

Offering Circular

1,000,000 Shares



Common Stock

We are offering 1,000,000 shares of our common stock. The public offering price is \$9.00 per share. Our common stock is listed on The Nasdaq Global Market under the symbol "SCPS". On January 25, 2021, the last sale price of our common stock on Nasdaq was \$12.09 per share.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and have elected to comply with certain reduced public company reporting requirements. As a smaller reporting company within the meaning of Rule 405, we are following the Form S-1 disclosure requirements for smaller reporting companies. This is a Regulation A+ Tier 2 offering. This offering circular is intended to provide the information required by Part I of Form S-1. This offering will begin as soon as practicable after this offering circular has been qualified by the United States Securities and Exchange Commission.

We have granted the underwriters an option to purchase up to an additional 150,000 shares of common stock at the public offering price less the underwriting discount.

See "Risk Factors" beginning on page 9 of this offering circular for a discussion of information that should be considered in connection with deciding whether to make an investment.

The Securities and Exchange Commission, or the Commission, does not pass upon the merits of or give its approval to any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering circular or other solicitation materials. The shares of common stock are offered pursuant to an exemption from registration with the Commission; however, the Commission has not made an independent determination that the shares of common stock offered are exempt from registration.

	Per Share	Total ⁽¹⁾
Public offering price	\$9.00	\$9,000,000
Underwriting discount ⁽²⁾	\$0.72	\$ 720,000
Proceeds, before expenses, to us	\$8.28	\$8,280,000

- (1) Assumes the underwriters have not exercised their option to purchase additional shares of common stock.
- (2) See "Underwriting" beginning on page 94 of this offering circular for additional information and a description of the compensation payable to, and other arrangements with, the underwriters.

The underwriters are offering the shares of common stock for sale on a firm commitment basis. The underwriters expect to deliver the shares of common stock against payment in New York, New York on or about January 29, 2021.

Sole Bookrunning Manager

The Benchmark Company

Co-Manager

Joseph Gunnar & Co., LLC

ABOUT THIS OFFERING CIRCULAR

This offering circular speaks only as of the date hereof.

We will amend this offering circular whenever the information it contains has become false or misleading in light of existing circumstances and for other purposes, such as to disclose material developments related to the securities offered hereby, to update required financial statements or if there has been a fundamental change in the information initially presented. We will file an amended offering circular as part of an amendment to our Form 1-A, which we will file with the Commission, or other appropriate regulatory bodies. Our shares of common stock may not be available for offer and sale to residents of every state.

This offering circular contains all of the representations by the company concerning this offering, and no person shall make different or broader statements than those contained herein. Investors are cautioned not to rely upon any information not expressly set forth in this offering circular.

Investment in small businesses involves a high degree of risk, and investors should not invest any funds in this offering unless they can afford to lose their entire investment. In making an investment decision, investors must rely on their own examination of the company and the terms of the offering, including the merits and risks involved.

This offering circular does not constitute an offer to sell or solicitation of an offer to buy in any jurisdiction in which such offer or solicitation would be unlawful or any person to who it is unlawful to make such offer or solicitation.

For investors outside of the United States, we have not taken any action which would permit the offering or possession or distribution of this offering circular in any jurisdiction where action for that purpose may be required. Investors must inform themselves about and observe any restrictions relating to this offering and the distribution of this offering circular outside the United States.

Neither the delivery of this offering circular nor any sale made hereunder shall, under any circumstances, create an implication that there as has been no change in the affairs of the company since the date hereof. Information contained in this offering circular is subject to completion or amendment.

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Any use of trade names, trademarks or service marks does not imply any relationship with, or endorsement or sponsorship of us by, any other companies. Each trade name, trademark or service mark of any other company appearing in this offering circular is the property of its respective holder. In this offering circular, we identify our lead drug candidate with a name solely for ease of use in referencing such drug candidate. Such drug candidate is also identified by its development name, CpG-STAT3siRNA, by our licensor and, from time to time, by us. Any name used by us in connection with CpG-STAT3siRNA for any purposes other than current ease of use or reference, if any, may be subject to regulatory and other approvals. Any use of such name to identify our drug candidate does not mean, nor is it meant to imply, that such drug candidate is or will be, at any point in the future, referred to by such name. Further, any use of such name to identify our drug candidate does not mean, nor is it meant to imply, that such drug candidate has obtained or will obtain regulatory approval.

SUMMARY

This summary highlights certain information appearing elsewhere in this offering circular. For a more complete understanding of this offering, you should read the entire offering circular carefully, including the risk factors and the financial statements.

Unless otherwise stated in this offering circular, “we”, “us”, “our”, “company”, “Scopus” and “Scopus BioPharma” refer to Scopus BioPharma Inc.

Overview

We are a biopharmaceutical company developing transformational therapeutics targeting serious diseases with significant unmet medical needs. Our mission is to improve patient outcomes and save lives. To achieve our mission, we are capitalizing on groundbreaking scientific and medical discoveries at some of the world’s foremost research and academic institutions.

Our lead development program is a novel, targeted immuno-oncology gene therapy for the treatment of multiple cancers. We have partnered with City of Hope, or COH, for CpG-STAT3siRNA, or CO-sTiRNA™, a STAT3 inhibitor gene therapy. Pre-clinical testing at City of Hope was designed to determine whether CO-sTiRNA would reduce growth and metastasis of various pre-clinical tumor models, including melanoma, and colon and bladder cancers, as well as leukemia and lymphoma. Based upon such testing, an investigational new drug application, or IND, for CO-sTiRNA for B-cell lymphoma is currently anticipated to be filed with the United States Food and Drug Administration, or FDA, in H1 2021. We currently anticipate that a first-in-human Phase 1 clinical trial for B-cell lymphoma will commence in H2 2021.

In conjunction with City of Hope, Phase 1 clinical trials for additional cancer indications are being contemplated for CO-sTiRNA in combination with immune checkpoint inhibitors and chimeric antigen receptor T-cells, or CAR-Ts.

Our second lead development program is MRI-1867, a peripherally-restricted, dual-action cannabinoid-1, or CB1, receptor inverse agonist and inhibitor of inducible nitric oxide synthase, or iNOS. We have partnered with the National Institutes of Health, or NIH, for MRI-1867 and are initially targeting systemic sclerosis, or SSc. Over-activation of CB1 and iNOS has been implicated in the pathophysiology of SSc, which includes fibrosis of the skin, lung, kidney, heart and the gastrointestinal tract. We are currently continuing to conduct pre-clinical work for MRI-1867 to support an IND filing with the FDA.

We are also partnered with The Hebrew University of Jerusalem, or Hebrew University, on several additional research and development programs. These programs relate to a proprietary opioid-sparing anesthetic and synthesis of novel compounds and new chemical entities, or NCEs.

Our Strategic Partners

Our strategic partners for our lead development and other programs are City of Hope, the NIH and Hebrew University. The researchers with whom we are working at each of our strategic partners are leaders in their respective fields.

City of Hope

City of Hope is a world-renowned, independent biomedical research and treatment center for cancer, diabetes, and other life threatening diseases. City of Hope’s unique research and development hybrid of the academic and commercial creates an infrastructure that enables City of Hope researchers and their commercial partners to submit numerous INDs to the FDA each year. In June 2020, we signed an exclusive, worldwide license for CO-sTiRNA.

National Institutes of Health

The NIH is the primary government agency in the United States responsible for biomedical and public health research. The NIH spends approximately \$39 billion annually to conduct and fund medical research seeking to enhance health, lengthen life and reduce illness and disability. The NIH is comprised of 27 separate

institutes and centers covering different biomedical disciplines. We are working with the Section of Neuroendocrinology of the Laboratory of Physiologic Studies, which are part of the National Institute on Alcohol Abuse and Alcoholism, or NIAAA. We own an exclusive, worldwide license from the NIH to three patents covering a series of novel dual-action CB1 receptor inverse agonists, which includes MRI-1867.

The Hebrew University of Jerusalem

Hebrew University has been a pioneer in the research of the endocannabinoid system, or ECS, for over 50 years. To better integrate and coordinate its extensive research in this area, in April 2017, Hebrew University established the *Multidisciplinary Center for Cannabinoid Research*, or MCCR. The MCCR is staffed by eminent scientists and medical doctors from a variety of faculties at Hebrew University and Hadassah University Medical Center. To date, we entered into two memorandums of understanding, or MOUs, and have executed two exclusive, worldwide licenses in connection with these programs covering the research results and any resulting patents.

Our Drug Candidates

Gene Therapy — STAT3 Inhibitor

Our licensed gene therapy, CpG-STAT3siRNA, or CO-sTiRNA, is a dual-action STAT3 inhibitor. STAT3 is a gene that drives tumor cell growth and anti-tumor immune suppression. CO-sTiRNA is a highly selective and targeted gene therapy that is designed to silence the activity of the STAT3 gene by way of RNA interference. CO-sTiRNA is also designed to stimulate TLR9 receptors and to activate the body's immune defense to recognize and kill cancer cells.

Cancer is caused by genetic mutations that result in the uncontrolled division and proliferation of abnormally functioning cells. The STAT3 gene plays a fundamental role in cell growth and division, cell movement and apoptosis in both tumor cells and tumor associated immune cells. Studies suggest that many cancers depend on the activity of STAT3 to survive and proliferate. The ability to selectively and temporarily silence STAT3 is highly desirable for certain cancer therapies.

We are working with Dr. Hua Yu and Dr. Marcin Kortylewski at City of Hope. Dr. Yu is the Billy and Audrey L. Wilder Professor in Tumor Immunotherapy, Associate Chair/Professor in the Department of Immuno-Oncology, and Co-Leader of the Cancer Immunotherapeutics Program. Dr. Kortylewski is an Associate Professor in the Department of Immuno-Oncology. Drs. Yu and Kortylewski are both leading experts in the role of STAT3 in tumor angiogenesis and tumor immune evasion and in oligonucleotide-based cancer immunotherapies and developed CO-sTiRNA. The strategy to pursue STAT3 inhibition was developed based on seminal discoveries by Dr. Yu and her team defining the key role of STAT3 in cancer cell survival and immune tolerance, combined with pioneering work by Dr. Kortylewski and his team on STAT3 targeting using TLR9-targeted delivery of siRNA oligonucleotide therapeutics into immune cells.

Multiple studies, including those conducted at City of Hope, have indicated STAT3 as a promising target in non-Hodgkin's lymphoma. There is growing evidence linking B-cell non-Hodgkin's lymphomas to persistent activation of STAT3. Pre-clinical testing at City of Hope was designed to determine whether CO-sTiRNA would reduce growth and metastasis of various cancers, including lymphoma, leukemia, and solid tumors including melanoma, and colon and bladder cancers. Pre-clinical studies in City of Hope laboratories indicated that intratumoral injection of CO-sTiRNA combined with radiation therapy, or RT, may prove to be efficacious in eradicating established tumors in pre-clinical models of human and mouse B-cell lymphoma. The therapeutic effect of CO-sTiRNA combined with RT may likely result from a two-pronged effect, reducing survival signaling in lymphoma cells, as well as decreasing tolerogenic/proangiogenic effects of the tumor microenvironment post-RT.

Local administration of CO-sTiRNA with RT resulted in complete rejection of mouse syngeneic B-cell lymphoma and significant growth inhibition of xenotransplanted tumors. Thus, the combination of local radiation and intratumoral injection of CO-sTiRNA may represent a novel approach to elicit an anti-tumor immune response in the host.

MRI-1867

We are developing MRI-1867, our licensed rationally designed, orally available, dual-action, hybrid, small molecule that is an inverse agonist of the CB1 receptor, as well as an inhibitor of the iNOS system.

To date, MRI-1867 has indicated numerous positive characteristics in pre-clinical animal model testing. Specifically, NIH researchers demonstrated that MRI-1867 has druggable pharmacodynamic, pharmacokinetic and stability properties using non-GLP in vitro and in vivo animal testing. Further, in vivo testing conducted by the NIH (and published in peer review journals) has, in relevant animal models, demonstrated successfully that, compared to a placebo, MRI-1867 has both slowed the progression of fibrosis and attenuated pre-existing fibrosis in two organs (liver and lungs) with highly potent and selective antagonism of both CB1 and iNOS. Importantly, in vivo animal studies have also demonstrated that MRI-1867 did not cross the blood brain barrier, eliminating the potential for adverse CNS side effects which can be present with other cannabinoids that bind to receptors in the brain. MRI-1867 has also exhibited sufficient bioavailability with oral delivery and supported once daily dosing. In connection with MRI-1867, pre-clinical work has been performed in the lab of Dr. George Kunos, the Scientific Director for the NIAAA and a leading researcher on the ECS with a focus on its role in certain fibrotic, inflammatory and metabolic diseases.

We are developing MRI-1867 for the treatment of SSc. SSc is a chronic, systemic autoimmune disease characterized by activation of innate and adaptive immune systems, an obliterative, proliferative vasculopathy of small blood vessels, and fibrosis of the skin and multiple internal organs. SSc can affect multiple internal organs in the body, including the lungs, heart, kidneys, joints, muscles, esophagus, stomach and intestines.

Approximately 90,000 people in the United States and Europe have SSc. The disease affects mainly adults, 80% of whom are women, with a mean age of onset of about 46 years of age in the United States. Based on these patient population characteristics, SSc has been classified as an orphan indication, which means it has no FDA-approved therapies.

Additional Research and Development Programs

Our additional research and development programs relate to a proprietary opioid-sparing anesthetic and synthesis of novel compounds and NCEs. Dr. Joseph (Yossi) Tam, D.M.D., Ph.D., who is a member of our scientific advisory board, heads the MCCR.

Proprietary Opioid-sparing Anesthetic

In collaboration with Dr. Alexander Binshtok of Hebrew University, we are evaluating the CBD-mediated activation of nociceptive, transient receptor potential cation channels, or TRPV1 and TRPA1 channels, for painless pain-selective anesthesia.

Synthesis of Novel Cannabinoids

In collaboration with Dr. Dmitry Tselikhovsky of Hebrew University, we are pursuing two programs seeking to synthesize novel cannabinoids: cannabinoid-based dual-action compounds and novel chemical derivatives based upon the molecular structure of existing cannabinoids. Both of these programs are intended to provide us with a series of proprietary NCEs for evaluation as potential drug candidates.

All of our drug candidates targeting the ECS will be synthetically produced and we intend to pursue FDA approval, as well as other U.S. and non-U.S. regulatory approvals for such drug candidates.

Our Approach

Our mission is to improve patient outcomes and save lives.

We are developing transformational therapeutics targeting serious diseases with significant unmet medical needs.

To achieve our mission, we seek to capitalize on ground-breaking scientific and medical discoveries at some of the world's foremost academic and research institutions. Our strategic partners, City of Hope, NIH and Hebrew University and their respective scientists, medical doctors and other senior researchers with whom we are working at each of our strategic partners are leaders in their respective fields.

We collaborate closely with our strategic partners. Such collaborations, we believe, will work to strengthen and deepen our relationships with our partners, with the potential to enhance our product development efforts and afford us access to additional opportunities. These relationships also have the potential to create a knowledge network effect across institutions and research professionals, thereby potentially accelerating the pathway to achieving our mission.

As we increase our capital resources, we may extend our business development efforts by seeking to identify promising new potential drug candidates owned by commercial entities. These may include other biopharmaceutical and biotechnology companies, as well as larger pharmaceutical companies both and in and outside the United States. Our finance and business development team is regularly exposed to emerging biopharmaceutical and biotechnology companies seeking strategic investments and alliances. Our leadership team's broad skills and deep relationships with capital sources will foster our ability, as we grow, to identify and attract earlier-stage biopharmaceutical companies seeking a strategic capital partner, joint venture or co-development partner and/or potential acquirer. As we mature, our plan is to identify drug candidates that have undergone pre-clinical and pre-IND evaluation and testing which provide empirical data, thereby providing greater visibility into the safety and biological activity of such drug candidates. This approach is designed to mitigate development pipeline risk, maximize capital resources utilization and accelerate the pathway to prospective commercialization.

We will also seek to balance our development pipeline with lower-risk programs with the potential to provide nearer-term revenue generation. We will also regularly evaluate our development pipeline and accelerate or decelerate certain programs to utilize our human and financial resources for their highest and best uses.

Our Team

We have assembled a team of multi-disciplinary innovators with exceptional domain expertise and experience in their respective disciplines. Our cross-functional team members are highly accomplished scientists, researchers, medical doctors, founders, investors, entrepreneurs, managers, directors and/or senior advisors of or to biopharmaceutical, pharmaceutical, biotechnology and other medical technology companies.

Our scientific and medical team has a combined total of more than 15 Ph.D.s, M.D.s and other graduate and post-graduate healthcare-related degrees with extensive experience in drug discovery, research, clinical development and commercialization. These professionals are complemented by our other senior team members with recognized leadership in venture capital, private equity, corporate finance, capital markets, corporate and securities law, mergers and acquisitions and licensing, who have advised and counseled diverse healthcare-related companies for many years.

Our combined team have played significant and innovative roles in numerous private and publicly-traded healthcare companies, among which are companies with some of the most storied names in biopharmaceuticals, pharmaceuticals, biotechnology and other medical technologies. Among these are companies that created paradigm-shifting, life-altering and life-saving medicines.

Our Scientific Advisory Board

We have assembled a team of recognized experts in cancer, fibrotic diseases (including SSc) and the ECS and other specialties and conditions. These experts serve on our scientific advisory board, which is distinct from our board of directors, and provide us with advice on product development, clinical trial design and implementation and unmet clinical needs in a variety of clinical specialties.

Recent Developments

Initial Public Offering

On December 18, 2020, we completed an initial public offering, or IPO, of our common stock at a public offering price of \$5.50 per share for aggregate gross proceeds, including our underwriters' exercise, in

full, of their over-allotment option, of \$3,162,500. Our common stock is listed on The Nasdaq Global Market under the symbol “SCPS”.

Additional Development Programs and Licenses

In June 2020, we entered into a license agreement with City of Hope, or COH License Agreement. In addition to the COH License Agreement, we also entered into a Sponsored Research Agreement, or SRA, relating to on-going research and development activities in collaboration with City of Hope. We obtained the right to negotiate the COH License Agreement with City of Hope from Bioscience Oncology Pty. Ltd., or Bioscience, which held the exclusive underlying right to negotiate the COH License Agreement. Simultaneously with the execution of the COH License Agreement, we also closed on related transactions with Bioscience and certain related parties (together with the COH License Agreement, the “Transactions”). In connection with the Transactions, we paid City of Hope and Bioscience aggregate consideration and expense reimbursements at closing of approximately \$455,000 in cash and issued 1,466,667 shares of our common stock together with 959,308 Series W warrants, or W Warrants. We are also obligated to pay additional consideration in cash and common stock, in some cases upon satisfaction of certain milestones.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus, or COVID-19, as a global pandemic, which continues to spread throughout the United States and around the world. We are continually monitoring the impact of the global pandemic on us, especially since we conduct activities in multiple locations, both in and outside of the United States. These locations are New York City and Los Angeles in the United States and Tel Aviv, Israel. At various times since the onset of the global pandemic, these locations have been severely affected by COVID-19 and, as a result, have been subject to various requirements to stay at home and self-quarantine, as well as constraints on mobility and travel, especially international travel.

In many locations, the primary focus of healthcare providers and hospitals has been to combat the virus. While we continue to advance our development programs, we are also continually assessing the impact of the global pandemic on our product development efforts, including any impact on the timing and/or costs for our clinical trials, IND-enabling work and other research and development activities. There is no certainty as to the length and severity of societal disruption caused by COVID-19. Consequently, we do not have sufficient visibility to predict the impact of the global pandemic on our operations and overall business, including delays in the progress of our planned pre-clinical work and clinical trials, or by limiting our ability to recruit physicians or clinicians to run our clinical trials, enroll patients or conduct follow-up assessments in our clinical trials. Further, the business or operations of our strategic partners and other third parties with whom we conduct business may also be adversely affected by the global pandemic. We continue to monitor the impact of the global pandemic, including regularly reevaluating the timing of our research and development and clinical milestones. In light of the more restrictive constraints on international travel, we continue to adjust program emphasis and prioritization. Until we are able to gain greater visibility as to the impact of the global pandemic, we intend to commit greater resources to our existing and future programs in the United States and are slowing investment in program development outside the United States.

Corporate Information

We were incorporated in the State of Delaware on April 18, 2017 under the name Project18 Inc. On December 11, 2017, we changed our name to Scopus BioPharma Inc. Our principal executive offices are located at 420 Lexington Avenue, New York, New York 10170. Office space is also made available to us in Tel Aviv, Israel. Our corporate telephone number is (212) 479-2513.

Our corporate website is www.scopusbiopharma.com. The information contained on or that can be accessed through our website is not incorporated by reference into this offering circular and you should not consider information on our website to be part of this offering circular or in deciding whether to purchase our common stock.

THE OFFERING

Common stock offered by us . . . 1,000,000 shares

Offering price \$9.00 per share

Our common stock is listed on the Nasdaq Global Market under the symbol "SCPS." On January 25, 2021, the last sale price of our common stock on Nasdaq was \$12.09 per share.

Common stock outstanding prior to this offering 14,577,597 shares

Common stock outstanding after this offering 15,577,597 shares

Use of proceeds We intend to use the proceeds from this offering to pay for product development, sponsored research, intellectual property protection and for working capital and general corporate purposes, including possible in-licensing, acquisitions and/or investments.

Lock-ups Each of our officers, directors and holders of 5% or more of our common stock has entered into a lock-up agreement with the representative of the underwriters, or Representative, that provides he, she or it will not sell, transfer or otherwise dispose of any of our securities until after the 90th day following the closing of this offering. Also, the shares of common stock issued by us prior to this offering may be subject to transfer restrictions set forth in agreements among us and the holders of such shares of common stock. These transfer restrictions provide that such shares of common stock are not transferrable or saleable for specified periods of time ranging from 180 days to various longer periods following December 16, 2020, the day our shares of common stock first traded on Nasdaq.

The Representative may elect to release any holder from its lock-up at any time or from time to time for any reason or no reason with respect to any or all of our securities or any portion thereof. No such release shall be deemed to obligate the Representative to grant any future releases to such holder or any other holder. In the event the Representative elects to release its lock-up with respect to any of our securities held by any officer or director of our company, they will notify us of the impending release and will announce the impending release through a major news service at least two business days prior to the effective date of such release.

Risk factors An investment in our company is highly speculative and involves a significant degree of risk. Prospective investors should carefully consider the Risk Factors beginning on page 9 before investing in our shares of common stock offered hereby.

Unless otherwise set forth in this offering circular or otherwise required by context, all information herein assumes and/or is subject to the following:

- the underwriters do not exercise their option to purchase up to an additional 150,000 shares of common stock;
- a public offering price of \$9.00 per share;
- 14,577,597 shares of common stock outstanding as of December 31, 2020, which includes 1,466,667 shares of common stock issued in connection with the Transactions, but which does not include

up to 2,533,333 additional shares which may become issuable upon satisfaction of milestones, one of which is the acceptance by the FDA of an IND relating to our lead development program, and conditions in connection with the Transactions;

- 10,084,234 shares of common stock being subject to lock-up agreements, other lock-up arrangements and/or other restrictions on sale, with the balance of our shares outstanding, or 4,493,363 shares as of December 31, 2020, not being subject to any restrictions on sale and being “unrestricted” in accordance with Nasdaq’s initial listing requirements;
- all warrants outstanding, except for 450,000 warrants issued to one of our strategic partners, including warrants which were previously designated as X Warrants, which, in accordance with the terms of applicable governing agreements and without any action required to be taken by warrant holders, automatically became W Warrants, are W Warrants, of which there are 8,434,438 outstanding, including 959,308 W Warrants issued in connection with the Transactions, but excluding W Warrants issuable upon conversion of up to approximately \$2.9 million principal amount of Convertible Notes, which are convertible into W Warrants at \$0.50 per W Warrant, and exclusive of W Warrants which may become issuable in connection with accrued interest on the Convertible Notes. Further, no W Warrants, which warrants are not exercisable until October 1, 2021, are included in calculations of beneficial ownership, as determined in accordance with Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act, since such warrants are not exercisable within 60 days of the date of this offering circular;
- each W Warrant is exercisable, at an exercise price of \$4.00, for one B Unit, each of which is comprised of one share of common stock and one Z Warrant, with each Z Warrant being exercisable at \$5.00 per share;
- there are no Z Warrants outstanding and none shall become outstanding until such time as the W Warrants become exercisable and the securities comprising the B Units are separable and separately traded;
- none of the 57,500 shares issuable upon exercise of the share purchase option issued to our underwriters in connection with our IPO, with an exercise price of \$6.875 per share, have been issued; and
- none of the 1,200,000 shares issuable upon the exercise of outstanding options under our 2018 Equity Incentive Plan, or 2018 Plan, with exercise prices ranging from \$1.50 to \$5.50 per share, have been issued, and excludes an additional 1,200,000 shares reserved for future issuance under our 2018 Plan.

SUMMARY FINANCIAL DATA

The following table sets forth a summary of our historical unaudited condensed consolidated financial data and consolidated financial data as of, and for the periods ended on, the dates indicated. The summary condensed consolidated financial data and consolidated financial data was derived from our unaudited condensed consolidated financial statements and audited consolidated financial statements, and should be read in conjunction with the unaudited condensed consolidated financial statements and consolidated financial statements and their respective accompanying notes, which are included elsewhere in this offering circular. In addition, the summary financial data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations, also included elsewhere in this offering circular.

	For the Years Ended December 31,		For the Six Months Ended June 30,		
	2018	2019	2019	2020	
Operating Data:					
Operating expenses	\$ 685,964	\$ 2,689,949	\$ 928,842	\$ 8,564,563	
Net loss	(685,964)	(2,689,949)	(928,842)	(8,651,397)	
Basic and diluted net loss per common share . .	(0.06)	(0.22)	(0.08)	(0.68)	
Weighted average common shares outstanding:					
Basic and diluted	10,570,933	12,021,650	11,546,748	12,684,116	
	As of December 31,		As of June 30,		
Balance Sheet Data:	2018	2019	2020	Pro Forma ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾
Cash	\$ 1,660	\$ 36,747	\$ 753,242	\$3,214,177	\$10,939,177
Total assets	132,638	771,682	1,508,828	3,960,408	11,685,408
Total liabilities	137,964	854,541	3,013,863	3,386,266	3,386,266
Total stockholders' equity (deficit)	(5,326)	(82,859)	(1,505,035)	574,142	8,299,142

- (1) "Pro Forma" information gives effect to equity and debt securities issued by us in financing and other transactions after June 30, 2020 and on or before December 31, 2020.
- (2) "Pro Forma As Adjusted" information gives effect to the Pro Forma information set forth in footnote 1 as adjusted for the sale of our shares of common stock in this offering.

RISK FACTORS

An investment in the securities offered by this offering circular involves a high degree of risk. You should consider carefully all of the material risks described below, together with the other information contained in this offering circular, before making a decision to invest in our common stock. If any of the following risk factors actually occur, our business, financial condition, results of operations and prospects could suffer, the trading price of our securities could decline and you could lose all or part of your investment.

Risks Relating to Our Business and Strategy

The novel coronavirus could have a material adverse impact on our business, results of operations, financial condition, cash flows or liquidity.

We note that the spread of the novel coronavirus, which causes the disease now known as COVID-19 (the “Coronavirus”), is a rapidly evolving public health emergency with global implications and at present we, as is common across industries and geographies, recognize that we could be adversely affected by a range of factors and developments, largely beyond our control, and we are unable to predict the outcomes of this even on a short-term basis. We continue to monitor the situation, among other objectives, to assess the impact of developments on our financial condition, results of operations, cash flows and liquidity.

We currently are unable to predict the duration and severity of the spread of the Coronavirus, and responses thereto, on our business and operations, and on our results of operations, financial condition, cash flow and liquidity, as these depend on rapidly evolving developments, which are highly uncertain and will be a function of factors beyond our control, such as the speed of contagion, the implementation of effective preventative and containment measures, the development of effective medical solutions, the timing and scope of governmental restrictions on public gatherings, mobility and other activities, financial and other market reactions to the foregoing, and reactions and responses of the populace both in affected regions and regions yet to be affected. While we expect we will suffer adverse effects, the more severe the outbreak and the longer it lasts, the more likely it is that the effects on us and our business will be materially adverse.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the drug candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for diseases that we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than our drug candidates that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive.

We believe that our ability to successfully compete will depend on, among other things:

- the results of our pre-clinical and clinical trials;
- our ability to recruit and enroll patients for clinical trials;

- the efficacy, safety and reliability of our drug candidates;
- the speed at which we develop drug candidates;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to maintain a good relationship with regulatory authorities;
- the timing and scope of regulatory approvals, if any;
- our ability to commercialize and market any of our drug candidates that receive regulatory approval;
- the price of our products;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect our intellectual property rights related to our products;
- our ability to manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of our drug candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer or less expensive than our future products, if any, or that reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our drug candidates obsolete, less competitive or not economical.

We intend to utilize third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves.

We intend to outsource substantial portions of our operations to third-party service providers, including the conduct of future pre-clinical and clinical studies, collection and analysis of data and manufacturing. Our agreements with third-party service providers and contract research organizations, or CROs, will be on a study-by-study and project-by-project basis. Typically, we may terminate the agreements with notice and are responsible for the supplier's previously incurred costs. In addition, any CRO that we retain will be subject to the FDA's and European Medicine Agency's, or EMA's, regulatory requirements and similar standards outside of the United States and Europe and we do not have control over compliance with these regulations by these providers. Consequently, if these providers do not adhere to applicable governing practices and standards, the development, manufacturing and commercialization of our drug candidates could be delayed or stopped, which could severely harm our business and financial condition.

Because we intend to rely on third parties, our internal capacity to perform these functions will be limited to management oversight. Outsourcing these functions involves the risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. It is possible that we could experience difficulties in the future with our third-party service providers. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There are a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. Our operations are currently conducted pursuant to management services agreements, which limits the internal resources we have available to identify and monitor third-party service providers. To the extent we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected, and we may be subject to the imposition of civil or criminal penalties if their conduct of clinical trials violates applicable law.

A variety of risks associated with potential international business relationships could materially adversely affect our business.

We may enter into agreements with third parties for the development and commercialization of our drug candidates in international markets. International business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- potentially reduced protection for our licensed intellectual property rights;
- potential third-party patent rights in countries outside of the United States;
- the potential for so-called “parallel importing,” which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

As we increase the number of our ongoing drug development programs and our drug candidates continue pre-clinical studies and, in the future, clinical trials, we will need to increase our drug development, scientific and administrative headcount to manage these programs. In addition, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage clinical programs effectively, which we anticipate being conducted at numerous clinical sites; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and

consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the expertise of our officers, directors, advisors and consultants, and our ability to implement our business strategy successfully could be seriously harmed if we were to lose their services. Replacing executive officers, directors, key employees, advisors and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

In addition, we have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

We utilize information technology systems and networks to process, transmit and store electronic information in connection with our business activities. As the use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data, all of which are vital to our operations and business strategy. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects.

Despite the implementation of security measures, our computer systems and those of our future CROs and other third-party service providers are vulnerable to damage or disruption from hacking, computer viruses, software bugs, unauthorized access or disclosure, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. Unauthorized access, loss or dissemination could disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information, and manage various general and administrative aspects of our business. To the extent that any such disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential, proprietary or personal information, we could incur liability, suffer reputational damage or poor financial performance or become the subject of regulatory actions by state, federal or non-US authorities, any of which could adversely affect our business.

Our future employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards, which could significantly harm our business.

We will be exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA and other U.S. and non-U.S. regulators, provide accurate information to the FDA and other U.S. and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information

obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Our board of directors plans to adopt a code of ethics and business conduct, but, even with such adoption, it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a drug candidate and may have to limit its commercialization.

The use of our drug candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or our potential future collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our drug candidates and loss of revenues;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our drug candidates.

Our insurance policies may be expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not know if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which may adversely affect our financial position and results of operations.

Risks Relating to Our Financial Position

We have never been profitable. Currently, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never generated revenue and have never been profitable and do not expect to generate revenue or be profitable in the foreseeable future. We have not yet begun any clinical trials or submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere for any of our drug candidates for any indication. We have incurred net losses since our inception, including net losses of \$8,651,397 and \$928,842 for the six months ended June 30, 2020 and 2019, respectively, and \$2,689,949 and \$685,964 for the years ended December 31, 2019 and 2018, respectively. We had an accumulated deficit of \$12,290,844 as of June 30, 2020.

To date, we have devoted most of our financial resources to licensing our intellectual property, sponsoring research with academic and medical research institutions and our corporate overhead. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase when we commence clinical trials and seek regulatory approvals for, our drug candidates, prepare for and begin the commercialization of any approved products, and add

infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years as we begin clinical trials and IND-enabling studies for our drug candidates and related activities required for regulatory approval and continue pursuing additional indications for our drug candidates in our future clinical trials. If any of our drug candidates fail in future clinical trials or do not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. As a result of the foregoing, we expect to continue to experience net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA, EMA or other regulatory authority to perform studies or trials in addition to those currently expected, or if there are any delays in commencing or completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

Our recurring losses from operations may raise doubt regarding our ability to continue as a going concern.

Because our continuing existence has been dependent upon raising capital to sustain our business, it raises doubt about our ability to continue as a going concern. Our independent registered public accounting firm has included an explanatory paragraph in its report on our consolidated financial statements stating there is doubt about our ability to continue as a going concern. Such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. See Note 1 of our condensed consolidated financial statements and consolidated financial statements.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We are currently funding the development of our drug candidates and prospective drug candidates. Developing pharmaceutical products, including conducting research, pre-clinical studies and clinical trials, is expensive. We will require additional future capital in order to begin and complete the research, development and clinical and regulatory activities necessary to bring our drug candidates to market in the future.

We intend to utilize our resources to continue our pre-clinical research studies, to fund the continued pre-clinical and subsequent clinical development of our drug candidates and to fund the research of prospective new drug candidates. Our financial resources will also be used for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our licensed patents to the extent required under our license agreements. Accordingly, we will continue to require substantial additional capital to continue our research and development activities. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our drug candidates under development.

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

- the progress, costs, results of and timing of our drug candidate trials for the treatment of cancer and SSc, and the future pre-clinical and clinical development of our drug candidates for other potential indications;
- the number and characteristics of drug candidates that we pursue;
- the ability of our drug candidates to progress through future pre-clinical and future clinical development successfully;
- our need to expand research and development activities;

- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our drug candidates;
- the costs of acquiring, licensing or investing in businesses, products, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio rights, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. Based on our current financial resources, our expected level of operating expenditures and the net proceeds and/or the anticipated net proceeds, respectively, from prior financings and currently contemplated securities offerings, including this offering, we believe that we will be able to fund our projected operating requirements for at least the next 12 months. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress on our development programs than anticipated. Thereafter, we will need to obtain additional financing to fund future clinical trials for our drug candidates and other expenses. We expect to finance our cash needs primarily through equity and debt offerings. We may also raise capital through government or other third-party funding and grants, collaborations and development agreements, strategic alliances and licensing arrangements.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares, if and when established, to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our drug development programs. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a biopharmaceutical company with a limited operating history. Our operations to date have been limited to the research and development of our drug candidates. We have not yet started clinical trials or obtained regulatory approvals for any of our drug candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our financial condition and operating results may significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval of our drug candidates in future pre-clinical development, including our ability to receive approval from the FDA and the EMA for our drug candidates, and our planned clinical and pre-clinical studies and other work, as the basis for review and approval of our drug candidates;
- delays in the commencement, enrollment and timing of clinical trials;
- difficulties in identifying and treating patients suffering from our target indications;
- the success of our future clinical trials through all phases of pre-clinical and clinical development;

- potential side effects of our drug candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain additional funding to develop our drug candidates;
- our ability to identify and develop additional drug candidates;
- market acceptance of our drug candidates;
- our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability to adhere to clinical study requirements directly or with third parties such as contract research organizations, or CROs;
- our dependency on third-party manufacturers to manufacture our products and key ingredients;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- the costs to us, and our ability and our third-party collaborators' ability to obtain, maintain and protect our licensed intellectual property rights;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- potential product liability claims.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

Risks Relating to Controlled Substances

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

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

Some of our drug candidates that we are developing may be subject to U.S. controlled substance laws and regulations and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during pre-clinical and clinical development and post-approval, and our financial condition.

