesting conditions pursuant to a consulting agreement entered with Mr. Jim Heppell, a former director of Skye and related party of the Company (Note 13). The vesting conditions of the stock option award provide that 50% of the options are vested upon grant and the remaining 50% will vest upon the sale of a real estate asset held by EHT at an amount greater than or equal to an amount specified in the agreement. None of the options were exercisable until the Acquisition was consummated on November 10, 2022, (Note 3). The conditions related to the sale of EHT's real estate are considered other conditions and the condition related to the closing of the Acquisition is considered a performance condition. When a performance condition is deemed to be probable of achievement, time-based vesting and recognition of stock-based compensation expense commences.

As a result, no share-based compensation expense will be recognized for these stock options until the performance condition is considered to be probable. As of December 31, 2022, the Company has determined that the sale of the real estate asset is not deemed probable, as the consummation of the sale is not solely within the control of the Company.

As of December 31, 2022, the Company has included $73,368 related to the first tranche of these awards in total stock-based compensation expense below. The Company has evaluated the second tranche and has determined that due to the other conditions contained in these awards that they will be recorded as liability options once the Acquisition is deemed probable and will be remeasured through their settlement date or cancellation (Note 15).

Restricted Stock Units

On December 14, 2021, the Company granted restricted stock units ("RSUs") to its executive management team. The RSUs cliff vest 33% per year on the anniversary of the grant date over a three year period.

The following is a summary of restricted stock unit activity during the year ended December 31, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2021	**4,000,000**	**$ 0.06**
Granted	—	—
Released	(1,333,333)	0.06
Unvested, December 31, 2022	**2,666,667**	**$ 0.06**

Awards Granted Outside the 2014 Amended and Restated Plan

During the year ended December 31, 2021, the Company granted 1,200,000 and 300,000 restricted shares of common stock to a non-employee consultant for investor relations services under two successive six month service contracts. Half of the shares will be issued within the first month of entering each service contract and the remaining half will be issued within thirty days from contract completion.

The following is a summary of restricted stock activity outside of the 2014 Amended and Restated Plan during the year ended December 31, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2021	**150,000**	**$ 0.13**
Granted	—	—
Released	(150,000)	0.13
***Unvested, December 31, 2022**	**—**	**$ —**

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 warrants with vesting provisions issued to a service provider (Note 6), and the RSUs discussed above, in its Consolidated Statements of Operations as follows:

	Year Ended December 31,	
	2022	**2021**
Research and development	$ 77,965	$ 59,653
General and administrative	530,234	809,553
	$ 608,199	**$ 869,206**

The total amount of unrecognized compensation cost was $964,853 as of December 31, 2022. This amount will be recognized over a weighted-average period of1.81 years.

2022 Employee Stock Purchase Plan

In June 2022, the Company's board of directors approved the 2022 Employee Stock Purchase Plan (the "ESPP"). Under which the Company will offer eligible employees the option to purchase common stock at a 15% discount to the lower of the market value of the stock at the beginning or end of each participation period under the terms of the ESPP. Total individual purchases in any year are limited to 15% of compensation. The ESPP was approved by the Company's stockholders on September 30, 2022. As of December 31, 2022, no shares were issued under the ESPP.

9. Loss 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 per share computations:

	For the Year Ended December 31, 2022		
	Loss (Numerator)	**Shares (Denominator)**	**Per-Share Amount**
Net loss	$ (19,481,602)		
Basic EPS and diluted EPS			
Net loss available to common stockholders	(19,481,602)	555,270,089	**$ (0.04)**

	For the Year Ended December 31, 2021		
	Income (Numerator)	Shares (Denominator)	Per-Share Amount
Net loss	$ (8,522,182)		
Basic EPS and diluted EPS			
Net loss available to common stockholders	(8,522,182)	406,599,390	**$ (0.02)**

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,	
	2022	2021
Stock options	42,995,062	35,405,000
Unvested restricted stock units	2,666,667	4,000,000
Unvested restricted stock	—	150,000
Common shares underlying convertible debt	4,660,471	5,393,684
Warrants	197,134,632	134,792,225

10. Income Taxes

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

	Year Ended December 31,	
	2022	2021
United States	$ (18,801,570)	$ (8,446,034)
Foreign	(673,291)	(74,048)
Pre-tax loss and comprehensive loss from operations	**$ (19,474,861)**	**$ (8,520,082)**

The components of the income tax expense consisted of the following:

	Year Ended December 31,	
	2022	2021
Current income tax expense		
State	6,741	2,100
Total current income tax expense	**6,741**	**2,100**

The Company is subject to taxation in the United States, various states, Australia, and Canada. The Company's tax years for 2019 (federal), 2018 (States), 2021 (Australia) and 2018 (Canada) and forward are subject to examination by the United States, state, Australian, and Canadian 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, 2022, the Company had federal and state NOLs aggregating $42,309,149 and $46,926,115, respectively. If not used, $13,129,037 of Federal NOLs and $46,792,947 of state NOLs will begin to expire in 2033. $29,180,112 of federal NOLs and $133,168 of state NOLs will carry forward indefinitely subject to an 80% limitation against taxable income. At December 31, 2022, the Company had Australia NOLs aggregating $ 131,687 which do not expire and $77,737,683 of Canadian NOLS which begin to expire in 2023.

At December 31, 2022, the Company had Canadian capital loss carryforwards of approximately $33,301,494 which may be carried forward indefinitely.

At December 31, 2022, the Company had federal and California research credit carryforwards of approximately $454,417 and $132,221, respectively. The federal research credit carry forwards will begin to expire in 2040, unless previously utilized. The California research credits will carry forward indefinitely. The Company's NOLs and research credit carryforwards are subject to a reserve. Additionally, the Company had Canadian SR&ED credits as of December 31, 2022 of $919,820 which may be carried forward indefinitely.

Utilization of the domestic NOL and research credits could 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 and credits 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 and credits 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 NOLs and credits 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):	**2022**	**2021**
State taxes	$ 756	$ 441
Amortization	61	109
Research and development credits	1,199,256	138,581
Capitalized research and development costs	1,000,777	—
Lease liability	16,565	33,906
Contingent legal accrual	1,306,097	—
Capital loss carryforwards	8,824,896	—
Net operating loss	30,648,168	8,887,647
Other	975,897	446,623
Gross deferred tax assets	**43,972,473**	**9,507,307**
Valuation allowance	(43,957,489)	(9,373,577)
Net deferred tax assets	**$ 14,984**	**$ 133,730**
Deferred tax liabilities		
Right-of-use asset	$ (14,984)	$ (30,939)
Discount - Amended Credit Agreement	—	(102,791)
Total deferred tax liabilities	**(14,984)**	**(133,730)**
Net deferred tax assets	**$ —**	**$ —**

The provision for income taxes on earnings subject to income taxes differs from the statutory Federal rate at December 31, 2022 and 2021, due to the following:

	As of December 31,	
	2022	2021
Expected income tax benefit at federal statutory tax rate	$ (4,089,720)	$ (1,789,217)
State income taxes, net of federal benefit	(749,744)	(475,287)
Change in fair value of warrants	(76,672)	4,445
Change in valuation allowance	(892,837)	1,783,362
Uncertain tax positions	884,911	557,016
Reduction in compound derivative	4,974,768	—
Non-deductible interest	35,624	36,731
Stock compensation	69,754	31,863
Research and development credits	(281,709)	(168,514)
Rate adjustment	—	785
Other permanent difference	132,366	20,916
Provision for income taxes	**$ 6,741**	**$ 2,100**

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, 2022. As a result of this valuation allowance, there are no income tax benefits reflected in the accompanying Consolidated Statements of Operations to offset pre-tax losses. During the year ended December 31, 2022, the valuation allowance increased by $34,583,912.

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 April 22, 2020, the Company entered into the PPP Loan with the PPP Loan Lender. 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. In 2021, the Company received forgiveness of the PPP loan. This amount is not considered taxable for Federal or state 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,	
	2022	2021
Unrecognized tax positions, beginning of the year	$ 1,784,626	$ 1,134,173
Gross increase - current period tax positions	1,087,413	687,598
Gross decrease – prior period tax positions	(19)	(37,145)
Unrecognized tax positions, end of year	**$ 2,872,020**	**$ 1,784,626**

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 Consolidated Balance Sheets at December 31, 2022 and 2021 and hasnot recognized interest and/or penalties in the Consolidated Statements of Operations for the years then ended.

11. Other Current Liabilities

Other current liabilities consist of the following:

	As of December 31	
	2022	2021
Research and development costs	$ 40,597	$ 140,953
Legal expense	227,350	133,537
Insurance loan payable	55,451	—
Board fees	—	44,984
Deposit - Verdelite SPA	553,800	—
Acquisition related contingent liability	134,896	—
Total other accrued liabilities	410,348	56,368
	$ 1,422,442	**$ 375,842**

12. Significant Contracts - University of Mississippi

UM 5050 and UM 8930 License Agreements

In July 2018, the Company renewed its ocular licenses for UM 5050 and UM 8930. 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, not to be unreasonably withheld, 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 SBI-200, 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, 2022, the Company has paid the fee due for the notice of patent allowance for the proprietary molecule under the UM 8930 License Agreement. In July 2022, the Company met milestone i) above under its UM 5050 license agreement upon submission of our application for authorization to conduct the Company's Phase 1 trial of SBI-100 OE to the Therapeutic Goods Administration in Australia. As of December 31, 2022, 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 agreement was terminated effective January 8, 2022 pursuant to a termination notice provided to UM by the Company on November 9, 2021, and none of the milestones under this license agreement were met.

13. Related Party Matters

Emerald Health Sciences

In January 2018, the Company entered into a securities purchase agreement with Sciences pursuant to which Sciences purchased a majority of the equity interest in the Company, resulting in a change in control (the "Emerald Financing"). While Sciences no longer maintains a controlling interest in the Company, it holds a significant equity interest as of December 31, 2022 and has provided the Company with financing under the Amended Credit Agreement (Note 6).

On December 19, 2019, the Company entered into an Independent Contractor Services Agreement with Dr. Avtar Dhillon, at the time, a member of Sciences Board of Directors and its CEO, pursuant to which Dr. Dhillon provided ongoing corporate finance and strategic business advisory services to the Company. In exchange for his services, Dr. Dhillon received a monthly fee of $10,000, per month for his services.

On September 14, 2021, Dr. Dhillon provided his notice to terminate the Independent Contractor Services Agreement, with an effective termination date of October 14, 2021. As of October 14, 2021, the Company no longer has any obligations or business relationship with Dr. Dhillon. No expenses were incurred under this agreement during the year ended December 31, 2022. Under this agreement, for the year ended December 31, 2021, the Company incurred fees of $94,516.

On May 18, 2022, Jim Heppell resigned from the Company's board of directors and concurrently entered into a consulting agreement with the Company pursuant to which Mr. Heppell will provide services mutually agreed upon by the Company. The consulting agreement has an initial minimum term of one-year and will be automatically renewed for a one-year period on the anniversary of the contract unless terminated with 60 days' notice. Under the consulting agreement, Mr. Heppell is entitled to a monthly fee of $6,300, which was increased to $16,600 per month upon the closing of the Acquisition. The consulting agreement provides Mr. Heppell with a termination payment in an amount equal to the monthly fees through the then-remaining term of the agreement if Mr. Heppell’s engagement is terminated by the Company without cause. In addition, Mr. Heppell was awarded 4,000,000 stock options which are subject to certain performance and other conditions (Note 8). The Company has accounted for the consulting contract as an in-substance severance arrangement and recognized $139,615 in severance expense during the year ended December 31, 2022. The accrual for Mr. Heppell's severance was adjusted to include the increased fee payments when the Company closed the Acquisition. As of December 31, 2022, the Company recognized $ 16,600, in accounts payable - related party and $75,503 in other current liabilities - related party under this consulting agreement.

As of December 31, 2022, Mr. Heppell is a board member of Emerald Health Pharmaceuticals, Inc. and was a board member of EHT until the closing of the Acquisition (Note 3). As of December 31, 2022, Sciences owns 12.4% and 48% of the Company and Emerald Health Pharmaceuticals, Inc., respectively. As of December 31, 2022, Mr. Heppell is also a board member and the CEO of Sciences. Mr. Heppell also served on VivaCell's board until he tendered his resignation on January 10, 2022.

In addition, the Board Observer Agreement in place with Sciences was amended in September 2021 to allow any board member or officer of Sciences to act as a representative of Sciences on a non-voting observer basis in meetings of the Board. On December 14, 2021, the Board Observer Agreement was terminated.

Emerald Health Pharmaceuticals, Inc.

On April 30, 2021, the Company entered into a month-to-month lease agreement with Emerald Health Pharmaceuticals, Inc. ("EHP") an affiliate of the Company with a significant common shareholder, as the sublessor and the Company as the sublessee. The Company shared the same office location as Emerald Health Pharmaceuticals in San Diego, California until the termination of the sublease on August 31, 2021. Under the sublease agreement, the Company paid monthly base rent of $4,000 in addition to its share of common area expenses and utilities. For the years ended December 31, 2022 and 2021, the Company recognized $— and $15,453, respectively, in expense under the sublease.

As of December 31, 2022, the Company has $11,300 in accounts payable due to EHP related to the purchase of office furniture.

VivaCell Biotechnology España, S.L.U (formerly known as Emerald Health Biotechnology España, S.L.U.)

In January 2021 and April 2021, the Company entered into two separate Collaborative Research Agreements pursuant to a Master Services Agreement with VivaCell Biotechnology España, S.L.U ("VivaCell"), a research and development entity with substantial expertise in cannabinoid science and a subsidiary of Emerald Health Research, Inc. which is 100% owned by Sciences. Under the Collaborative Research Agreements, VivaCell will provide research and development services pursuant to agreed upon project plans for the research and development of SBI-200 and the preclinical development services for novel derivatives. The term of each agreement is initially for a one-year period. The agreements terminate upon delivery and acceptance of the final deliverables under the project plans or if either party is in breach of the terms of the contract and such breach remains uncured for 45 days. Payment for services are based on the negotiated amounts for the completion of agreed upon objectives as provided in the Collaborative Research Agreements. For the years ended December 31, 2022 and 2021, the Company incurred $87,927 and $220,418, respectively, in expenses under the Collaborative Research Agreements. As of December 31, 2021, the Company has recognized a prepaid asset in the amount of $8,056 to be offset against future research and development costs under the Collaborative Research Agreements. No amounts were due to or from VivaCell under these agreements for the year ended December 31, 2022.

On October 11, 2021, the Company entered into an Exclusive Sponsored Research Agreement (the “ESRA”) with VivaCell to fund certain research and development programs which are of mutual interest to both the Company and VivaCell. The Company will have the right to use all data, products, and information, including intellectual property which are generated in the performance of the research under each and all projects funded by the Company pursuant to the ESRA, and VivaCell assigns and agrees to assign, to the Company all rights to any intellectual property created or reduced-to-practice under, or as a part of, a project funded by the Company pursuant to the ESRA.