Some of the drug candidates we plan to develop may contain controlled substances as defined in the Controlled Substances Act of 1970, or 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 Drug Enforcement Administration, or 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, with Schedule II

substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

While cannabis, cannabis extracts, and some cannabinoids are Schedule I controlled substances (except the DEA has de-scheduled CBD included in *Epidiolex*), products approved for medical use in the United States that contain cannabis, cannabis extracts, some cannabinoids or synthetic cannabinoids have been, and we expect should be, placed on Schedules II through V, since approval by the FDA satisfies the “accepted medical use” requirement.

If and when our drug candidates receive FDA approval, we expect the finished dosage forms of our cannabinoid-based drug candidates may be listed by the DEA as a Schedule II, III, IV, or V controlled substance for it to be prescribed for patients in the United States. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. In addition, the scheduling process may take one or more years beyond FDA approval, thereby delaying the launch of our drug products in the United States. However, the DEA must issue a temporary order scheduling the drug within 90 days after the FDA approves the drug and the DEA receives a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services. Furthermore, if the FDA, DEA, or any foreign regulatory authority determines that any of our drug candidates may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of our drug products.

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 drug candidates. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are distinct jurisdictions, they may separately schedule our drug candidates. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners or clinical sites must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

To conduct clinical trials with our drug candidates in the United States prior to approval, each of our research sites may be required to obtain and maintain a DEA researcher registration that will allow those sites to handle and dispense the drug 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 drug candidates is, and, if approved, our commercial products may 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 drug 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 drug 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 any of those registrations could result in increased costs to us. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program may make physicians less willing to prescribe, and pharmacies to dispense, our products, if approved.

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

In the United States, the DEA regulates activities relating to the supply of cannabis for medical research and/or commercial development, including the requirement to obtain annual registrations to manufacture or distribute pharmaceutical products derived from cannabis extracts. The National Institute on Drug Abuse, or NIDA, also plays a role in oversight of the cultivation of cannabis for medicinal research. We do not currently handle any controlled substances, but we plan to partner with third-parties to engage in the research and development of our drug candidates, which may include synthetically-derived cannabinoids, or derivatives thereof, that are found in cannabis for medical purposes. This may require that our third-party service providers obtain and maintain the necessary DEA registrations, and be subject to other regulatory requirements.

Laws and regulations affecting therapeutic uses of cannabinoids are constantly evolving and the legalization and use of medical and recreational cannabis in the U.S. and elsewhere may impact our business.

There is a substantial amount of change occurring in the U.S. regarding the use of medical and adult-use cannabis products. While cannabis products not approved by the FDA are Schedule I substances as defined under federal law, and their possession and use is not permitted according to federal law, 34 states in the United States, plus the District of Columbia, Puerto Rico and Guam, have legalized the use of medical cannabis. Eleven states, plus the District of Columbia, have legalized the use of adult-use cannabis. Sixteen states have legalized high-CBD, low-THC oils for a limited class of patients and 13 states, plus the U.S. Virgin Islands, have decriminalized cannabis, which generally means that there is no arrest, prison time, or criminal record for the first-time possession of a small amount of cannabis for personal consumption. The 2018 U.S. Farm Bill de-scheduled cannabinoid extracts and other material derived from certain hemp plants with extremely low THC content, although the marketing of such products for medical or other purposes would still be subject to regulatory premarketing approval requirements and other applicable laws and regulations, including by the FDA. Although our business is quite distinct from that of medical cannabis companies, future legislation authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved cannabis products could affect our business, results of operations, financial condition or prospects.

The potential ongoing evolution of laws and regulations affecting the research and development of cannabinoid-based medical drugs and treatments could detrimentally affect our business. Laws and regulations related to the therapeutic uses of cannabinoid-based drugs may be subject to changing interpretations. These changes may require us to incur substantial costs associated with legal and compliance fees and may ultimately require us to alter our business plan. Furthermore, violations or alleged violation of these laws could disrupt our business and result in a material adverse effect on our business, results of operations and financial condition. 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.

To date, we have conducted all research and development activities concerning our drug candidates, including those which are or contain cannabinoids, in the U.S. through the NIH (with respect to MRI-1867), which we believe has complied with all applicable laws, or in Israel (with respect to our candidates currently being developed at Hebrew University). We intend to continue our drug development activities in the U.S. in compliance with all applicable laws and in other jurisdictions, including Israel, with more favorable

laws and regulations regarding research using cannabinoids. We do not believe that any of our current operations are subject to federal or state laws regarding the possession or use of cannabis.

Risks Relating to Regulatory Review and Approval of our Drug Candidates

In respect of our drug candidates targeting rare indications, orphan drug exclusivity may afford limited protection, and if another party obtains orphan drug exclusivity for the drugs and indications we are targeting, we may be precluded from commercializing our drug candidates in those indications during that period of exclusivity.

The first New Drug Application, or NDA, applicant with an Orphan Drug Designation for a particular active moiety to treat a specific disease or condition that receives FDA approval is usually entitled to a seven-year exclusive marketing period in the U.S. for that drug, for that indication. We intend to rely, in part, on this orphan drug exclusivity and other regulatory exclusivities to protect our NCEs and, potentially, our other products and drug candidates from competitors, and we expect to continue relying in part on these regulatory exclusivities in the future. The duration of that exclusivity period could be impacted by a number of factors, including the FDA's later determination that the request for designation was materially defective, that the manufacturer is unable to supply sufficient quantities of the drug, or that the extension of the exclusivity period established by the Improving Regulatory Transparency for New Medical Therapies Act does not apply. There is no assurance that we will successfully obtain Orphan Drug Designation for other drug candidates or other rare diseases or that a drug candidate for which we receive Orphan Drug Designation will be approved, or that we will be awarded orphan drug exclusivity upon approval as, for example, the FDA may reconsider whether the eligibility criteria for such exclusivity have been met and/or maintained. Moreover, a drug product with an active moiety that is a different cannabinoid from that in any of our drug candidate or, under limited circumstances, the same drug product, may be approved by the FDA for the same indication during the period of marketing exclusivity. The limited circumstances include a showing that the second drug is clinically superior to the drug with marketing exclusivity through a demonstration of superior safety or efficacy or that it makes a major contribution to patient care. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a drug candidate we are pursuing for the same indication before us, approval of our drug candidate would be blocked during the period of marketing exclusivity unless we could demonstrate that our drug candidate is clinically superior to the approved product. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a drug candidate we are pursuing for a different orphan indication, this may negatively impact the market opportunity for our drug candidate. There have been legal challenges to aspects of the FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, including whether two drugs are the same drug product, and future challenges could lead to changes that affect the protections potentially afforded our products in ways that are difficult to predict. In a recent successful legal challenge, a court invalidated the FDA's denial of orphan exclusivity to a drug on the grounds that the drug was not proven to be clinically superior to a previously approved product containing the same ingredient for the same orphan use. In response to the decision, the FDA released a policy statement stating that the court's decision is limited just to the facts of that particular case and that the FDA will continue to require the sponsor of a designated drug that is the "same" as a previously approved drug to demonstrate that its drug is clinically superior to that drug upon approval in order to be eligible for orphan drug exclusivity, or in some cases, to even be eligible for marketing approval. In the future, there is the potential for additional legal challenges to the FDA's orphan drug regulations and policies, and it is uncertain how such challenges might affect our business.

In the European Union, if a marketing authorization is granted for a medicinal product that is designated an orphan drug, that product is entitled to ten years of marketing exclusivity. During the period of marketing exclusivity, subject to limited exceptions, no similar medicinal product may be granted a marketing authorization for the orphan indication. There is no assurance that we will successfully obtain orphan drug designation for future rare indications or orphan exclusivity upon approval of any of our drug candidates that have already obtained designation. Even if we obtain orphan exclusivity for any drug candidate, the exclusivity period can be reduced to six years if at the end of the fifth year it is established that the orphan designation criteria are no longer met or if it is demonstrated that the orphan drug is sufficiently profitable that market exclusivity is no longer justified. Further, a similar medicinal product may be granted a marketing authorization for the same indication notwithstanding our marketing exclusivity if

we are unable to supply sufficient quantities of our product, or if the second product is safer, more effective or otherwise clinically superior to our orphan drug. In addition, if a competitor obtains marketing authorization and orphan exclusivity for a product that is similar to a drug candidate we are pursuing for the same indication, approval of our drug candidate would be blocked during the period of orphan marketing exclusivity unless we could demonstrate that our drug candidate is safer, more effective or otherwise clinically superior to the approved product.

We cannot be certain that any of our drug candidates will receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.

Our business currently depends entirely on the successful development and commercialization of our drug candidates. Our ability to generate revenue related to product sales, if ever, will depend on the successful development and regulatory approval of our drug candidates and our licensing of our drug candidates, in one or more of their targeted indications.

Through our research agreements, we are currently researching our drug candidates and thus have no products approved for sale and cannot guarantee that there will ever have marketable products. The development of a drug candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States, the EMA in Europe and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our drug candidates in the United States or Europe until we receive approval of a NDA from the FDA or a Marketing Authorization Application, or MAA, from the EMA, respectively. We have not submitted any marketing applications for any of our drug candidates.

NDAs and MAAs must include extensive pre-clinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a NDA or a MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit a NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of drug candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a drug candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, pre-clinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our drug candidates or other products. Also, regulatory approval for any of our drug candidates may be withdrawn.

Before we submit a NDA to the FDA or a MAA to the EMA for any of our drug candidates, we must successfully complete pre-clinical studies and subsequent clinical trials. We cannot predict whether our future trials and studies will be successful or whether regulators will agree with our conclusions regarding the pre-clinical studies we have conducted to date.

If we are unable to obtain approval from the FDA, the EMA or other regulatory agencies for our drug candidates, or if, subsequent to approval, we are unable to successfully commercialize our drug candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

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

If we receive regulatory approvals, we plan to market our drug candidates in jurisdictions where we have limited or no experience in marketing, developing and distributing our products and cannot guarantee

that we will ever have marketable products. Certain markets have substantial legal and regulatory complexities that we may not have experience navigating. We are subject to a variety of risks inherent in doing business internationally, including risks related to the legal and regulatory environment in non-U.S. jurisdictions, including with respect to privacy and data security, trade control laws and unexpected changes in laws, regulatory requirements and enforcement, as well as risks related to fluctuations in currency exchange rates and political, social and economic instability in foreign countries. If we are unable to manage our international operations successfully, our financial results could be adversely affected.

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

Delays in the commencement, enrollment and completion of pre-clinical studies and clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our drug candidates.

Delays in the commencement, enrollment and completion of our future pre-clinical studies and clinical trials could increase our product development costs or limit the regulatory approval of our drug candidates. Based on our current financial resources, our expected level of operating expenditures and expected net proceeds of this offering and other currently contemplated securities offerings, government, other third-party funding or combinations thereof, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, we believe that we will be able to fund our projected operating requirements for at least the next 12 months. We, however, will require additional funding for our business activities. In addition, we do not know whether any future trials or studies of our other drug candidates, including any confirmatory clinical trial of our drug candidates, will begin on time or will be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for the commencement of pre-clinical and clinical trials;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our drug candidates;
- inability to obtain approval from institutional review boards, or IRBs, to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients;
- inability to timely manufacture sufficient quantities of the drug candidate required for a clinical trial;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our drug candidates; and
- inability to retain enrolled patients after a clinical trial is underway.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In addition, any future clinical trial may be suspended or terminated at any time by us, our future collaborators, the FDA or other regulatory authorities due to a number of factors, including:

- our failure to conduct a clinical trial in accordance with regulatory requirements of our clinical protocols;
- unforeseen safety issues or any determination that any future clinical trial presents unacceptable health risks;
- lack of adequate funding to begin any future clinical trial due to unforeseen costs or other business decisions; and
- a breach of the terms of any agreement with, or for any other reason by, future collaborators that have responsibility for the clinical development of any of our drug candidates.

In addition, if we, or any of our potential future collaborators, are required to conduct additional clinical trials or other pre-clinical studies of our drug candidates beyond those contemplated, our ability to obtain regulatory approval of these drug candidates and generate revenue from their sales would be similarly harmed.

Our drug candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Unforeseen side effects from any of our drug candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The range and potential severity of possible side effects from systemic therapies is significant. The results of future clinical trials may show that our drug candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings.

If any of our drug candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our drug candidates, if approved, it is less likely that they will be widely used.

Market acceptance and sales of our drug candidates, if approved, will depend on reimbursement policies and may be affected by, among other things, future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain that reimbursement will be available for our drug candidates, if approved. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our drug candidates. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize our drug candidates.

In March 2010, the Patient Protection and Affordable Care Act, or PPACA, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, ACA, became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of our current or future drug candidates. In addition, some members of the U.S. Congress have been seeking to overturn at least portions of the legislation and we expect they will continue to review and assess this legislation and alternative health care reform proposals. We cannot predict whether new proposals will be made or adopted, when they may be adopted or what impact they may have on us if they are adopted.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further 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. Strong, partisan disagreement in Congress has prevented implementation of various PPACA provisions, and the Trump Administration has made repeal of the PPACA a priority. One of the first executive orders of the Trump administration granted federal agencies broad powers to unwind regulations under the PPACA. On January 11, 2017, the Senate voted to approve a "budget blueprint" allowing Republicans to repeal parts of the law while avoiding Democrat filibuster. The "Obamacare Repeal Resolution" passed 51 — 48 in the Senate. Certain legislators are continuing their efforts to repeal the PPACA, although there is little clarity on how such a repeal would be implemented and what a PPACA replacement might look like. For the immediate future, there is significant uncertainty regarding the health care, health care coverage and health care insurance markets.

The U.S. government has in the past considered, is currently considering and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. Future significant changes in the healthcare systems in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether other healthcare policies, including policies stemming from legislation or regulations affecting our business, may be proposed or enacted in the future; what effect such policies would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our drug candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, if any, one or more of our U.S. licensed patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug candidate will be shortened and our competitors may obtain approval of competing products following our licensed patent expiration, and our revenue could be reduced, possibly materially.

If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as “fraud and abuse” laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions such as Europe have similar laws. These laws include false claims and anti-kickback statutes. If we market our products and our products are paid for by governmental programs, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program 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 the purchase, lease or order of any healthcare item or service covered by Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers or formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which apply to items and services covered by Medicaid and other state programs, or, in several states, apply regardless of the payor. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates.

If the FDA and EMA and other regulatory agencies do not approve the manufacturing facilities of our future contract manufacturers for commercial production, we may not be able to commercialize any of our drug candidates.

We do not currently intend to manufacture the pharmaceutical products that we plan to sell. We currently have no agreements with contract manufacturers for the production of the active pharmaceutical ingredients and the formulation of sufficient quantities of drug product for our drug candidates’ pre-clinical studies and clinical trials and that we believe we will need to conduct prior to seeking regulatory approval.

We do not have agreements for commercial supplies of any of our drug candidates and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to commercialize a drug candidate if it is approved. Additionally, the facilities used by any contract manufacturer to manufacture a drug candidate must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the drug candidate manufactured at that facility. We will be completely dependent on these third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conform to our specifications and current good manufacturing practice requirements of any governmental agency whose jurisdiction to which we are subject, our drug candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the drug candidates, including:

- the possibility that we are unable to enter into a manufacturing agreement with a third party to manufacture our drug candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could cause the delay of approval or commercialization of our drug candidates, cause us to incur higher costs or prevent us from commercializing our drug candidates successfully. Furthermore, if any of our drug candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our drug candidates and to have any such new source approved by the government agencies that regulate our products.

Even if our drug candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Our drug candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices, or cGMPs. As such, we and our contract manufacturers will be subject to continual review and periodic inspections to assess compliance with cGMPs. 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 EMA and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved.

If a regulatory agency 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, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our drug candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;

- require us or our potential future collaborators to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Risks Relating to the Commercialization of Our Products

Even if approved, our drug candidates may not achieve broad market acceptance among physicians, patients and healthcare payors, and as a result our revenues generated from their sales may be limited.

The commercial success of our drug candidates, if approved, will depend upon their acceptance among the medical community, including physicians, health care payors and patients. The degree of market acceptance of our drug candidates will depend on a number of factors, including:

- limitations or warnings contained in our drug candidates' FDA-approved labeling;
- changes in the standard of care or availability of alternative therapies at similar or lower costs for the targeted indications for any of our drug candidates;
- limitations in the approved clinical indications for our drug candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing and distribution support;
- availability of reimbursement from managed care plans and other third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness;
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- the extent to which our drug candidates are approved for inclusion on formularies of hospitals and managed care organizations;
- whether our drug candidates are designated under physician treatment guidelines for the treatment of the indications for which we have received regulatory approval;
- adverse publicity about our drug candidates or favorable publicity about competitive products;
- convenience and ease of administration of our drug candidates; and
- potential product liability claims.

If our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients, the medical community and healthcare payors, sufficient revenue may not be generated from these products and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

We have no sales, marketing or distribution capabilities and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no sales, marketing or distribution capabilities. To develop internal sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources,

some of which will be committed prior to any confirmation that our initial drug candidate or any of our other drug candidates will be approved. For drug candidates where we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including:

- we or our third-party sales collaborators may not be able to attract and build an effective marketing or sales force;
- the cost of securing or establishing a marketing or sales force may exceed the revenues generated by any products; and
- our direct sales and marketing efforts may not be successful.

We may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties.

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our drug candidates and our financial condition and operating results.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we may seek collaborations with companies that have more experience. Additionally, if any of our drug candidates receives marketing approval, we may enter into sales and marketing arrangements with third parties with respect to our unlicensed territories. If we are unable to enter into arrangements on acceptable terms, if at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our drug candidates.

When we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For example, we may relinquish the rights to a drug candidate in jurisdictions outside of the United States. Our collaboration partner may not devote sufficient resources to the commercialization of our drug candidates or may otherwise fail in their commercialization. The terms of any collaboration or other arrangement that we establish may not be favorable to us. In addition, any collaboration that we enter into may be unsuccessful in the development and commercialization of our drug candidates. In some cases, once we have begun pre-clinical and initial clinical development of a drug candidate, we may be responsible for continuing research, or research programs under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of this development. If we are unable to reach agreements with suitable collaborators for our drug candidates, we would face increased costs, we may be forced to limit the number of our drug candidates we can commercially develop or the territories in which we commercialize them and we might fail to commercialize products or programs for which a suitable collaborator cannot be found. If we fail to achieve successful collaborations, our operating results and financial condition may be materially and adversely affected.

If serious adverse events or other undesirable side effects are identified during the development of a drug candidate for one indication, we may need to abandon our development of the drug candidate for other indications.

Drug candidates in clinical stages of development have a high risk of failure. We cannot predict when, or if, a drug candidate will prove effective or safe in humans or will receive regulatory approval. New side effects could, however, be identified as we begin clinical trials for our drug candidate in additional indications. If new side effects are found during the development of a drug candidate for any indication, if known side effects are shown to be more severe than previously observed or if a drug candidate is found to have other unexpected characteristics, we may need to abandon our development of a drug candidate for all potential indications. We cannot assure you that additional or more severe adverse side effects with respect to a drug

candidate will not develop in when we begin clinical trials, which could delay or preclude regulatory approval of a drug candidate or limit its commercial use.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our licensed patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on our licensors and us obtaining and maintaining patent protection and trade secret protection of our current and future drug candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our drug candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities and the right under our licensed patent to contest alleged infringement.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our licensed intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future, are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform similar to, or better than, ours in a way that is not covered by the claims of our licensed or owned patents;
- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of patents we have or are licensed to us;
- we might not have been the first to make the inventions covered by any pending patent applications which have been or may be filed;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain, or are licensed to us, may not provide us with any competitive advantages;
- we, or our licensors, may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Without patent protection on the composition of matter of our drug candidates, our ability to assert our patents to stop others from using or selling our drug candidates in a non-pharmaceutically acceptable formulation may be limited.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our drug candidates or methods involving

these candidates in the parent patent application. We plan to pursue and request our licensors to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in the parent patent application.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. 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 information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets may be expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Our commercial success will depend, in part, on our ability, and the ability of our licensors, to obtain and maintain patent protection. Our licensors' failure to obtain and maintain patent protection for our products may have a material adverse effect on our business.

Pursuant to our license agreements with City of Hope and the NIH and license agreements and MOUs with the Hebrew University's technology transfer office, we have obtained and may obtain rights to certain patents. For additional information regarding these license agreements, see "*Business — Intellectual Property.*" In the future, we may seek rights from third parties to other patents or patent applications. Our success will depend, in part, on our ability and the ability of our licensors to maintain and/or obtain and enforce patent protection for our proposed products and to preserve our trade secrets, and to operate without infringing upon the proprietary rights of third parties. Patent positions in the field of biotechnology and pharmaceuticals are generally highly uncertain and involve complex legal and scientific questions. We cannot be certain that we or our licensors were the first inventors of inventions covered by our licensed patents or that we or they were the first to file. Accordingly, the patents licensed to us may not be valid or afford us protection against competitors with similar technology. The failure to maintain and/or obtain patent protection on the technologies underlying our proposed products may have material adverse effects on our competitive position and business prospects.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we may obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits may be expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions.

There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the U.S. Patent and Trademark Office, or USPTO, in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and stop us from commercializing or increase the costs of commercializing our drug candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our drug candidates, or manufacture or use of our drug candidates, will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our

collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our drug candidates to market and be precluded from manufacturing or selling our drug candidates.

We cannot be certain that others have not filed patent applications for technology covered by pending applications subject to our license agreements, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. Currently, we rely upon our licensors to fund the payments under our license agreements. We are required to reimburse our licensors for these fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during

the patent application process. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Risks Associated with Our Common Stock

The public offering price per share in this offering may be determined by negotiation with the representative of the underwriters.

Our common stock is listed on The Nasdaq Global Market under the symbol “SCPS”. On January 25, 2021, the last sale price of our common stock on Nasdaq was \$12.09 per share. The public offering price may be determined by negotiation between us and the representative of the underwriters. Principal factors to be considered in determining the public offering price include the last sale price of our common stock immediately prior to this offering, recent market prices of, and demand for, publicly-traded securities of comparable companies, the general condition of the securities markets at the time of our offering and such other factors as may be deemed relevant by the underwriters and us. Notwithstanding such considerations, the determination of the public offering price may entail less certainty than in the pricing of securities of more established operating companies.

Our executive officers, directors and principal stockholders have the ability to control all matters submitted to stockholders for approval.

Upon completion of this offering, our executive officers, directors and stockholders who own 5% or more of our currently outstanding shares of common stock, will beneficially own shares, in the aggregate, representing approximately 50% of our shares of common stock to be outstanding after this offering. As a result, if these stockholders were to choose to act together, they would continue to be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act collectively, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of the company on terms that other stockholders may desire.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.

As permitted by Section 102(b)(7) of the Delaware General Corporation Law, our certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our certificate of incorporation and by-laws provide that we shall indemnify, to the fullest extent authorized by the Delaware General Corporation Law, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of the company or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our certificate of incorporation provides that indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney’s fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to,

the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against the company.

Management will have discretion as to the use of proceeds from this offering.

The net proceeds from this offering will be used for the purposes described under “Use of Proceeds.” The Company reserves the right to use the funds obtained from this offering for other purposes not presently contemplated that it deems to be in the best interests of the company and its stockholders in order to address changed circumstances or opportunities. Because of the foregoing, the success of the company will be substantially dependent upon the discretion and judgment of the company’s management with respect to application and allocation of the net proceeds of this offering. Investors for the securities offered hereby will be entrusting their funds to the company’s management, upon whose judgment and discretion the investors must depend.

Although our common stock is listed on Nasdaq, there can be no assurance that an active and liquid public market will fully develop or be sustained.

Our common stock is listed on The Nasdaq Global Market. Notwithstanding such listing, there can be no assurance that an active or liquid public market will fully develop or be sustained. In the absence of an active or liquid public market, investors may have difficulty buying and selling or obtaining market quotations; market visibility for our securities may be limited; and a lack of visibility for our securities may have a depressive effect on any market price for our securities. Moreover, there can be no assurance that securities analysts of brokerage firms will provide coverage of our company, if at all. In the event there is no active or liquid public market for our common stock or coverage of our company by securities analysts of brokerage firms, you may be unable to dispose of your common stock at desirable prices or at all. Moreover, there is a risk that our common stock could be delisted from Nasdaq or any other trading market on which it may be listed or quoted.

The lack of an active or liquid public market may impair our ability to raise capital to continue to fund operations by selling securities and may impair our ability to acquire additional intellectual property assets by using our securities as consideration.

Financial Industry Regulatory Authority sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

Financial Industry Regulatory Authority, or FINRA, rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares once publicly traded, have an adverse effect on the market for our common stock, and thereby depress our share price.

The market price of our common stock may be volatile and purchasers of our common stock could incur substantial losses.

The market price of our common stock may be volatile and subject to wide fluctuations in response to various factors. The stock market in general, and the market for new drug companies, in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may also be influenced by many additional factors, including the following:

- our ability to successfully commercialize, and realize revenues from sales of, any products we may develop;
- the performance, safety and side effects of any drug candidates we may develop;
- the success of competitive products or technologies;
- results of clinical studies of any drug candidates we may develop or those of our competitors;
- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to any products we may develop;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our drug candidates, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or other products we may develop;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our securities, other comparable companies or our industry generally;
- general economic, industry and market conditions; and
- the other risks described in this “*Risk Factors*” section.

Volatility and wide fluctuations of the market price for our common stock could result in purchasers of our common stock incurring substantial losses.

These broad market and industry factors may seriously harm the market price of our securities, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and prospects.

Our outstanding securities, including shares eligible for future sale, may have an adverse effect on the market price of our securities.

We have outstanding 14,577,597 shares of common stock and 8,884,438 warrants as of December 31, 2020. Of such outstanding shares, 4,493,363 shares are not subject to any restrictions on sale and are

“unrestricted” in accordance with Nasdaq’s initial listing requirements. Any sale, or the prospect of any such sales, of our securities could have an adverse effect on the market price for our securities or on our ability to obtain future financing. Further, if and to the extent our warrants, or any additional warrants we issue, are exercised, you may experience dilution to your holdings. Any of the foregoing may have a depressive effect on the price of our securities. Additionally, while the balance of our outstanding shares, or 10,084,234 shares, are subject to lock-up agreements, lock-up arrangements and/or other restrictions on sale, any release, or the prospect of any such releases, may also place downward pressure on the price of our securities.

We do not intend to pay dividends on our common stock.

We have not paid any cash dividends on our shares of common stock to date. The payment of cash dividends on our common stock in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition and will be within the discretion of our board of directors. It is the present intention of our board of directors to retain all earnings, if any, for use in our business operations and, accordingly, our board of directors does not anticipate declaring any dividends on our common stock in the foreseeable future. As a result, any gain you will realize on shares of our common stock will result solely from the appreciation of such shares.

You will experience immediate and substantial dilution.

The difference between the public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering constitutes the dilution to the investors in this offering. Our prior stockholders acquired their common stock prior to this offering at substantially less than investors are paying in this offering, significantly contributing to this dilution. Upon consummation of this offering, after giving effect to the sale of common stock in this offering, investors in the shares of our common stock will incur an immediate and substantial dilution of approximately \$8.47 per share (the difference between the pro forma as adjusted net tangible book value per share of \$0.53, and the offering price of \$9.00 per share). This is because investors in this offering will be contributing approximately 41.9% of the total amount paid to us for our outstanding shares of common stock after this offering, but will only own approximately 6.4% of our outstanding shares of common stock. Accordingly, the per-share purchase price investors will be paying substantially exceeds our per share pro forma as adjusted net tangible book value.

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of an initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock may suffer or be more volatile.

Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the

Securities Act, for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to public company-related compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are currently subject to disclosure and/or reporting requirements under both Regulation A and the Securities Exchange Act of 1934, as amended, or the Exchange Act, the other rules and regulations of the SEC, and the rules and regulations of Nasdaq and/or any trading market on which our securities may be quoted or traded. The expenses required to adequately report as a public company will be material, and compliance with the various reporting and other requirements applicable to public companies will require considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, beginning as early as our annual report on Form 10-K for the fiscal year ended December 31, 2020. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and as our business expands we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the Commission or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our by-laws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following.

- our board of directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors has the right to appoint directors to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our board of directors;
- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; and
- our board of directors is able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

These provisions may also frustrate or prevent any attempts by our stockholders to replace or remove our current management or members of our board of directors. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Our certificate of incorporation and by-laws include a forum selection clause, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or agents.

Our certificate of incorporation and by-laws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- (a) any derivative action or proceeding brought on our behalf;
- (b) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees, or agents to us or to our stockholders;
- (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, the certificate of incorporation, or the by-laws; or

(d) any action asserting a claim governed by the internal affairs doctrine

except that our by-laws provide that as to each of (a) through (d) above, any claim (i) as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within ten (10) days following such determination), (ii) which is vested in the exclusive jurisdiction of a court or forum other than such court or (iii) for which such court does not have subject matter jurisdiction. In no event, however, shall the Court of Chancery, under our by-laws, constitute an exclusive forum for actions, including derivative actions arising under the Securities Act or the Exchange Act, thereby allowing any such actions to be filed in any court having jurisdiction. Our by-laws further provide that if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for the matters specified above.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees, or agents, which may discourage lawsuits against us or our directors, officers, employees, or agent. If a court were to find either exclusive-forum provision in our certificate of incorporation or By-laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

The statements contained in this offering circular that are not purely historical are forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “would” and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this offering circular may include, for example, statements about our:

- limited operating history;
- reliance on third parties for research;
- results of operations;
- ability to manage growth;
- regulatory or operational risks;
- success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- capital structure;
- unpredictable events, such as the COVID-19 pandemic, and associated disruptions could seriously harm our future revenues and financial condition, delay our operations, increase our costs and expenses, and impact our ability to raise capital;
- ability to obtain additional financing when and if needed; and
- liquidity.

The forward-looking statements contained in this offering circular are based on current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control), including, but not limited to, the duration and spread of the COVID-19 pandemic and those factors described under the heading “Risk Factors”, or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

USE OF PROCEEDS

We estimate that the net proceeds of this offering will be approximately \$7.7 million from the sale of our common stock offered by us in this offering based upon the public offering price of \$9.00 per share, and after deducting estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations and to facilitate our future access to the public capital markets. We will likely use the net proceeds of this offering for:

- Conducting pre-clinical and clinical development for our current and future drug candidates;
- Funding our existing and sponsoring new research programs;
- Prosecuting patent applications and protecting our intellectual property rights; and
- Working capital and general corporate purposes.

More specifically, we currently anticipate that approximately \$4.0 million of the net proceeds of this offering will be used for the clinical and/or pre-clinical development of CO-sTiRNA and MRI-1867, as well as our other current and future additional research and development programs. We believe that such net proceeds will be sufficient for us to complete the planned Phase 1 clinical trial process for CO-sTiRNA in B-cell lymphoma and to continue pre-clinical testing and evaluation of MRI-1867 and other research and development programs, as further set forth below.

We may use a portion of the net proceeds of this offering to in-license, acquire or invest in complementary businesses, technologies, products or other assets, including intellectual property and other rights. We do not have any current commitments to do so. In addition, we may seek to repurchase our outstanding securities from time to time in market or private transactions. We have no current commitments or obligations to do so.

Based on our current financial resources, our expected level of operating expenditures and the net proceeds and/or anticipated net proceeds, respectively, from prior financings and currently contemplated securities offerings, including this offering, we believe that we will be able to fund our projected operating requirements for at least the next 12 months. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress on our development programs than anticipated. Thereafter, we will need to obtain additional financing to fund future clinical trials for our drug candidates and other expenses. We expect to finance our cash needs primarily through equity and debt offerings. We may also raise capital through government or other third-party funding and grants, collaborations and development agreements, strategic alliances and licensing arrangements.

Also, we do not currently have sufficient visibility to predict the sufficiency of our financial resources based upon the unpredictability and potential adverse impact of the global pandemic on our operations and overall business.

The expected use of net proceeds of this offering represents our intentions based upon our present plans and business conditions. We cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. Accordingly, we will have significant flexibility in applying the net proceeds of this offering. The timing and amount of our actual expenditures will be based on many factors, including our ability to obtain additional financing, the progress, cost and results of our clinical and pre-clinical trials and other development efforts for CO-sTiRNA, MRI-1867 and our additional research and development programs and other factors described in “*Risk Factors*”, as well as the amount of cash we use in our operations.

Pending the use of the net proceeds described above, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities.

DILUTION

The difference between the public offering price per share in this offering and the pro forma as adjusted net tangible book value per share after this offering constitutes the dilution to investors in this offering. Net tangible book value per share is determined by dividing our net tangible book value, which is our total tangible assets less total liabilities, by the total number of outstanding shares of common stock.

As of June 30, 2020, on an actual basis, pro forma basis and pro forma as adjusted basis, our net tangible book value is as follows:

	Actual	Pro Forma ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾
Net book value	\$(1,505,035)	\$ 574,142	\$ 8,299,142
Less: intangible assets	—	—	—
Net tangible book value	\$(1,505,035)	\$ 574,142	\$ 8,299,142
Total common shares outstanding	13,975,691	14,577,597	15,577,597
Net tangible book value per common share	\$ (0.11)	\$ 0.04	\$ 0.53

- (1) “Pro Forma” information gives effect to equity and debt securities issued by us in financing and other transactions after June 30, 2020 and on or before December 31, 2020.
- (2) “Pro Forma As Adjusted” information gives effect to the Pro Forma information set forth in footnote 1 as adjusted for the sale of our shares of common stock in this offering.

After giving effect to the sale of the shares of common stock in this offering, on a pro forma as adjusted basis, our net tangible book value would be approximately \$8.3 million, or \$0.53 per common share, after deducting the expenses of this offering totaling approximately \$1.3 million. This would represent an immediate increase in pro forma as adjusted net tangible book value of \$0.49 per share to our existing stockholders and an immediate dilution of \$8.47 per share to investors purchasing shares of common stock in this offering.

The following table illustrates the dilution to new investors on a per-share basis:

Public offering price per share of common stock		\$ 9.00
Pro forma net tangible book value per common share before this offering	\$ 0.04	
Increase in pro forma as adjusted net tangible book value per common share attributable to investors purchasing shares of common stock in this offering . . .	0.49	
Pro forma as adjusted net tangible book value per share after this offering		0.53
Dilution to new investors		\$ 8.47

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2020 on an actual basis, a pro forma basis and a pro forma as adjusted basis to give effect to the events described in footnotes (1) and (2) below.

	Actual	Pro Forma ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾
Convertible notes payable, net	\$ 1,426,245	\$ 1,798,648	\$ 1,798,648
Stockholders' equity (deficit):			
Preferred Stock, \$0.001 par value, 20,000,000 shares authorized; none issued and outstanding	\$ —	\$ —	\$ —
Common Stock, \$0.001 par value, 50,000,000 shares authorized; 13,975,691 shares issued and outstanding (actual); 14,577,597 shares issued and outstanding (pro forma); and 15,577,597 shares issued and outstanding (pro forma as adjusted)	13,976	14,578	15,578
Additional paid-in capital	12,304,487	14,412,412	22,136,412
Note receivable	(1,500,000)	(1,500,000)	(1,500,000)
Accumulated deficit	(12,290,844)	(12,320,193)	(12,320,193)
Accumulated other comprehensive loss	(32,654)	(32,654)	(32,654)
Total stockholders' equity (deficit)	(1,505,035)	574,142	8,299,142
Total capitalization	\$ (78,790)	\$ 2,372,790	\$ 10,097,790

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- (1) "Pro Forma" information gives effect to equity and debt securities issued by us in financing and other transactions after June 30, 2020 and on or before December 31, 2020.
- (2) "Pro Forma As Adjusted" information gives effect to the Pro Forma information set forth in footnote 1 as adjusted for the sale of our shares of common stock in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and consolidated financial statements and related notes appearing elsewhere in this offering circular. Some of the information contained in this discussion and analysis or set forth elsewhere in this offering circular, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements involving risks and uncertainties and should be read together with the "Risk Factors" section of this offering circular for a discussion of important factors which could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company developing transformational therapeutics targeting serious diseases with significant unmet medical needs. Our mission is to improve patient outcomes and save lives. To achieve our mission, we are capitalizing on groundbreaking scientific and medical discoveries at some of the world's foremost research and academic institutions.

Our lead development program is a novel, targeted immuno-oncology gene therapy for the treatment of multiple cancers. We have partnered with the City of Hope for CO-sTiRNA, which is a STAT3 inhibitor gene therapy. Pre-clinical testing at City of Hope was designed to determine whether CO-sTiRNA would reduce growth and metastasis of various pre-clinical tumor models, including melanoma, and colon and bladder cancers, as well as leukemia and lymphoma. Based upon such testing, an IND for CO-sTiRNA for B-cell lymphoma is currently anticipated to be filed with the FDA in H1 2021. We currently anticipate that a first-in-human Phase 1 clinical trial for B-cell lymphoma will commence in H2 2021.

In conjunction with City of Hope, Phase 1 clinical trials for additional cancer indications are being contemplated for CO-sTiRNA in combination with immune checkpoint inhibitors and CAR-Ts.

Our second lead development program is MRI-1867, a peripherally-restricted, dual-action CB1 receptor inverse agonist and inhibitor of iNOS. We have partnered with the NIH for MRI-1867 and are initially targeting SSc. Over-activation of CB1 and iNOS has been implicated in the pathophysiology of SSc, which includes fibrosis of the skin, lung, kidney, heart and the gastrointestinal tract. We are currently continuing to conduct pre-clinical work for MRI-1867 to support an IND filing with the FDA.

We are also partnered with Hebrew University on several additional research and development programs. These programs relate to a proprietary opioid-sparing anesthetic and synthesis of novel compounds and NCEs.

We intend to pursue FDA approval, as well as other U.S. and non-U.S. regulatory approvals, for our proprietary drug candidates. We believe that the rigorous safety and efficacy testing required to obtain FDA approval will distinguish our drugs from the proliferation of commoditized cannabinoid products in the marketplace. FDA approval will also allow us to legally market our drugs with claims of therapeutic benefit for specific diseases and indications which cannot be done with non-FDA approved products. Finally, obtaining approval will allow us to overcome the legal obstacles that exist under state and federal laws to the marketing, selling and transportation of cannabinoids and cannabinoid associated products. By pursuing this strategy, we hope to gain a competitive advantage over non-approved products and encourage healthcare providers to prescribe our products for the diseases and indications for which our products are intended at higher prices when compared to non-approved products.

We have devoted substantially all of our resources to our development efforts relating to our drug candidates, including sponsoring research with world-renowned academic and medical research institutions, designing future pre-clinical studies, providing general and administrative support for these operations and securing and protecting our licensed intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. From inception (April 18, 2017) until June 30, 2020, we have funded our operations primarily through the private placement of convertible notes, common stock and warrants.

We have incurred net losses in each year since our inception. As of June 30, 2020, we had an accumulated deficit of \$12,290,844. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that all our expenses will increase substantially as we:

- continue our research and development efforts;
- contract with third-party research organizations to manage our clinical and pre-clinical trials for our drug candidates;
- outsource the manufacturing of our drug candidates for clinical testing and pre-clinical trials;
- seek to obtain regulatory approvals for our drug candidates;
- maintain, expand and protect our intellectual property portfolio;
- add operational, financial and management information systems and personnel to support our research and development and regulatory efforts; and
- operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our drug candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the commercialization of any of our current or future drug candidates. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through equity and debt offerings. We may also raise capital through government or other third-party funding and grants, collaborations and development agreements, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our drug candidates.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements and consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of these condensed consolidated financial statements and consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are 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. Our actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this offering circular. We believe that the accounting policies are critical for fully understanding and evaluating our financial condition and results of operations.

Net Loss Per Share

Basic net loss per common share attributable to common shareholders is calculated by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Since the company was in a loss position for all periods presented, basic net loss per share is the same as dilutive net loss per share as the inclusion of all potential dilutive common shares which consist of stock options and warrants, would be anti-dilutive.

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to companies that are not emerging growth companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an “emerging growth company” until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of an initial public offering; (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Financial Overview

Six Months Ended June 30, 2020 versus Six Months Ended June 30, 2019

The following table summarizes our results of operations for the six months ended June 30, 2020 and June 30, 2019:

	Six Months Ended June 30,	
	2020	2019
Operating Expenses:		
General and Administrative	\$ 1,279,689	\$ 731,422
Research and Development	7,284,874	197,420
Loss from Operations	<u>(8,564,563)</u>	<u>(928,842)</u>
Net Loss	<u>(8,651,397)</u>	<u>(928,842)</u>

Our net losses were \$8,651,397 and \$928,842 for the six months ended June 30, 2020 and June 30, 2019, respectively.

Revenue

We did not generate any revenue in either six-month period. Our ability to generate product revenues in the future will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more drug candidates in the United States.

Operating Expenses

General and Administrative Expenses

General and administrative expenses consist primarily of costs related to our personnel and management services agreements, or MSAs. Other significant general and administrative expenses include, accounting and legal services, expenses associated with obtaining and maintaining patents and the expenses related to the issuance of stock options to our President and certain of our scientific and senior advisors. We incurred general and administrative expenses in the six months ended June 30, 2020 and June 30, 2019 of \$1,279,689

and \$731,422, respectively. We attribute this growth in our general and administrative expenses to a greater level of our business activities (managing our research programs at City of Hope, the NIH and Hebrew University, negotiating and executing our license agreements, pursuing patent protection for our intellectual property, investigating additional business opportunities, retaining new employees and preparing for our IPO, including increased costs to comply with corporate governance, internal controls and similar requirements applicable to public companies), all of which have increased the amounts payable (i) under our MSAs; (ii) in compensation and benefits; and (iii) to our accounting and legal advisors. In this regard, in the six months ended June 30, 2020 compared to the same period in 2019, approximately an additional \$81,255 and \$383,195 were attributable to increased amounts payable under our MSAs, including the Hopper MSA, and compensation and benefits payable to our president, respectively. For the six months ended June 30, 2019, the Company had no expenses attributable to either the Hopper MSA or to our president since the Hopper MSA and the retention of our president occurred subsequent to June 30, 2019. Of the total general and administrative expenses attributable to our president, \$166,994 represents half of his annual base compensation for 2020, including \$16,994 of payroll taxes and fees, all of which have been paid in cash, \$150,000 represents an accrual for his guaranteed bonus for 2020, and \$66,201 is the value of the compensatory charge associated with the prior grant of stock options to our president.

Research and Development Expenses

We recognize research and development expenses as they are incurred. Our research and development expenses consist of fees incurred under our agreements with City of Hope, the NIH and Hebrew University, including the expenses associated with warrants issued in connection with the agreements with Hebrew University. For the six months ended June 30, 2020 and June 30, 2019, we incurred research and development expenses of \$7,284,874 and \$197,420, respectively. These expenses increased primarily as a result of us entering into the COH License Agreement and SRA relating to CO-sTiRNA, including our related transactions with Bioscience Oncology. The aggregate upfront expenses relating to the COH License Agreement and Bioscience Oncology were recognized in “Research and Development” expenses during the six months ended June 30, 2020. We plan to increase our research and development expenses for the foreseeable future as we continue the clinical and pre-clinical development of our two lead drug candidates, CO-sTiRNA and MRI-1867, and to further advance the development of our other research and development programs, subject to the availability of additional funding.

Fiscal Year Ended December 31, 2019 Versus Fiscal Year Ended December 31, 2018

The following table summarizes our results of operation for the fiscal years ended December 31, 2019 and December 31, 2018:

	<u>Year Ended December 31, 2019</u>	<u>Year Ended December 31, 2018</u>
Operating Expenses:		
General and Administrative	\$ 2,226,837	\$ 408,425
Research and Development	<u>463,111</u>	<u>277,539</u>
Loss from Operations	(2,689,949)	(685,964)
Net Loss	<u>(2,689,949)</u>	<u>(685,964)</u>

Our net losses were \$2,689,949 and \$685,964 for the fiscal years ended December 31, 2019 and December 31, 2018, respectively. We anticipate our fiscal year net losses will increase as we continue to advance our research and drug development activities and incur additional general and administrative expenses to meet the needs of our business.

Revenue

We did not have any revenue during our fiscal year ended December 31, 2019 or for the period from April 18, 2017 (inception) through December 31, 2018. Our ability to generate product revenues in the future will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and

then successfully commercialize a drug candidate in the United States. In the event we choose to pursue a partnering arrangement to commercialize a drug candidate or other products outside the United States, we would expect to initiate additional research and development in the future.

Operating Expenses

General and Administrative Expenses

General and administrative expenses consist primarily of costs related to our management services agreements, or MSAs. Other significant general and administrative expenses include, accounting and legal services, expenses associated with obtaining and maintaining patents and the expenses related to the issuance of stock options to certain of our advisory board members. For the fiscal years ended December 31, 2019 and December 31, 2018, we incurred \$2,226,837 and \$408,425 of general and administrative expenses, respectively. We attribute this growth in our general and administrative expenses primarily to a greater level of business activities being conducted in 2019 compared to 2018, including costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants.

We expect that our general and administrative expenses will increase due to the further development of our drug candidates. We believe that these increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur increased costs to comply with corporate governance, internal controls and similar requirements applicable to public companies.

Research and Development and Expenses

Since our inception, we have focused our resources on our research and development activities. We recognize research and development expenses as they are incurred. Our research and development expenses consist of fees paid under our agreements with Hebrew University and the NIH, including the expenses associated with warrants issued in connection with the agreements with Hebrew University. For the fiscal years ended December 31, 2019 and December 31, 2018, we incurred \$463,111 and \$277,539 in research and development expenses, respectively. We plan to increase our research and development expenses for the foreseeable future as we continue the development of our drug candidates and other indications and to further advance the development of other potential drug candidates, subject to the availability of additional funding.

Liquidity and Capital Resources

We have incurred losses since our inception and, as of June 30, 2020, we had an accumulated deficit of \$12,290,844. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations. We expect to finance our cash needs primarily through equity and debt offerings. We may also raise capital through government or other third-party funding and grants, collaborations and development agreements, strategic alliances and licensing arrangements. In June 2020, we issued an aggregate initial principal amount of \$1,659,600 of convertible notes (“Convertible Notes”) in a private placement (“Convertible Notes Private Placement”). The Convertible Notes have an annual interest rate of 10% per annum, a scheduled maturity on the earlier of July 31, 2021 or a change of control of the company, and are convertible, including accrued and unpaid interest, into W Warrants at a conversion price of \$0.50 per W Warrant. For each \$1.00 of initial principal, the purchaser also received one W Warrant. Between February 2020 and June 2020, we issued, on a direct basis, convertible notes and W Warrants on identical terms to those of the Convertible Notes Private Placement in an aggregate initial principal amount of \$636,230 for \$187,500 in cash with the balance as consideration for legal and management services rendered. Between July 2020 and September 2020, we raised additional capital in offerings of debt, including pursuant to the Convertible Notes Private Placement, and equity securities in an aggregate amount of approximately \$450,000 in gross proceeds. To enhance our liquidity and capital resources, we have from time to time issued convertible notes and warrants to various parties, including related parties, to satisfy certain fees and other payables. We may also seek to satisfy other obligations and payables through the issuance of additional convertible notes and warrants. On December 18, 2020, we

completed an IPO of our common stock at a public offering price of \$5.50 per share for aggregate gross proceeds, including our underwriters' exercise, in full, of their over-allotment option, of \$3,162,500.

Since April 18, 2017 (inception) through June 30, 2020, we have funded our operations principally with \$5,418,462 in gross proceeds from the sale of convertible notes, common stock, warrants, and units comprised of common stock and warrants, and the exercise of a portion of such warrants. As of June 30, 2020, we had cash of \$753,242. Between July 2020 and September 2020, we raised an additional approximately \$450,000 in gross proceeds from the sale of our debt, including pursuant to the Convertible Notes Private Placement, and equity securities. In addition, on December 18, 2020, we completed our IPO raising aggregate gross proceeds of \$3,162,500.

Future Funding Requirements

We have not generated any revenue. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our drug candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue to research, develop, and seek regulatory approval for, our drug candidates. We expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our drug candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based on our current financial resources, our expected level of operating expenditures and the net proceeds and/or anticipated net proceeds, respectively, from prior financings and currently contemplated securities offerings, including this offering, we believe that we will be able to fund our projected operating requirements for at least the next 12 months. This period could be shortened if there are any significant increases in planned spending on development programs or more rapid progress on our development programs than anticipated. Thereafter, we will need to obtain additional financing to fund future clinical trials for our drug candidates and other expenses. We expect to finance our cash needs primarily through debt and equity offerings. We may also raise capital through government or other third-party funding and grants, collaborations and development agreements, strategic alliances and licensing arrangements. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of additional capital outlays and operating expenditures necessary to complete the development of our drug candidates. Thereafter, we will need to obtain additional financing to fund future clinical trials for our drug candidates. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our drug candidates.

Our future capital requirements will depend on many factors, including:

- the progress, costs, results and timing of our drug candidates' future clinical studies and future pre-clinical trials, and the clinical development of our drug candidates for other potential indications beyond their initial target indications;
- the willingness of the FDA and the EMA to accept our future drug candidate clinical trials, as well as our other completed and planned clinical and pre-clinical studies and other work, as the basis for review and approval of our drug candidates;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue, including our drug candidates in future pre-clinical development;
- the ability of our drug candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;

- the costs of acquiring, licensing or investing in businesses, products, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our licensed intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the duration and spread of the COVID-19 pandemic, and associated operational delays and disruptions and increased costs and expenses; and
- the economic and other terms, timing and success of any collaboration, licensing or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of debt financings and equity offerings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of debt and equity securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us.

We have considered the spread of the COVID-19 coronavirus outbreak, which the World Health Organization has declared a “Public Health Emergency of International Concern.” The COVID-19 outbreak is disrupting supply chains and affecting production and sales across a range of industries. The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the pandemic and its impact on our employees and vendors, and our ability to raise capital, all of which are uncertain and cannot be predicted. At this point, the extent to which COVID-19 may impact our financial condition or results of operations is uncertain.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The FASB issued this update to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The guidance of ASU 2016-02 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that reporting period, and for all other entities, the amendments are effective for fiscal years beginning after December 15, 2021, and interim periods within that reporting period. We do not currently hold any leases and therefore adoption of ASU 2016-02 is not expected to have a material impact on our condensed consolidated financial statements and consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily

Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (“ASU 2017-11”). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. The amendments in Part I of this ASU are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, including EGCs, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The company’s early adoption of ASU 2017-11 on January 1, 2019 did not have a material impact on the condensed consolidated financial statements or condensed consolidated financial statements.

As previously noted, we, as an emerging growth company, have elected to take advantage of the benefits of the extended transition period provided for in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards, which allows us to defer adoption of certain accounting standards until those standards would otherwise apply to private companies unless otherwise noted.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the condensed consolidated financial statements or consolidated financial statements as a result of future adoption.

Controls and Procedures

We are not currently required to maintain an effective system of internal controls as defined by Section 404 of the Sarbanes-Oxley Act. As of the date of this offering circular, we have not completed an assessment, nor have our auditors tested our systems of internal controls.

Effect of Inflation and Changes in Prices

We do not believe that inflation and changes in prices will have a material effect on our operations.

OUR BUSINESS

We are a biopharmaceutical company developing transformational therapeutics targeting serious diseases with significant unmet medical needs. Our mission is to improve patient outcomes and save lives. To achieve our mission, we are capitalizing on groundbreaking scientific and medical discoveries at some of the world's foremost research and academic institutions.

Our lead development program is a novel, targeted immuno-oncology gene therapy for the treatment of multiple cancers. We have partnered with the City of Hope for CO-sTiRNA, which is a STAT3 inhibitor gene therapy. Pre-clinical testing at City of Hope was designed to determine whether CO-sTiRNA would reduce growth and metastasis of various pre-clinical tumor models, including melanoma, and colon and bladder cancers, as well as leukemia and lymphoma. Based upon such testing, an IND for CO-sTiRNA for B-cell lymphoma is currently anticipated to be filed with the FDA in H1 2021. We currently anticipate that a first-in-human Phase 1 clinical trial for B-cell lymphoma will commence in H2 2021.

In conjunction with City of Hope, Phase 1 clinical trials for additional cancer indications are being contemplated for CO-sTiRNA in combination with immune checkpoint inhibitors and CAR-Ts.

Our second lead development program is MRI-1867, a peripherally-restricted, dual-action CB1 receptor inverse agonist and inhibitor of iNOS. We have partnered with the NIH for MRI-1867 and are initially targeting systemic sclerosis, or SSc. Over-activation of CB1 and iNOS has been implicated in the pathophysiology of SSc, which includes fibrosis of the skin, lung, kidney, heart and the gastrointestinal tract. We are currently continuing to conduct pre-clinical work for MRI-1867 to support an IND filing with the FDA.

We are also partnered with Hebrew University on several additional research and development programs. These programs relate to a proprietary opioid-sparing anesthetic and synthesis of novel compounds and NCEs.

We intend to pursue FDA approval, as well as other U.S. and non-U.S. regulatory approvals, for our proprietary drug candidates. We believe that the rigorous safety and efficacy testing required to obtain FDA approval will distinguish our drugs from the proliferation of commoditized cannabinoid products in the marketplace. FDA approval will also allow us to legally market our drugs with claims of therapeutic benefit for specific diseases and indications which cannot be done with non-FDA approved products. Finally, obtaining approval will allow us to overcome the legal obstacles that exist under state and federal laws to the marketing, selling and transportation of cannabinoids and cannabinoid associated products. By pursuing this strategy, we hope to gain a competitive advantage over non-approved products and encourage healthcare providers to prescribe our drugs for the diseases and indications for which they are intended at higher prices when compared to non-approved products.

Recent Developments

Initial Public Offering

On December 18, 2020, we completed an IPO of our common stock at a public offering price of \$5.50 per share for aggregate gross proceeds, including our underwriters' exercise, in full, of their over-allotment option, of \$3,162,500. Our common stock is listed on The Nasdaq Global Market under the symbol "SCPS".

Additional Development Programs and Licenses

In June 2020, we entered into a license agreement with City of Hope. In addition to the COH License Agreement, we also entered into a SRA relating to on-going research and development activities in collaboration with City of Hope. We obtained the right to negotiate the COH License Agreement with City of Hope from Bioscience, which held the exclusive underlying right to negotiate the COH License Agreement. Simultaneously with the execution of the COH License Agreement, we also closed on the Transactions. In connection with the Transactions, we paid City of Hope and Bioscience aggregate consideration and expense reimbursements at closing of approximately \$455,000 in cash and issued 1,466,667 shares of our common stock together with 959,308 W Warrants. We are also obligated to pay additional consideration in cash and common stock, in some cases upon satisfaction of certain milestones.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus, or COVID-19, as a global pandemic, which continues to spread throughout the United States and around the world. We are continually monitoring the impact of the global pandemic on us, especially since we conduct activities in multiple locations, both in and outside of the United States. These locations are New York City and Los Angeles in the United States and Tel Aviv, Israel. At various times since the onset of the global pandemic, these locations have been severely affected by COVID-19 and, as a result, have been subject to various requirements to stay at home and self-quarantine, as well as constraints on mobility and travel, especially international travel.

In many locations, the primary focus of healthcare providers and hospitals has been to combat the virus. While we continue to advance our development programs, we are also continually assessing the impact of the global pandemic on our product development efforts, including any impact on the timing and/or costs for our clinical trials, IND-enabling work and other research and development activities. There is no certainty as to the length and severity of societal disruption caused by COVID-19. Consequently, we do not have sufficient visibility to predict the impact of the global pandemic on our operations and overall business, including delays in the progress of our planned pre-clinical work and clinical trials, or by limiting our ability to recruit physicians or clinicians to run our clinical trials, enroll patients or conduct follow-up assessments in our clinical trials. Further, the business or operations of our strategic partners and other third parties with whom we conduct business may also be adversely affected by the global pandemic. We continue to monitor the impact of the global pandemic, including regularly reevaluating the timing of our research and development and clinical milestones. In light of the more restrictive constraints on international travel, we continue to adjust program emphasis and prioritization. Until we are able to gain greater visibility as to the impact of the global pandemic, we intend to commit greater resources to our existing and future programs in the United States and are slowing investment in program development outside the United States.

Our Strategic Partners

Our strategic partners for our lead development and other programs are City of Hope, the NIH and Hebrew University. The researchers with whom we are working at each of our strategic partners are leaders in their respective fields.

City of Hope

City of Hope is a world-renowned, independent biomedical research and treatment center for cancer, diabetes, and other life threatening diseases. City of Hope's unique research and development hybrid of the academic and commercial creates an infrastructure that enables City of Hope researchers and their commercial partners to submit numerous INDs to the FDA each year. In June 2020, we signed an exclusive, worldwide license for CO-sTiRNA.

National Institutes of Health

The NIH is the primary government agency in the United States responsible for biomedical and public health research. The NIH spends approximately \$39 billion annually to conduct and fund medical research seeking to enhance health, lengthen life and reduce illness and disability. The NIH is comprised of 27 separate institutes and centers covering different biomedical disciplines. We are working with the Section of Neuroendocrinology of the Laboratory of Physiologic Studies, which are part of the National Institute on Alcohol Abuse and Alcoholism, or NIAAA. We own an exclusive, worldwide license from the NIH to three patents covering a series of novel dual-action CB1 receptor inverse agonists, which includes MRI-1867.

The Hebrew University of Jerusalem

Hebrew University has been a pioneer in the research of the ECS for over 50 years. To better integrate and coordinate its extensive research in this area, in April 2017, Hebrew University established the MCCR. The MCCR is staffed by eminent scientists and medical doctors from a variety of faculties at Hebrew

University and Hadassah University Medical Center. To date, we entered into two MOUs and have executed two exclusive, worldwide licenses in connection with these programs covering the research results and any resulting patents.

Our Drug Candidates

Gene Therapy — STAT3 Inhibitor

Our licensed gene therapy, CpG-STAT3siRNA, or CO-sTiRNA, is a dual-action STAT3 inhibitor. STAT3 is a gene that drives tumor cell growth and anti-tumor immune suppression. CO-sTiRNA is a highly selective and targeted gene therapy that is designed to silence the activity of the STAT3 gene by way of RNA interference. CO-sTiRNA is also designed to stimulate TLR9 receptors and to activate the body's immune defense to recognize and kill cancer cells.

Cancer is caused by genetic mutations that result in the uncontrolled division and proliferation of abnormally functioning cells. The STAT3 gene plays a fundamental role in cell growth and division, cell movement and apoptosis in both tumor cells and tumor associated immune cells. Studies suggest that many cancers depend on the activity of STAT3 to survive and proliferate. The ability to selectively and temporarily silence STAT3 is highly desirable for certain cancer therapies.

We are working with Dr. Hua Yu and Dr. Marin Kortylewski at City of Hope. Dr. Yu is the Billy and Audrey L. Wilder Professor in Tumor Immunotherapy, Associate Chair/Professor in the Department of Immuno-Oncology, and Co-Leader of the Cancer Immunotherapeutics Program. Dr. Kortylewski is an Associate Professor in the Department of Immuno-Oncology. Drs. Yu and Kortylewski are both leading experts in the role of STAT3 in tumor angiogenesis and tumor immune evasion and in oligonucleotide-based cancer immunotherapies and developed CO-sTiRNA. The strategy to pursue STAT3 inhibition was developed based on seminal discoveries by Dr. Yu and her team defining the key role of STAT3 in cancer cell survival and immune tolerance, combined with pioneering work by Dr. Kortylewski and his team on STAT3 targeting using TLR9-targeted delivery of siRNA oligonucleotide therapeutics into immune cells.

Multiple studies, including those conducted at City of Hope, have indicated STAT3 as a promising target in non-Hodgkin's lymphoma. There is growing evidence linking B-cell non-Hodgkin lymphomas to persistent activation of STAT3. Pre-clinical testing at City of Hope was designed to determine whether CO-sTiRNA would reduce growth and metastasis of various cancers, including lymphoma, leukemia, and solid tumors including melanoma, and colon and bladder cancers. Pre-clinical studies in City of Hope laboratories indicated that intratumoral injection of CO-sTiRNA combined with radiation therapy, or RT, may prove to be efficacious in eradicating established tumors in pre-clinical models of human and mouse B-cell lymphoma. The therapeutic effect of CO-sTiRNA combined with RT may likely result from a two-pronged effect, reducing survival signaling in lymphoma cells, as well as decreasing tolerogenic/proangiogenic effects of the tumor microenvironment post-RT.

Local administration of CO-sTiRNA with RT resulted in complete rejection of mouse syngeneic B-cell lymphoma and significant growth inhibition of xenotransplanted tumors. Thus, the combination of local radiation and intratumoral injection of CO-sTiRNA may represent a novel approach to elicit an anti-tumor immune response in the host.

National Institutes of Health Program

We own an exclusive, worldwide license from the NIH to three patents covering a series of cannabinoid receptor mediating compounds developed by Dr. George Kunos, Scientific Director of the National Institute on Alcohol Abuse and Alcoholism of the NIH and leading researcher on endocannabinoids and the endocannabinoid system.

These novel dual-action cannabinoid receptor mediating compounds are proprietary NCEs that are CB1 receptor antagonists and inhibitors of inducible nitric oxide synthase, or iNOS. Over activation of CB1 and iNOS has been implicated in the pathophysiology of SSc, which includes fibrosis of the skin, lung, kidney, heart, and the gastrointestinal tract.

Our license enables us to use these cannabinoid receptor mediating compounds for the commercial development as a new therapeutic for the treatment of SSc and other skin fibrotic diseases.

Systemic Sclerosis

SSc is a chronic, systemic autoimmune disease characterized by activation of innate and adaptive immune systems, an obliterative, proliferative vasculopathy of small blood vessels, and fibrosis of the skin and multiple internal organs. Approximately 90,000 people in the United States and Europe have SSc. The disease affects mainly adults (80% of SSc patients are women) with mean age of onset about 46 years of age in the United States. Based on these patient population characteristics, SSc is classified as an orphan indication.

SSc can affect multiple internal organs in the body, including the lungs, heart, kidneys, joints, muscles, esophagus, stomach and intestines. Clinically apparent organ involvement that occurs in more than a third of these patients includes thickened skin, Raynaud's phenomenon, esophageal symptoms, pulmonary fibrosis, restrictive lung disease, edematous skin, joint contractures, digital ulcers, and muscle weakness.

Less frequently occurring, yet life-threatening manifestations include pulmonary artery hypertension (about 1 in 5 patients), cardiac conduction blocks (about 1 in 10 patients), and renal crisis (about 1 in 50 patients). In the United States, SSc is the most-deadly of the systemic autoimmune diseases. The median disease duration for an individual who dies of SSc is 7.1 years from the onset of symptoms. About 85% of deaths caused by SSc are the result of pulmonary fibrosis, pulmonary artery hypertension, or cardiovascular disease, such as sudden death.

Currently, there are no FDA-approved therapies specifically for SSc, although therapies have been approved for the pulmonary artery hypertension associated with this disease. Immunosuppressants with significant toxicities are commonly used to treat SSc, however, as far as we know, there is a general absence of clinical data to support their use.

We believe there is general agreement in the SSc community that an effective anti-inflammatory and anti-fibrotic drug would address a significant unmet medical need in SSc, especially a drug that is orally administered, can be used chronically with other commonly prescribed medications for SSc, and is not immunosuppressive. We believe such a therapy would be positively received by the market.

MRI-1867

We are developing the cannabinoid receptor mediating compound, MRI-1867, for the treatment of SSc. MRI-1867 is a rationally designed, orally available, dual-action, hybrid, small molecule that is an inverse agonist of the endocannabinoid system/CB1 receptor, or CB1, as well as an inhibitor of the iNOS system. To date, MRI-1867 has demonstrated numerous positive characteristics in pre-clinical animal model testing.

Specifically, NIH researchers have indicated that MRI-1867 has druggable pharmacodynamic, pharmacokinetic and stability properties using non-GLP *in vitro* and *in vivo* animal testing. Further, *in vivo* testing conducted by the NIH (published in peer review journals) has, in relevant animal models, demonstrated successfully that, compared to a placebo, MRI-1867 has both slowed the progression of fibrosis and attenuated pre-existing fibrosis in two organs (liver and lungs) with highly potent and selective antagonism of both CB1 and iNOS. Importantly, *in vivo* animal studies have also demonstrated that MRI-1867 did not cross the blood brain barrier, eliminating the potential for adverse CNS side effects which can be present with other cannabinoids that bind to receptors in the brain. MRI-1867 has also exhibited sufficient bioavailability with oral delivery and supported once daily dosing.

Cooperative Research and Development Agreement

We have entered into a CRADA with NIH. A CRADA, which is authorized under 15 U.S.C. §3710a, allows a federal laboratory to undertake joint research and development activities with a non-federal party. Under the CRADA, we are advancing the research undertaken to date in connection with the potential therapeutic benefits of using MRI-1867 as a treatment for SSc. The research being conducted under the CRADA is being carried out by Dr. Kunos and his team at NIH. Preliminary *in vivo* studies

demonstrated a reduction in pre-existing fibrosis as compared to placebo in the treatment of bleomycin-induced skin fibrosis. Our company is funding Dr. Kunos' research over a two-year period under a proprietary research plan. The cost to our company is approximately \$240,000 for the two-year study.

Development Plan

Based on the published data for MRI-1867 in liver and lung fibrosis and the preliminary positive data in skin fibrosis generated under the CRADA, we intend to commence additional studies to support an IND submission to the FDA for MRI-1867. Prior to this submission, our company plans to file a pre-IND meeting request with FDA to confirm that the planned chemistry, manufacturing, and controls, or CMC, and non-clinical tasks will support the initiation of a Phase 1 clinical trial. By doing so, we may receive feedback from the FDA that will enable us to modify the development plan for MRI-1867 early on, expediting the overall development process and avoiding a waste of resources. Additionally, given the significant unmet clinical need and lack of an FDA-approved treatment for SSc, we also plan to submit an orphan drug designation request for MRI-1867 for the treatment of SSc. We plan to file an IND for MRI-1867 in 2021. We continue to adjust our program emphasis and prioritization and we are slowing investments in programs outside of the United States. Accordingly, until we are able to gain visibility as to the impact of the global pandemic, we are revising our planning relating to the timing for filing an IND for MRI-1867 with the FDA.

Hebrew University Programs

We are working with leading researchers at Hebrew University on three projects, which seek to identify novel cannabinoid-based therapeutics for development. These projects are being conducted pursuant to the MOUs between us and Yissum Research Development Company of the Hebrew University, which we refer to as Yissum. Under these MOUs, we are responsible for funding the costs of prescribed research projects. This research is conducted under the auspices of a named researcher. We have the exclusive right to negotiate for licenses of the intellectual property resulting from this research, including any patents that are filed. To date, we have executed two licenses in connection with these MOUs.

Proprietary CBD-mediated, Opioid-sparing Anesthetics

In collaboration with Dr. Alexander Binshtok of Hebrew University, we are evaluating the CBD-mediated activation of nociceptive, transient receptor potential cation channels, or TRPV1 and TRPA1 channels, for painless pain-selective anesthesia. Dr. Binshtok is studying the effects of approved anesthetics in combination with CBD on sodium currents and action potential. The research will be carried out, under our company's sponsorship and supervision, by Dr. Binshtok and his team at Hebrew University.

In a previous study, Dr. Binshtok discovered that the injection of capsaicin, a TRPV1 and TRPA1 channel activator, in combination with QX-314, a lidocaine derivative, *in-vivo* effectively silenced pain and itch. Building upon these prior results, our sponsored research program with Dr. Binshtok was designed to determine whether CBD, a TRPV1 and TRPA1 channel activator, could be used as an alternative to capsaicin in combination with chloroprocaine, an approved anesthetic, to result in painless selective long-term pain relief without paralytic, autonomic or neurotoxic side effects.

Based on the foregoing, we are currently working with Dr. Binshtok to optimize potential treatment regimens, as well as to conduct safety and efficacy studies. We believe that our proprietary combinations of CBD with approved anesthetics may be eligible for the FDA's 505(b)(2) development pathway; provided, however, there can be no assurance that we will be able to avail ourselves of such pathway. This pathway was introduced to avoid duplication of studies already performed on drug compounds, in this case both CBD and the anesthetics, and would significantly reduce the future time and costs associated with clinical development.

We believe our proprietary combinations of CBD with approved anesthetics would be applicable in multiple clinical settings including:

- opioid-sparing post-operative pain management
- nerve block anesthesia

- epidural anesthesia during childbirth (i.e., pain relief while retaining the ability to “push”)
- spinal anesthesia, particularly in patients susceptible to low blood pressure (e.g., the elderly)
- dental anesthesia
- inflammatory, cancer and neuropathic pain and itch

Each of these potential applications represents a significant market opportunity in the United States, as well as globally.

Additionally, we believe that opioid-sparing, pain-selective anesthetics may also reduce the need for the use of highly-addictive opioids in tandem with anesthetics or for general stand-alone pain management helping to address a growing opioid epidemic in the United States. According to the Center for Disease Control and Prevention, or CDC, there were nearly 30,000 overdose deaths related to opioids in 2017. The U.S. Federal Government budgeted approximately \$4.6 billion for 2018 to combat the growing opioid epidemic. Given the growing health and economic impact of opioids, we believe an opioid-sparing anesthetic, such as those in our novel class of pain-selective anesthetics, would be well-received by the market and may be considered for an expedited review by the FDA.