The Company has agreed to pay to VivaCell a royalty based on any and all licensing revenue or other consideration paid to the Company by a third-party licensee, assignee or purchaser of intellectual property rights created under the ESRA. In addition, upon a change of control transaction, the Company has agreed to pay an amount equal to the royalty percentage multiplied by the fair value of the intellectual property created under the ESRA. Pursuant to the ESRA, VivaCell will provide a budget to be approved by the Company for each project, and the Company will make payments in accordance with the approved budget and pay an annual retainer to VivaCell of $200,000 per year. For the years ended December 31, 2022 and 2021, the Company incurred $200,000 and $44,624 in expenses under the ESRA. As of December 31, 2022 and 2021, the Company has recognized accounts payable of $50,000 and a prepaid asset in the amount of $5,376 to be offset against future research and development costs under the ESRA.

The initial term of the agreement is one year, with automatic renewal for successive one-year terms unless either party terminates upon 60 days' prior written notice to the other party pursuant to the ESRA.

On March 1, 2022, the Company entered into a research project with VivaCell under the ESRA Agreement for the development of a screening platform for anteroposterior ocular diseases. The project budget is $190,500. For the year ended December 31, 2022, the Company incurred $167,000 of research and development expenses under the ESRA. As of December 31, 2022, the Company recognized $7,835, in other current liabilities - related parties related to the first research project. As of December 31, 2022, the Company recognized $47,001, in accounts payable - related parties under this agreement.

Management Conflicts

The Company's CEO Punit Dhillon, was a board member of the Company and EHT (Note 3) through the closing date of the Acquisition. Mr. Dhillon also served as a board member of Sciences, VivaCell and, Emerald Health Pharmaceuticals, Inc. ("EHP") until he tendered his resignation from such boards on August 10, 2020, September 22, 2021 and August 19, 2022, respectively. On July 8, 2022, Punit Dhillon was appointed to serve as the interim principal executive officer of EHP under a consulting arrangement. On October 28, 2022, Mr. Dhillon resigned as the interim principal executive officer of EHP and the consulting arrangement was terminated.

On February 28, 2022, the Company entered into a standard consulting agreement with the CEO's brother to assist with diligence on the EHT Acquisition due to his knowledge and expertise as a former executive of EHT. Compensation under the agreement is for a rate of approximately $73 per hour. The consulting agreement may be terminated by either party upon providing 15 days of advance notice. For the year ended December 31, 2022, the Company incurred $46,684, in consulting expenses under this agreement of which $21,977 is included in wind down costs. As of December 31, 2022, the Company recorded $12,511 to other current liabilities - related parties related to this consulting agreement.

14. Commitments and Contingencies

Office Lease

The Company leases office space for its corporate headquarters, located at 1250 El Camino Real, San Diego, California 92130. The lease is effective from September 1, 2021 through October 31, 2023 and contains a renewal option for a two-year extension after the current expiration date. The Company does not expect that the renewal option will be exercised, and has therefore excluded the option from the calculation of the right of use asset and lease liability. The lease provides for two months of rent abatement and the initial monthly rent is $8,067 per month with annual increases of 3% commencing on November 1, 2022. The lease includes non-lease components (i.e., property management costs) that are paid separately from rent, based on actual costs incurred, and therefore were not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the lease term.

For the years ended December 31, 2022 and 2021, lease expense comprised of $90,701 and $30,234, respectively in lease cost from the Company's non-cancellable operating lease.

The remaining lease term and discount rate related to the operating lease are presented in the following table:

	December 31, 2022
Weighted-average remaining term – operating lease (in years)	0.83
Weighted-average discount rate – operating lease	12 %

Future minimum lease payments as of December 31, 2022 are presented in the following table:

Year:	
2023	83,093
Total future minimum lease payments:	83,093
Less imputed interest	(4,393)
Total	**$ 78,700**

Reported as:

	December 31, 2022	December 31, 2021
Operating lease liability	$ 78,700	$ 82,372
Operating lease liability, net of current portion	—	78,700
Total lease liability	**$ 78,700**	**$ 161,072**

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.

Wendy Cunning vs Skye Bioscience, Inc.

The Company is a party to a legal proceeding with a former employee alleging, among other things, wrongful termination, violation of whistleblower protections under the Sarbanes-Oxley Act of 2002 and retaliation under California law against the Company relating to certain actions and events that occurred with the Company's former management during the employee's employment term from March 2018 to July 2019. The case, entitled Wendy Cunning vs Skye Bioscience, Inc., was filed in U.S. District Court for the Central District of California (the "Cunning Lawsuit"). On January 18, 2023, a jury rendered a verdict in favor of Ms. Cunning and awarded her $512,500 in economic damages (e.g., lost earnings, future earnings and interest), $840,960 in non-economic damages (e.g., emotional distress) and $3,500,000 in punitive damages. The plaintiff's counsel has also filed a motion for attorney fees claiming fees of $1,351,850 and a multiplier of 1.5, for a total of $2,027,775. The Company strongly believes that this case was incorrectly decided as to liability, the amount of compensatory damages, and the appropriateness and amount of punitive damages. The Company intends to challenge the verdict in the trial court and appeal and pursue reimbursement under its existing insurance polices, but given the jury verdict, we have determined that a loss is probable and accordingly have recorded a legal contingency expense and a current balance sheet liability for the total amount of the jury verdict. The Company has recorded an aggregate estimate for the legal contingency of $6,205,310 based on the outcome Management assessed to be the best estimate that is reasonably possible to occur. Dependent on the appeal, it is reasonably possible that the legal contingency booked could materially change after the issuance of these financials.

EHT Class Action Lawsuit

In July 2020, Emerald Health Therapeutics, Inc., a subsidiary of the Company, was added as a defendant in a proposed class action commenced against a large number of Canadian license holders including Aurora Cannabis Inc.; Aurora Cannabis Enterprises Inc.; AuroraCo.; Aleafiaco; Aleafia Health Inc.; Canopy Growth Corporation; Emblem Cannabis Corp.; Hexo Corp.; HexoCo; Cronos Group Inc.; Cronosco; Tilray Canada Ltd.; Organigram Holdings Inc.; OrganigramCo; MediPharm Labs Corp.; MediPharmCo; CanopyCo; Aphria Inc.; Broken Coast Cannabis Ltd.; AphriaCo; Emerald Cannabis Corporation; and EmeraldCo. The proposed class action was commenced in the Alberta Court of Queen's Bench sitting at Calgary. The plaintiffs allege that the defendants, including Emerald Health Therapeutics, Inc., marketed and sold medicinal and recreational cannabis products with an advertised content of THC and CBD and that the amount of THC and/or CBD as contained on the label was wrong and outside the permissible variability limits. The claim alleges the following causes of action indiscriminately against all of the defendants: breach of contract and breach of consumer protection legislation, including the various Sale of Goods Acts and Consumer Protection Acts; common law and statutory misrepresentation; negligence in product labelling; breach of the duty to warn; unjust enrichment; waiver of tort. The claim seeks an aggregate of $505 million in damages as against all of the defendants) and $5,000,000 in punitive damages against each defendant plus an accounting of revenues from each defendant. We are disputing the allegations and have been and will continue to vigorously defend against the claims. The Company disputes the allegations and has been and will continue to vigorously defend against the claims. The proceedings are still at an early stage. Estimating an amount or range of possible losses resulting from litigation proceedings is inherently difficult, particularly where key factual and legal issues have not been resolved. For these reasons, the ultimate timing or outcome cannot be predicted, or possible losses or a range of possible losses cannot be reasonably estimated.

15. Subsequent Events

Sciences Warrant Exercise and Conversion of Amended Credit Agreement

Effective February 16, 2023, Company and Sciences entered into the MTA. Sciences is the largest stockholder of the Company, with beneficial ownership of17.44% of the Company's outstanding common stock following the transactions described below.