Synthesis of Novel Cannabinoids

In collaboration with Dr. Dmitry Tselikhovsky of Hebrew University, we are pursuing two programs seeking to synthesize novel cannabinoids: cannabinoid-based dual-action compounds and novel chemical derivatives based upon the molecular structure of existing cannabinoids. Both of these programs are intended to provide us with a series of proprietary NCEs for evaluation as potential drug candidates.

Cannabinoid-based Dual-action Compounds

Our first program seeks to create new dual-action, cannabinoid-based hybrid NCEs which improve upon the efficacy, side effects or a combination of both compared to FDA-approved drugs and other promising drug candidates currently under development. Our initial strategy is to focus on indications that have been proven to be responsive to cannabinoids and cannabinoid therapeutics such as certain metabolic, autoimmune and inflammatory diseases. Once we have completed the synthesis portion of our program, we will contract with third-party CROs to perform *in vitro* receptor binding assays to determine which indications these compounds may address. Based on the results of these receptor binding assays, we will decide which compounds to advance *in vivo* testing and which compounds would benefit from further chemical refinement. We are initially targeting the creation of approximately four new proprietary compounds as part of this program.

Novel Chemical Derivatives of Existing Cannabinoids

Our second program seeks to create novel derivatives of two cannabinoids, CBG (which is a precursor to CBD and THC) and THCV, which we intend to evaluate for their potential therapeutic benefits. We are initially targeting the creation of approximately four and ten new proprietary CBG and THCV compounds, respectively, as part of this program.

CBG is a non-psychoactive cannabinoid found in cannabis that is believed to boost anandamide, a naturally occurring endocannabinoid that increases dopamine levels and is responsible for regulating various bodily functions related to mood, sleep and appetite. In addition, CBG is also believed to be a possible inhibitor of the psychoactive effects of THC. CBG is believed to have potential benefits in the areas of pain relief, inflammatory bowel disease/colitis, anti-cancer and anti-bacterial activities, neurodegenerative diseases (e.g., Huntington’s disease), cachexia, depression, overactive bladder and various forms of epilepsy.

THCV is a psychoactive cannabinoid found in cannabis that shares a similar molecular structure to THC. Despite the structural similarities to THC, the psychoactive properties of THCV are more difficult to define. In low doses, THCV is believed to be an antagonist of the CB1 receptor. In high doses, however, THCV is believed to be an agonist of the CB1 receptor similar to THC. Unlike THC, which increases appetite,

THCV has the opposite effect of suppressing appetite making it a popular research target for weight loss and diabetes drugs. Further, THCV is also believed to have anti-inflammatory, anti-anxiety and anti-seizure properties, as well as being effective at reducing tremors associated with central nervous system conditions such as amyotrophic lateral sclerosis, or ALS, Parkinson's disease and Alzheimer's disease.

That fact that CBG and THCV already demonstrate biological activity gives us reason to believe that their derivatives will also be biologically active. These derivatives may also demonstrate different biological activity than their respective parent compounds.

Once we complete the chemical design and synthesis of these derivative cannabinoid compounds, we intend to test them in *in vitro* receptor binding assays to determine the best potential indications for further development.

Commercialization

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We may build our own commercial infrastructure or utilize contract reimbursement specialists, sales people, medical education specialists, distribution or other collaboration arrangements and take other steps to establish the necessary commercial infrastructure at such time as we believe that one of our drug candidates is approaching marketing approval.

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 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 drug candidates, including obtaining FDA and other regulatory approvals for drug 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 drug candidates.

Intellectual Property

The proprietary nature of, and protection for, our drug candidates and our discovery programs, processes and know-how are important to our business. We need to rely upon our licensors to obtain patent protection in the United States and internationally for our drug candidates and our discovery programs, and any other inventions to which we have rights under our license agreements, where available and when appropriate. To the extent we will be able to do so, our policy will be to work with our licensors to pursue, maintain our licensed patents and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. We will also rely on trade secrets that may be important to the development of our business.

Our commercial success will depend in part on obtaining and maintaining patent protection by collaborating with our licensors and trade secret protection of our current and future drug candidates and the methods used to develop and manufacture them, as well as successfully defending any patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of pending patent applications our licensors file or with respect to any patent applications our licensors file in the future, nor can we be sure that any existing patents or any patents that may be granted in the future upon which we rely will be commercially useful in protecting our drug candidates, discovery programs and processes. For this and more comprehensive risks related to our licensed intellectual property, please see "*Risk Factors — Risks Relating to Our Intellectual Property.*"

Intellectual Property Licenses

We acquired exclusive, worldwide rights from City of Hope for CO-sTiRNA, including the patent rights and associated know-how. Under the COH License Agreement, we are required to commercially develop CO-sTiRNA, including through all phases of clinical trials, and to eventually obtain marketing approval. Upon the grant of the COH License Agreement, we paid City of Hope an upfront license fee and reimbursed certain patent fees and expenses in an aggregate amount of approximately \$215,000, and issued 200,000 shares of our common stock and 47,965 of our W warrants. Over the course of the COH License Agreement, we are required to attain certain diligence milestones and are obligated to raise a prescribed amount of capital to support the costs associated with development of CO-sTiRNA. We also are required to make development milestone payments, which total approximately \$3.5 million in the aggregate, for each indication. These milestone payments are tied to achieving certain clinical milestones and obtaining marketing approvals. We also must make sales milestone payments tied to achieving net sales starting at \$50 million in a year up to \$1 billion in a year, which payments total \$57.5 million in the aggregate. We are also subject to paying base royalties on sales, such royalty rate being a mid-single digit percentage of sales, subject to minimum annual royalties. Royalty terms are determined on a country-by-country basis and extend to the later of 15 years following the expiration of patent protection in such country or, in cases of know-how, 15 years from the first commercial sale. Starting in 2021, we also must pay an annual license maintenance fee, such fee being less than \$50,000 per year, which will be a credit against base royalties in a license year once we become obligated to pay such royalties in a license year. The COH License Agreement is subject to termination upon an uncured material breach by either party or our bankruptcy.

Through our wholly-owned subsidiary, Vital Spark, Inc. or VSI, we own a license from the NIH, pursuant to which we have an exclusive, worldwide rights with respect to three patents related to cannabinoid receptor mediating compounds for use in connection with SSc. We are required under the license agreement to use reasonable commercial efforts to bring the licensed products and licensed processes to practical application, which includes adhering to an agreed upon commercial development plan and meeting certain performance benchmarks. Upon execution of the license agreement, we paid a license fee and reimbursed certain patent fees and expenses in an aggregate amount of approximately \$120,000. In addition, we are required to pay to NIH minimum annual royalties, such minimum amount being \$25,000 per year, which are credited against any earned royalties on product sales, such royalty rate being less than 5% of product sales. We are also obligated to pay royalties in connection with the achievement of certain prescribed milestones tied to clinical development and market approvals in prescribed countries. Such milestone payments total approximately \$2,100,000 in the aggregate. We are responsible for funding the patent prosecution costs NIH incurs for the patents licensed to us. We have the right to surrender the license in any country for which we determine not to fund patent prosecution costs.

We have two license agreements with Yisum. The first is to the patent and associated research results relating to the CBD combinations with approved anesthetics resulting from our MOU with Dr. Binshtok. The second is to the research results relating to the synthesis of novel cannabinoid dual-action compounds and novel chemical derivatives of CBG and THCV resulting from our MOU with Dr. Tsevlkhovskiy. Under the first license agreement and under the second license agreement, solely with respect to regulated products, we have agreed to pay milestone payments upon achievement of certain clinical development and product approval milestones. The first of these payments is due upon dosing of the first patient in the first in-human clinical trial. The second becomes due upon the dosing of the first patient in a pivotal Phase IIb/Phase III trial. The last three payments are tied to marketing approvals in the United States and in other countries. These milestone payments total approximately \$1,225,000 in the aggregate for each license agreement. We will also pay percentage royalties tied to sales of any drug product that may arise in the future based upon the licensed patent. Such percentage royalty rate is less than 5% of product sales. This license is worldwide subject, however, to our funding patent prosecutions on a country by country basis. We have agreed, at a minimum, to fund patent prosecutions in the United States, Canada, Japan, China, India, the United Kingdom, Germany and France. In addition, under our second license agreement, as for non-regulated products, we have agreed to pay two milestone payments totaling \$100,000, the first payment being due upon establishing the commercial optimization of any product we develop and the second upon developing a small-scale pilot manufacturing plant. The royalty rate for non-regulated products is 60% of the percentage royalty rate for regulated products.

Manufacturing

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

For our future drug candidates, we aim to identify and qualify manufacturers and researchers to provide the application program interface, or API, and fill-and-finish services prior to submission of an NDA to the FDA. We expect to continue to fund the development of drug candidates that can be produced cost-effectively at contract manufacturing facilities.

Marketing

Given our stage of development, we have not yet established marketing capabilities. We may perform marketing functions ourselves or through third parties, or may take other steps to establish the necessary marketing infrastructure if any of our drug candidates are approved.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our drug candidates must be approved by the FDA through the NDA, process before they may be legally marketed in the United States and by the European Medical Association, or EMA, through the Marketing Authorization Application, or MAA, process before they may be legally marketed in Europe. Our drug candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Regulation of Cannabis and Cannabinoids

DEA Regulation

Cannabis, cannabis extracts and some cannabinoids are regulated as “controlled substances” as defined in 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, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Cannabis, cannabis extracts and some cannabinoids are listed by the DEA as Schedule I controlled substances under the CSA, except that the DEA has de-scheduled CBD included in *Epidiolex*. The manufacture, shipment, storage, sale and use of such Schedule I controlled substances 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.

State Regulation

The states also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition.

The Single Convention on Narcotics Drugs 1961

Many countries, including the United States, are parties to the 1961 Single Convention on Narcotic Drugs, or the Single Convention, which is an international treaty that governs international trade and domestic control of narcotic substances, including cannabis and cannabis extracts. The Single Convention requires all parties to take measures to limit the production, manufacture, export, import, distribution of, trade in, and use and possession of cannabis exclusively to medical and scientific purposes. In particular, the Single Convention requires member countries to establish a government agency to oversee the cultivation of marijuana and establish a monopoly on the wholesale trade of marijuana, and it provides that this role must be filled by a single government agency if the member country's constitution so permits.

National Institute on Drug Abuse

Pursuant to the Single Convention, National Institute on Drug Abuse, or NIDA, oversees the cultivation of research-grade cannabis for medicinal research on behalf of the United States Government. NIDA has historically fulfilled this obligation through a contract that it administers with University of Mississippi, or UM. UM has been the sole NIDA contractor to grow cannabis for research purposes since 1968. The contract is open for competitive bidding at periodic intervals. Since 1999, the term of the contract has been five years. UM engaged in a competitive bidding process for the next contract interval and was awarded the contract in 2015. Under the NIDA contract, UM grows, harvests, stores, ships and analyzes cannabis of different varieties, as NIDA requires. In August 2016 the DEA announced that it would consider granting registrations for the cultivation of cannabis for research and development purposes outside of the NIDA contract process. We are not aware of any entity that has received such a registration under this process.

UM has represented that it also grows cannabis for purposes of researching cannabis extracts, and has in the past grown cannabis, purified cannabis extracts, and distributed extracts for purposes of developing drug candidates, separate and apart from its contract with NIDA. UM has indicated that it conducted these activities pursuant to separate registrations from the DEA and that it plans to seek the necessary additional DEA registrations to conduct the contemplated activities in connection with our partnership, in compliance with applicable law and the United States' obligations under the Single Convention. However, there is a risk that regulatory authorities may disagree and decline to authorize UM to engage in these activities.

United States Food and Drug Administration Regulation

NDA Approval Processes

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters;
- product seizures;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement, or civil or criminal penalties.

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

- completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices, or GLPs, or other applicable regulations;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Once a pharmaceutical candidate is identified for development, it will enter the pre-clinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious

suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with IRB regulations.

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

- *Phase 1.* The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* Clinical trials are performed on a limited patient population intended 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.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support the approval of the new drug. If a Phase 2 clinical trial is the subject of discussion at the end of Phase 2 meeting with the FDA, a sponsor may be able to request a Special Protocol Assessment, or SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to published guidance on the SPA process, a sponsor which meets the prerequisites may make a specific request for a SPA and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. A SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally,

appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf-life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth review. NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval, which is described in Subpart H of 21 CFR Part 314, provides for an earlier approval for a new drug that is intended to treat a serious or life-threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a drug candidate receiving accelerated approval perform post-marketing clinical trials.

In the recently enacted Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law requires the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's 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 generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are considered to be therapeutically equivalent to the listed drug, are commonly referred to as “generic equivalents” to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug in accordance with state law.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA’s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA 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 ANDA 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 of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA 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.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA or 505(b)(2) application seeking approval of a drug that references a version of the NCE drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA or 505(b)(2) application that includes the change.

An ANDA or 505(b)(2) application may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification and thus no ANDA or 505(b)(2) application may be filed before the expiration of the exclusivity period.

For a botanical drug, the FDA may determine that the active moiety is one or more of the principal components or the complex mixture as a whole. This determination would affect the utility of any five-year exclusivity as well as the ability of any potential generic competitor to demonstrate that it is the same drug as the original botanical drug.

Five-year and three-year exclusivities do not preclude FDA approval of a 505(b)(1) application for a duplicate version of the drug during the period of exclusivity, provided that the 505(b)(1) applicant conducts or obtains a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug’s testing phase — the time between IND submission and NDA submission — and all of the review phase — the time between NDA submission

and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the PTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to \$500,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

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 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 (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. We intend to apply for orphan drug designation for MRI-1867 for SSc and any other of our drug candidates that we develop for diseases or conditions that satisfy the requirements for orphan drug designation. There can be no assurance that we will receive orphan drug designation for MRI-1867 for SSc, or any other drug candidates that we may develop for the treatment of SSc or other orphan diseases.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, or BPCA, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

To receive the six-month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act, or PREA, requires all applications (or supplements to an application) submitted under section 505 of the FDCA (21 U.S.C. Section 355) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain a pediatric

assessment unless the applicant has obtained a waiver or deferral. It also authorizes the FDA to require holders of approved NDAs for marketed drugs to conduct pediatric studies under certain circumstances. In general, PREA applies only to those drugs developed for diseases and/or conditions that occur in both the adult and pediatric populations. Products intended for pediatric-specific indications will be subject to the requirements of PREA only if they are initially developed for a subset of the relevant pediatric population.

As part of the FDASIA, Congress reauthorized both BPCA and PREA, which were slated to expire on September 30, 2012, and made both laws permanent.

Post-approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record-keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other countries governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In the European Union, our future products may also be subject to extensive regulatory requirements. Similar to the United States, the marketing of medicinal products is subject to the granting of marketing

authorizations by regulatory agencies. Also, as in the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

Medicinal products require a marketing authorization before they may be placed on the market in the European Economic Area, or EEA, comprising the member states of the European Union as well as Iceland, Liechtenstein and Norway. There are various application procedures available, depending on the type of product involved. The centralized procedure gives rise to marketing authorizations that are valid throughout the EEA. Applicants file marketing authorization applications with the European Medicines Agency, or EMA, where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use, or CHMP. The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. The centralized procedure is compulsory for medicinal products that (1) are derived from specified biotechnology processes, (2) contain a new active substance (not yet approved on November 20, 2005) indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions, (3) are orphan medicinal products or (4) are advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products). For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, as long as the CHMP agrees that (i) the medicine concerned contains a new active substance (not yet approved on November 20, 2005), (ii) the medicine is a significant therapeutic, scientific, or technical innovation, or (iii) if its authorization under the centralized procedure would be in the interest of public health.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (1) a national procedure, which results in a marketing authorization in a single EEA member state; (2) the decentralized procedure, in which applications are submitted simultaneously in two or more EEA member states; and (3) the mutual recognition procedure, which must be used if the product has already been authorized in at least one other EEA member state, and in which the EEA member states are required to grant an authorization recognizing the existing authorization in the other EEA member state, unless they identify a serious risk to public health.

Marketing authorization applications must usually include the results of clinical trials. Clinical trials of medicinal products in the EEA must be conducted in accordance with EEA and national regulations and the International Conference on Harmonization guidelines on GCP. Prior to commencing a clinical trial in a particular EEA member state, the sponsor must obtain a clinical trial authorization from the competent authority and a positive opinion from an independent ethics committee.

In the EEA, companies developing a new medicinal product must agree a Pediatric Investigation Plan (PIP) with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, e.g., because the relevant disease or condition occurs only in adults. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date.

Reimbursement

Sales of any product we successfully develop will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sales of our drug candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, enacted in March 2010, is expected to have a significant impact on the health care industry. ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of ACA on pharmaceutical companies, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. In addition, some members of the U.S. Congress have been seeking to overturn at least portions of the legislation and we expect they will continue to review and assess this legislation and alternative health care reform proposals. Any legal challenges to ACA, as well as Congressional efforts to repeal ACA, add to the uncertainty of the legislative changes enacted as part of ACA.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Employees

Our executive management consists of four members, one of whom, our President, is employed pursuant to an employment agreement, and three of whom provide services to us pursuant to MSAs.

The executive services of our Chairman, Vice Chairman and Executive Committee Chairman are provided to us pursuant to an MSA, or Portfolio Services MSA, between HCFP/Portfolio Services LLC, or Portfolio Services, and us. Upon closing of the Transactions and as contemplated thereby, we entered into an MSA with an affiliate of Paul E. Hopper, or Hopper MSA. As further contemplated by and in connection with the Transactions, Mr. Hopper assumed the position of Co-Chairman. In connection with Mr. Hopper's need to commit greater time to another biopharmaceutical company, unrelated to us, undertaking a series of financing transactions, including an IPO, Mr. Hopper resigned as our Co-Chairman. We intend to replace the pre-existing MSA for services relating to Dr. Morris C. Laster and the Hopper MSA, although there can be no assurance that we will actually enter into any such MSAs. Mr. Hopper continues to serve as a non-officer and non-employee director of the company. See "*Management.*"

Our executive officers are supported by additional personnel associated with the entities that provide services to the company pursuant to our management services agreements. We also utilize consultants in the ordinary course of business with expertise in various aspects of the drug development process.

For additional information relating to arrangements with our management, see "*Certain Relationships and Related Party Transactions.*"

Facilities

Our corporate headquarters is located at 420 Lexington Avenue, in New York, New York, where office space is made available to us pursuant to the Portfolio Services MSA. Effective as of May 1, 2019, the Portfolio Services MSA provides for a \$3,000 per month fee for such office space and facilities. Office space is also made available to us in Tel Aviv, Israel. We believe that our facilities are suitable and adequate for our current needs.

Legal Proceedings

We are not a party to any legal proceedings.

MANAGEMENT

Executive Officers, Directors and Advisors

The table below sets forth our executive officers, directors and advisors.

Name	Age	Position
Joshua R. Lamstein	51	Chairman and Director
Robert J. Gibson, CFA	41	Vice Chairman, Secretary, Treasurer and Director
Ashish P. Sanghrajka	47	President and Director
Aharon Schwartz, Ph.D.	76	Scientific Advisory Board Chairman and Executive Chairman — Scopus Israel
Morris C. Laster, M.D.	56	Scientific Advisory Board Member and Senior Medical Advisor and Director — Scopus Israel
Ira Scott Greenspan	62	Senior Advisor, Director and Executive Committee Chairman
Paul E. Hopper	64	Director
David S. Battleman, M.D.	54	Director
David A. Buckel, CMA	59	Director
Raphael (“Rafi”) Hofstein, Ph.D.	71	Director
Lesley Russell, MB.Ch.B., MRCP	60	Director
David Weild IV	64	Director
David Silberg	71	Senior Advisor — Scopus Israel

Joshua R. Lamstein has been a Chairman and a director since our inception. Mr. Lamstein became sole Chairman in October 2020. Since 2014, Mr. Lamstein has also been Vice Chairman of HCFP and Co-Chairman and Co-Managing Partner of HCFP/Capital Partners. HCFP/Capital Partners is a co-founder of Scopus. Mr. Lamstein is also a senior officer and/or director of other portfolio companies of HCFP/Capital Partners, including serving as Co-Chairman of GSP Nutrition Inc., which markets nutritional supplements under the *Sports Illustrated* brand name. He also serves as a Venture Partner of a seed-stage venture fund with approximately \$100 million of assets under management. Mr. Lamstein has worked in venture capital and private equity for over 20 years, including as a Managing Director of GF Capital Private Equity Fund, a \$240 million middle market private equity fund, and as a Partner of LMS Capital, a FTSE 250 London Stock Exchange-listed investment trust. Mr. Lamstein initiated the trust’s presence in San Francisco and Silicon Valley. He began his career in private equity at Apollo Advisors, a global alternative investment manager now known as Apollo Global Management, Inc. Prior thereto he was an investment banker in New York and London at Lehman Brothers. Mr. Lamstein has been a member of the board of directors of numerous private and public companies including, in his capacity as a Venture Partner, the following portfolio companies: Canvs.ai, Feed.fm, Rocksbox and TrueAnthem. Previously, from 2013 until 2018, Mr. Lamstein was a director of Penske Media Group, a private global media company, as a designee of the Quadrangle Group, a private equity firm. Mr. Lamstein is also a Senior Advisor to John Snow, Inc. and JSI Research & Training Institute, Inc., a non-profit global public health management consulting and research organization dedicated to improving the health of individuals and communities throughout the world. Mr. Lamstein is also on the Board of Trustees of World Education, Inc., a non-profit organization that provides training and technical assistance in literacy, health and HIV and AIDS education around the world.

We believe Mr. Lamstein is well-qualified to be on our board of directors due to his broad experience in private equity, venture capital, and investing in and managing early-stage ventures, his widespread relationships in the private equity and venture capital communities and his knowledge of public healthcare.

Mr. Lamstein received his B.A., *with honors*, from Colgate University and his M.B.A. from the MIT Sloan School of Management.

Robert J. Gibson, CFA has been Vice Chairman, Secretary and Treasurer and a director since our inception. Since May 2016, Mr. Gibson also has been an Executive Vice President of HCFP and

Co-Chairman of HCFP/Capital Markets LLC, a middle-market investment bank. Until joining HCFP, Mr. Gibson was Senior Vice President — Investment Banking, specializing in biotechnology, biopharmaceutical and specialty pharmaceutical companies, at CRT Capital Group LLC, a middle market investment bank. Mr. Gibson rejoined CRT in 2014 after having been previously employed at such firm from 2003 to 2008, most recently as a Vice President — Investment Banking, specializing in healthcare. Mr. Gibson began his career in the Healthcare Investment Banking Group at Bear, Stearns & Co. Inc. From 2009 to 2014, Mr. Gibson was Senior Vice President, overseeing healthcare investments, at Balance Point Capital Partners, L.P., a middle market private equity fund, which, together with a related fund, then had approximately \$150 million of assets under management.

We believe Mr. Gibson is well-qualified to be on our board of directors due to his extensive experience in both investment banking and private equity, including advising, raising capital and investing in biotechnology, biopharmaceutical specialty pharmaceutical and other healthcare companies.

Mr. Gibson is a Chartered Financial Analyst, or CFA. Mr. Gibson received his B.A., *magna cum laude*, from Amherst College.

Ashish P. Sanghrajka has been our President since August 2019 and became a director in June 2020. For more than 25 years prior to joining us, Mr. Sanghrajka was an investment banker across multiple sectors, with a particular concentration in biotechnology, biopharmaceuticals and pharmaceuticals. Most recently, Mr. Sanghrajka was Managing Director — Equity Capital Markets, at Mizuho Securities USA LLC, the U.S. capital markets affiliate of one of the world's largest financial institutions. Prior to joining Mizuho in 2011, Mr. Sanghrajka was a Managing Director in the United States for Collins Stewart, a leading U.K.-based growth company investment bank, which acquired C.E. Unterberg, Towbin and subsequently was acquired by Canaccord Financial Inc. From 2002 to 2010, Mr. Sanghrajka was the Managing Partner of BIO-IB, a boutique investment bank specializing in licensing/partnering and mergers and acquisitions for emerging private and publicly-held healthcare companies, with an emphasis on biotechnology, biopharmaceuticals and pharmaceuticals. From 1994 to 2002, Mr. Sanghrajka was an investment banker specializing in healthcare and other growth sectors at ABN Amro Rothschild (including predecessors ING Barings and Furman Selz).

Mr. Sanghrajka has served as a board member of numerous private and public companies and non-profit organizations, including the Lung Cancer Research Foundation.

We believe Mr. Sanghrajka is well-qualified to be on our board of directors due to his extensive experience in licensing, partnering, mergers and acquisitions and investment banking and capital markets for biotechnology and biopharmaceutical companies and his extensive relationships with private equity and venture capital firms and other institutional investors specializing in biotechnology and biopharmaceutical investments. Mr. Sanghrajka also maintains close relationships with leading Wall Street investment bankers and research analysts specializing in biotechnology and biopharmaceutical industries.

Mr. Sanghrajka received his B.S. in Engineering and Applied Sciences from the University of Rochester and his Certificate in Finance from the University of Rochester Simon Business School.

Aharon Schwartz, Ph.D. has been our Scientific Advisory Board Chairman and in 2020 also assumed the position of Executive Chairman of Scopus BioPharma Israel Ltd, or Scopus Israel. Since 2004, Dr. Schwartz has been the Chairman of the Board of BioLineRx Ltd. (Nasdaq: "BLRX"), and a director of Foamix Pharmaceuticals Ltd. (Nasdaq: "FOMX") and Protalix BioTherapeutics, Inc. (NYSE American: "PLX"), all publicly-traded biopharmaceutical/specialty pharmaceutical companies. From 1975 to 2011, Dr. Schwartz served in various management positions at Teva Pharmaceutical Industries Limited (NYSE: "TEVA"), most recently as Vice President — Head of Teva Innovative Ventures. Dr. Schwartz's prior positions at Teva included Vice President — Strategic Business Planning and New Ventures; Vice President — Global Products Division; Vice President — Copaxone Division; Vice President — Business Development; and Head of the Pharmaceuticals Division.

Dr. Schwartz received his B.Sc. in Chemistry and Physics from Hebrew University, his M.Sc. in Organic Chemistry from the Technion and his Ph.D. from the Weizmann Institute of Science. Dr. Schwartz also holds an additional Ph.D. in history and philosophy of science from Hebrew University.

Morris C. Laster, M.D. is a Scientific Advisory Board member and a Senior Medical Advisor and director of Scopus Israel. From our inception until June 2020, Dr. Laster was a director and provided executive services to us pursuant to the Clil MSA. Dr. Laster is a co-founder of the company and identified and initiated licensing negotiations with the NIH for MRI-1867. In connection with and as contemplated by the Transactions, Mr. Hopper replaced Dr. Laster as a director and as our Co-Chairman. The pre-existing Clil MSA is being replaced by a new services agreement. Also in June 2020, Dr. Laster assumed the position of Co-Managing Partner with responsibility for launching the \$100 million OurCrowd Pandemic Innovation Fund. Since 2013, Dr. Laster has been a Medical Venture Partner of OurCrowd, a global equity investment and crowdfunding platform, a capacity in which he has led investments of approximately \$80 million in 23 early-stage biopharmaceutical, biotechnology and other medical technology companies. Dr. Laster is currently a director of several OurCrowd portfolio companies, including: BrainQ Technologies, DreaMed Diabetes, Ltd., and HIL Applied Medical. Dr. Laster is also Chairman of OncoHost, a private, clinical-stage precision oncology company. Dr. Laster has been a founder, founding senior officer, director and/or scientific advisor of numerous publicly-traded biotechnology and other medical technology companies, including: BioLineRx Ltd. (Nasdaq: “BLRX”); BiondVax Pharmaceuticals Ltd (Nasdaq: “BVXY”); Keryx Biopharmaceuticals, Inc., a public company on Nasdaq which completed a merger in December 2018 with Akebia Therapeutics, Inc. (Nasdaq: “AKBA”); and Kitov Pharma Ltd. (Nasdaq: “KTOV”). Dr. Laster was a practicing physician prior to beginning his career in biotechnology investing and entrepreneurship as a Vice President — Medical Venture Capital at Paramount Capital Investments LLC. In this position, Dr. Laster was part of the founding teams of additional companies formerly trading on Nasdaq, including Neose Technologies, Inc., which sold its intellectual property and other assets to Novo Nordisk A/S and BioGeneriX AG, and Progenitor Inc., which, at its inception, was a subsidiary of Interneuron Pharmaceuticals, Inc., which was also previously publicly-traded on Nasdaq. Dr. Laster received his B.S., *magna cum laude*, in Biology from the University at Albany, New York and his M.D. from Downstate Medical Center in Brooklyn, New York.

Ira Scott Greenspan has been a Senior Advisor and director since our inception and Executive Committee Chairman since May 2019. Mr. Greenspan is Chairman and Chief Executive Officer of HCFP and Co-Chairman and Co-Managing Partner of HCFP/Capital Partners, and certain other affiliates of HCFP. Each of HCFP and Mr. Greenspan is a co-founder of Scopus. For more than 25 years, Mr. Greenspan has been a senior executive, partner and/or director of HCFP and its predecessors and related entities, including having served as Chairman and Co-Managing Partner of HCFP/Brenner Equity Partners, the indirect majority shareholder of HCFP/Brenner Securities LLC, a middle market investment bank originally founded by former senior executives and directors of Drexel Burnham Lambert. For more than five years prior to entering the financial services industry, Mr. Greenspan was a corporate and securities lawyer at leading New York law firms, including as a Partner of the New York predecessor of Blank Rome. He began his law career at the New York predecessor of Sidley Austin.

Mr. Greenspan has been chairman and/or a member of the boards of directors of numerous public and private companies, most recently including: PAVmed Inc., a publicly-traded multi-product medical device company (Nasdaq: “PAVM”), of which he was a co-founder and Senior Advisor and/or director from inception in 2014 until October 2018; Co-Chairman and a director of Global Sports Properties Inc., an owner of a portfolio of sports assets, or GSP; and an officer, director and/or senior advisor to certain of its affiliates and subsidiaries. Mr. Greenspan worked in the Branch of Small Issues of the Division of Corporation Finance in the New York Regional Office of the Securities and Exchange Commission during law school and also advised family offices on the then increasing internationalization of securities markets and the evolving extraterritorial scope of the U.S. securities laws, resulting from both regulatory and judicial action.

We believe Mr. Greenspan is well-qualified to be on our board of directors due to his significant experience advising entrepreneurial growth companies as both a financial services executive and corporate and securities lawyer, his pioneering role in numerous innovative corporate finance products and strategies, his role as a founder or founding advisor of numerous private and public companies, including biopharmaceutical, biotechnology and other medical technology companies, his investment experience with early-stage companies, his experience as a director of numerous private and publicly-traded companies, and his extensive relationships in the financial community.

Mr. Greenspan received his B.A., *with high distinction*, from Harpur College/Binghamton University, where he was elected to Phi Beta Kappa and Pi Sigma Alpha and was the recipient of the University Foundation Award recognizing him as one of the top students in his graduating class. Mr. Greenspan received his J.D. from New York University School of Law, where he was on the Editorial Board of the *Annual Survey of American Law*, an honorary law journal.

Paul E. Hopper joined us as a director upon the closing of the Transactions, immediately prior to which Mr. Hopper was Executive Chairman of Bioscience Oncology Pty., Ltd. At such time, Mr. Hopper also became our Co-Chairman, a position from which he resigned in October 2020. Mr. Hopper is Executive Chairman of Chimeric Therapeutics Limited, a CAR-T cell therapy company. Mr. Hopper has also been a founder, chairman, senior officer and/or director of numerous private and publicly-traded biotechnology, biopharmaceutical and other healthcare-related companies in the United States and Australia, including: Imugene Limited, a clinical-stage immuno-oncology company publicly-traded on the Australian Securities Exchange, or ASX (ASX: “IMU”); Viralytics Ltd., an immuno-oncology company targeting treatments for metastatic melanoma and other cancers, which was publicly-traded on the ASX prior to the company’s sale to Merck & Co. (NYSE: “MRK”) in 2018 for A\$502 million (or approximately US\$394 million at the time of sale); and Polynoma LLC, a private immuno-oncology company developing a novel polyvalent antigen therapy for the treatment of melanoma, in which a controlling stake was sold to CK Life Sciences International (Holdings) Inc., a publicly-traded company on the Hong Kong Stock Exchange (HK: “0775”) and a subsidiary of Cheung Kong (Holdings) Limited, a Hong Kong multinational conglomerate now part of CK Hutchinson Holdings Limited, the Chairman of which was Li Ka-shing. Mr. Hopper is Chairman of the Life Sciences Portfolio Managers Trust.

We believe that Mr. Hopper is well-qualified to be on our board of directors due to his experience as a biotechnology investor, entrepreneur and executive, particularly his experience in identifying and selecting new medical technologies. Mr. Hopper received a B.A. from the University of New South Wales in Sydney, Australia and has completed several Advanced Management Programs at Harvard Business School.

David S. Battleman, M.D. joined us as a director in December 2020 in connection with our IPO. He was a Senior Advisor to us from November 2019 until his appointment as a director. Since 2012, Dr. Battleman has served as the Founding Principal of TrueNorth Lifesciences, which provides strategic consulting and financial advisory services relating principally to drug development, acceleration, optimization and commercialization for early-stage life sciences companies. Dr. Battleman was previously a Senior Principal in the research and development and commercial strategy practice at IMS Health Holdings, Inc., a Fortune 500 company providing data and consulting services to the pharmaceutical industry. Prior to joining IMS Health, Dr. Battleman was a Consultant in the healthcare practice of Bain & Company, a leading management consulting firm, and a Director at Pfizer Inc. (NYSE: “PFE”), one of the world’s largest pharmaceutical companies with responsibility for value-based product strategies for various early-stage and established pharmaceutical products. Dr. Battleman was also an Assistant Professor at Weill Medical College of Cornell University. Dr. Battleman is a director of PAVmed Inc. (Nasdaq: “PAVM”).

We believe Dr. Battleman is well-qualified to serve on our board of directors due to his extensive experience spanning across academia, the pharmaceutical industry and management consulting, as well as his widespread investor relationships resulting from advising investors, including family offices and institutions, in connection with biotech-related and other healthcare investments.

Dr. Battleman received his B.A. in Biology from The Johns Hopkins University, his M.D. from the Weill Medical College of Cornell University, his MSc. from the Harvard T.H. Chan School of Public Health and his M.B.A. from The Wharton School at the University of Pennsylvania.

David A. Buckel, CMA joined us as a director in December 2020 in connection with our IPO. He was a Senior Advisor to us from November 2019 until his appointment as a director. Since 2007, Mr. Buckel has served as President and Managing Director of BVI Venture Services, an outsourced provider of financial, accounting, management and other professional services to private and small public companies. Mr. Buckel serves as a director of SharpSpring, Inc. (Nasdaq: “SHSP”), a publicly-traded cloud-based marketing technology company, head of the audit committee and a member of the nominating and corporate governance committees. From 2003 to 2007, Mr. Buckel served as Chief Financial Officer of Internap Network Services Corporation (Nasdaq: “INAP”), a publicly-traded IT infrastructure services company. Mr. Buckel

previously served as an officer, Chief Financial Officer and/or director of numerous additional private and Nasdaq-listed public companies.

We believe Mr. Buckel is well-qualified to serve on our board of directors due to his broad experience as a board member and Chief Financial Officer of numerous private and publicly-traded emerging growth companies, his deep knowledge of public accounting and corporate governance, and his expertise in serving on board committees, especially as a member and/or head of public company audit committees.

Mr. Buckel received his B.S. in Accounting from Canisius College and his M.B.A. from the Syracuse University Martin J. Whitman School of Management. Mr. Buckel is a Certified Management Accountant.

Raphael (“Rafi”) Hofstein, Ph.D. joined us as a member of our board of directors in December 2020 in connection with our IPO. From 2009 to March 2020, Dr. Hofstein was President and Chief Executive Officer of Toronto Innovation Acceleration Partners, or TIAP. TIAP, formerly named MaRS Innovation, is a consortium of leading universities, teaching hospitals and other institutions and research institutes with the mandate of identifying life sciences and other technology research from within the consortium and investing in newly-created or other early-stage ventures organized to advance and commercialize scientific breakthroughs. Industry partners of TIAP include Amgen, Baxter, GlaxoSmithKlein, Johnson & Johnson, Merck, Pfizer and Takeda. Over 50 new life sciences and other healthcare-related companies were launched and/or financed during Dr. Hofstein’s tenure with TIAP. Dr. Hofstein has been a founder, executive and/or director, including serving as chairman, with a number of TIAP biopharmaceutical, biotechnology and other healthcare-related portfolio companies, including: Fibrocor Therapeutics, Inc., a private biotechnology company targeting fibrotic diseases; Encycle Therapeutics Inc., a private biotechnology company which was acquired for consideration of up to approximately \$80 million in 2019 by Zealand Pharma A/S (Nasdaq: “ZEAL”), a publicly-traded biotechnology company; Notch Therapeutics Inc., a private biotechnology company focused on gene-edited T cell therapies, which has a strategic partnership with Allogene Therapeutics, Inc. (Nasdaq: “ALLO”), a publicly-traded biotechnology company; and Triphase Accelerator, a private Toronto-based drug development company which entered into a strategic partnership with Celgene relating to early-stage oncology assets.

From 1990 to 2009, Dr. Hofstein was President and Chief Executive Officer of Hadasit Ltd., the technology transfer company of Hadassah University Hospital, the teaching hospital of Hebrew University. Dr. Hofstein also founded and, from 2006 to 2011, was Chairman of Hadasit Bio-Holdings Ltd., a then publicly-traded holding company for biopharmaceutical and biotechnology companies (TASE: “HDST”). Dr. Hofstein has been a founder, executive and/or director, including serving as chairman, of subsidiaries and affiliates of Hadasit, including: BioLineRx Ltd. (Nasdaq: “BLRX”); Exalenz Bioscience Ltd., a TASE-listed company which was acquired by Meridian Bioscience, Inc. (Nasdaq: “VIVO”); and KAHR Medical Ltd., a private biotechnology company developing immune-oncology therapies. During this period, Dr. Hofstein was also a Venture Partner at Medica Venture Partners, a leading medical technology venture capital firm in Israel, and a director of Evogene Ltd., a publicly-traded company on Nasdaq (Nasdaq: “EVGN), and LifeBond Limited Ltd., which was acquired by C.R. Bard. Previously, Dr. Hofstein was Vice President — Business Development for Ecogen Inc., a publicly-traded agricultural biotechnology company on Nasdaq until its acquisition by Monsanto, prior to which he was a Scientific Director for Ecogen in Israel.

Dr. Hofstein has also been an officer, director and/or advisor of numerous not-for-profit life sciences-related entities, including: Centre for Commercialization of Regenerative Medicine, or CCRM, a public/private consortium supporting the development of gene and cell therapies and regenerative medicine; Life Sciences Ontario, an organization seeking to advance the life sciences sector in Ontario; and Clinical Trials Ontario, an independent organization established to advance patient care. Previously, Dr. Hofstein was Scientific Director of Biotechnological Applications Ltd. and Manager of Research and Development and Chief of Immunochemistry at the International Genetic Scientific Partnership, both pivotal organizations in the development of Israel’s biotechnology industry. Dr. Hofstein co-founded the Israel Life Science Industry Organization, or ILSI, and the Israel Tech Transfer Network, or ITTN, both private organizations seeking to advance the life sciences sector in Israel.

We believe Dr. Hofstein is well-qualified to be on our board of directors due to his broad experience across multiple scientific and medical sectors for numerous public and private biopharmaceutical,

biotechnology and pharmaceutical companies; his role as a founder or member of the founding team for many private and public biopharmaceutical, biotechnology and other medical technology companies, including in his capacities as Chairman and/or President and Chief Executive Officer of TIAP and Hadasit; his corporate governance experience gained by serving as a member of numerous board of directors, including as chairman, and various board committees and his widespread relationships throughout the biotechnology ecosystem, including entrepreneurs, managers and private equity and venture capital investors on a global basis.

Dr. Hofstein received his B.Sc. in Chemistry and Physics from Hebrew University and his M.Sc. and Ph.D. in Life Sciences and Chemistry from the Weizmann Institute of Science. Dr. Hofstein was awarded the Chaim Weizmann Post-Doctoral Fellowship and the Hereditary Disease Foundation Fellowship while completing his post-doctoral training and research in the Department of Neurobiology at Harvard Medical School.

Lesley Russell, MB.Ch.B, MRCP (UK) joined us as a member of our board of directors in December 2020 in connection with our IPO. From 2013 to November 2017, Dr. Russell served as Chief Medical Officer for Innocall Holdings plc and TetraLogic Pharmaceuticals Corporation, which were, during Dr. Russell's tenures, Nasdaq-listed public biotechnology/biopharmaceutical companies. Until 2012, Dr. Russell was Senior Vice President and Global Head, Research and Development, Global Branded Products of Teva Pharmaceuticals USA, a subsidiary of Teva Pharmaceutical Industries Limited (NYSE: "TEVA"), a global pharmaceutical company. Dr. Russell assumed this position upon the acquisition in 2011 by Teva of Cephalon, Inc., which previously was a leading independent biopharmaceutical company publicly-traded on Nasdaq. Dr. Russell was at Cephalon from 2000 to 2011, serving in positions of increasing responsibility and seniority. Dr. Russell was Executive Vice President and Chief Medical Officer from 2006 to 2011. Prior to joining Cephalon, Dr. Russell was Vice President — Clinical Research of MedImmune Inc., the same position she held at U.S. Bioscience, Inc., which was acquired by MedImmune in 1999. Dr. Russell joined U.S. Bioscience in 1996 and previously was Senior Director of Clinical Research and Director of Clinical Research. MedImmune and U.S. Bioscience were then leading biopharmaceutical companies publicly-traded on Nasdaq and the American Stock Exchange, respectively. MedImmune was subsequently acquired by AstraZeneca PLC. Dr. Russell was previously held medical and clinical research positions at Eli Lilly (UK) and Amgen (UK).

Dr. Russell currently serves as a director of Enanta Pharmaceuticals, Inc. (Nasdaq: "ENTA"), Imugene Limited (ASX: "IMU"), each a publicly-traded biotechnology company. Dr. Russell also serves as a member of the board of directors of Sojournix Inc., a privately-held biopharmaceutical company. In January 2019, Sojournix completed a \$44 million Series C venture capital financing. Dr. Russell previously served as a director of Endocyte, Inc., a Nasdaq-listed public company acquired by Novartis in December 2018 and for AMAG Pharmaceuticals, Inc. (Nasdaq: "AMAG"), a publicly-traded biopharmaceutical company. Dr. Russell also serves as a member of the board of directors for Melmark, Inc., a not-for-profit organization serving adults and children with severe intellectual and physical disabilities.

We believe Dr. Russell is well-qualified to be on our board of directors due to her diverse experience across multiple disciplines for numerous public and private biotechnology, biopharmaceutical and pharmaceutical companies, including serving as a senior executive officer; acting as director and member (including as Chair) of audit, nominating, compensation and executive committees of boards of directors; managing all aspects of the drug development and regulatory approval processes for oncology and non-oncology drug candidates on a global basis, specifically clinical trial design and implementation, regulatory and marketing approval submissions and medical affairs (consisting of both medical communications and education); actively engaging in the acquisition and/or in-licensing of clinical assets; raising capital; and maintaining a network of key relationships with corporate and regulatory professionals within the biotechnology, biopharmaceutical and pharmaceutical industries.

Dr. Russell received her MB.Ch.B from the University of Edinburgh Faculty of Medicine. She is a member of the Royal College of Physicians and is registered with the General Medical Council.

David Weild IV joined us as a director in December 2020 in connection with our IPO. He was a Senior Advisor to us from November 2019 until his appointment as a director. For more than 15 years, Mr. Weild has been Chairman and Chief Executive Officer of Weild & Co. (including its predecessors), a boutique

investment bank focused on emerging growth companies. From 2008 to 2013, Mr. Weild also served concurrently as Senior Advisor — Capital Markets for Grant Thornton, a global public accounting firm. From 2000 to 2003, Mr. Weild was Vice Chairman of Nasdaq and served as a member of Nasdaq’s Executive Committee. For more than 13 years prior to joining Nasdaq, Mr. Weild was an executive of Prudential Securities Inc., including Head of Corporate Finance, Head of the Global Equities Transaction Group and President of Prudentialsecurities.com. Mr. Weild is a director of PAVmed Inc. (Nasdaq: “PAVM”) and BioSig Technologies Inc. (Nasdaq: “BSGM”), both medical technology companies. Mr. Weild is a recognized expert on capital formation and capital markets structure and co-authored a number of definitive white papers that were key catalysts for new legislation and regulatory reforms, including the JOBS Act.

We believe Mr. Weild is well-qualified to serve on our board our directors due to his experience serving on the boards of directors of multiple medical technology companies, including his service on audit committees, extensive expertise in corporate finance, his deep knowledge and recognized leadership in capital formation and capital markets structure and his widespread relationships in the financial community.

Mr. Weild received his B.A. from Wesleyan University and M.B.A. from New York University Stern School of Business. Mr. Weild also studied at the Sorbonne, Ecoles des Hautes Etudes Commerciales (HEC Paris) and the Stockholm School of Economics.

David Silberg has been a Senior Advisor to us and Scopus Israel since October 2018. Since 2000, Mr. Silberg has served as Managing Director of Mercator Research Ltd., a business, financial and strategic advisory firm. Until 2009, Mercator Research served as the representative in Israel for Mercator Capital, a cross-border private equity and investment banking firm. Mr. Silberg was responsible for developing Mercator’s principal and investment banking activities in Israel, including business development with Israel’s leading technology companies and venture capital firms. For more than 25 years prior to founding Mercator, Mr. Silberg held various positions in the Office of the Prime Minister of Israel, reaching the rank of Head of Directorate, a position equivalent to Brigadier General. While in the Prime Minister’s Office, Mr. Silberg was responsible for, among other things, high level legal, diplomatic, financial and defense assignments and played an active role in the peace negotiations between various Israeli Prime Ministers and the Heads of State of certain Arab countries, culminating in the 1994 Middle East peace agreements. In connection with these breakthrough achievements, Mr. Silberg was awarded a Distinction of Honor from the Israeli Prime Minister’s Office.

Mr. Silberg received an LL.B. degree from Tel-Aviv University Law School and an M.A., *with honors*, from the Haifa University. Mr. Silberg is also a graduate of the IDF National Defense College and of the Advanced Management Program of the INSEAD Business School in Fontainebleau, France.

Scientific Advisory Board

Set forth below is summary biographical information for the members of our Scientific Advisory Board.

Aharon Schwartz, Ph.D. is chairman of our Scientific Advisory Board. For biographical information, see “*Management — Executive Officers, Directors and Advisors.*”

Morris C. Laster, M.D. is a member of our Scientific Advisory Board. For biographical information, see “*Management — Executive Officers, Directors and Advisors.*”

Joseph (Yossi) Tam, D.M.D., Ph.D. has served on our Scientific Advisory Board since October 2018. Dr. Tam is director of Hebrew University’s *Multidisciplinary Center on Cannabinoid Research*, one of the world’s leading institutes for conducting and coordinating research about cannabinoids. Dr. Tam is also head of the Obesity and Metabolism Laboratory at the Hebrew University’s Institute for Drug Research in the Faculty of Medicine, and serves as a senior lecturer in the Department of Pharmacology at the Hebrew University. Dr. Tam’s research projects over the past seventeen years has crossed subjects, disciplines and methodologies, yet the main research interests are focused on the different pathophysiological aspects of the endocannabinoid system. Dr. Tam received his B.Med.Sc., M.Sc., D.M.D. and Ph.D. from Hebrew University.

Robert Spiera, M.D. has served on our Scientific Advisory Board since October 2017. Dr. Spiera is the Director of the Vasculitis and Scleroderma Program at the Hospital for Special Surgery and is a Professor of Clinical Medicine at Weill Cornell Medical College. He is the principal investigator in several clinical trials and observational studies focusing on Scleroderma, Vasculitis, and Polymyalgia Rheumatica. Dr. Spiera specializes in the treatment of various rheumatologic conditions including Scleroderma, Vasculitis, Systemic Lupus Erythematosus, Granulomatosis with Polyangiitis, Rheumatoid Arthritis, and many other conditions. He has authored over 100 publications relating to Scleroderma, Vasculitis, and other rheumatic diseases. Dr. Spiera received his M.D. from Yale University School of Medicine.

Yair Levy, M.D. has served on our Scientific Advisory Board since October 2017. Dr. Levy is the Head of the Department of Internal Medicine at Tel Aviv University — Sackler Faculty of Medicine. He has also served as the Head of the Department of Medicine at Meir Medical Center in Israel and in various positions at The Chaim Sheba Medical Center in Israel, most recently serving as the Deputy Head of the Department of Medicine. In addition, Dr. Levy has been a principal investigator for approximately 40 clinical trials in the area of rheumatologic diseases. Dr. Levy received his B.Sc. and M.D. from Technion Medical School in Haifa, Israel.

Tim Ahfeldt, Ph.D. has served on our Scientific Advisory Board since August 2019. Since September 2017, Dr. Ahfeldt has been an Assistant Professor in the Departments of Neuroscience and Neurology at the Icahn School of Medicine at Mount Sinai, where he is also a member of the Ronald M. Loeb Center for Alzheimer's disease, Friedman Brain Institute, and Black Family Stem Cell Institute. For more than 10 years prior thereto, Dr. Ahfeldt was affiliated with Harvard University and Massachusetts General Hospital as a Visiting Scholar, Research Associate, and Teaching Fellow. Dr. Ahfeldt has served as a Consultant to Amgen Inc. (Nasdaq: AMGN) since 2018 and Q-State Biosciences, Inc., a Cambridge, Massachusetts private biotechnology company, since 2016. Dr. Ahfeldt received his Bachelor's degree from The Berlin School of Economics and his M.S. and Ph.D. in biochemistry and molecular biology from the University of Hamburg, Germany.

Composition of our Board of Directors

Our board of directors currently consists of ten members. In accordance with our certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to the directors whose terms then expire will be elected to serve until the annual meeting that is three years following the election. Our directors are divided among the three classes as follows:

Class A: David S. Battleman, M.D., Raphael Hofstein, Ph.D. and Lesley Russell, MB.Ch.B., MRCP

Class B: Paul E. Hopper, Joshua R. Lamstein, Ashish P. Sanghrajka and David A. Buckel

Class C: Ira Scott Greenspan, Robert J. Gibson and David Weild IV

Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal. There are no family relationships among any of our directors or executive officers.

Our certificate of incorporation provides that the authorized number of directors comprising our board of directors shall be fixed by a majority of the total number of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the classes as nearly equally as possible.

Director Independence

Drs. Battleman, Hofstein and Russell, and Messrs. Buckel, Hopper and Weild is each considered an "independent director" under the Nasdaq listing rules, which is defined generally as a person other than an officer or employee of the company or its subsidiaries or any other individual having a relationship, which, in the opinion of the company's board of directors would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. Our independent directors will have regularly scheduled meetings at which only independent directors are present.

Audit Committee

We maintain an audit committee of the board of directors, which consists of Messrs. Buckel and Weild and Dr. Russell, each of whom is an independent director under Nasdaq's listing standards. Mr. Buckel is the Chair of the audit committee. The audit committee's duties, which are specified in our Audit Committee Charter, include, but are not limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our Form 10-K;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies.

Financial Experts on Audit Committee

The audit committee will at all times be composed exclusively of "independent directors" who are "financially literate" as defined under Nasdaq listing standards. Nasdaq listing standards define "financially literate" as being able to read and understand fundamental financial statements, including a company's balance sheet, income statement and cash flow statement.

In addition, we must certify to Nasdaq that the audit committee has, and will continue to have, at least one member who has past employment experience in finance or accounting, requisite professional certification in accounting, or other comparable experience or background that results in the individual's financial sophistication. The board of directors has determined that each of Messrs. Buckel and Weild and Dr. Russell each qualify as an "audit committee financial expert," as defined under rules and regulations of the SEC.

Compensation Committee

We maintain a compensation committee of the board of directors, which consists of Drs. Russell and Hofstein and Mr. Buckel, each of whom is an independent director under Nasdaq's listing standards. Dr. Russell is the Chair of the compensation committee. The compensation committee's duties, which are specified in our Compensation Committee Charter, include, but are not limited to:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our executive officers and evaluating our executive officers' performance in light of such goals and objectives;
- reviewing and approving the compensation of all of our executive officers (including through our management services agreements described below);
- reviewing our executive compensation policies and plans;

- implementing and administering our incentive compensation equity-based remuneration plans;
- assisting management in complying with our proxy statement and annual report disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our executive officers and employees;
- if required, producing a report on executive compensation to be included in our annual proxy statement; and
- reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors.

Nominating Committee

We maintain a nominating committee of the board of directors, which consists of Mr. Weild and Drs. Battleman and Hofstein, each of whom is an independent director under Nasdaq's listing standards. Mr. Weild is the Chair of the nominating committee. The nominating committee is responsible for overseeing the selection of persons to be nominated to serve on our board of directors. The nominating committee considers persons identified by its members, management, stockholders, investment bankers and others.

The guidelines for selecting nominees, which are specified in the Nominating Committee Charter, generally provide that persons to be nominated:

- should have demonstrated notable or significant achievements in business, education or public service;
- should possess the requisite intelligence, education and experience to make a significant contribution to the board of directors and bring a range of skills, diverse perspectives and backgrounds to its deliberations; and
- should have the highest ethical standards, a strong sense of professionalism and intense dedication to serving the interests of the stockholders.

The nominating committee will consider a number of qualifications relating to management and leadership experience, background and integrity and professionalism in evaluating a person's candidacy for membership on the board of directors. The nominating committee may require certain skills or attributes, such as financial or accounting experience, to meet specific board needs that arise from time to time and will also consider the overall experience and makeup of its members to obtain a broad and diverse mix of board members. The nominating committee does not distinguish among nominees recommended by stockholders and other persons.

Executive Committee

We maintain an executive committee of the board of directors, which consists of Messrs. Greenspan, Lamstein and Gibson. Mr. Greenspan is the Chair of the executive committee. The role of the executive committee includes, but is not limited to, implementing the Board's fiduciary, strategic, and other plans, policies, and decisions consistent with the Company's vision, mission and guiding principles. The executive committee assists the company in decision making between meetings of the board of directors or in circumstances where the full board of directors may not be immediately available, and any such decisions will be reviewed at the next regularly scheduled or special board meeting, as the case may be. The executive committee can act on behalf of the entire board of directors, subject to such limitations imposed by law or the board of directors.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on our website. We expect that any amendments to the code, or any waivers of its requirements, will be disclosed on our website.

Executive Compensation

Summary Compensation Table

The following table sets forth the compensation paid or accrued during the fiscal years ended December 31, 2019 and December 31, 2020 to our named executive officers.

Name and Principal Position	Year	Salary	Bonus	Awards	Compensation ⁽¹⁾	Total
Morris C. Laster, M.D.	2020	—	—	—	\$128,333	\$128,333
<i>Co-Chairman</i>	2019	—	—	—	\$300,000	\$300,000
Joshua R. Lamstein	2020	—	—	—	\$180,000	\$180,000
<i>Chairman</i>	2019	—	—	—	\$195,000	\$195,000
Robert J. Gibson	2020	—	—	—	\$180,000	\$180,000
<i>Vice Chairman</i>	2019	—	—	—	\$195,000	\$195,000
Ashish P. Sanghrajka	2020	\$300,000	\$300,000	—	—	\$600,000
<i>President</i>	2019	\$125,000	\$130,000	\$397,204	—	\$652,204
Ira Scott Greenspan	2020	—	—	—	\$180,000	\$180,000
<i>Executive Committee Chairman</i>	2019	—	—	—	—	—

(1) See “Narrative to Summary Compensation Table,” below for additional information relating to compensation.

Narrative to Summary Compensation Table

Employment Agreements, Arrangements or Plans

In connection with the Transactions in June 2020, we amended and restated the employment agreement of Ashish P. Sanghrajka. Under the amended agreement, Mr. Sanghrajka will continue to serve as president of the Company and was appointed as a director and, in connection therewith, relinquished his role as our chief financial officer. The term of the agreement runs through December 31, 2022 and thereafter is subject to annual renewal terms if not otherwise terminated at the end of the initial term or any renewal term. The agreement provides for the payment of an annual base salary of \$300,000 for the remainder of 2020 and increases to \$360,000 and \$414,000 for the years ended December 31, 2021 and 2022. Guaranteed bonuses are payable of \$300,000, \$324,000 and \$372,000 for the years ended December 31, 2020, 2021 and 2022, respectively. If renewed thereafter, target bonuses will be established for Mr. Sanghrajka. Mr. Sanghrajka also can earn bonuses of \$500,000 and \$1,000,000, half payable in cash and half payable in our shares, if the Company achieves a market capitalization after one year from the date of its initial public offering of \$250,000,000 and \$500,000,000 measured over a 30 consecutive trading day period. If Mr. Sanghrajka is terminated without cause or if he terminates the agreement for good reason, as defined in the agreement, he is to receive one year severance plus a prorated bonus unless the termination occurs within 90 days from the date of a change of control, in which event he is to receive 18 months of severance. The amended agreement maintains in effect the confidentiality and the restrictive covenants set forth in the initial employment agreement.

For 2019 and 2020, we obtained the services of our additional executive officers, including our two then Co-Chairmen and Vice Chairman pursuant to MSAs. The services of Dr. Morris C. Laster were provided pursuant to an MSA with Clil Medical Ltd., or Clil, an affiliate of Dr. Laster, or Clil MSA. This agreement provided for a monthly management services fee for executive services provided by Dr. Laster and the reimbursement of reasonable and properly documented out-of-pocket expenses. We paid or accrued fees under the Clil MSA in the amounts of \$300,000 and \$128,333 in 2019 and 2020, respectively. In connection with and as contemplated by the Transactions, we entered into the Hopper MSA. As further contemplated by and in connection with the Transactions, Mr. Hopper assumed the position of Co-Chairman. In connection with Mr. Hopper’s need to commit greater time to another biopharmaceutical company, unrelated to us, undertaking a series of financing transactions, including an IPO, Mr. Hopper resigned as

our Co-Chairman. We intend to replace the pre-existing MSA for services relating to Dr. Morris C. Laster and the Hopper MSA, although there can be no assurance that we will actually enter into any such MSAs. Mr. Hopper continues to serve as a non-officer and non-employee director of the company. See “*Management.*”

The services of our Chairman, Vice Chairman and Executive Committee Chairman are provided pursuant to the Portfolio Services MSA. Under this agreement, we pay Portfolio Services a monthly management services fee for executive management, general advisory and administrative services. We paid or accrued fees to Portfolio Services under the Portfolio Services MSA in the amounts of \$390,000 and \$540,000 in 2019 and 2020, respectively.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth the outstanding equity awards for our named executive officers as of December 31, 2020:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Ashish P. Sanghrajka	141,667	158,333	\$3.00	July 31, 2029

We have no outstanding stock awards to any executive officer.

Director Compensation

Each of our non-executive directors receives annual director fees of \$40,000. Audit committee, compensation committee and nominating committee members each receive an additional annual fee of \$5,000. The chair of each of the audit, compensation and nominating committee receives an additional annual fee of \$5,000. Directors who are also executive officers receive no additional compensation for serving as directors. Additionally, in connection with their initial appointment as directors, we granted each of our non-executive directors an option representing the right to purchase an aggregate of 100,000 shares exercisable at \$5.50 per share, which was our IPO price per share. The options were issued under our stock plan and vest quarterly in arrears over 36 months. We will also reimburse directors for costs incurred in attending board and committee meetings.

2018 Equity Incentive Plan

On September 24, 2018, our board of directors and stockholders adopted our 2018 Equity Incentive Plan, or the stock plan. The stock plan is designed to enable us to offer our employees, officers, directors and consultants whose past, present and/or potential contributions to us have been, are or will be important to our success, an opportunity to acquire a proprietary interest in us. The various types of incentive awards that may be provided under the stock plan are intended to enable us to respond to changes in compensation practices, tax laws, accounting regulations and the size and diversity of our business. The stock plan, as amended, reserves 2,400,000 shares of common stock for issuance in accordance with the stock plan’s terms.

All of our officers, directors, employees and consultants, as well as those of our subsidiaries, are eligible to be granted awards under the stock plan. An incentive stock option may be granted under the stock plan only to a person who, at the time of the grant, is an employee of ours or our subsidiaries. All awards are subject to approval by the board of directors. As of the date of this offering circular, 1,200,000 options have been granted under the stock plan.

Administration

The stock plan is administered by our board of directors. Subject to the provisions of the stock plan, the board of directors determines, among other things, the persons to whom from time to time awards may

be granted, the specific type of awards to be granted, the number of shares subject to each award, share prices, any restrictions or limitations on the awards, and any vesting, exchange, deferral, surrender, cancellation, acceleration, termination, exercise or forfeiture provisions related to the awards.

Stock Subject to the Plan

Shares of stock subject to other awards that are forfeited or terminated will be available for future award grants under the stock plan. Shares of common stock that are surrendered by a holder or withheld by the company as full or partial payment in connection with any award under the stock plan, as well as any shares of common stock surrendered by a holder or withheld by the company or one of its Subsidiaries to satisfy the tax withholding obligations related to any award under the stock plan, shall not be available for subsequent awards under the stock plan.

Under the stock plan, on a change in the number of shares of common stock as a result of a dividend on shares of common stock payable in shares of common stock, common stock forward split or reverse split or other extraordinary or unusual event that results in a change in the shares of common stock as a whole, the terms of the outstanding award will be proportionately adjusted.

Eligibility

Awards may be granted under the stock plan to employees, officers, directors and consultants who are deemed to have rendered, or to be able to render, significant services to us and who are deemed to have contributed, or to have the potential to contribute, to our success.

Types of Awards

Options. The stock plan provides both for “incentive” stock options as defined in Section 422 of the Code and for options not qualifying as incentive options, both of which may be granted with any other stock based award under the stock plan. The board determines the exercise price per share of common stock purchasable under an incentive or non-qualified stock option, which may not be less than 100% of the fair market value on the day of the grant or, if greater, the par value of a share of common stock. However, the exercise price of an incentive stock option granted to a person possessing more than 10% of the total combined voting power of all classes of stock may not be less than 110% of the fair market value on the date of grant. The aggregate fair market value of all shares of common stock with respect to which incentive stock options are exercisable by a participant for the first time during any calendar year, measured at the date of the grant, may not exceed \$100,000 or such other amount as may be subsequently specified under the Code or the regulations thereunder. An incentive stock option may only be granted within a ten-year period commencing on September 24, 2018 and may only be exercised within ten years from the date of the grant, or within five years in the case of an incentive stock option granted to a person who, at the time of the grant, owns common stock possessing more than 10% of the total combined voting power of all classes of our stock. Subject to any limitations or conditions the board may impose, stock options may be exercised, in whole or in part, at any time during the term of the stock option by giving written notice of exercise to us specifying the number of shares of common stock to be purchased. The notice must be accompanied by payment in full of the purchase price, either in cash or, if provided in the agreement, in our securities or in combination of the two.

Generally, stock options granted under the stock plan may not be transferred other than by will or by the laws of descent and distribution and all stock options are exercisable during the holder’s lifetime, or in the event of legal incapacity or incompetency, the holder’s guardian or legal representative. If the holder is an employee, no stock options granted under the stock plan may be exercised by the holder unless he or she is employed by us or a subsidiary of ours at the time of the exercise and has been so employed continuously from the time the stock options were granted. However, in the event the holder’s employment is terminated due to disability, the holder may still exercise his or her vested stock options for a period of 12 months or such other greater or lesser period as the board may determine, from the date of termination or until the expiration of the stated term of the stock option, whichever period is shorter. Similarly, should a holder die while employed by us or a subsidiary of ours, his or her legal representative or legatee under his or her will may exercise the decedent holder’s vested stock options for a period of 12 months from the date of his or her death, or such other greater or lesser period as the board may determine or until the expiration of the stated term

of the stock option, whichever period is shorter. If the holder's employment is terminated due to normal retirement, the holder may still exercise his or her vested stock options for a period of 12 months from the date of termination or until the expiration of the stated term of the stock option, whichever period is shorter. If the holder's employment is terminated for any reason other than death, disability or normal retirement, the stock option will automatically terminate, except that if the holder's employment is terminated without cause, then the portion of any stock option that is vested on the date of termination may be exercised for the lesser of three months after termination of employment, or such other greater or lesser period as the board may determine but not beyond the balance of the stock option's term.

Stock Appreciation Rights. Under the stock plan, stock appreciation rights may be granted to participants who have been, or are being, granted stock options under the stock plan as a means of allowing the participants to exercise their stock options without the need to pay the exercise price in cash or without regard to the grant of options. A stock appreciation right entitles the holder to receive an amount equal to the excess of the fair market value of a share of common stock over the grant price of the award which cannot be less than the fair market value of a share at the time of grant.

Restricted Stock. Under the stock plan, shares of restricted stock may be awarded either alone or in addition to other awards granted under the stock plan. The board determines the persons to whom grants of restricted stock are made, the number of shares to be awarded, the price if any to be paid for the restricted stock by the person receiving the stock from us, the time or times within which awards of restricted stock may be subject to forfeiture, the vesting schedule and rights to acceleration thereof, and all other terms and conditions of the restricted stock awards.

Restricted stock awarded under the stock plan may not be sold, exchanged, assigned, transferred, pledged, encumbered or otherwise disposed of, other than to us, during the applicable restriction period. In order to enforce these restrictions, the stock plan provides that all shares of restricted stock awarded to the holder remain in our physical custody until the restrictions have terminated and all vesting requirements with respect to the restricted stock have been fulfilled. Except for the foregoing restrictions, the holder will, even during the restriction period, have all of the rights of a stockholder, including the right to receive and retain all regular cash dividends and other cash equivalent distributions as we may designate, pay or distribute on the restricted stock and the right to vote the shares.

Other Stock-Based Awards. Under the stock plan, other stock-based awards may be granted, subject to limitations under applicable law, that are denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, shares of common stock, as deemed consistent with the purposes of the stock plan. These other stock-based awards may be in the form of deferred stock awards and stock issued in lieu of bonuses. These other stock-based awards may include performance shares or options, whose award is tied to specific performance criteria. These other stock-based awards may be awarded either alone, in addition to, or in tandem with any other awards under the stock plan.

Other Limitations. The board may not modify or amend any outstanding option or stock appreciation right to reduce the exercise price of such option or stock appreciation right, as applicable, below the exercise price as of the date of grant of such option or stock appreciation right.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, we describe below transactions and series of similar transactions over the two most recently completed fiscal years, as well as the current fiscal year, to which we were a party or will be a party, in which:

- The amounts involved exceeded or will exceed the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and
- Any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Since inception, we have obtained executive management and other services pursuant to MSAs. The services of our Chairman, Vice Chairman and Executive Committee Chairman are provided to us by HCFP/Portfolio Services LLC, or Portfolio Services, pursuant to a management services agreement, or MSA, between Portfolio Services and us, or Portfolio Services MSA. Under the Portfolio Services MSA, these executives commit a significant portion of their business time to us. Services provided by our executive officers under the Portfolio Services MSA and certain other arrangements set forth below are supported by additional personnel of the entities which provide such services. The Portfolio Services MSA, as amended, provides for a monthly management services fee of \$50,000 per month and a monthly fee for office space and facilities of \$3,000 per month. The aggregate management fees paid and/or accrued under the Portfolio Services MSA were \$129,000 and \$420,000 in 2018 and 2019, respectively. We are also obligated to reimburse reasonable and properly documented out-of-pocket expenses. Portfolio Services is an affiliate of HCFP Inc. and HCFP LLC, together HCFP. These entities and other affiliated entities, including HCFP/Strategy Advisors LLC, or Strategy Advisors, HCFP/Direct Investments LLC, or Direct Investments, and HCFP/Capital Partners, or Capital Partners, are also affiliates of three of our directors. In addition to our arrangements with Portfolio Services, we also obtain specialized strategy advisory services and we have engaged in other transactions with such entities. We paid an aggregate of \$200,000 for such services in 2019. To assist us with our liquidity requirements, from time to time, HCFP and Direct Investments have invested in our securities, provided us with cash advances and paid certain expenses to third-parties on our behalf in an aggregate amount of approximately \$250,000, \$162,000 of this amount was invested in our private placements on the same terms as third-party investors in such private placements. Cash advances and expenses paid on our behalf aggregated approximately \$88,000, all of which have been repaid in full as of July 2020. To further address our liquidity, Portfolio Services agreed to defer some of our payment obligations pursuant to the Portfolio Services MSA in the aggregate amount of \$200,000. In June 2020, Portfolio Services agreed to exchange \$200,000 of deferred payments into \$200,000 of our convertible notes and warrants, also on the same terms of unaffiliated investors. Also in June 2020, an affiliate of Capital Partners purchased 3,000,000 W Warrants in exchange for a \$1,500,000 note. In addition to the foregoing amounts, HCFP and certain of its affiliates and related parties, have also invested in us prior to the periods covered herein.

In 2019 and 2020, we retained HCFP/Capital Markets LLC, or Capital Markets, of which an executive officer and director is an affiliate, to act as placement agent in connection with the sale of our equity and debt securities. We paid Capital Markets placement fees and other fees and non-accountable expense allowances, in the aggregate, of \$113,524 in 2019 and \$203,710 in 2020 as of the date hereof.

Upon the closing of the Transactions in June 2020, Paul E. Hopper was appointed as our other Co-Chairman and a director pursuant to the Hopper MSA with Kiliniwata Investments Pty, Ltd, as Trustee for the Life Sciences Portfolio Managers Trust, an affiliate of Mr. Hopper. The Hopper MSA provided for a monthly fee of \$12,500 and reimbursement of reasonable and properly documented out-of-pocket expenses. As contemplated in connection with the Transactions and Mr. Hopper assumed the position of Co-Chairman. In connection with Mr. Hopper's need to commit greater time to another biopharmaceutical company, unrelated to us, Mr. Hopper resigned as our Co-Chairman. Through the date of Mr. Hopper's resignation as Co-Chairman, we paid \$58,333 under the Hopper MSA. We intend to replace the pre-existing MSA for services relating to Dr. Morris C. Laster and the Hopper MSA. Under such agreement with Dr. Laster, we had previously paid and/or accrued aggregate management fees of \$120,000 and \$300,000 in 2018 and 2019, respectively. Concurrently with the foregoing, we entered into an amended and restated

employment agreement with our President with terms that are set forth in this offering circular in the Executive Compensation section. Further, in connection with the Transactions, we paid total consideration and expense reimbursements of \$240,000 in cash, 1,266,667 shares of common stock and 911,343 W Warrants, of which Mr. Hopper received \$184,875 in cash, 706,333 shares of our common stock and 508,193 W Warrants. Also, in connection with the Transactions, Mr. Sanghrajka, as a shareholder of Bioscience, received, as consideration, 190,000 shares of our common stock and 136,702 W Warrants.