Under the MTA, Sciences agreed to exercise 16,641,486 warrants to purchase common stock of the Company (the "MTA Warrants"). Under the MTA, the parties agreed that the aggregate exercise price for the MTA Warrants of $ 282,905 was to be paid through a reduction in the debt owed by the Company to Sciences (the "Credit Consideration") under that certain Amended Credit Agreement. On February 22, 2023, the Company issued 16,641,486 shares of common stock to Sciences in connection with the exercise of the MTA Warrants.

Pursuant to the terms of the MTA, after the application of the Credit Consideration to the amounts owed under the Amended Credit Agreement, Sciences agreed to convert the remaining balance of $1,597,236 owed by the Company to Sciences under the Amended Credit Agreement into 41,379,164 shares of common stock of the Company at a conversion price of $0.0386, in accordance with an amendment to the Amended Credit Agreement set forth in the MTA.

Following the issuance of shares described above, the Amended Credit Agreement was terminated in its entirety per the terms of the MTA. Additionally, under the MTA, Sciences agreed to use its best efforts to transfer all of the common stock of the Company held by Sciences to its shareholders on a pro-rata basis at or immediately prior to the Company's listing to a nationally recognized stock exchange, subject to compliance with applicable securities laws.

Termination of Related Party Contractor

On February 9, 2023, the Company terminated the consulting agreement with Mr. Jim Heppell. The second tranche of stock options issued to Mr. Heppell were cancelled upon the closing of the Verdélite SPA.

Divestiture of VDL

On February 9, 2023, EHT, and C3 entered into a second amendment to theVerdélite SPA whereby the parties amended the Verdélite SPA to allow for the first installment payment to be paid through a promissory note (the "Promissory Note").

On February 9, 2023, the parties closed the transactions contemplated by the Verdélite SPA and on February 10, 2023, the Promissory Note was paid off in its entirety and the Company received a closing payment of $5,547,000. Upon the divestiture of the VDL, C3 and VDL are not considered related parties to the Company. Refer to Note 3 for additional information on the Verdélite SPA, including the payment terms of the remaining installments.

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

Exhibit Number	Description of Exhibit
2.1	Arrangement Agreement, dated May 11, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on May 11, 2022)
2.2	Amendment No. 1 to the Arrangement Agreement, dated June 14, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on June 17, 2022)
2.3	Amendment No. 2 to the Arrangement Agreement, dated July 15, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on July 21, 2022)
2.4	Amendment No. 3 to the Arrangement Agreement, dated October 18, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 19, 2022)
2.5	Loan Agreement and Note, dated October 17, 2022, by and between the Company and EHT (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on October 19, 2022)
2.6	Share Purchase Agreement, dated November 8, 2022, by and between Emerald Health Therapeutics, Inc., 14428773 Canada Inc., Verdelite Sciences, Inc., Verdelite Property Holdings, Inc. and C3 Centre Holding Inc. (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed on November 14, 2022)
2.7	Amendment No. 1 to the Share Purchase Agreement, dated January 26, 2023, by and between Emerald Health Therapeutics, Inc., 14428773 Canada Inc., Verdelite Sciences, Inc., Verdelite Property Holdings, Inc. and C3 Centre Holding Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on January 27, 2023)
2.8	Amendment No. 2 to the Share Purchase Agreement, dated February 9, 2023, by and between Emerald Health Therapeutics, Inc., 14428773 Canada Inc., Verdelite Sciences, Inc., Verdelite Property Holdings, Inc. and C3 Centre Holding Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on February 15, 2023)
3.1	Articles of Incorporation of Registrant, as amended (incorporated by reference to Exhibit 3.1 to our Report on Form 10-K filed on March 2, 2021)
3.2	Amended and Restated Bylaws of Registrant (incorporated by reference to Exhibit 3.2 to our Report on Form 10-K filed on March 2, 2021)
4.1	Pre 2015 Common Stock Warrants (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K filed on November 3, 2014)
4.2	2015, 2016 and 2017 Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed August 20, 2015)
4.3	2018 Emerald Financing Warrants (incorporated by reference to Exhibit 4.1 and contained in Exhibit 10.1 in exhibit to our Current Report on Form 8-K filed January 22, 2018)
4.4	Emerald Multi-Draw Credit Agreement Warrants (incorporated by reference to Exhibit 4.10 to our Annual Report on Form 10-K filed on March 14, 2019)
4.5	2019 Common Stock Warrants (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on November 21, 2019)
4.6	2020 Common Stock Warrants (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on August 5, 2020)
4.7	2021 Inducement Warrants (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.8	September 2021 Lock-up Agreement (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.9	2021 Common Stock Warrants (incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.1	2021 Pre-Funded Warrants (incorporated by reference to Exhibit 4.2 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.11	2021 Common Stock Warrants to Placement Agent (incorporated by reference to Exhibit 4.3 to our Quarterly Report on Form 10-Q filed November 10, 2021)
4.12*	2022 Form of Warrant Issued to Former EHT Warrant Holders

4.13	Piggyback Registration Rights Agreement, dated December 14, 2022, by and between the Company and Emerald Health Sciences, Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on December 19, 2022)
4.14*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
10.1†	Skye Bioscience, Inc. 2014 Amended and Restated Omnibus Incentive Plan (incorporated by reference to Appendix D our definitive proxy statement filed on August 31, 2022)
10.2†	Form of Stock Option Agreement under 2014 Amended and Restated Omnibus Incentive Plan (incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on November 3, 2014)
10.3†	Form of Restricted Stock Unit Agreement under 2014 Amended and Restated Omnibus Incentive Plan (incorporated by reference to Exhibit 10.5 to our Annual Report on Form 10-K filed on March 28, 2022)
10.4†	Form of Stock Option Award Agreement - For Canadian Optionees under 2014 Amended and Restated Omnibus Incentive Plan (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on November 14, 2022)
10.5†	Notice of Option Amendment (incorporated by reference to Exhibit 10.6 to our Annual Report on Form 10-K filed on March 28, 2022)
10.6†	Skye Bioscience, Inc. 2022 Employee Stock Purchase Plan (incorporated by reference to Appendix C to our definitive proxy statement filed on August 31, 2022)
10.7†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on January 12, 2015)
10.8†	Officer Change in Control Severance Plan (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on February 27, 2015)
10.9†	Employment Agreement, dated August 10, 2020, by and between Emerald Bioscience, Inc. and Punit Dhillon (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on August 12, 2020)
10.10†	Employment Agreement, dated October 4, 2021, by and between Skye Bioscience, Inc. and Kaitlyn Arsenault (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 6, 2021)
10.11**	License Agreement, dated January 10, 2017, between Nemus and the University of Mississippi, School of Pharmacy (UM 5070) (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K/A filed on January 20, 2017)
10.12**	Restated and Amended License Agreement, dated as of May 24, 2019, by and between the Company and University of Mississippi, School of Pharmacy (UM 5050) (incorporated by reference to Exhibit 10.12 to our Annual Report on Form 10-K filed on March 28, 2022)
10.13**	Restated and Amended License Agreement, dated as of May 24, 2019, by and between the Company and University of Mississippi, School of Pharmacy (UM 8930) (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 29, 2019)
10.14	Amended and Restated Multi-Draw Credit Agreement, dated April 29, 2020, by and between Emerald Bioscience, Inc. and Emerald Health Sciences, Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 29, 2020)
10.15	Amendment No. 2 to the Amended and Restated Multi-Draw Credit Agreement, dated March 29, 2021 (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed May 7, 2021)
10.16	Amendment No. 3 to the Amended and Restated Multi-Draw Credit Agreement, dated September 15, 2021 (incorporated by reference to Exhibit 10.17 to our Annual Report on Form 10-K filed on March 28, 2022)
10.17	Amendment and Acknowledgment Agreement, dated November 17, 2022, by and between the Company and Emerald Health Sciences, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 23, 2022)
10.18	Amendment No. 5 to Multi-Draw Credit Agreement, dated December 30, 2022, by and between the Company and Emerald Health Sciences, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 6, 2023)
10.19	Master Transaction Agreement, dated February 16, 2023, by and between the Company and Emerald Health Sciences, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 23, 2023)