Transactions between us and any of our officers and directors or their respective affiliates are or will be on terms believed by us to be no less favorable to us than are available from unaffiliated third parties. Our Audit Committee Charter contains our related-party transaction policy, which will provide policies and procedures for related-party transactions that are consistent with Nasdaq and other accepted corporate governance standards.

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS

The following table sets forth information regarding the beneficial ownership of our common shares as of December 31, 2020, as adjusted to reflect the sale of the shares of common stock in this offering (assuming none of the individuals or entities listed purchase shares in this offering) and exclusive of any shares of common stock attributable to W Warrants, which are not exercisable within 60 days of the date of this offering circular, by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding shares;
- each of our executive officers and directors; and
- all of our executive officers and directors as a group.

Unless otherwise indicated, we believe that all persons named in the table have sole voting and investment power with respect to all shares beneficially owned by them. Additionally, except as otherwise indicated, beneficial ownership reflected in the table has been determined in accordance with Rule 13d-3 promulgated under the Exchange Act.

Name and Address of Beneficial Owner ⁽¹⁾	Amount and Nature of Beneficial Ownership	Approximate Percentage of Outstanding Shares of Common Stock	
		Prior to Offering	After Offering
<i>5% Stockholders</i>			
HCFP/Capital Partners 18B-1 LLC	1,350,000	9.2%	8.6%
Morris C. Laster, M.D. ⁽²⁾	4,926,000	33.5%	31.3%
<i>Directors and Executive Officers</i>			
Ira Scott Greenspan ⁽³⁾	1,503,334	10.2%	9.6%
Joshua R. Lamstein ⁽⁴⁾	1,466,197	10.0%	9.3%
Paul E. Hopper ⁽⁵⁾	706,333	4.8%	4.5%
Ashish P. Sanghrajka ⁽⁶⁾	331,667	2.3%	2.1%
Robert J. Gibson ⁽⁷⁾	212,052	1.4%	1.3%
David A. Buckel ⁽⁸⁾	5,941	*	*
David S. Battleman, M.D.	—	*	*
Raphael Hofstein, Ph.D.	—	*	*
Lesley Russell, MB.Ch.B, MRCP (UK)	—	*	*
David Weild IV	—	*	*
All directors and executive officers as a group (10 Individuals) ⁽³⁾⁽⁴⁾⁽⁵⁾⁽⁶⁾⁽⁷⁾⁽⁸⁾	2,875,524	19.5%	18.3%

* Indicates less than 1%

- (1) Unless otherwise indicated, the business address of each of the individuals and entities is 420 Lexington Avenue, Suite 300, New York, New York 10170.
- (2) Represents shares of common stock over which Dr. Laster has voting and dispositive power.
- (3) Includes shares held by HCFP/Capital Partners 18B-1 LLC, of which Mr. Greenspan is a member and co-manager, and HCP/Advest LLC, of which Mr. Greenspan is a member and sole manager. Accordingly, he is deemed to have shared voting and dispositive power and sole voting and dispositive power over the shares held by HCFP/Capital Partners 18B-1 LLC and HCP/Advest LLC, respectively. Mr. Greenspan disclaims beneficial ownership of shares held by these entities, except to the extent of his proportionate pecuniary interest therein.
- (4) Includes shares held by HCFP/Capital Partners 18B-1 LLC, of which Mr. Lamstein is a member and co-manager. Accordingly, he is deemed to have shared voting and dispositive power over the shares held

by this entity. Mr. Lamstein disclaims beneficial ownership of shares held by this entity, except to the extent of his proportionate pecuniary interest therein. Also includes an aggregate of 3,000 shares held by Mr. Lamstein's minor children.

- (5) Includes shares held by Moreglade Pty. Limited, of which Mr. Hopper is a Director. Accordingly, he is deemed to have sole voting and dispositive power over the shares held by Morglade Pty. Limited. Mr. Hopper disclaims beneficial ownership of shares held by this entity, except to the extent of his proportionate pecuniary interest therein.
- (6) Includes 141,667 shares of common stock issuable pursuant to outstanding stock options to purchase our common stock which are exercisable within 60 days of the date of this offering circular. Also includes an aggregate of 40,000 shares held by Mr. Sanghrajka's minor children.
- (7) Includes shares held by Dayber Snow LLC, of which Mr. Gibson is a member and co-manager. Accordingly, he is deemed to have shared voting and dispositive power over the shares held by this entity. Mr. Gibson disclaims beneficial ownership of shares held by this entity, except to the extent of his proportionate pecuniary interest therein. Also includes an aggregate of 2,000 shares held by Mr. Gibson's minor children.
- (8) Includes shares held by BVI Ventures LLC, of which Mr. Buckel is the sole owner. Accordingly, he is deemed to have sole voting and dispositive power over the shares held by BVI Ventures LLC.

HCFP/Capital Partners, Ira Scott Greenspan and Dr. Morris C. Laster may be deemed to be our "founders" and "promoters", as such terms are defined under the federal securities laws.

SECURITIES BEING OFFERED AND DESCRIPTION OF SECURITIES

General

Our authorized capital stock consists of 50,000,000 shares of common stock, \$0.001 par value, and 20,000,000 shares of preferred stock, \$0.001 par value. We are offering 1,000,000 shares of our common stock at a public offering price of \$9.00 per share. The following description summarizes the material terms of our capital stock. Because it is only a summary, it may not contain all the information that is important to you.

Common Stock

Holders of our common stock of record are entitled to one vote for each share held on all matters to be voted on by stockholders. Our board of directors is divided into three classes with only one class of directors being elected in each year and each class serving a three-year term. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. Holders of our common stock are entitled to receive ratable dividends when, as and if declared by the board of directors out of funds legally available therefor.

Upon our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

There are 14,577,597 shares of common stock outstanding as of December 31, 2020.

Preferred Stock

Our board of directors is authorized, without action by the stockholders, to designate and issue up to an aggregate of 20,000,000 shares of preferred stock in one or more series. Our board of directors can designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes, could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of the company, which might harm the market price of our common stock. See also "*Certain Anti-Takeover Provisions of our Certificate of Incorporation and By-Laws*".

Our board of directors will make any determination to issue such shares based on its judgment as to the company's best interests and the best interests of our stockholders. We have no shares of preferred stock outstanding.

Repurchases

We may seek to repurchase our outstanding securities from time to time in market or private transactions.

Dividends

We have not paid any cash dividends on our shares of common stock to date. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition and will be within the discretion of our board of directors. It is the current intention of our board of directors to retain all earnings, if any, for use in our business operations and, accordingly, our board of directors does not anticipate declaring any dividends in the foreseeable future.

Warrants

Each W Warrant entitles the holder to purchase at a price of \$4.00 per W Warrant one B Unit. Each B Unit consists of one share of common stock and one Z Warrant. The W Warrant will become exercisable on October 1, 2021 and will expire on September 30, 2026 or earlier upon redemption.

Each Z Warrant entitles the holder to purchase at a price of \$5.00 per Z Warrant one share of common stock. The Z Warrant will become exercisable on July 1, 2022 and will expire on June 30, 2027, or earlier upon redemption.

All of our warrants outstanding, except for 450,000 warrants issued to one of our strategic partners, including warrants which were previously designated as X warrants, which, in accordance with the terms of applicable governing agreements and without any action required to be taken by warrant holders, automatically became W Warrants upon the initial closing pursuant to the February 2020 Offering Circular in July 2020. The W Warrants make up a single class of warrants with identical terms.

No W Warrant or Z Warrant will be exercisable for cash unless we have a current effective and current registration statement or qualified offering statement covering the securities issuable upon exercise of such warrants and a current prospectus or offering circular relating to such securities. Notwithstanding the foregoing, if a registration statement or offering statement covering the securities issuable upon exercise of a W Warrant or Z Warrant has not been declared effective or qualified by the date upon which such warrants become exercisable, holders of such warrants may, until such time as there is an effective registration statement or offering statement and during any period when we shall have failed to maintain an effective registration statement or qualified offering statement, exercise their warrants on a cashless basis pursuant to the exemption provided by Section 3(a)(9) of the Securities Act. If cashless exercise is permitted, each holder of our W Warrants or Z Warrants exercising on a cashless basis would pay the exercise price by surrendering their warrants for that number of securities equal to the quotient obtained by dividing: (x) the product of the number of securities underlying the warrants, and the difference between the “fair market value” and the warrant exercise price by (y) the fair market value. For these purposes, “fair market value” will mean the volume weighted average price of the securities as reported during the ten (10) trading day period ending on the trading day prior to the date that notice of exercise is received by the warrant agent from the holder of such warrants or securities broker or intermediary. In the absence of any trading of the B Units upon the exercise of the W Warrants, the fair market value of the B Units will be determined by our board of directors.

Commencing on October 1, 2022 and July 1, 2023, we may redeem the outstanding W Warrants and Z Warrants, respectively, at our option, in whole or in part, at a price of \$0.001 per warrant:

- at any time while the warrants are exercisable;
- upon a minimum of 30 days’ prior written notice of redemption;
- if, and only if, the volume weighted average price per share of our common stock equals or exceeds \$8.00 for the W Warrants and \$10.00 for the Z Warrants (subject to adjustment) for the 20 trading days ending two trading days prior to the sending of the notice; and
- if, and only if, there is a current registration statement or offering statement in effect with respect to the securities underlying such warrants commencing five business days prior to the 20-day trading period and continuing each day thereafter until the date of redemption.

If the foregoing conditions are satisfied and we issue a notice of redemption, each warrant holder can exercise his, her or its warrant prior to the scheduled redemption date. In such event, we have the right to require exercise on a cashless basis. However, the price of the shares of our common stock may fall below the respective trigger prices for redemption as well as the respective warrant exercise prices after the redemption notices are issued.

The redemption criteria for our warrants have been established at a price which is intended to provide warrant holders a reasonable premium to the initial exercise price and provide a sufficient differential between the then-prevailing share price and the warrant exercise price so that if the share price declines as a result of a redemption call, the redemption will not cause the share price to drop below the exercise price of the warrants.

A holder of a warrant may notify us in writing if it elects to be subject to a requirement that such holder will not have the right to exercise such warrant, to the extent that after giving effect to such exercise, such person (together with such person's affiliates), to the warrant agent's actual knowledge, would beneficially own in excess of 9.9% of the shares of common stock outstanding immediately after giving effect to such exercise.

If the number of outstanding shares of common stock is increased by a stock dividend payable in shares of common stock, or by a split-up of shares of common stock or other similar event, then, on the effective date of such stock dividend, split-up or similar event, the number of shares of common stock issuable on exercise of each warrant will be increased in proportion to such increase in the outstanding shares of common stock.

If the number of outstanding shares of our common stock is decreased by a consolidation, combination, reverse stock split or reclassification of shares of common stock or other similar event, then, on the effective date of such consolidation, combination, reverse stock split, reclassification or similar event, the number of shares of common stock issuable on exercise of each warrant will be decreased in proportion to such decrease in outstanding shares of common stock.

Whenever the number of shares of common stock purchasable upon the exercise of the warrants is adjusted, as described above, the warrant exercise price will be adjusted by multiplying the warrant exercise price immediately prior to such adjustment by a fraction (x) the numerator of which will be the number of shares of common stock purchasable upon the exercise of the warrants immediately prior to such adjustment, and (y) the denominator of which will be the number of shares of common stock so purchasable immediately thereafter.

In the event we, at any time while the W Warrants are outstanding, pay a stock dividend, subdivide outstanding shares of common stock into a larger number of shares, combine (including by way of a reverse stock split) outstanding shares of common stock into a smaller number of shares, issue, in the event of a recapitalization or reclassification of shares of common stock, any shares of our capital stock or effect any such similar event, then appropriate proportionate adjustments shall be made by increasing or decreasing (i) the number of outstanding W Warrants and, if Series B Units have been issued based on any prior exercises of the W Warrants, the number of outstanding Series B Units and (ii) the exercise price of the W Warrants and the exercise price of the Z Warrants such that (x) each issued and issuable Series B Unit shall always be comprised of one share of common stock and one Z Warrant, (y) the proportionate ownership interest of a holder of the W Warrant remains the same determined as if all W Warrants and Z Warrants have been exercised immediately prior to any such event and (z) the aggregate amount initially payable upon the issuance of the W Warrant to exercise such W Warrant and Z Warrant underlying the B Unit shall be the same before and after any such event. Any such adjustment made shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or reclassification.

The warrants will be issued in registered form under a warrant agreement between Continental Stock Transfer and Trust Company, as warrant agent, and us. Investors should review a copy of the warrant agreement, which is filed as an exhibit to the offering statement of which this offering circular is a part, for a complete description of the terms and conditions applicable to the warrants.

The warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the warrant agent, with the exercise form on the reverse side of the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price (or on a cashless basis, if applicable), by certified or official bank check payable to us, for the number of warrants being exercised. The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No fractional shares will be issued upon exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will comply with Section 155 of the

Delaware General Corporation Law (which provides that Delaware companies shall either (1) arrange for the disposition of fractional interests by those entitled thereto, (2) issue scrip or warrants in registered form (either represented by a certificate or uncertificated) or in bearer form (represented by a certificate) which shall entitle the holder to receive a full share upon the surrender of such scrip or warrants aggregating a full share or (3) round-up such aggregate shares to the nearest whole number of such shares).

Yissum Warrant

In October 2018, in connection with our MOUs we issued to Yissum a warrant to purchase up to 450,000 shares of our common stock at an exercise price of \$1.50 per share. A portion of the warrant representing 50,000 underlying shares was immediately exercisable with additional portions of the warrant vesting upon the execution of certain licensing agreements. As of the date of this offering circular, the warrant is exercisable for up to 250,000 shares of our common stock.

Share Purchase Option

In connection with our IPO, we issued to our underwriters a share purchase option exercisable for 57,500 shares of our common stock at an exercise price of \$6.875 per share.

Our Transfer Agent and Warrant Agent

The transfer agent for our securities and warrant agent for our warrants is Continental Stock Transfer and Trust Company, or Continental. We have agreed to indemnify Continental in its roles as transfer agent and warrant agent, its agents and each of its shareholders, directors, officers and employees against all claims and losses that may arise out of acts performed or omitted for its activities in that capacity, except for any claims and losses due to any gross negligence or intentional misconduct of the indemnified person or entity.

Continental has agreed that it has no right of set-off or any right, title, interest or claim of any kind to, or to any or Continental, monies in, the cash collateral account, and has irrevocably waived any right, title, interest or claim of any kind to, or to any monies in, the cash collateral account that it may have now or in the future. Accordingly, any indemnification provided will only be able to be satisfied, or a claim will only be able to be pursued, solely against us and our assets outside the cash collateral account and not against the any monies in the cash collateral account or interest earned thereon.

Listing of our Securities

Our common stock is listed on The Nasdaq Global Market under the symbol “SCPS”.

Certain Anti-Takeover Provisions of our Certificate of Incorporation and By-laws

Special meeting of stockholders

Our by-laws provide that special meetings of our stockholders may be called only by a majority vote of our board of directors.

Preferred stock

Our certificate of incorporation provides authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval.

Exclusive Forum

Our certificate of incorporation and by-laws provide that the Court of Chancery of the State of Delaware or, if such court does not have jurisdiction, the federal district court for the District of Delaware, shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim for breach of a fiduciary duty owed by any director, officer, employee or agent of the Corporation to the Corporation or the Corporation’s stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law, the certificate of incorporation or the by-laws or (iv) any action asserting a claim

governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Under our by-laws, these provisions do not apply to any claim brought to enforce any duty or liability arising under the Securities Act or the Exchange Act, thereby allowing any such claims to be filed in any court having jurisdiction. Although we believe these provisions benefit the company by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, they may have the effect of discouraging lawsuits against our officers and directors.

SHARES ELIGIBLE FOR FUTURE SALE

We have 14,577,597 shares of common stock outstanding as of December 31, 2020. After giving effect to this offering, we will have 15,577,597 shares of common stock outstanding. Of such shares, 10,084,234 shares of common stock are subject to lock-up agreements, other lock-up arrangements and/or other restrictions on sale for specified periods of time ranging from 180 days to various longer periods up to the third anniversary of December 16, 2020, the date our common stock first traded on Nasdaq, subject to any releases from such contractual lock-up agreements, other lock-up arrangements and/or other restrictions on sale. The balance of our shares outstanding, or 5,493,363 shares of common stock, including the shares being sold in this offering, are not subject to any restrictions on sale and are “unrestricted” in accordance with Nasdaq’s initial listing requirements. This number of shares includes shares of common stock sold in this offering, shares of common stock issued in our IPO and shares of common stock available for sale under Rule 144 as described below.

Rule 144

A person who has beneficially owned restricted shares of common stock or warrants for at least six months would be entitled to sell their securities under Rule 144 provided that (i) such person is not deemed to have been an affiliate of the company at the time of, or at any time during the three months preceding, a sale and (ii) the company is subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares of common stock for at least six months but who are an affiliate of the company at the time of, or any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period a number of shares that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing by such person of a notice on Form 144 with respect to the sale;

A person who has beneficially owned restricted shares of common stock or warrants for at least 12 months would be entitled to sell their securities under Rule 144 without restriction, provided that such person is not deemed to have been an affiliate of the company at the time of, or at any time during the three months preceding, a sale.

Sales under Rule 144 may also be limited by manner of sale provisions and notice requirements and to the availability of current public information about the subject company.

Lock-Up Agreements

Each of our officers, directors and holders of 5% or more of our common stock has entered into a lock-up agreement with the Representative that provides he, she or it will not sell, transfer or otherwise dispose of any of our securities until after the 90th day following the closing of this offering. Also, the shares of common stock issued by us prior to this offering may be subject to transfer restrictions set forth in agreements among us and the holders of such shares of common stock. These transfer restrictions provide that such shares of common stock are not transferrable or saleable for specified periods of time ranging from 180 days to various longer periods up to the third anniversary of the day our shares of common stock first trade on Nasdaq.

The Representative may elect to release any holder from its lock-up at any time or from time to time for any reason or no reason with respect to any or all of our securities or any portion thereof. No such release shall be deemed to obligate the Representative to grant any future releases to such holder or any other holder. In the event the Representative elects to release its lock-up with respect to any of our securities held by any officer or director of our company, they will notify us of the impending release and will announce the impending release through a major news service at least two business days prior to the effective date of such release.

In connection with the establishment of any trading market for our shares of common stock, certain of our executive officers, directors and/or employees may enter into written trading plans that are intended to

comply with Rule 10b5-1 under the Exchange Act. Sales under any such trading plans would not be permitted until the expiration or waiver of the lock-up restrictions applicable thereto.

Registration Statements on Form S-8

Upon completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of common stock issued or reserved for issuance under the stock plan. Shares covered by this registration statement will be eligible for sale in the public markets, upon the expiration or release from the terms of any applicable lock-up agreements and/or subject to vesting requirements relating to such shares.

UNDERWRITING

We are offering the shares of common stock described herein through the underwriters named below. The Benchmark Company, LLC is acting as representative of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase, and we have agreed to sell to the underwriters, the number of shares of common stock listed next to each of its name in the following table:

Underwriter	Number of Shares
The Benchmark Company, LLC	850,000
Joseph Gunnar & Co., LLC	150,000
Total	<u>1,000,000</u>

The underwriters are committed to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares of common stock as described below, if they purchase any shares of common stock. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

The underwriters are offering the shares of common stock, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the closing of this offering, permits the underwriters to purchase a maximum of 150,000 additional shares of common stock from us to cover over-allotments. If the underwriters exercise all or part of this option, they will purchase shares of common stock covered by the option at the public offering price that appears on the cover page of this offering circular, less the underwriting discount. If this option is exercised in full, the total proceeds paid by the public will be \$10,350,000 and the total proceeds to us, after deducting the underwriting discount and the underwriter's non-accountable expense allowance, but before other expenses, will be \$9,342,000. We have agreed to pay to the underwriters a non-accountable expense allowance equal to 2.0% of the gross proceeds raised in this offering (excluding any proceeds raised from the exercise of the underwriters' over-allotment option). We have also agreed to reimburse the underwriters for reasonable out-of-pocket expenses in an amount not to exceed \$120,000.

Sales of shares of common stock made outside of the United States may be made by affiliates of the underwriters. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares of common stock at the prices and upon the terms stated therein, and, as a result, will thereafter bear any risk associated with changing the offering price to the public or other selling terms.

The following table shows the public offering price, underwriting discount, non-accountable expense allowance and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option:

	Per Share	Without Over-Allotment	With Over-Allotment
Public offering price	\$9.00	\$9,000,000	\$10,350,000
Underwriting discount	\$0.72	\$ 720,000	\$ 828,000
Non-accountable expense allowance	\$0.18	\$ 180,000	\$ 180,000
Proceeds, before expenses, to us	\$8.10	\$8,100,000	\$ 9,342,000

Our shares of common stock are offered subject to a number of conditions, including:

- receipt and acceptance of our shares of common stock by the underwriters; and

- the underwriters' right to reject orders in whole or in part.

In connection with this offering, the underwriters or securities dealers may distribute offering circulars electronically.

Underwriting Discount

The shares of common stock sold by the underwriters to the public will initially be offered at the initial offering price set forth on the cover of this offering circular. All investors in this offering will pay the same price and receive the same terms. Any shares of common stock sold by the underwriters to securities dealers may be sold at a discount of up to \$0.45 per share from the public offering price. Sales of shares of common stock made outside of the United States may be made by affiliates of the underwriters. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares of common stock at the prices and upon the terms stated therein, and, as a result, will thereafter bear any risk associated with changing the offering price to the public or other selling terms.

Purchase Options

The underwriters will be issued purchase options exercisable for 100,000 shares of our common stock at an exercise price of \$11.25 per share, which shares of common stock shall be entitled to demand and piggy-back registration rights for five and seven years, respectively. Such purchase options will be subject to FINRA Rule 5110(g). Under FINRA Rule 5110(e), the underwriter purchase options and any shares issued upon exercise of the underwriter purchase options shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days beginning on the date of commencement of sales of this offering, except the transfer of any share:

- by operation of law or by reason of reorganization of the Company;
- to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth below for the remainder of the time period;
- if the aggregate amount of securities of the Company held by the holder of the underwriter purchase options or related persons do not exceed 1% of the securities being offered;
- that is beneficially owned on a pro rata basis by all equity owners of an investment fund; provided, that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or
- the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

Lock-Up Arrangements

Our officers, directors, and/or holders of 5% or more of our outstanding shares of common stock have agreed with our underwriters not to sell, transfer or otherwise dispose of any of the securities of the Company which they hold prior to or at the closing of the offering under this offering circular until after the 90th day following the closing of this offering.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities under the Securities Act. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriter may be required to make in respect of those liabilities.

Determination of Offering Price

Our common stock is listed on The Nasdaq Global Market under the symbol "SCPS." On January 25, 2021, the last sale price of our common stock on Nasdaq was \$12.09 per share. The public offering price

may be determined by negotiation between us and the representative of the underwriters. Principal factors to be considered in determining the public offering price include the last sale price of our common stock immediately prior to this offering, recent market prices of, and demand for, publicly-traded securities of comparable companies, the general condition of the securities markets at the time of our offering and such other factors as may be deemed relevant by the underwriters and us. Notwithstanding such considerations, the determination of the public offering price may entail less certainty than in the pricing of securities of more established operating companies.

Price Stabilization, Short Positions

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of the shares of common stock during and after this offering, including:

- stabilizing transactions;
- short sales;
- purchases to cover positions created by short sales;
- imposition of penalty bids; and
- syndicate covering transactions.

Stabilizing transactions consist of bids or purchases made for the purpose of preventing or retarding a decline in the market price of our shares of common stock while this offering is in progress. Stabilization transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. These transactions may also include making short sales of our shares of common stock, which involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering and purchasing shares of common stock on the open market to cover short positions created by short sales. Short sales may be “covered short sales,” which are short positions in an amount not greater than the underwriters’ option to purchase additional shares of common stock referred to above, or may be “naked short sales,” which are short positions in excess of that amount.

The underwriters may close out any covered short position by either exercising their option, in whole or in part, or by purchasing shares of common stock in the open market. In making this determination, the underwriters will consider, among other things, the price of shares of common stock available for purchase in the open market as compared to the price at which they may purchase shares of common stock through the over-allotment option.

Naked short sales are short sales made in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of common stock in the open market that could adversely affect investors who purchased in this offering.

The underwriters also may impose a penalty bid. This occurs when a particular underwriter repays to the representative of the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares of common stock sold by or for the account of that underwriter in stabilizing or short covering transactions.

These stabilizing transactions, short sales, purchases to cover positions created by short sales, the imposition of penalty bids and syndicate covering transactions may have the effect of raising or maintaining the market price of our shares of common stock or preventing or retarding a decline in the market price of our shares of common stock. As a result of these activities, the price of our shares of common stock may be higher than the price that otherwise might exist in the open market. The underwriters may carry out these transactions on the Nasdaq, in the over-the-counter market or otherwise. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares of common stock. Neither we, nor the underwriters, make any representation that the underwriter will engage in these stabilization transactions or that any transaction, once commenced, will not be discontinued without notice.

Additional Future Arrangements

We are not under any contractual obligation to engage any of the underwriters to provide any services for us after this offering, and have no present intent to do so. However, the underwriters may assist us in raising additional capital in the future. If any of the underwriters provide services to us after this offering, we may pay such underwriter fair and reasonable fees that would be determined at that time in an arm's length negotiation; provided, that no agreement will be entered into with any underwriter and no fees for such services will be paid to any underwriter prior to the date that is 90 days from the date of this offering circular, unless FINRA determines that such payment would not be deemed underwriter's compensation in connection with this offering.

Electronic Distribution

An offering circular in electronic format may be made available on internet sites or through other online services maintained by the underwriters participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the offering circular in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of the offering circular or the offering statement of which this offering circular forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter and should not be relied upon by investors.

Selling Restrictions

Notice to Prospective Investors in Canada

Resale Restrictions

We intend to distribute our securities in the Province of Ontario, Canada (the "Canadian Offering Jurisdiction") by way of a private placement and exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in such Canadian Offering Jurisdiction. Any resale of our securities in Canada must be made under applicable securities laws that will vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Canadian resale restrictions in some circumstances may apply to resales of interests made outside of Canada. Canadian purchasers are advised to seek legal advice prior to any resale of our securities. We may never be a "reporting issuer," as such term is defined under applicable Canadian securities legislation, in any province or territory of Canada in which our securities will be offered and there currently is no public market for any of the securities in Canada, and one may never develop. Canadian investors are advised that we have no intention to file a prospectus or similar document with any securities regulatory authority in Canada qualifying the resale of the securities to the public in any province or territory in Canada.

Representations of Purchasers

A Canadian purchaser will be required to represent to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase our securities without the benefit of a prospectus qualified under those securities laws;
- where required by law, that the purchaser is purchasing as principal and not as agent;
- the purchaser has reviewed the text above under Resale Restrictions; and
- the purchaser acknowledges and consents to the provision of specified information concerning its purchase of our securities to the regulatory authority that by law is entitled to collect the information.

Rights of Action — Ontario Purchasers Only

Under Ontario securities legislation, certain purchasers who purchase a security offered by this offering circular during the period of distribution will have a statutory right of action for damages, or while still the owner of our securities, for rescission against us in the event that this offering circular contains a misrepresentation without regard to whether the purchaser relied on the misrepresentation. The right of action for damages is exercisable not later than the earlier of 180 days from the date the purchaser first had knowledge of the facts giving rise to the cause of action and three years from the date on which payment is made for our securities. The right of action for rescission is exercisable not later than 180 days from the date on which payment is made for our securities. If a purchaser elects to exercise the right of action for rescission, the purchaser will have no right of action for damages against us. In no case will the amount recoverable in any action exceed the price at which our securities were offered to the purchaser and if the purchaser is shown to have purchased the securities with knowledge of the misrepresentation, we will have no liability. In the case of an action for damages, we will not be liable for all or any portion of the damages that are proven to not represent the depreciation in value of our securities as a result of the misrepresentation relied upon. These rights are in addition to, and without derogation from, any other rights or remedies available at law to an Ontario purchaser. The foregoing is a summary of the rights available to an Ontario purchaser. Ontario purchasers should refer to the complete text of the relevant statutory provisions.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein are located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All of our assets and the assets of those persons are located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Collection of Personal Information

If a Canadian purchaser is resident in or otherwise subject to the securities laws of the Province of Ontario, the Purchaser authorizes the indirect collection of personal information pertaining to the Canadian purchaser by the Ontario Securities Commission (the “OSC”) and each Canadian purchaser will be required to acknowledge and agree that the Canadian purchaser has been notified by us (i) of the delivery to the OSC of personal information pertaining to the Canadian purchaser, including, without limitation, the full name, residential address and telephone number of the Canadian purchaser, the number and type of securities purchased and the total purchase price paid in respect of the securities, (ii) that this information is being collected indirectly by the OSC under the authority granted to it in securities legislation, (iii) that this information is being collected for the purposes of the administration and enforcement of the securities legislation of Ontario, and (iv) that the title, business address and business telephone number of the public official in Ontario who can answer questions about the OSC’s indirect collection of the information is the Administrative Assistant to the Director of Corporate Finance, the Ontario Securities Commission, Suite 1903, Box 5520, Queen Street West, Toronto, Ontario, M5H 3S8, Telephone: (416) 593-8086, Facsimile: (416) 593-8252.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (“ASIC”), in relation to the offering. This offering circular does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the “Corporations Act”), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares of common stock may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares of common stock without disclosure to investors under Chapter 6D of the Corporations Act.

The shares of common stock applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares of common stock must observe such Australian on-sale restrictions.

This offering circular contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this offering circular is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in the Dubai International Financial Centre

This offering circular relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (“DFSA”). This offering circular is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this offering circular nor taken steps to verify the information set forth herein and has no responsibility for the offering circular. The shares of common stock to which this offering circular relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares of common stock offered should conduct their own due diligence on such shares of common stock. If you do not understand the contents of this offering circular you should consult an authorized financial advisor.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a “relevant member state”), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the “relevant implementation date”), an offer of shares of common stock described in this offering circular may not be made to the public in that relevant member state prior to the publication of a offering circular in relation to the shares of common stock that has been approved by the competent authority in that relevant member state or, where appropriate, approved in another relevant member state and notified to the competent authority in that relevant member state, all in accordance with the Prospectus Directive, except that, with effect from and including the relevant implementation date, an offer of our shares of common stock may be made to the public in that relevant member state at any time:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100, or, if the relevant member state has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by the issuer for any such offer; or natural or legal persons (other than qualified investors as defined below) subject to obtaining the prior consent of the underwriter for any such offer; or
- in any other circumstances that do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each purchaser of shares of common stock described in this offering circular located within a relevant member state will be deemed to have represented, acknowledged and agreed that it is a “qualified investor” within the meaning of Article 2(1)(e) of the Prospectus Directive.

For the purpose of this provision, the expression an “offer to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for the shares of common stock, as the expression may be varied in that member state by any measure

implementing the Prospectus Directive in that member state, and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the PD 2010 Amending Directive to the extent implemented by the relevant member state) and includes any relevant implementing measure in each relevant member state, and the expression 2010 PD Amending Directive means Directive 2010/73/EU. We have not authorized and do not authorize the making of any offer of shares of common stock through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the shares of common stock as contemplated in this offering circular. Accordingly, no purchaser of the shares of common stock, other than the underwriters, is authorized to make any further offer of the shares of common stock on behalf of us or the underwriters.

Notice to Prospective Investors in Switzerland

The shares of common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares of common stock or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, or the shares of common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares of common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares of common stock.

Notice to Prospective Investors in the United Kingdom

This offering circular is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as a “relevant person”). The shares of common stock are only available to, and any invitation, offer or agreement to purchase or otherwise acquire such shares of common stock will be engaged in only with, relevant persons. This offering circular and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in France

Neither this offering circular nor any other offering material relating to the shares of common stock described in this offering circular has been submitted to the clearance procedures of the Autorité des Marchés Financiers or by the competent authority of another member state of the European Economic Area and notified to the Autorité des Marchés Financiers. The shares of common stock have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this offering circular nor any other offering material relating to the shares of common stock has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the shares of common stock to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (investisseurs qualifiés) and/or to a restricted circle of investors (cercle restreint d'investisseurs), in each case investing for their own account, all as defined in, and in accordance with, Article L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (Règlement Général) of the Autorité des Marchés Financiers, does not constitute a public offer (appel public à l'épargne).

The shares of common stock may be resold directly or indirectly, only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

Notice to Prospective Investors in Hong Kong

The shares of common stock may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the shares of common stock may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

Notice to Prospective Investors in Japan

The shares of common stock have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This offering circular has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this offering circular and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of common stock may not be circulated or distributed, nor may the shares of common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the shares of common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such shares, debentures and units of shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

Notice to Prospective Investors in Italy

The offering of the shares of common stock offered hereby in Italy has not been registered with the Commissione Nazionale per la Società e la Borsa (“CONSOB”) pursuant to Italian securities legislation and, accordingly, the shares of common stock offered hereby cannot be offered, sold or delivered in the Republic of Italy (“Italy”) nor may any copy of this offering circular or any other document relating to the shares of common stock offered hereby be distributed in Italy other than to professional investors (operatori qualificati) as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of 1 July, 1998 as subsequently amended. Any offer, sale or delivery of the shares of common stock offered hereby or distribution of copies of this offering circular or any other document relating to the shares of common stock offered hereby in Italy must be made:

- by an investment firm, bank or intermediary permitted to conduct such activities in Italy in accordance with Legislative Decree No. 58 of 24 February 1998 and Legislative Decree No. 385 of 1 September 1993 (the “Banking Act”);
- in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy; and
- in compliance with any other applicable laws and regulations and other possible requirements or limitations which may be imposed by Italian authorities.

Notice to Prospective Investors in Israel

In the State of Israel, the shares of common stock offered hereby may not be offered to any person or entity other than the following:

- a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;
- a provident fund as defined in Section 47(a)(2) of the Income Tax Ordinance of the State of Israel, or a management company of such a fund;
- an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981, (d) a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint services company, acting for their own account or from the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- a company that is licensed as an investment advisor, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;
- a company that is a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968;

- a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);
- an entity primarily engaged in capital markets activities in which all of the equity owners meet one or more of the above criteria; and
- an entity, other than an entity formed for the purpose of purchasing shares of common stock in this offering, in which the shareholders equity (including pursuant to foreign accounting rules, international accounting regulations and U.S. generally accepted accounting rules, as defined in the Securities Law Regulations (Preparation of Annual Financial Statements), 1993) is in excess of NIS 250 million.