10.2	Collaborative Research Agreement, dated January 2021, by and between Skye Bioscience, Inc. and Emerald Health Biotechnology España, S.L., (incorporated by reference to Exhibit 10.63 to our Annual Report on Form 10-K filed on March 10, 2021)
10.21**	Collaborative Research Agreement, dated April 2021, by and between Skye Bioscience, Inc. and Emerald Health Biotechnology España, S.L., (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on August 6, 2021)
10.22**	Exclusive Sponsored Research Agreement, dated October 11, 2021, by and between the Company and Emerald Health Biotechnology España, S.L. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 15, 2021)
10.23	Office Lease, dated as of August 25, 2021, by and between ROIC California, LLC and the Company (incorporated by reference to Exhibit 99.1 to our Current Report on Form 8-K filed on September 15, 2021)
16.1	Changes in Registrant's Certifying Accountant - Letter of Mayer Hoffman McCann P.C. to the Securities and Exchange Commission, dated June 17, 2022 (incorporated by reference to Exhibit 16.1 to our Current Report on Form 8-K filed on June 17, 2022)
16.2	Changes in Registrant's Certifying Accountant - Letter of Friedman, LLP to the Securities and Exchange Commission, dated September 29, 2022 (incorporated by reference to Exhibit 16.1 to our Current Report on Form 8-K filed on October 3, 2022)
21.1*	Subsidiaries of the Registrant
23.1*	Independent Registered Public Accounting Firm's Consent
23.2*	Independent Registered Public Accounting Firm's Consent
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
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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 31, 2023

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

March 31, 2023

By: */s/ Kaitlyn Arsenault*
Kaitlyn Arsenault
Its: Chief Financial 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 31, 2023
Punit Dhillon
Its: Chief Executive Officer, Chairman
(Principal Executive Officer)

By: */s/ Kaitlyn Arsenault* March 31, 2023
Kaitlyn Arsenault
Its: Chief Financial Officer
(Principal Financial and Accounting Officer)

By: */s/ Margaret Dalesandro* March 31, 2023
Margaret Dalesandro
Its: Director

By: */s/ Deborah Charych* March 31, 2023
Deborah Charych
Its: Director

By: */s/ Praveen Tyle* March 31, 2023
Praveen Tyle
Its: Director

By: */s/ Keith Ward* March 31, 2023
Keith Ward
Its: Director

THE WARRANTS REPRESENTED HEREBY WILL BE VOID AND OF NO VALUE UNLESS EXERCISED WITHIN THE TIME LIMITS HEREIN PROVIDED.

EMERALD HEALTH THERAPEUTICS, INC.
COMMON SHARE PURCHASE WARRANT

Dated: _____

Number of Warrants: _____ Warrant Certificate No.: _____

THIS IS TO CERTIFY THAT, for value received,

_____

(the "**Holder**")

is the registered holder of ___ common share purchase warrants (the "**Warrants**") of **EMERALD HEALTH THERAPEUTICS, INC.** (the "**Corporation**"). Each Warrant entitles the Holder to subscribe for and purchase, subject to the terms hereof including, without limitation, certain adjustment provisions, one common share (a "**Share**") in the authorized share structure of the Corporation until 5:00 p.m. (Vancouver time) _____(the "**Expiry Time**"), for an exercise price of CAD$_per Share (the "**Exercise Price**"), after which time the Warrants represented hereby shall expire, all subject to adjustment as hereinafter provided.

If at any time following the date hereof, the closing price of the Corporation's Shares on the TSX Venture Exchange, or such other principal stock exchange on which the Shares are then listed, is greater than $_per Share for a period of ten consecutive trading days (the "**Triggering Event**"), the Corporation may, at its option, accelerate the Expiry Time to the date that is 15 days following the date on which the Corporation sends notice to all Warrant holders of the new expiry date (the "**Notice Date**").

1. The right to acquire Shares may only be exercised by the Holder, or its legal representative or attorney, within the time set forth above by:

   (a) duly completing and executing the Exercise Form attached hereto as Appendix A; and

   (b) surrendering this Warrant Certificate and delivering a completed Exercise Form and a certified cheque, wire transfer or bank draft in an amount equal to the Exercise Price multiplied by the number of Shares to be acquired, subject to adjustment in accordance with the terms hereof, to the Corporation at the address shown on the Exercise Form.

2. This Warrant Certificate will effectively be surrendered only upon personal delivery hereof or, if sent by mail or other means of transmission, upon actual receipt thereof by the Corporation at the address shown on the Exercise Form or such other address as may be specified by the Corporation, in a written notice to the Holder, from time to time. The Corporation will, on the date it receives the duly executed Exercise Form and the Exercise Price for the number of Shares specified in the Exercise Form, issue that number of Shares specified in the Exercise Form as fully paid and non-assessable Shares of the Corporation.

3. No fractional Shares are to be issued upon exercise of the Warrants, but rather the number of Shares to be issued shall be rounded down to the nearest whole number.

4. Subject to Section 5, upon the exercise of all or any of the Warrants in the manner described above, the person or persons in whose name or names the Shares issuable upon exercise of the Warrants are to be issued will be deemed for all purposes to be the holder or holders of record of such Shares and the Corporation covenants that it will cause certificates representing such Shares to be delivered or mailed to the person or persons at the address or addresses specified in the Exercise Form within five business days of the surrender of this Warrant Certificate.

5. The Holder of this Warrant Certificate may acquire any lesser number of Shares than the total number of Shares which may be acquired upon exercise of the Warrants represented by this Warrant Certificate. In such event, the Holder will be entitled to receive a new Warrant Certificate representing Warrants exercisable to acquire up to the balance of the Shares which may be acquired. The Corporation will deliver such new Warrant Certificate, without charge, to the Holder within three business days of the surrender of this Warrant Certificate.

6. The Warrants are non-transferrable.

7. The Holder of this Warrant Certificate may, at any time prior to the Expiry Time, upon surrender of this Warrant Certificate to the Corporation, exchange this Warrant Certificate for other Warrant Certificates entitling the Holder to acquire, in the aggregate, the same number of Shares, at the same Exercise Price and on the same terms as may be acquired under this Warrant Certificate. The Corporation will deliver such new Warrant Certificates to the Holder within seven trading days of such surrender of this Warrant Certificate.

8. The holding of the Warrants evidenced by this Warrant Certificate will not constitute the Holder hereof a shareholder of the Corporation or entitle the Holder to any right or interest in respect thereof except as expressly provided for herein.

9. Upon receipt by the Corporation of evidence reasonably satisfactory to the Corporation of the loss, theft, destruction or mutilation of this Warrant Certificate and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Corporation in customary and reasonable form and, in the case of mutilation, upon surrender and cancellation of this Warrant Certificate, the Corporation will execute and deliver to the Holder a new Warrant Certificate within seven trading days thereof.

10. Nothing herein contained or done pursuant hereto shall obligate the Holder to subscribe for or the Corporation to issue any shares except those shares in respect of which the Holder shall have exercised its right to purchase hereunder in the manner provided herein.

11. Issuance and delivery of certificates for the Shares upon exercise of this Warrant will be made without charge to the Holder for any issue or transfer tax, withholding tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses will be paid by the Corporation; provided, however, that the Corporation will not be required to pay any tax which may be payable in respect of any transfer involved in the registration of any certificates for Shares or Warrants in a name other than that of the Holder or an affiliate thereof. The Holder will be responsible for all other tax liability that may arise as a result of holding this Warrant or receiving Shares upon exercise hereof.