Any offeree of the shares of common stock offered hereby in the State of Israel shall be required to submit written confirmation that it falls within the scope of one of the above criteria. This offering circular will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

LEGAL MATTERS

The validity of the securities offered in this offering circular are being passed upon for us by Greenberg Traurig, LLP, Tysons Corner, Virginia. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York, is acting as counsel for the underwriters. From time to time, Greenberg Traurig has represented the underwriters and Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. has represented us, in all cases unrelated to this offering.

EXPERTS

The consolidated financial statements of Scopus BioPharma Inc. and Subsidiaries included in this offering circular and elsewhere in the offering statement of which this offering circular forms a part have been so included in reliance upon the report (which contains an explanatory paragraph relating to the company's ability to continue as a going concern as discussed in Note 1 to the consolidated financial statements) of Citrin Cooperman & Company, LLP independent registered public accountants, upon the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Commission a Regulation A Offering Statement on Form 1-A, which includes exhibits, schedules and amendments, under the Securities Act, with respect to this offering of securities. Although this offering circular, which forms a part of the Form 1-A, contains all material information included in the Form 1-A, parts of the Form 1-A have been omitted as permitted by rules and regulations of the Commission. We refer you to the Form 1-A and its exhibits for further information about us, our securities and this offering. The Form 1-A and its exhibits, as well as each of our other reports filed with the Commission, can be inspected and copied at the Commission's public reference room at 100 F. Street, N.E., Washington, D.C. 20549. The public may obtain information about the operation of the public reference room by calling the Commission at 1-800-SEC-0330. In addition, the Commission maintains a website at <http://www.sec.gov>, which contains the Form 1-A and other reports, proxy and information statements and information regarding issuers that file electronically with the Commission. We are currently subject to disclosure and/or reporting requirements under both Regulation A and the Exchange Act. As of December 15, 2020, we are required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the Commission pursuant to the Exchange Act. Our annual report for the fiscal year ended December 31, 2019, as well as each of our other reports filed with the Commission, can be inspected and copied at the public reference room and on the Commission's website referred to above.

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SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash	\$ 753,242	\$ 36,747
Value added tax receivable	1,004	562
Deferred offering costs	731,182	627,016
Prepaid expenses	20,461	103,697
Total current assets	<u>1,505,889</u>	<u>768,023</u>
Property and equipment, net	2,939	3,659
Total assets	<u>\$ 1,508,828</u>	<u>\$ 771,682</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued expenses	\$ 1,587,618	\$ 854,541
Other liabilities		
Convertible notes payable, net	<u>1,426,245</u>	<u>—</u>
Total liabilities	<u>3,013,863</u>	<u>854,541</u>
COMMITMENTS AND CONTINGENCIES (NOTES 6 AND 9)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 20,000,000 shares authorized; 0 shares issued and outstanding	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 13,975,691 and 12,509,024 shares issued and outstanding	13,976	12,509
Additional paid-in capital	12,304,487	3,577,533
Note receivable	(1,500,000)	—
Accumulated deficit	(12,290,844)	(3,639,447)
Accumulated other comprehensive loss	(32,654)	(33,454)
Total stockholders' equity (deficit)	<u>(1,505,035)</u>	<u>(82,859)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 1,508,828</u>	<u>\$ 771,682</u>

See accompanying notes to the condensed consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND
COMPREHENSIVE LOSS
(Unaudited)**

	Six Months Ended June 30,	
	2020	2019
Revenues	\$ —	\$ —
Operating expenses:		
General and administrative	1,279,689	731,422
Research and development	7,284,874	197,420
Total operating expenses	8,564,563	928,842
Loss from operations	(8,564,563)	(928,842)
Other expense:		
Interest expense	(85,145)	—
Other expenses	(1,689)	—
Loss before income taxes	(8,651,397)	(928,842)
Income tax expense	—	—
Net loss	(8,651,397)	(928,842)
Comprehensive income (loss):		
Foreign currency translation adjustment	800	(677)
Total comprehensive loss	\$ (8,650,597)	\$ (929,519)
Net loss per common share:		
Basic and diluted	\$ (0.68)	\$ (0.08)
Weighted-average common shares outstanding:		
Basic and diluted	12,684,116	11,546,748

See accompanying notes to the condensed consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Note Receivable</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>				<u>Deficit</u>	<u>Loss</u>
Balances as of December 31, 2019	12,509,024	\$12,509	\$ 3,577,533	\$ —	\$ (3,639,447)	\$(33,454)	\$ (82,859)
Issuance of common stock for acquired in-process research and development . .	1,466,667	1,467	5,865,200	—	—	—	5,866,667
Issuance of units and warrants – net of issuance costs of \$55,687	—	—	1,241,244	—	—	—	1,241,244
Issuance of warrants relating to note receivable	—	—	1,500,000	(1,500,000)	—	—	—
Stock-based compensation expense	—	—	120,510	—	—	—	120,510
Foreign currency translation adjustment	—	—	—	—	—	800	800
Net loss	—	—	—	—	(8,651,397)	—	(8,651,397)
Balances as of June 30, 2020	<u>13,975,691</u>	<u>\$13,976</u>	<u>\$12,304,487</u>	<u>\$(1,500,000)</u>	<u>\$(12,290,844)</u>	<u>\$(32,654)</u>	<u>\$(1,505,035)</u>

See accompanying notes to the condensed consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	\$(8,651,397)	\$ (928,842)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	711	38
Acquired in-process research and development – through issuance of common stock and warrants	6,346,321	—
Stock-based compensation	120,510	79,854
Amortization of debt issuance costs and debt discount	64,879	—
Changes in operating assets and liabilities:		
Value added tax receivable	(437)	8,995
Other receivable	—	(2,227)
Due from affiliate	—	(3,086)
Prepaid expenses and other assets	82,772	(77,751)
Accounts payable and accrued expenses	1,091,712	10,015
Net cash used in operating activities	(944,929)	(913,004)
Cash flows from investing activities:		
Purchases of property and equipment	—	(2,255)
Cash flows from financing activities:		
Gross proceeds from issuance of Convertible Notes payable	1,231,400	—
Issuance costs related to the issuance of convertible notes payable	(110,973)	—
Gross proceeds from issuance of units and warrants	617,700	1,075,992
Issuance costs related to the issuance of units and warrants	(55,687)	(4,762)
Proceeds from the exercise of warrants	—	858,855
Payment of deferred offering costs	(22,618)	(135,625)
Net cash provided by financing activities	1,659,822	1,794,460
Effects of changes in foreign currency exchange rates on cash	1,602	(11,441)
Net increase in cash	716,495	867,760
Cash, beginning of period	36,747	1,660
Cash, end of period	\$ 753,242	\$ 869,420
Supplemental disclosure of cash flow information:		
Non-cash financing activity:		
Deferred offering costs in accounts payable and accrued expenses	\$ 81,548	\$ 258,220
Deferred financing costs on convertible notes payable in accounts payable and accrued expenses	58,214	—
Purchase price for Bioscience Oncology payable in cash in accounts payable and accrued expenses	364,222	—
Convertible notes issued in lieu of cash	240,939	—
W Warrants issued in lieu of cash	199,577	—
Cash paid during the period for:		
Interest	268	—

See accompanying notes to the condensed consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business

Nature of Operations

Scopus BioPharma Inc. (“Scopus”) was incorporated in the State of Delaware on April 18, 2017 under the name Project18 Inc. (“Project18”). On December 11, 2017, Project18 changed its name to Scopus BioPharma Inc. On June 1, 2017, Scopus acquired all the outstanding common stock of Vital Spark, Inc. (“VSI”) for a total purchase price of \$15. VSI had not engaged in any business transactions prior to the acquisition date. On July 8, 2018, Scopus formed a wholly-owned subsidiary, Scopus BioPharma Israel Ltd. (“SBI”), and has funded operations to date through intercompany loans.

Scopus and its subsidiary, VSI, are headquartered in New York, and SBI is headquartered in Jerusalem, Israel. Scopus, VSI and SBI are collectively referred to as the “Company”. The Company is a biopharmaceutical company developing transformational therapeutics targeting serious diseases with significant unmet medical needs.

Going Concern

The provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 205-40, *Presentation of Financial Statements — Going Concern* (ASC 205-40) requires management to assess an entity’s ability to continue as a going concern within one year of the date the financial statements are issued. In each reporting period (including interim periods), an entity is required to assess conditions known and reasonably knowable as of the financial statement issuance date to determine whether it is probable an entity will not meet its financial obligations within one year from the financial statement issuance date. Substantial doubt about an entity’s ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate it is probable the entity will be unable to meet its financial obligations as they become due within one year after the date the financial statements are issued.

The Company is an early-stage company and has not generated revenues to date. As such, the Company is subject to all of the risks associated with early stage companies. Since inception, the Company has incurred losses and negative cash flows from operating activities which have been funded from the issuance of convertible notes, common stock, and warrants (see Note 7). The Company does not expect to generate positive cash flows from operating activities in the near future, if at all, until such time it completes the development of its drug candidates, including obtaining regulatory approvals, and anticipates incurring operating losses for the foreseeable future.

The Company incurred net losses of \$8,651,397 for the six months ended June 30, 2020 and had an accumulated deficit of \$12,290,844 as of June 30, 2020. The Company’s net cash used in operating activities was \$944,929 for the six months ended June 30, 2020.

The Company’s ability to fund its operations is dependent upon management’s plans, which include raising capital through issuances of debt and equity securities, securing research and development grants, generating sufficient revenues and controlling the Company’s expenses. A failure to raise sufficient financing, generate sufficient revenues, or control expenses, among other factors, will adversely impact the Company’s ability to meet its financial obligations as they become due and payable and to achieve its intended business objectives.

This evaluation is further impacted by the current spread of the COVID-19 coronavirus. While uncertain at this time, the extent of its impacts depends largely on the spread and duration of the outbreak, and may result in disruptions to capital raises, its employees, and vendors which could result in negative impacts to its operational and financial results.

Accordingly, management has concluded this raises substantial doubt of the Company’s ability to continue as a going concern within one year after the date the condensed consolidated financial statements are issued.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business (continued)

The Company's condensed consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities should the Company be unable to continue as a going concern.

Basis of Presentation and Principles of Consolidation

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to such rules and regulations. In management's opinion, the accompanying statements reflect adjustments necessary to present fairly the financial position, results of operations, and cash flows for those periods indicated, and contain adequate disclosure to make the information presented not misleading. Adjustments included herein are of a normal, recurring nature unless otherwise disclosed in the footnotes. The financial statements and notes thereto should be read in conjunction with the Company's audited financial statements and notes thereto for the year ended December 31, 2019 included in the Company's Annual Report on Form 1-K, as filed with the SEC on May 15, 2020. The accompanying balance sheet at December 31, 2019 has been derived from the audited balance sheet at December 31, 2019 contained in the above referenced Form 1-K. Results of operations for interim periods are not necessarily indicative of the results of operations for a full year.

Foreign Currency

The functional currency of Scopus and VSI is the US Dollar, and the functional currency of SBI is the Israeli New Shekel. All assets and liabilities of SBI are translated at the current exchange rate as of the end of the period and the related translation adjustments are recorded as a separate component of accumulated other comprehensive loss. Revenue and expenses are translated at average exchange rates in effect during the period. Foreign currency transaction gains and losses resulting from, or expected to result from, transactions denominated in a currency other than the functional currency are recognized in "General and administrative" expenses in the condensed consolidated statements of operations and comprehensive loss.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Significant estimates in these condensed consolidated financial statements include those related to the fair value of common stock, warrants, stock-based compensation, the provision or benefit for income taxes and the corresponding valuation allowance on deferred tax assets, and probability of meeting certain milestones. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates, judgments, and methodologies. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Due to the inherent uncertainty involved in making estimates, actual results could differ materially from those estimates.

Offering Costs

The Company capitalizes certain legal, accounting, and other third-party fees directly associated with in-process financings as deferred offering costs. The deferred offering costs are recognized as an offset against the proceeds upon consummation of an offering. As of June 30, 2020 and December 31, 2019, the Company

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business (continued)

capitalized \$731,182 and \$627,016, respectively, of deferred offering costs related to the Company’s Proposed Public Offering (See Note 2).

Financing Costs

The Company defers certain legal and other third-party financing costs directly associated with debt issuances as deferred financing costs. The deferred financing costs are recognized as an offset against the related issued debt and amortized using the effective interest rate method through maturity. Through June 30, 2020, the Company deferred \$224,674 of financing costs which were allocated to the Convertible Notes and W Warrants (see Note 5). For the six months ended June 30, 2020 and 2019, amortization of deferred financing costs was \$14,314 and \$0, respectively. As of December 31, 2019, there were no deferred financing costs.

Net Loss Per Share

Basic net loss per common share attributable to common shareholders is calculated by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding for the year. Since the Company was in a loss position for all years presented, basic net loss per share is the same as dilutive net loss per share as the inclusion of the weighted-average number of all potential dilutive common shares which consist of convertible debt, stock options and warrants, would be anti-dilutive.

The following table presents the potentially dilutive shares that were excluded from the computation of diluted net (loss) per share of common stock attributable to common stockholders, because their effect was anti-dilutive:

	For the six months ended June 30,	
	2020	2019
Warrants	6,282,237	2,169,000
Convertible Notes (if converted)	1,624,886	—
Stock options	600,000	175,000
Contingent consideration in common stock	306,227	—
Total	8,813,350	2,344,000

JOBS Act Accounting Election

The Company is an “emerging growth company”, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to avail itself of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

Significant Accounting Policies

The Company’s accounting policies are the same as those described in Note 2 to the Company’s Consolidated Financial Statements for the year ended December 31, 2019 in its Annual Report on Form 1-K filed on May 15, 2020.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the condensed consolidated financial

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business (continued)

statements as a result of future adoption.

2. Proposed Public Offering

The Company is undertaking a proposed public offering of its common stock (the “Proposed Public Offering”). The Company has applied to have its common stock listed on the Nasdaq Global Market under the symbol “SCPS”.

3. Bioscience Oncology Transaction

On June 10, 2020, the Company completed the acquisition of Bioscience Oncology Pty. Ltd. (“Bioscience Oncology”), a pre-clinical biopharmaceutical company which held a single asset, the exclusive right to negotiate a license agreement for a STAT3 inhibitor drug candidate (the “STAT3 Inhibitor”) with City of Hope (see Note 6). The transaction was accounted for as an asset acquisition as the purchase primarily related to a single asset. The aggregate upfront expense, including the upfront license fees paid to City of Hope, totaled \$7.1 million, comprised of \$773,654 which was paid or is payable in cash and the issuance of an aggregate of 1,466,667 shares of common stock and 959,308 W Warrants. Pursuant to asset acquisition accounting, acquired in-process research and development with no alternative future use is expensed at acquisition. Accordingly, this amount was recognized in “Research and development” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss during the six months ended June 30, 2020. Under the terms of the agreement, Bioscience Oncology is eligible to receive additional contingent consideration of up to \$10.1 million upon the achievement of specified milestones payable in shares of the Company’s common stock, which will be recorded when it is determined the corresponding milestones are probable to be achieved.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of:

	June 30, 2020	December 31, 2019
Professional fees	\$ 670,515	\$559,706
Patent license fees	353,892	37,364
Management service fees and expenses	208,911	70,197
Other accounts payable and accrued expenses	354,301	187,274
Total accounts payable and accrued expenses	\$1,587,618	\$854,541

Amounts due to related parties included in accounts payable and accrued expenses totaled \$230,949 and \$117,342 as of June 30, 2020 and December 31, 2019, respectively (see Note 9, Related Party Transactions).

5. Debt

In April 2020, the Company amended the terms of its December 2019 Private Placement (see Note 7) to issue convertible promissory notes (“Convertible Notes”) with W Warrants (“Convertible Notes Private Placement”) in an initial principal amount of up to \$1,000,000, which was subsequently increased to \$3,000,000. The Convertible Notes have an annual interest rate of 10% and a scheduled maturity on the earlier of July 31, 2021 or a change of control of the Company (the “Maturity Date”). For each \$1.00 of initial principal, the purchaser will also receive one W Warrant. Prior to the Maturity Date, the holder may elect to convert each \$1.00 of initial principal amount of Convertible Notes plus accrued and unpaid interest into W Warrants at a conversion price of \$0.50 per W Warrant.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

5. Debt (continued)

Through June 30, 2020, the Company issued an aggregate initial principal amount of \$1,659,600 of Convertible Notes as part of the Convertible Notes Private Placement for \$1,659,600 in cash less issuance costs of \$224,674. From July 1, 2020 through September 14, 2020 the Company issued an additional aggregate initial principal amount of \$342,005 of Convertible Notes as part of the Convertible Notes Private Placement for \$342,005 in cash less issuance costs of \$35,401.

Between February 2020 and June 2020, the Company issued convertible notes and warrants on identical terms to those of the Convertible Notes Private Placement to HCFP/Portfolio Services LLC (“Portfolio Services”) (see Note 9), investors and vendors, on a direct basis, in an aggregate initial principal amount of \$636,230 for \$187,500 in cash with the balance as consideration for legal and management services rendered. An additional 100,000 W Warrants were issued as consideration for legal services rendered to satisfy outstanding accounts payable.

Investors who purchased W Warrants in the December 2019 Private Placement prior to the amendment of its terms may elect to surrender two W Warrants for the purchase of \$1.00 of initial principal amount of Convertible Notes.

There were no balances related to the Convertible Notes as of December 31, 2019. Balances related to the Convertible Notes as of June 30, 2020 included:

	June 30, 2020
Convertible Notes principal amount	\$2,295,830
Unamortized discount	(714,712)
Deferred financing costs	(154,873)
Convertible Notes payable, net	<u>\$1,426,245</u>

The Convertible Notes principal amount, net of issuance costs, was allocated to the Convertible Notes and W Warrants, based on their respective relative fair value, resulting in an allocation of \$1,361,366 and \$709,790 to the Convertible Notes and W Warrants, respectively, with the resulting difference of \$934,464 being recognized as debt discount, amortized as interest expense over the term of the Convertible Notes. The amount allocated to the W Warrants was recognized as an increase to “Additional paid-in capital” in the accompanying condensed consolidated statements of stockholders’ equity (deficit) under the caption “Issuance of units.”

Interest expense for the six months ended June 30, 2020 totaled \$85,145, which includes \$20,266 of interest expense and \$64,879 of debt discount.

6. Commitments and Contingencies

Agreement Related to Intellectual Property Rights

In July 2017, VSI as “Licensee” entered into a Patent License Agreement (the “Patent License Agreement”) with The U.S. Department of Health and Human Services, as represented by the National Institute on Alcohol Abuse and Alcoholism (“NIAAA”) and the National Institute on Drug Abuse (“NIDA”) of the National Institutes of Health (“NIH”), (collectively “Licensor”). In the course of conducting biomedical and behavioral research, the Licensor developed inventions that may have commercial applicability. The Licensee acquired commercialization rights to certain inventions in order to develop processes, methods, or marketable products for public use and benefit.

Upon execution of the Patent License Agreement, VSI paid the Licensor an aggregate of \$121,040, which included an upfront non-refundable fee of \$50,000 and \$71,040 for certain patent expenses incurred

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

6. Commitments and Contingencies (continued)

by the Licensor prior to the execution of the Patent License Agreement relating to patent applications. The Company determined that the Patent License Agreement did not meet the definition of a business pursuant to the guidance prescribed in FASB ASC Topic 805, *Business Combinations*, as the transaction principally resulted in the acquisition of intellectual property rights only. In this regard, the Company did not acquire any employees or tangible assets, or any processes, protocols, or operating systems. Additionally, at the time of the transaction, there were no activities being conducted related to the licensed patents. The Company recognized as expense the acquired intellectual property rights as of the transaction date on the basis that the costs of an intangible asset purchased from others for use in a research and development activity for which there are no alternative future uses are recorded as research and development expense at the time such costs are incurred. In addition, patent fee reimbursement under the Patent license agreement was \$13,360 and \$12,960 for the six months ended June 30, 2020 and 2019, respectively. These costs are included in “Research and development” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss.

Pursuant to the terms of the Patent License Agreement, VSI is required to make minimum annual royalty payments of \$25,000, with the first payment due on January 1, 2019. The Company paid the first annual payment of \$25,000 in January 2019, which is included in “Research and development” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and shall be credited against any earned royalties due for sales made in that year, throughout the term of the Patent License Agreement. The Company paid the second annual payment of \$25,000 in December 2019, which is included in “Prepaid expenses” in the accompanying condensed consolidated balance sheets. For the six months ended June 30, 2020, \$12,500 of this prepaid royalty expense was recognized in “Research and development” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. The Patent License Agreement also provides for payments from VSI to the Licensor upon the achievement of certain product development and regulatory clearance milestones, as well as royalty payments on net sales upon the commercialization of products developed utilizing the licensed patents. Through June 30, 2020, the Licensor has not achieved any milestones and therefore VSI has not made any milestone payments.

VSI is obligated to pay earned royalties based on a percentage of net sales, as defined in the Patent License Agreement, of licensed product throughout the term of the Patent License Agreement. Since April 18, 2017 (inception) through June 30, 2020, there have been no sales of licensed products. In addition, VSI is also obligated to pay the Licensor additional sublicensing royalties on the fair market value of any consideration received for granting each sublicense. Through June 30, 2020, VSI has not entered into any sublicensing agreements and therefore no sublicensing consideration has been paid to Licensor.

Cooperative Research and Development Agreement

Effective January 11, 2018, VSI signed a two-year Cooperative Research and Development Agreement (the “CRADA Agreement”) with the NIH for preclinical testing relating to the Patent License Agreement described above. The term of the CRADA Agreement can be extended, beyond the initial two-year term, by agreement in writing by both parties. Pursuant to the terms of the CRADA Agreement, each party will provide scientific staff and other support necessary to conduct the research and other activities described in the research plan. Funds provided by VSI pursuant to the terms of the CRADA Agreement will be used by the NIH to acquire technical, statistical, and administrative support for the research activities, as well as pay for supplies and travel expenses.

Effective October 31, 2018, VSI and NIH amended the CRADA Agreement to defer funding for year two subject to additional testing by NIH and approval of the results by VSI. Subsequently, on May 6, 2019, VSI and NIH entered into a second amended agreement to proceed with the second year of the agreement pursuant to an updated research plan. On May 7, 2019, the Company made the first of two equal payments of \$55,870 to NIH.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

6. Commitments and Contingencies (continued)

Total expenses incurred in connection with the CRADA Agreement for the six months ended June 30, 2020 and 2019 amounted to \$31,039 and \$24,831, respectively. These expenses are included in “Research and development” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. As of June 30, 2020 and December 31, 2019, \$55,870 and \$24,831 were recognized in “Accounts payable and accrued expenses” in the accompanying condensed consolidated balance sheets, respectively, related to the CRADA Agreement.

Memorandums of Understanding

Effective July 28, 2018, SBI entered into two Memorandums of Understanding (“MOUs”) with Yissum Research Development Company (“Yissum”) of the Hebrew University of Jerusalem Ltd. (“Hebrew University”). Pursuant to the terms of the MOUs, SBI shall provide funding for research and development studies to be performed by researchers at Hebrew University in the areas of cannabinoid therapeutics and cannabinoid synthesis over a two-year period. Funds provided by SBI pursuant to the terms of MOUs will be used by the researchers at Hebrew University to acquire technical, statistical, and administrative support for the research activities, as well as pay for supplies. SBI has the exclusive right to license the study results by providing written notice to Yissum during the respective study periods or within 60 days of the studies’ completion. Upon providing such notice, SBI and Yissum shall negotiate a license agreement for the commercial development and exploitation of the study results. SBI shall be entitled to reimbursement of the amounts funded for the research and development studies and patent prosecution costs, if any, in the event Yissum enters into a license agreement with a third party, subject to certain conditions.

The fees incurred in connection with these MOU’s for the six months ended June 30, 2020 and 2019 amounted to \$29,646 and \$75,496, respectively. These fees are included in “Research and development” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. The Company also recorded a prepaid expense of \$0 and \$29,646 in connection with these MOU’s which are included in “Prepaid expenses” in the accompanying condensed consolidated balance sheets as of June 30, 2020 and December 31, 2019, respectively.

Effective March 5, 2019, the Company entered in a license agreement with Yissum with respect to the results of the research relating to the combination of cannabidiol with approved anesthetics as a potential treatment for the management of pain. Under the license agreement, the Company is obligated to pay earned royalties based on a percentage of net sales, as defined in the license agreement, including net sales generated from sub-licensees. In addition, the Company will be obligated to make payments upon the achievement of certain clinical development and product approval milestones. From March 5, 2019 through June 30, 2020, there have been no sales of licensed products by the Company nor has the Company entered into any sub-licensing agreements. Further, none of the milestones in the agreement have been reached and therefore as of June 30, 2020, there is no obligation to make any milestone payments.

Effective August 8, 2019, the Company entered into a second license agreement with Yissum with respect to the research results relating to the synthesis of novel cannabinoid dual-action compounds and novel chemical derivatives of cannabigerol and tetrahydrocannabivarin. Under this license agreement, the Company is required to pay earned royalties based upon a percentage of net sales at one percentage for regulated products and a lesser percentage for non-regulated products. The Company is obligated to pay development milestone payments tied to regulated products totaling \$1,225,000 in the aggregate and \$100,000 for non-regulated products in the aggregate. None of the milestones in the agreement have been reached and therefore as of June 30, 2020 there is no obligation to make any milestone payments.

City of Hope License Agreement and Sponsored Research Agreement

In June 2020, the Company entered into an exclusive, worldwide license agreement with City of Hope relating to the STAT3 Inhibitor (the “COH License Agreement”). In addition to the COH License Agreement,

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

6. Commitments and Contingencies (continued)

the Company also entered into a Sponsored Research Agreement (the “SRA”) relating to on-going research and development activities in collaboration with City of Hope relating to the STAT3 Inhibitor. The Company obtained the right to negotiate the COH License Agreement with City of Hope from Bioscience Oncology as part of the Bioscience Oncology transaction (see Note 3). Under the terms of the COH License Agreement, the Company is obligated to pay earned royalties based on a percentage of net sales, as defined in the COH License Agreement, including net sales generated from sub-licensees. In addition, the Company is obligated to make payments in cash upon the achievement of certain clinical development and product approval milestones totaling \$3,525,000 in the aggregate. None of the milestones in the COH License Agreement have been reached and therefore as of June 30, 2020, there is no obligation to make any milestone payments. Pursuant to the terms of the SRA, the Company has committed to fund on-going research and development at City of Hope for two years in accordance with a predetermined funding schedule. Total expenses incurred in connection with the SRA were \$13,889 for the six months ended June 30, 2020. These expenses are included in “Research and development” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss.

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. Notwithstanding, legal proceedings are subject to inherent uncertainties, and an unfavorable outcome, if such event were to occur, could include monetary damages and could result in a material adverse impact on the Company’s business, financial position, results of operations, and cash flows.

7. Stockholders’ Equity

Preferred Stock

The Company is authorized to issue 20,000,000 shares of preferred stock with a par value of \$0.001 per share with such designation, rights and preferences as may be determined from time-to-time by the Company’s board of directors. Authority is expressly vested in the board of directors to authorize the issuance of one or more series of preferred stock. All 20,000,000 shares remained unissued as of June 30, 2020.

Common Stock

The Company is authorized to issue 50,000,000 shares of common stock with a par value of \$0.001 per share. The number of authorized shares of common stock may be increased or decreased (but not below the number of shares of common stock then outstanding) by an affirmative vote of the holders of a majority of the common stock.

On June 1, 2017, the Company issued 10,000,000 shares of its common stock at a price of \$0.001 per share to HCFP II LLC (“HCFP II”), an affiliated entity, as founders’ stock, for an aggregate purchase price of \$10,000. On June 2, 2017, HCFP II transferred such shares to other affiliated entities.

In December 2017 and January 2018, the Company issued a total of 361,518 and 138,482 shares, respectively, at a price of \$1.00 per share, resulting in net proceeds of \$355,122 and \$128,040, respectively, after issuance costs.

The powers, preferences and rights of the holders of the common stock are junior to the preferred stock and are subject to all the powers, rights, privileges, preferences and priorities of the preferred stock. The holder of each share of common stock shall have the right to one vote per share. Each holder of common stock shall be entitled to receive dividends and distributions (whether payable in cash or otherwise) as declared by the board of directors of the Company, subject to the rights of any class of preferred stock

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

7. Stockholders' Equity (continued)

outstanding. In the event of any liquidation, dissolution or winding-up of the Company (whether voluntary or involuntary), the assets available for distribution to holders of common stock will be in equal amounts per share.

Equity Units

On July 20, 2018, the Company offered up to 266,667 units at a price of \$1.50 per unit (the "\$1.50 Units") in a private placement transaction. During the first quarter of 2019, the Company increased the private offering of \$1.50 Units to 1,000,000 \$1.50 Units, on the same terms. Each Unit is comprised of one share of the Company's common stock and two warrants ("\$1.50 Unit Warrants"). Each \$1.50 Unit Warrant is exercisable for one share of the Company's common stock at a price of \$1.00 per share, expires on July 31, 2023, and carries a mandatory exchange feature as described in the relevant warrant subscription agreement. The exercise price is not subject to adjustment, except in the event of stock dividends and stock splits. Further, in the event of a Fundamental Transaction, as defined in the agreement, the holders can participate *pari passu* with common stockholders in the consideration paid by an acquirer for the Company's shares. The Company issued a total of 266,667 \$1.50 Units in 2018 resulting in net proceeds of \$390,930 after issuance costs. The Company received \$24,008 in 2018 relating to 16,005 \$1.50 Units which were subsequently issued in January 2019 following the increase in number of \$1.50 Units offered. The Company recorded the \$24,008 as an advance deposit on equity units as of December 31, 2018, which was reclassified to equity upon issuance of the applicable \$1.50 Units in January 2019.

During the year ended December 31, 2019, the Company sold an additional 717,328 \$1.50 Units (excluding the 16,005 \$1.50 Units that were issued in January 2019 related to the advance deposits received in 2018 for such \$1.50 Units) resulting in net proceeds of \$1,071,230 after issuance costs.

The holders of the \$1.50 Unit Warrants discussed above have the same rights to receive dividends or other distribution of assets as the holders of common stock. As such, these \$1.50 Unit Warrants are considered participating securities under the two-class method of calculating the net loss per share. The Company has incurred net losses to date, and as the holders of these \$1.50 Unit Warrants are not contractually obligated to share in the losses, there is no impact on the Company's net loss per share calculation for the years presented.

On May 6, 2019, pursuant to the terms of the \$1.50 Unit Warrants, the Company provided a Notice of Trigger Date to the holders of its \$1.50 Unit Warrants informing such holders that the deadline to exercise their \$1.50 Unit Warrants at an exercise price of \$1.00 per share was May 16, 2019 (the "Trigger Date"). Any \$1.50 Unit Warrants not exercised by the Trigger Date will automatically become identical to and of the same class as the W Warrants. A total of 858,855 \$1.50 Unit Warrants were exercised in connection with such notice generating \$858,855 in proceeds for the Company.

On June 11, 2019, the Company offered up to 200,000 units at a price of \$3.00 per unit in a private placement transaction (the "\$3.00 Units"). Each \$3.00 Unit is comprised of one share of the Company's common stock and two warrants ("\$3.00 Unit Warrants"). Each \$3.00 Unit Warrant shall be identical to and be of the same class as the W Warrants. In July 2019, the Company issued 150,169 of the \$3.00 Units resulting in net proceeds of \$330,132 after issuance costs.

On February 4, 2020, the Company offered up to 200,000 Series A units at a price of \$5.00 per unit in a Regulation A+ Tier II offering (the "A Units"). Each A Unit consists of one share of the Company's common stock and two Series W Warrants ("W Warrants"). Each W Warrant is exercisable for one Series B Unit ("B Unit"). Each B Unit consists of one share of common stock and one Series Z Warrant ("Z Warrant"). Each Z Warrant is exercisable for one share of common stock. The exercise price of the W Warrant is \$4.00, and the exercise price of the Z Warrant is \$5.00. The W Warrants and Z Warrants will be exercisable commencing on October 1, 2021 and July 1, 2022, respectively, and expire on September 30, 2026

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

7. Stockholders' Equity (continued)

and June 30, 2027, respectively, unless previous exercised. As of June 30, 2020, no A Units had been issued. Through September 14, 2020, the Company had issued 21,906 A Units resulting in net proceeds of \$104,830 after issuance costs.

Warrants

On December 10, 2019, the Company offered up to 1,000,000 W Warrants at a price of \$0.50 per W Warrant in a private placement transaction ("December 2019 Private Placement"). In December 2019 and January 2020, the Company issued 500,000 and 4,000 W Warrants resulting in net proceeds of \$138,432 and \$1,800, respectively, after issuance costs. In April 2020, the Company amended the terms of the December 2019 Private Placement as described in the Convertible Notes Private Placement (see Note 5).

On July 16, 2020 and in connection with the initial closing of the A Units, all of the Company's outstanding warrants, including any X Warrants but excluding the Yissum Warrant Shares, automatically became an equal number of W Warrants. For presentation purposes, the term "W Warrants" is used throughout these notes in cases where the warrants referenced have subsequently become W Warrants.

On October 3, 2018, the Company issued a warrant to Yissum, entitling Yissum to purchase up to 450,000 shares ("Warrant Shares") of the Company's common stock at an exercise price of \$1.50 per share of common stock and which warrant expires on October 3, 2025. This warrant was issued as consideration to Yissum in connection with the execution of the MOUs (see Note 6). Upon issuance of this warrant, it was immediately exercisable for 50,000 Warrant Shares. Additional Warrant Shares vest upon the execution of license agreements within a specified number of days upon notice by the Company of its intent to enter into such license agreements.

The Company determined that as of December 31, 2018, it was probable that the Company would enter into at least one license agreement. Accordingly, for the year ended December 31, 2018, the Company recognized compensation expense for the 50,000 Warrant Shares that were immediately exercisable upon issuance of the warrant and 50,000 Warrant Shares relating to the probable execution of a license agreement.

Effective March 5, 2019 and August 8, 2019, the Company entered into separate license agreements with Yissum with respect to the results and intellectual property generated from research being conducted at Hebrew University under one of the MOUs (see Note 6). As a result of the first and second license agreements being executed within a specified period after notice, the Company recognized compensation expense in connection with the vesting of an additional 50,000 and 100,000 Warrant Shares, respectively.

The estimated fair value of the Yissum Warrant Shares at grant date was \$0.59 per Warrant Share, calculated using Black-Scholes option pricing model using the following assumptions; fair value of underlying common stock of \$1.00, contractual life of 7 years; risk free interest rate of 3.06%; volatility of 68%, and dividend yield of 0%. There has been no history of dividend payments and there are no expectations of dividend payments during the next several years.

The Company recognized stock-based compensation expense related to Warrant Shares during the six months ended June 30, 2020 and 2019, of \$0 and \$59,434, respectively. This expense is included in "Research and development" expenses in the accompanying condensed consolidated statements of operations and comprehensive loss.

In conjunction with the Convertible Notes issued through June 30, 2020, the Company issued 2,295,830 W Warrants (see Note 5). In addition, on April 1, 2020 100,000 W Warrants were issued as consideration for legal services rendered to satisfy outstanding accounts payable. On June 5, 2020, the Company issued to HCFP/Capital Partners 18-B-2 LLC ("CP18B2") 3,000,000 W Warrants in consideration of a \$1.5 million contingent promissory note ("Note Receivable"). The Note Receivable accrues interest at a rate of 1% per annum. Payment of this Note Receivable is contingent on exercise or sale of the W Warrants prior to

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

7. Stockholders' Equity (continued)

their expiration. If the W Warrants have not been sold or exercised prior to their expiration by CP18B2, no payment of principal and interest of the Note Receivable is required.