12. From and after the date hereof, the Exercise Price and the number of Shares deliverable upon the exercise of the Warrants will be subject to adjustment as follows:

(a) In case of any reclassification or redesignation of or amendment to the Shares or change of the Shares into other shares, or in case of the consolidation, merger, reorganization, arrangement of the Corporation, amalgamation or other form of business combination of the Corporation with or into any other company or entity which results in any reclassification of the Shares or a change or exchange of the Shares into other shares, or in case of any sale, lease, exchange or transfer (in one or a series of related transactions) of the undertaking or assets of the Corporation as an entirety or substantially as an entirety to another person (any such event, a "**Reclassification of Shares**"), at any time prior to the Expiry Time, the Holder will, after the effective date of such Reclassification of Shares and upon exercise of the right to purchase Shares hereunder, be entitled to receive, and will accept, in lieu of the number of Shares to which the Holder was theretofore entitled upon such exercise, the kind and amount of shares and other securities or property which the Holder would have been entitled to receive as a result of such Reclassification of Shares if, on the effective date thereof, the Holder had been the registered holder of the number of Shares to which the Holder was theretofore entitled upon such exercise. The Exercise Price will, on the effective date of the Reclassification of Shares, be adjusted by multiplying the Exercise Price in effect immediately prior to such Reclassification of Shares by the number of Shares purchasable pursuant to this

Warrant Certificate immediately prior to the Reclassification of Shares, and dividing the product thereof by the number of successor securities determined in accordance with this section. If necessary, appropriate adjustments will be made in the application of the provisions set forth in this section with respect to the rights and interests thereafter of the Holder in order that the provisions set forth in this section will thereafter correspondingly be made applicable as nearly as may be reasonable in relation to any shares or other securities or property thereafter deliverable upon the exercise of the Warrants evidenced hereby. Any successor company, entity or persons shall assume the obligations of the Corporation arising under this Warrant Certificate.

(b) If and whenever at any time prior to the Expiry Time the Corporation:

(i) subdivides the Shares into a greater number of shares;

(ii) consolidates the Shares into a lesser number of shares; or

(iii) issues Shares, Participating Shares or Convertible Securities (both such terms as defined below in paragraph (g)) to all or substantially all of the holders of Shares by way of a stock dividend or other distribution on the Shares payable in Shares, Participating Shares or Convertible Securities;(any such event, a "**Capital Reorganization**") and any such event results in an adjustment in the Exercise Price pursuant to paragraph (c), the number of Shares purchasable pursuant to the Warrants evidenced hereby will be adjusted contemporaneously with the adjustment of the Exercise Price by multiplying the number of Shares theretofore purchasable on the exercise thereof by a fraction the numerator of which will be the Exercise Price in effect immediately prior to such adjustment and the denominator of which will be the Exercise Price resulting from such adjustment.

(c) If and whenever at any time prior to the Expiry Time, the Corporation undertakes Capital Reorganization, the Exercise Price will, on the effective date, in the case of a subdivision or consolidation, or on the record date, in the case of a stock dividend, be adjusted by multiplying the Exercise Price in effect on such effective date or record date by a fraction: (A) the numerator of which will be the number of Shares and Participating Shares outstanding immediately before giving effect to such Capital Reorganization; and (B) the denominator of which is the number of Shares and Participating Shares outstanding immediately after giving effect to such Capital Reorganization. The number of Shares and Participating Shares outstanding will include the deemed conversion into or exchange for Shares or Participating Shares of any Convertible Securities distributed by way of stock dividend or other such distribution. Such adjustment will be made successively whenever any event referred to in this paragraph occurs.

(d) Any issue of Shares, Participating Shares or Convertible Securities by way of a stock dividend or other such distribution will be deemed to have been made on the record date thereof for the purpose of calculating the number of outstanding Shares hereunder.

(e) If and whenever at any time prior to the Expiry Time, the Corporation sets a record date for the issuance of rights, options or warrants (other than the Warrants evidenced hereby) to all or substantially all the holders of Shares entitling them, for a period expiring not more than 45 days after such record date, to subscribe for or purchase Shares, Participating Shares or Convertible Securities at a price per share (or having a conversion or exchange price per share) of less than 95% of the Current Value (as defined below) of the Shares on such record date (any such event, a "**Rights Offering**"), the Exercise Price will be adjusted immediately after such record date so that it will equal the price determined by multiplying the Exercise Price in effect on such record date by a fraction:

(i) the numerator of which will be the aggregate of: (A) the number of Shares outstanding on such record date; and (B) a number determined by dividing whichever of the following is applicable by the Current Value (as hereinafter defined) of the Shares on the record date: (1) the amount obtained by multiplying the number of Shares or Participating Shares which the holders of Shares are entitled to subscribe for or purchase by the subscription or purchase

price; or (2) the amount obtained by multiplying the maximum number of Shares or Participating Shares which the holders of Shares are entitled to receive on the conversion or exchange of the Convertible Securities by the conversion or exchange price per share; and

(ii) the denominator of which will be the aggregate of: (A) the number of Shares outstanding on such record date; and (B) whichever of the following is applicable: (1) the number of Shares or Participating Shares which the holders of Shares are entitled to subscribe for or purchase; or (2) the maximum number of Shares or Participating Shares which the holders of Shares are entitled to receive on the conversion or exchange of the Convertible Securities.

Any Shares owned by or held for the account of the Corporation will be deemed not to be outstanding for the purpose of any such computation. Such adjustment will be made successively whenever such a record date is set.

To the extent that such Rights Offering is not so made or any such rights, options or warrants are not exercised prior to the expiration thereof, the Exercise Price will then be readjusted to the Exercise Price which would then be in effect if such record date had not been fixed or if such expired rights, options or warrants had not been issued.

(f) If and whenever at any time prior to the Expiry Time, the Corporation sets a record date for the distribution to all or substantially all the holders of Shares of:

(i) shares of any class, whether of the Corporation or any other company;

(ii) rights, options or warrants;

(iii) evidences of indebtedness; or

(iv) other assets or property (including cash and securities);

and if such distribution does not constitute a Capital Reorganization or a Rights Offering or does not consist of rights, options or warrants entitling the holders of Shares to subscribe for or purchase Shares, Participating Shares or Convertible Securities for a period expiring not more than 45 days after such record date and at a price per share (or having a conversion or exchange price per share) of at least 95% of the Current Value of the Shares on such record date (any such non- excluded event, a "**Special Distribution**"), the Exercise Price will be adjusted immediately after such record date so that it will equal the price determined by multiplying the Exercise Price in effect on such record date by a fraction: (A) the numerator of which will be the amount by which (1) the amount obtained by multiplying the total number of Shares outstanding on such record date by the Current Value of the Shares on such record date, exceeds (2) the aggregate fair market value (as determined by the external auditors of the Corporation, which determination will be conclusive) to the holders of such Shares of such Special Distribution; and (B) the denominator of which will be the total number of Shares outstanding on such record date multiplied by such Current Value.

Any Shares owned by or held for the account of the Corporation will be deemed not to be outstanding for the purpose of any such computation. Such adjustment will be made successively whenever such a record date is fixed.

To the extent that such Special Distribution is not so made or any such rights, options or warrants are not exercised prior to the expiration thereof, the Exercise Price will then be readjusted to the Exercise Price which would then be in effect if such record date had not been fixed or if such expired rights, options or warrants had not been issued.

(g) For the purpose of this Warrant: (i) "**Participating Share**" means a share (other than a Share) that carries the right to participate in earnings to an unlimited degree; and (ii) "**Convertible Security**" means a security convertible into or exchangeable for a Share or a Participating Share or both.

(h) No adjustment pursuant to this Warrant Certificate will be made in respect of dividends (payable in cash, Shares or Participating Shares) declared payable on the Shares in any fiscal year of the Corporation to the extent that the aggregate value of such dividends, when aggregated with the aggregate value of any dividends previously declared payable on the Shares in such fiscal year, do not exceed 50% of the aggregate consolidated net income of the Corporation, before extraordinary items, for its immediately preceding fiscal year.

(i) In any case in which this Warrant Certificate will require that an adjustment will become effective immediately after a record date for an event referred to herein, the Corporation may defer, until the occurrence of such event, issuing to the Holder, upon the exercise of the Warrants evidenced hereby after such record date and before the occurrence of such event, the additional Shares or securities or other property issuable upon such exercise by reason of the adjustment required by such event; provided, however, that the Corporation will deliver to the Holder within seven business days an appropriate instrument evidencing the Holder's right to receive such additional Shares or securities or other property upon the occurrence of the event requiring such adjustment and the right to receive any distributions made on any such additional Shares or securities or other property on and after such exercise.

(j) The adjustments provided for in this Warrant Certificate are cumulative, will, in the case of adjustments to the Exercise Price, be computed to the nearest one-tenth of one cent and will apply (without duplication) to successive Reclassifications of Shares, Capital Reorganizations, Rights Offerings and Special Distributions; provided that, notwithstanding any other provision of this section, no adjustment of the Exercise Price will be required unless such adjustment would require an increase or decrease of at least 1% of the Exercise Price then in effect (except upon a consolidation of the outstanding Shares); provided, however, that any adjustments which by reason of this paragraph are not required to be made will be carried forward and taken into account in any subsequent adjustment.

(k) No adjustment in the number of Shares which may be purchased upon exercise of the Warrants evidenced hereby or in the Exercise Price will be made pursuant to this Warrant Certificate if the Holder is entitled to participate in such event on the same terms *mutatis mutandis* as if the Holder had exercised the Warrants evidenced hereby for Shares prior to the effective date or record date of such event.

(l) In the event of any question arising with respect to the adjustments provided in this Warrant Certificate, such question will conclusively be determined by a firm of chartered accountants appointed by the Corporation and acceptable to the Holder (who may but need not be the Corporation's auditors). Such accountants will have access to all necessary records of the Corporation and such determination will be binding upon the Corporation and the Holder.

(m) As a condition precedent to the taking of any action which would require an adjustment in the subscription rights pursuant to the Warrant, including the Exercise Price and the number of such classes of shares or other securities or property which are to be received upon the exercise thereof, the Corporation will take all corporate action which may, in the opinion of external counsel, be necessary in order that the Corporation has reserved and there will remain unissued out of its authorized capital a sufficient number of Shares for issuance upon the exercise of the Warrants evidenced hereby, and that the Corporation may validly and legally issue as fully paid and non-assessable all the shares of such classes or other securities or may validly and legally distribute the property which the Holder is entitled to receive on the full exercise thereof in accordance with the provisions hereof.

(n) At least 21 days prior to the effective date or record date, as the case may be, of any event which requires an adjustment in the subscription rights pursuant to this Warrant Certificate, including the Exercise Price and the number and classes of shares or other securities or property which are to be

received upon the exercise thereof, the Corporation will give notice to the Holder of the particulars of such event and the required adjustment.

(o) No adjustment to the Exercise Price that requires TSX Venture Exchange (the "**Exchange**") approval will be made without such approval, and the Corporation will use its best efforts at all times to obtain such consent and/or approval from the Exchange as may be necessary or desirable to allow for the full operation of the provisions contained herein.

13. For the purpose of any computation under this Warrant Certificate, the "**Current Value**" of the Shares at any date will be determined as:

(a) the weighted average closing price of the Shares traded through the facilities of the Exchange or such other exchange on which the Shares are listed for the seven trading days prior to that date;

(b) if the Shares are not listed on the Exchange, the weighted average closing price of the Shares traded through the facilities of such other stock exchange or quotation system on which the Shares are listed or through which the Shares are quoted for the five trading days prior to that date; or

(c) if the Shares are not listed on the Exchange or any other stock exchange or quoted through a quotation system, the fair value thereof as determined in good faith by an independent brokerage or accounting firm selected by the Corporation and satisfactory to the Holder. The Corporation will be solely responsible for paying all fees and expenses of such independent brokerage firm.

14. In the event that this Warrant is exercised before __ the certificate representing the Common Shares issued upon such exercise shall bear the following legends:

"UNLESS PERMITTED UNDER SECURITIES LEGISLATION, THE HOLDER OF THIS SECURITY MUST NOT TRADE THE SECURITY BEFORE__.

WITHOUT PRIOR WRITTEN APPROVAL OF TSX VENTURE EXCHANGE AND COMPLIANCE WITH ALL APPLICABLE SECURITIES LEGISLATION, THE SECURITIES REPRESENTED BY THIS CERTIFICATE MAY NOT BE SOLD, TRANSFERRED, HYPOTHECATED OR OTHERWISE TRADED ON OR THROUGH THE FACILITIES OF TSX VENTURE EXCHANGE OR OTHERWISE IN CANADA OR TO OR FOR THE BENEFIT OF A CANADIAN RESIDENT __."

15. This Warrant and the Shares underlying this Warrant have not been and will not be registered under the United States Securities Act of 1933, as amended (the "**U.S. Securities Act**") and applicable state securities laws and the Corporation has no current intention to effect such registration. Warrants may only be exercised within the United States or by or on behalf of a U.S. Person (as defined in Regulation S of the U.S. Securities Act), or a person within the United States and the Shares issued upon exercise of Warrants may be delivered to an address in the United States only if the Warrants and the Shares are registered under the U.S. Securities Act and applicable state securities laws or such exercise is made in accordance with an exemption from the registration requirements of the U.S. Securities Act and applicable state securities laws, such exemption to be evidenced by such certificates and other evidence reasonably satisfactory to the Corporation and the Corporation shall be entitled to rely upon such confirmation.

16. This Warrant Certificate will enure to the benefit of and will be binding upon the Holder and the Corporation and their respective successors and permitted assigns. The expression the "**Holder**" as used herein will include the Holder's assigns whether immediate or derivative.

17. This Warrant Certificate is governed and construed in accordance with the laws of the Province of British Columbia.

18. All dollar amounts referred to in this Warrant Certificate are in lawful currency of Canada.

19. Time is of the essence hereof.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF the Corporation has caused this Warrant Certificate to be executed by its duly authorized officer.

EMERALD HEALTH THERAPEUTICS, INC.

Per: ____ Authorized Signatory

APPENDIX A

EXERCISE FORM

TO: **EMERALD HEALTH THERAPEUTICS, INC.**
c/o 2500 Park Place, 666 Burrard Street Vancouver, British Columbia V6C 2X8

The undersigned holder of the attached Warrant Certificate hereby subscribes for
__ common shares (the "**Shares**") in the share capital of EMERALD HEALTH THERAPEUTICS, INC. pursuant to the terms of the Warrant Certificate at the Exercise Price (as defined in the Warrant Certificate) on the terms specified in the Warrant Certificate and contemporaneously with the execution and delivery hereof makes payment therefor on the terms specified in the Warrant Certificate.

(Please check the ONE box applicable):

□ A. The undersigned holder (i) at the time of exercise of the Warrants and execution and delivery of this exercise form is not in the United States; (ii) is not a U.S. person,
(iii) is not exercising the Warrants for the account or benefit of a U.S. person or person in the United States; and (iv) the delivery of the underlying Shares will not be to an address in the United States.

□ B. The undersigned holder (a) is the original U.S. purchaser who purchased the Warrants pursuant to the Corporation's private placement Unit, (b) is exercising the Warrants for its own account or for the account of a disclosed principal that was named in the subscription agreement pursuant to which it purchased such Units, and (c) is, and such disclosed principal, if any, is an "accredited investor" as defined in Rule 501(a) of Regulation D under the United States Securities Act of 1933, as amended (the "1933 Act") at the time of exercise of these Warrants and the representations and warranties of the holder made in the original subscription agreement remain true and correct as of the date of exercise of these Warrants.

□ C. The undersigned holder has delivered to the Corporation an opinion of counsel (which will not be sufficient unless it is from counsel of recognized standing and in form and substance satisfactory to the Corporation) to the effect that an exemption from the registration requirements of the 1933 Act and applicable state securities laws is available.

The undersigned holder understands that unless Box A above is checked, the certificate representing the Shares issued upon exercise of the Warrants will, unless the issuance of such securities has been registered under the 1933 Act and applicable state securities laws, bear a legend restricting transfer unless an exemption from such registration requirements is available.

"U.S. person" and "United States" are used as defined in Regulation S under the 1933 Act.

The undersigned irrevocably hereby directs that__Shares be issued and delivered as follows:

Name in Full	Address	Number of Shares

Note: Certificates representing Shares will not be registered or delivered to an address in the United States unless Box B or C above is checked.

DATED this __day of__, 20__.

WARRANTHOLDER:

Per:____ Authorized Signatory

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Skye Bioscience, Inc. ("Company," "we," "our" and "us") has one class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock.

Description of Common Stock

General

The following summary of the terms of our common stock does not purport to be complete and is subject to and qualified in its entirety by reference to our Articles of Incorporation (as amended, the "articles of incorporation"), and Amended and Restated Bylaws (the "bylaws"), which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our certificate of incorporation and our bylaws for additional information.

Under our articles of incorporation, the total number of shares of all classes of stock that we have authority to issue is 5,050,000,000, consisting of 5,000,000,000 shares of common stock, par value $0.001 per share and 50,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

General

The holders of common stock of the Company are not entitled to pre-emptive or other similar subscription rights to purchase any of our securities. Our common stock is neither convertible nor redeemable. Unless the board of directors of the Company determines otherwise, the Company will issue all of its capital stock in uncertificated form.

Voting Rights

The holders of shares of our common stock are entitled to one non-cumulative vote per share.

Dividends and Distributions

Subject to preferences that may apply to any shares of the Company's preferred stock outstanding at the time, the holders of outstanding shares of common stock are entitled to receive dividends out of funds legally available at the times and in the amounts that the Company's board of directors may determine.

Liquidation Rights

Upon the Company's liquidation, dissolution or winding-up, the assets legally available for distribution to the Company's stockholders would be distributable ratably among the holders of common stock after payment of liquidation preferences on any Company preferred stock outstanding at that time and any creditors.
The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock that the Company may designate and issue in the future.

Rights of Repurchase

The Company will not have any rights to repurchase shares of its common stock.

Pre-Emptive or Similar Rights

The common stock is not entitled to preemptive rights and is not subject to redemption.

Preferred Stock

The board of directors of the Company has authority to issue shares of Company preferred stock in one or more series, to fix for each such series such voting powers (full or limited, or no voting powers), designations, preferences, qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, redemption privileges and liquidation preferences for the issue of such series all to the fullest extent permitted by the Nevada Revised Statutes and any other applicable Law ("Nevada Law"). The issuance of Company preferred stock could have the effect of decreasing the trading price of the shares of common stock, restricting dividends on the Company's capital stock, diluting the voting power of the common stock, impairing the liquidation rights of the Company's capital stock, or delaying or preventing a change in control of the Company.

Exclusive Jurisdiction of Certain Actions

Our articles of incorporation require, to the fullest extent permitted by law, that (1) derivative actions brought in the name of the Company, (2) actions against directors, officers, employees and agents of the Company or the Company's stockholders for breach of fiduciary duty, (3) actions asserting any claim arising under any provision of Nevada Law or the articles of incorporations or bylaws, and (4) and other actions asserting a claim under the internal affairs doctrine may be brought only in the Eighth Judicial District Court of Clark County in the state of Nevada (or, if the Eighth Judicial District Court of Clark County does not have jurisdiction, the federal district court for the District of Nevada).

Transfer Agent

The transfer agent for our common stock is ClearTrust, LLC.

Subsidiaries of the Registrant

Name of Entity	Formation Date	Jurisdiction of Incorporation	Holder of Stock
Nemus	July 17, 2012	California, USA	Skye Bioscience, Inc.
Skye Bioscience Pty Ltd.	August 9, 2019	Australia	Skye Bioscience, Inc.
Emerald Health Therapeutics, Inc.	July 31, 2007	British Columbia, Canada	Skye Bioscience, Inc.
Avalite Sciences, Inc.	March 3, 2005	British Columbia, Canada	Emerald Health Therapeutics, Inc.
Verdelite Sciences, Inc.	August 19, 2013	Quebec, Canada	Emerald Health Therapeutics, Inc.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Skye Bioscience, Inc. on Form S-3 (Registration No. 333-2582423) and Form S-8 (Nos. 333-245177, 333-227860 and 333-223439) of our report dated March 31, 2023, (which includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern) with respect to our audit of the Consolidated financial statements of Skye Bioscience, Inc. as of and for the year ended December 31, 2022, which report is included in this Annual Report on Form 10-K of Skye Bioscience for the year ended December 31, 2022.

/s/ Marcum LLP

East Hanover, New Jersey
March 31, 2023

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements on Form S-3 (No. 333-258243) and Form S-8 (Nos. 333-245177, 333-227860 and 333-223439) of Skye Bioscience, Inc., formerly known as Emerald Bioscience, Inc., and Subsidiaries ("Company") of our report dated March 25, 2022 (which includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern) on our audit of the consolidated financial statements of the Company as of December 31, 2021, and for the year then ended, which report is included in this Annual Report on Form 10-K of the Company as of and for the year ended December 31, 2022.

/s/ Mayer Hoffman McCann P.C.

Irvine, California
March 31, 2023

EXHIBIT 31.1

Certification of Principal Executive Officer
Required By Rule 13a-14(A) of the Securities Exchange Act of 1934, As Amended,
As Adopted Pursuant To Section 302 of the Sarbanes--Oxley Act of 2002

I, Punit Dhillon, certify that:

1. I have reviewed this annual report on Form 10-K of Skye Bioscience, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Ru1es 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Ru1es 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particu1arly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 31, 2023

/s/ Punit Dhillon

Punit Dhillon, Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification of Principal Financial and Accounting Officer
Required By Rule 13a-14(A) of the Securities Exchange Act of 1934, As Amended,
As Adopted Pursuant To Section 302 of the Sarbanes--Oxley Act of 2002

I, Kaitlyn Arsenault, certify that:

1. I have reviewed this annual report on Form 10-K of Skye Bioscience, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Ru1es 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Ru1es 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particu1arly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 31, 2023

/s/ Kaitlyn Arsenault
Kaitlyn Arsenault
(Principal Financial and Accounting Officer)

EXHIBIT 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

In connection with the Annual Report of Skye Bioscience, Inc., a Nevada corporation (the "Company") on Form 10-K for the year ending December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Punit Dhillon, Chief Executive Officer of the Company, hereby certify, that, to my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002:

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

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

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

/s/ Punit Dhillon

Punit Dhillon
Chief Executive Officer
(Principal Executive Officer)

March 31, 2023

EXHIBIT 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

In connection with the Annual Report of Skye Bioscience, Inc., a Nevada corporation (the "Company") on Form 10-K for the year ending December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kaitlyn Arsenault, Chief Financial Officer of the Company, hereby certify, that, to my knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002:

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

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

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

/s/ Kaitlyn Arsenault

Kaitlyn Arsenault
Chief Financial Officer
(Principal Financial and Accounting Officer)

March 31, 2023