The table below summarizes all warrant activity for the six months ended June 30, 2020:

	<u>Warrants</u>	<u>Weighted- average Exercise Price</u>
Outstanding at December 31, 2019	2,391,483	\$2.10
Issued	6,359,138	4.00
Exercised	—	—
Forfeited	—	—
Outstanding at June 30, 2020	<u>8,750,621</u>	<u>\$3.87</u>
Warrants exercisable at June 30, 2020	<u>1,391,145</u>	<u>\$3.55</u>

As of June 30, 2020, the remaining contractual term of the outstanding warrants was 6.20 years.

8. Stock Options

Effective September 24, 2018, the Company approved the Scopus BioPharma Inc. 2018 Equity Incentive Plan (the "Plan"), and reserved 1,000,000 shares of the Company's common stock, such amount subsequently being increased to 2,400,000 shares, for issuance under the Plan. The stock options shall be granted at an exercise price per share equal to at least the fair market value of the shares of common stock on the date of grant and generally vest over a three-year period.

Stock option activity is summarized as follows for June 30, 2020:

	<u>Options</u>	<u>Weighted- average Exercise Price</u>	<u>Weighted- average Grant Date Fair Value</u>
Outstanding at December 31, 2019	600,000	\$2.56	\$1.21
Granted	—	—	—
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at June 30, 2020	<u>600,000</u>	<u>\$2.56</u>	<u>\$1.21</u>
Vested and exercisable at June 30, 2020	<u>232,138</u>	<u>\$2.17</u>	<u>\$1.10</u>
Unvested at June 30, 2020	<u>367,862</u>	<u>\$2.70</u>	<u>\$1.27</u>

Stock-based compensation associated with vesting options was \$120,510 and \$20,420 for the six months ended June 30, 2020 and 2019, respectively. This cost is included in "General and administrative" expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. As of June 30, 2020, total unrecognized stock-based compensation expense of \$467,821 is expected to be recognized over the remaining weighted-average contractual term of 2.00 years.

9. Related Party Transactions

The Company has a management services agreement, as amended, with Portfolio Services, an affiliated entity, to provide management services to the Company including, without limitation, financial and accounting resources, general business development, corporate development, corporate governance, marketing strategy, strategic development and planning, coordination with service providers and other

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

9. Related Party Transactions (continued)

services as agreed upon between the parties. The Company pays Portfolio Services a monthly management services fee plus related expense reimbursement. This management services agreement was initially in effect for a period of one year and is automatically renewable for successive one-year terms unless terminated prior to the end of such term as set forth in the management services agreement. Effective July 1, 2018, the Company amended the management services agreement with Portfolio Services to include an additional monthly fee of \$1,500 for the provision of office space and facilities to the Company, which was subsequently increased to \$3,000 effective May 1, 2019. Effective July 1, 2020 the monthly management services fee was increased from \$40,000 to \$50,000 per month.

For the six months ended June 30, 2020 and 2019, the Company incurred expenses of \$258,000 and \$162,000, respectively, related to this management services agreement. The costs are included in “General and administrative” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. Amounts prepaid to Portfolio Services were \$0 and \$40,000 as of June 30, 2020 and December 31, 2019, respectively, and are included in “Prepaid expenses” on the accompanying condensed consolidated balance sheets. Amounts payable to Portfolio Services as of June 30, 2020 and December 31, 2019 were \$10,380 and \$0, respectively, and are included in “Accounts payable and accrued expenses” on the accompanying condensed consolidated balance sheets.

On September 1, 2017, the Company entered into a management services agreement, as amended, with Clil Medical Ltd. (“Clil”) for Morris C. Laster, M.D., the sole principal of Clil, to serve as the Company’s Chief Executive Officer. The Company shall pay Clil a monthly management services fee, plus related expense reimbursements. This agreement was in effect for a period of one year and is automatically renewable for successive one-year terms unless terminated prior to the end of such term as set forth in the management services agreement. Effective January 1, 2019 the monthly management services fee was increased from \$10,000 to \$25,000 per month. As contemplated in connection with the Bioscience Oncology transaction, this management services agreement was terminated in June 2020 and is being replaced by a new agreement for services relating to Dr. Laster. For the six months ended June 30, 2020 and 2019, the Company incurred expenses of \$128,333 and \$151,442, respectively, related to this management services agreement. These costs are included in “General and administrative” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss. As of June 30, 2020 and December 31, 2019, the total amounts due to Clil were \$198,530 and \$70,197, respectively, and are included in “Accounts payable and accrued expenses” on the accompanying condensed consolidated balance sheets.

On June 10, 2020, the Company entered into a management services agreement with Kiliniwata Investments Pty, Ltd (“Kiliniwata”) for Paul E. Hopper, an affiliate of Kiliniwata, to serve as the Company’s Co-Chairman. The Company shall pay Kiliniwata a monthly management services fee of \$12,500, plus related expense reimbursements. For the six months ended June 30, 2020, the Company incurred expenses of \$8,333 related to this management services agreement. As of June 30, 2020 the amount due to Kiliniwata was \$8,333 and is included in “Accounts payable and accrued expenses” on the accompanying condensed consolidated balance sheets.

HCFP/Strategy Advisors LLC (“Strategy Advisors”), an affiliated entity, provides strategy advisory and consulting services to the Company from time to time. During the six months ended June 30, 2020 and 2019, the Company expensed and paid Strategy Advisors an aggregate of \$0 and \$100,000, respectively. These costs are included in “General and administrative” expenses in the accompanying condensed consolidated statements of operations and comprehensive loss.

On March 28, 2019, the Company entered into an agreement with HCFP/Capital Markets LLC (“Capital Markets”), an affiliated entity, to serve as the exclusive placement agent in a private offering of the Company’s securities (the \$3.00 Units — see Note 7). For the six months ended June 30, 2020 and 2019, the Company paid Capital Markets \$0 and \$50,000, respectively, for certain documentation and placement fees and a non-accountable expense allowance for such services in accordance with the terms of the related agreement.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

9. Related Party Transactions (continued)

On December 10, 2019, the Company entered into an agreement with Capital Markets to serve as the exclusive placement agent in a private offering of the Company’s securities (the “December 2019 Private Placement” — see Note 7), which was amended on April 30, 2020 to incorporate the Convertible Notes Private Placement (see Note 5). HCFP/Direct Investments LLC (“Direct Investments”), an affiliated entity, purchased 224,000 W Warrants in the December 2019 Private Placement on the same terms as the non-affiliated investors. The Company shall pay placement agent fees and a non-accountable expense allowance for such services in accordance with the terms of the related agreement. In 2019 and during the six months ended June 30, 2020, the Company incurred expenses of \$25,000 and \$166,160, respectively, in connection with this agreement. As of June 30, 2020 and December 31, 2019, amounts due to Capital Markets were \$0 and \$6,500 and are included in “Accounts payable and accrued expenses” on the accompanying condensed consolidated balance sheets.

In January, February, and May 2020, Direct Investments advanced a total of \$60,662 to the Company. On February 26, 2020, the Company repaid \$47,698 of such advances, including \$268 in interest. As of June 30, 2020, \$13,630 remains outstanding, including \$130 of accrued interest, and is included in “Accounts payable and accrued expenses” in the accompanying condensed consolidated balance sheet.

On April 9, 2020, one of the Company’s directors invested \$7,500 in the Notes issued as part of the Company Direct Offering. On June 1, 2020, Portfolio Services was issued an aggregate principal amount of \$200,000 of Notes under the Company Direct Offering as consideration for management services rendered. On June 5, 2020, the Company issued to CP18B2, an affiliated entity, 3,000,000 W Warrants in consideration of a Note Receivable (see — Note 7).

Related party amounts included in “Accounts payable and accrued expenses” in the accompanying condensed consolidated balance sheets were as follows:

	June 30, 2020	December 31, 2019
Portfolio Services	10,380	—
Clil Medical Ltd.	198,530	70,197
HCFP LLC	76	645
Capital Markets	—	6,500
Kiliniwata	8,333	—
Direct Investments	13,630	—
Total	230,949	117,342

10. Income Taxes

The Company did not provide for any income taxes for the six months ended June 30, 2020 and 2019. The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company’s history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of June 30, 2020 and December 31, 2019. Management reevaluates the positive and negative evidence at each reporting period.

The tax years 2017 through 2019 remain open to examination by the Internal Revenue Service. However, since the Company has net operating loss carryforwards, which may be utilized in future years to offset taxable income, those years may also be subject to review by relevant taxing authorities if utilized, notwithstanding that the statute for assessment may have closed. There are not currently ongoing or

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

10. Income Taxes (continued)

pending examinations in any jurisdictions.

11. Subsequent Events

The Company has evaluated subsequent events through September 25, 2020, which is the date the condensed consolidated financial statements were available to be issued. Any material subsequent events that occurred during this time have been properly recognized or disclosed in the condensed consolidated financial statements and accompanying notes.

In March 2020, the World Health Organization declared the outbreak of a novel strain of coronavirus, or COVID-19, as a global pandemic, which continues to spread throughout the United States and around the world. The Company is continually monitoring the impact of the global pandemic on its business, especially since the Company conducts activities in multiple locations, both in and outside of the United States. These locations are New York City and Los Angeles in the United States and Jerusalem and Tel Aviv in Israel. At various times since the onset of the global pandemic, these locations have been severely affected by COVID-19 and, as a result, have been subject to various requirements to stay at home and self-quarantine, as well as constraints on mobility and travel, especially international travel.

In many locations, the primary focus of healthcare providers and hospitals has been to combat the virus. While the Company continues to advance its development programs, the Company is also continually assessing the impact of the global pandemic on its product development efforts, including any impact on the timing and/or costs for its clinical trials, IND-enabling work, and other research and development activities. There is no certainty as to the length and severity of societal disruption caused by COVID-19. Consequently, the Company does not have sufficient visibility to predict the impact of the global pandemic on its operations and overall business, including delays in the progress of its planned pre-clinical work and clinical trials, or by limiting its ability to recruit physicians or clinicians to run its clinical trials, enroll patients or conduct follow-up assessments in its clinical trials. Further, the business or operations of its strategic partners and other third parties with whom the Company conducts business may also be adversely affected by the global pandemic. The Company continues to monitor the impact of the global pandemic, including regularly reevaluating the timing of its research and development and clinical milestones. In light of the more restrictive constraints on international travel, the Company continues to adjust program emphasis and prioritization. Until the Company is able to gain greater visibility as to the impact of the global pandemic, the Company intends to commit greater resources to its existing and future programs in the United States and is slowing investment in program development outside the United States.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Scopus BioPharma Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Scopus BioPharma Inc. and Subsidiaries (the “Company”) as of December 31, 2019 and 2018, the related consolidated statements of comprehensive loss, stockholders’ equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, and the results of their consolidated operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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’s recurring losses from operations, recurring cash used in operating activities, accumulated deficit and absence of revenue generation raise substantial doubt about its ability to continue as a going concern. Management’s plans concerning these matters are also discussed in Note 1 to the financial statements. The 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ CITRIN COOPERMAN & COMPANY, LLP

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

New York, New York
May 15, 2020

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash	\$ 36,747	\$ 1,660
Value added tax receivable	562	27,859
Deferred offering costs	627,016	—
Prepaid expenses	103,697	103,119
Total current assets	768,023	132,638
Property and equipment, net	3,659	—
Total assets	\$ 771,682	\$ 132,638
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 854,541	\$ 113,956
Advance deposit on equity units	—	24,008
Total liabilities	854,541	137,964
COMMITMENTS AND CONTINGENCIES (NOTES 5 and 8)		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 20,000,000 shares authorized; 0 shares issued and outstanding	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 12,509,024 and 10,766,667 shares issued and outstanding, respectively	12,509	10,767
Additional paid-in capital	3,577,533	942,969
Accumulated deficit	(3,639,447)	(949,498)
Accumulated other comprehensive loss	(33,454)	(9,564)
Total stockholders' deficit	(82,859)	(5,326)
Total liabilities and stockholders' deficit	\$ 771,682	\$ 132,638

See accompanying notes to the consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the years ended December 31,	
	2019	2018
Revenues	\$ —	\$ —
Operating expenses:		
General and administrative	2,226,837	408,425
Research and development	463,111	277,539
Total operating expenses	2,689,949	685,964
Net loss	(2,689,949)	(685,964)
Comprehensive loss:		
Foreign currency translation adjustment	(23,890)	(9,564)
Total comprehensive loss	\$ (2,713,839)	\$ (695,528)
Net loss per common share:		
Basic and diluted	\$ (0.22)	\$ (0.06)
Weighted-average common shares outstanding:		
Basic and diluted	12,021,650	10,570,933

See accompanying notes to the consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2017 . .	10,361,518	\$10,362	\$ 354,760	\$ (263,534)	\$ —	\$ 101,588
Issuance of common stock – net of issuance costs of \$10,442	138,482	138	127,902	—	—	128,040
Issuance of Units – net of issuance costs of \$9,070 . . .	266,667	267	390,663	—	—	390,930
Stock-based compensation expense	—	—	10,210	—	—	10,210
Warrant expense	—	—	59,434	—	—	59,434
Foreign currency translation adjustment	—	—	—	—	(9,564)	(9,564)
Net loss	—	—	—	(685,964)	—	(685,964)
Balance, December 31, 2018 . .	<u>10,766,667</u>	<u>\$10,767</u>	<u>\$ 942,969</u>	<u>\$ (949,498)</u>	<u>\$ (9,564)</u>	<u>\$ (5,326)</u>
Issuance of Units and warrants – net of issuance costs of \$236,705	883,502	884	1,562,919	—	—	1,563,803
Stock-based compensation expense	—	—	124,498	—	—	124,498
Warrant expense	—	—	89,151	—	—	89,151
Warrant exercise	858,855	859	857,996	—	—	858,855
Foreign currency translation adjustment	—	—	—	—	(23,890)	(23,890)
Net loss	—	—	—	(2,689,949)	—	(2,689,949)
Balance, December 31, 2019 . .	<u>12,509,024</u>	<u>\$12,509</u>	<u>\$3,577,533</u>	<u>\$(3,639,447)</u>	<u>\$(33,454)</u>	<u>\$ (82,859)</u>

See accompanying notes to the consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	<u>For the years ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
Cash flows from operating activities:		
Net loss	\$(2,689,949)	\$(685,964)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	664	—
Warrant expense	89,151	59,434
Stock-based compensation	124,498	10,210
Changes in operating assets and liabilities:		
Value added tax receivable	28,929	(28,489)
Prepaid expenses	6,376	(105,450)
Accounts payable and accrued expenses	319,929	2,942
Net cash used in operating activities	<u>(2,120,402)</u>	<u>(747,317)</u>
Cash flows from investing activities:		
Purchase of property and equipment	<u>(4,251)</u>	<u>—</u>
Cash flows from financing activities:		
Gross proceeds from issuance of common stock	—	138,482
Issuance costs related to the issuance of common stock	—	(10,442)
Gross proceeds from issuance of Units and warrants	1,776,500	400,000
Issuance costs related to the issuance of Units and warrants	(236,705)	(9,070)
Proceeds from the exercise of warrants	858,855	
Proceeds from subscription receivable	—	54,652
Deposit on equity units		24,008
Payment of deferred offering costs	(214,937)	—
Net cash provided by financing activities	<u>2,183,713</u>	<u>597,630</u>
Effect of changes in foreign currency exchange rates on cash	(23,973)	(6,871)
Net change in cash	35,087	(156,558)
Cash – beginning of year	1,660	158,218
Cash – end of year	<u>\$ 36,747</u>	<u>\$ 1,660</u>
Supplemental disclosures of cash flow information:		
Non-cash financing activity:		
Units issued on advance deposit	\$ 24,008	\$ —
Deferred offering costs in accounts payable and accrued expenses	\$ 412,079	\$ —

See accompanying notes to the consolidated financial statements.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business

Nature of Operations

Scopus BioPharma Inc. (“Scopus”) was incorporated in the State of Delaware on April 18, 2017 under the name Project18 Inc. (“Project18”). On December 11, 2017, Project18 changed its name to Scopus BioPharma Inc. On June 1, 2017, Scopus acquired all the outstanding common stock of Vital Spark, Inc. (“VSI”) for a total purchase price of \$15. VSI had not engaged in any business transactions prior to the acquisition date. On July 8, 2018, Scopus formed a wholly-owned subsidiary, Scopus BioPharma Israel Ltd. (“SBI”), and has funded operations to date through intercompany loans.

Scopus and its subsidiary, VSI, are headquartered in New York, and SBI is headquartered in Jerusalem, Israel. Scopus, VSI and SBI are collectively referred to as the “Company”. The Company is a biotechnology company focused on developing novel therapeutics targeting the endocannabinoid system.

Going Concern

The provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 205-40, *Presentation of Financial Statements — Going Concern* (ASC 205-40) requires management to assess an entity’s ability to continue as a going concern within one year of the date the financial statements are issued. In each reporting period (including interim periods), an entity is required to assess conditions known and reasonably knowable as of the financial statement issuance date to determine whether it is probable an entity will not meet its financial obligations within one year from the financial statement issuance date. Substantial doubt about an entity’s ability to continue as a going concern exists when conditions and events, considered in the aggregate, indicate it is probable the entity will be unable to meet its financial obligations as they become due within one year after the date the financial statements are issued.

The Company is an early-stage company and has not generated revenues to date. As such, the Company is subject to all of the risks associated with early stage companies. Since inception, the Company has incurred losses and negative cash flows from operating activities which have been funded from the issuance of common stock and equity units (see Note 6). The Company does not expect to generate positive cash flows from operating activities in the near future, if at all, until such time it completes the development of its drug candidates, including obtaining regulatory approvals, and anticipates incurring operating losses for the foreseeable future.

The Company incurred net losses of \$2,689,949 and \$685,964 for the years ended December 31, 2019 and 2018, respectively, and has an accumulated deficit of \$3,639,447 as of December 31, 2019. The Company’s net cash used in operating activities was \$2,120,402 for the year ended December 31, 2019.

The Company’s ability to fund its operations is dependent upon management’s plans, which include raising capital through issuances of equity securities, securing research and development grants, generating sufficient revenues and controlling the Company’s expenses. A failure to raise sufficient capital, generate sufficient revenues, or control expenses, among other factors, will adversely impact the Company’s ability to meet its financial obligations as they become due and payable and to achieve its intended business objectives.

This evaluation is further impacted by the current spread of the COVID-19 coronavirus. While uncertain at this time, the extent of its impacts depends largely on the spread and duration of the outbreak, and may result in disruptions to capital raises, our employees, and vendors which could result in negative impacts to our operational and financial results.

Accordingly, management has concluded this raises substantial doubt of the Company’s ability to continue as a going concern within one year after the date the consolidated financial statements are issued.

The Company’s consolidated financial statements have been prepared on a going concern basis which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business (continued)

of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and pursuant to the rules and regulations of the United States Securities and Exchange Commission (“SEC”). All intercompany transactions and balances have been eliminated in consolidation.

Certain prior year amounts have been reclassified to conform to current year presentation. Certain amounts in the consolidated financial statements and accompanying notes may not add due to rounding. All percentages have been calculated using unrounded amounts.

Foreign Currency

The functional currency of Scopus and VSI is the US Dollar, and the functional currency of SBI is the Israeli New Shekel. All assets and liabilities of SBI are translated at the current exchange rate as of the end of the year and the related translation adjustments are recorded as a separate component of accumulated other comprehensive loss. Revenue and expenses are translated at average exchange rates in effect during the year. Foreign currency transaction gains and losses resulting from, or expected to result from, transactions denominated in a currency other than the functional currency are recognized in “General and administrative” expenses in the consolidated statements of comprehensive loss.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. Significant estimates in these consolidated financial statements include those related to the fair value of common stock, warrants, stock-based compensation, the provision or benefit for income taxes and the corresponding valuation allowance on deferred tax assets. In addition, management’s assessment of the Company’s ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates, judgments, and methodologies. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Due to the inherent uncertainty involved in making estimates, actual results could differ materially from those estimates.

Cash

The Company maintains its cash at major financial institutions with high credit quality. At times, the balance of its cash deposits may exceed federally insured limits, and there is no insurance on cash deposits within Israel. The Company has not experienced and does not anticipate any losses on deposits with commercial banks and financial institutions which exceed federally insured limits.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation on property and equipment is calculated using the straight-line method over the estimated useful lives of the assets as follows:

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

	Estimated Useful Life
Computer equipment	3years

Depreciation expense charged to operations for the years ended December 31, 2019 and 2018 amounted to \$664 and \$0, respectively.

Revenues

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers* (“ASC 606”), and its various amendments as of January 1, 2018. The core principle of ASC 606 is to recognize revenue when promised goods or services are transferred to customers in an amount equal to the consideration to which the entity expects to be entitled for those goods and services. ASC 606 defines a five-step process to achieve this core principle, and in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and for all other entities for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, although early adoption is permitted. As the Company has not generated any revenues from April 18, 2017 (inception) through December 31, 2019, the adoption did not have any impact on the Company’s financial position, results of operations and cash flows for the years ended December 31, 2019 or 2018.

Research & Development Expenses

Research and development expenses are expensed as incurred and consist principally of internal and external costs which includes the cost of patent licenses, contract research services, laboratory supplies, as well as development and manufacture of preclinical compounds and consumables.

Offering Costs

The Company capitalizes certain legal, accounting, and other third-party fees directly associated with in-process equity financing as deferred offering costs. The deferred offering costs are recognized as an offset against the proceeds upon consummation of the offering. As of December 31, 2019, the Company recognized \$627,016 of deferred offering costs related to the Company’s Proposed Public Offering (See Note 3). There were no deferred offering costs as of December 31, 2018.

Fair Value Measurements

Certain assets and liabilities are carried at fair value in accordance with U.S. GAAP. Fair value is defined as the price which would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. A three-tier fair value hierarchy which prioritizes the inputs used in the valuation methodologies, are as follows:

Level 1

Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2

Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets which are not active, or other inputs observable or can be corroborated by observable market data.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

Level 3

Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

At December 31, 2019 and 2018, the carrying amounts of the Company's financial instruments, including cash, deferred offering costs, accounts payable and accrued expenses, and advance deposit on equity units, approximate their respective fair value due to the short-term nature of these instruments.

Income Taxes

Income taxes are accounted for under the asset and liability method, as required by FASB ASC Topic 740, *Income Taxes*. The Company provides for foreign, federal, and state income taxes currently payable, as well as for those deferred due to timing differences between reporting income and expenses for financial statement purposes versus tax purposes and for the expected future tax benefit to be derived from tax loss and tax credit carry forwards. Deferred tax assets and liabilities are recognized for the future tax consequences attributed to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted income tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

The effect of a change in income tax rates is recognized as income or expense in the period that includes the enactment date. The Company and VSI file a consolidated U.S. federal and combined New York State and New York City income tax return, and SBI files a foreign income tax return with the Israel Tax Authority.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. There were no uncertain tax positions as of December 31, 2019 and 2018.

Stock-Based Compensation

The Company accounts for share-based payments in accordance with *ASU 2018-07 — Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, as of January 1, 2018 to account for non-employee stock-based compensation in accordance with FASB ASC Topic 718, *Stock Compensation* (which previously included only share-based payments to employees and non-employee directors). Under the guidance, the fair value of share-based payments granted to non-employees are no longer required to be re-measured each reporting period over the vesting term. The Company measures and records compensation expense related to share-based payment awards based on the grant date fair value using the Black-Scholes option pricing model. Forfeitures are recognized when they occur. The Company calculates the fair value of options granted using the Black-Scholes option-pricing model using the following assumptions:

Expected Volatility — Due to the lack of substantial company-specific historical and implied volatility data of its common stock, the Company has based its estimate of expected volatility on the historical volatility of a group of similar public companies. When selecting these companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

Expected Term — The expected term of the Company’s options represents the period that the stock-based awards are expected to be outstanding. The Company has limited historical data upon which it can estimate the expected lives of the share-based payment awards and accordingly has used the simplified method allowable under SEC Staff Accounting Bulletin Topic 14 for employee holders and the contractual term for non-employee holders.

Risk-Free Interest Rate — The risk-free interest rate is based on the implied yield currently available on US Treasury zero-coupon issues with a term that is equal to the expected term of the options at the grant date.

Dividend Yield — The Company has not declared or paid dividends to date and does not anticipate declaring dividends in the foreseeable future. As such, the dividend yield has been estimated to be zero.

Net Loss Per Share

Basic net loss per common share attributable to common shareholders is calculated by dividing net loss attributable to common shareholders by the weighted average number of common shares outstanding for the year. Since the Company was in a loss position for all years presented, basic net loss per share is the same as dilutive net loss per share as the inclusion of all potential dilutive common shares which consist of stock options and warrants, would be anti-dilutive.

JOBS Act Accounting Election

The Company is an “emerging growth company”, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to avail itself of this exemption from new or revised accounting standards, and, therefore, will not be subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. The FASB issued this update to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The guidance of ASU 2016-02 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that reporting period, and for all other entities, the amendments are effective for fiscal years beginning after December 15, 2020, and interim periods within that reporting period. The Company does not currently hold any leases and therefore its adoption of ASU 2016-02 is not expected to have a material impact on the consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (“ASU 2017-11”)*. Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies (continued)

Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect.

The amendments in Part I of this ASU are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company's early adoption of ASU 2017-11 on January 1, 2019 did not have a material impact on the consolidated financial statements.

The Company, an emerging growth company, has elected to take advantage of the benefits of the extended transition period provided for in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards, which allows the Company to defer adoption of certain accounting standards until those standards would otherwise apply to private companies unless otherwise noted.

The Company has reviewed other recent accounting pronouncements and concluded they are either not applicable to the business or no material effect is expected on the consolidated financial statements as a result of future adoption.

3. Proposed Public Offering

The Company is undertaking a proposed public offering of its securities (the "Proposed Public Offering"). The Company intends to seek a trading market for its securities on an exchange, OTC Market, or alternative trading venue.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of:

	<u>December 31, 2019</u>	<u>December 31, 2018</u>
Professional fees	\$559,706	\$ 30,550
Due to affiliate	645	18,923
Patent license fees	36,719	36,717
Management services fees and expenses	70,197	27,766
Other accounts payable and accrued expenses	<u>187,274</u>	<u>—</u>
Total accounts payable and accrued expenses	<u>\$854,541</u>	<u>\$113,956</u>

Amounts due to affiliate includes expenses incurred by HCFP LLC on behalf of the Company (see Note 8, Related Party Transactions).

5. Commitments and Contingencies

Agreement Related to Intellectual Property Rights

In July 2017, VSI as "Licensee" entered into a Patent License Agreement (the "Patent License Agreement") with The U.S. Department of Health and Human Services, as represented by the National Institute on Alcohol Abuse and Alcoholism ("NIAAA") and the National Institute on Drug Abuse ("NIDA") of the National Institutes of Health ("NIH"), (collectively "Licensor"). In the course of conducting

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Commitments and Contingencies (continued)

biomedical and behavioral research, the Licensor developed inventions that may have commercial applicability. The Licensee acquired commercialization rights to certain inventions in order to develop processes, methods, or marketable products for public use and benefit.

Upon execution of the Patent License Agreement, VSI paid the Licensor an aggregate of \$121,040, which included an upfront non-refundable fee of \$50,000 and \$71,040 for certain patent expenses incurred by the Licensor prior to the execution of the Patent License Agreement relating to patent applications. The Company determined that the Patent License Agreement did not meet the definition of a business pursuant to the guidance prescribed in FASB ASC Topic 805, *Business Combinations*, as the transaction principally resulted in the acquisition of intellectual property rights only. In this regard, the Company did not acquire any employees or tangible assets, or any processes, protocols, or operating systems. Additionally, at the time of the transaction, there were no activities being conducted related to the licensed patents. The Company recognized as expense the acquired intellectual property rights as of the transaction date on the basis that the costs of an intangible asset purchased from others for use in a research and development activity for which there are no alternative future uses are recorded as research and development expense at the time such costs are incurred. In addition, patent fee reimbursement under the Patent license agreement was \$25,920 and \$25,918 for the years ended December 31, 2019 and 2018, respectively, and are included in “Research and development” expenses in the accompanying consolidated statements of comprehensive loss.

Pursuant to the terms of the Patent License Agreement, VSI is required to make minimum annual royalty payments of \$25,000, with the first payment due on January 1, 2019. The Company paid the first annual payment of \$25,000 in January 2019, which is included in “Research and development” expenses in the accompanying consolidated statements of comprehensive loss. Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and shall be credited against any earned royalties due for sales made in that year, throughout the term of the Patent License Agreement. The Company paid the second annual payment of \$25,000 in December 2019, which is included in “Prepaid expenses” in the accompanying consolidated balance sheets. The Patent License Agreement also provides for payments from VSI to the Licensor upon the achievement of certain product development and regulatory clearance milestones, as well as royalty payments on net sales upon the commercialization of products developed utilizing the licensed patents. Through December 31, 2019, the Licensor has not achieved any milestones and therefore VSI has not made any milestone payments.

VSI is obligated to pay earned royalties based on a percentage of net sales, as defined in the Patent License Agreement, of licensed product throughout the term of the Patent License Agreement. Since April 18, 2017 (inception) through December 31, 2019, there have been no sales of licensed products. In addition, VSI is also obligated to pay the Licensor additional sublicensing royalties on the fair market value of any consideration received for granting each sublicense. Through December 31, 2019, VSI has not entered into any sublicensing agreements and therefore no sublicensing consideration has been paid to Licensor.

Cooperative Research and Development Agreement

Effective January 11, 2018, VSI signed a two-year Cooperative Research and Development Agreement (the “CRADA Agreement”) with the NIH for preclinical testing relating to the Patent License Agreement described above. The term of the CRADA Agreement can be extended, beyond the initial two-year term, by agreement in writing by both parties. Pursuant to the terms of the CRADA Agreement, each party will provide scientific staff and other support necessary to conduct the research and other activities described in the research plan. Funds provided by VSI pursuant to the terms of the CRADA Agreement will be used by the NIH to acquire technical, statistical, and administrative support for the research activities, as well as pay for supplies and travel expenses.

Effective October 31, 2018, VSI and NIH amended the CRADA Agreement to defer funding for year two subject to additional testing by NIH and approval of the results by VSI. Subsequently, on May 6, 2019,

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Commitments and Contingencies (continued)

VSI and NIH entered into a second amended agreement to proceed with the second year of the agreement pursuant to an updated research plan. On May 7, 2019, the Company made the first of two equal payments of \$55,870 to NIH.

Total expenses incurred in connection with the CRADA Agreement for the years ended December 31, 2019 and 2018 amounted to \$80,701 and \$130,000, respectively, and are included in “Research and development” expenses in the accompanying consolidated statements of comprehensive loss.

Memorandums of Understanding

Effective July 28, 2018, SBI entered into two Memorandums of Understanding (“MOUs”) with Yissum Research Development Company (“Yissum”) of the Hebrew University of Jerusalem Ltd. (“Hebrew University”). Pursuant to the terms of the MOUs, SBI shall provide funding for research and development studies to be performed by researchers at Hebrew University in the areas of cannabinoid therapeutics and cannabinoid synthesis over a two-year period. Funds provided by SBI pursuant to the terms of MOUs will be used by the researchers at Hebrew University to acquire technical, statistical, and administrative support for the research activities, as well as pay for supplies. SBI has the exclusive right to license the study results by providing written notice to Yissum during the respective study periods or within 60 days of the studies’ completion. Upon providing such notice, SBI and Yissum shall negotiate a license agreement for the commercial development and exploitation of the study results. SBI shall be entitled to reimbursement of the amounts funded for the research and development studies and patent prosecution costs, if any, in the event Yissum enters into a license agreement with a third party, subject to certain conditions.

The fees incurred in connection with these MOU’s for the years ended December 31, 2019 and 2018 amounted to \$215,740 and \$62,187, respectively, and are included in “Research and development” expenses in the accompanying consolidated statements of comprehensive loss. The Company also recorded a prepaid expense of \$29,646 and \$103,044 in connection with these MOU’s which are included in “Prepaid expenses” in the accompanying consolidated balance sheets as of December 31, 2019 and 2018, respectively.

Effective March 5, 2019, the Company entered in a license agreement with Yissum with respect to the results of the research relating to the combination of cannabidiol with approved anesthetics as a potential treatment for the management of pain. Under the license agreement, the Company is obligated to pay earned royalties based on a percentage of net sales, as defined in the license agreement, including net sales generated from sub-licensees. In addition, the Company will be obligated to make payments upon the achievement of certain clinical development and product approval milestones. From March 5, 2019 through December 31, 2019, there have been no sales of licensed products by the Company nor has the Company entered into any sub-licensing agreements. Further, none of the milestones in the agreement have been reached and therefore as of December 31, 2019, there is no obligation to make any milestone payments.

Effective August 8, 2019, the Company entered into a second license agreement with Yissum with respect to the research results relating to the synthesis of novel cannabinoid dual-action compounds and novel chemical derivatives of cannabigerol and tetrahydrocannabivarin. Under this license agreement, the Company is required to pay earned royalties based upon a percentage of net sales at one percentage for regulated products and a lesser percentage for non-regulated products. The Company is obligated to pay development milestone payments tied to regulated products totaling \$1,225,000 in the aggregate and \$100,000 for non-regulated products in the aggregate. None of the milestones in the agreement have been reached and therefore as of December 31, 2019 there is no obligation to make any milestone payments.

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. Notwithstanding, legal proceedings are subject to inherent uncertainties, and an

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5. Commitments and Contingencies (continued)

unfavorable outcome, if such event were to occur, could include monetary damages and could result in a material adverse impact on the Company's business, financial position, results of operations, and cash flows.

6. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 20,000,000 shares of preferred stock with a par value of \$0.001 per share with such designation, rights and preferences as may be determined from time-to-time by the Company's board of directors. All 20,000,000 shares remained unissued as of December 31, 2019.

Authority is expressly vested in the board of directors to authorize the issuance of one or more series of preferred stock.

Common Stock

The Company is authorized to issue 50,000,000 shares of common stock with a par value of \$0.001 per share. The number of authorized shares of common stock may be increased or decreased (but not below the number of shares of common stock then outstanding) by an affirmative vote of the holders of a majority of the common stock.

On June 1, 2017, the Company issued 10,000,000 shares of its common stock at a price of \$0.001 per share to HCFP II LLC ("HCFP II"), an affiliated entity, as founders' stock, for an aggregate purchase price of \$10,000. On June 2, 2017, HCFP II transferred such shares to other affiliated entities.

In December 2017 and January 2018, the Company issued a total of 361,518 and 138,482 shares, respectively, at a price of \$1.00 per share, resulting in net proceeds of \$355,122 and \$128,040, respectively, after issuance costs.

The powers, preferences and rights of the holders of the common stock are junior to the preferred stock and are subject to all the powers, rights, privileges, preferences and priorities of the preferred stock. The holder of each share of common stock shall have the right to one vote per share. Each holder of common stock shall be entitled to receive dividends and distributions (whether payable in cash or otherwise) as declared by the board of directors of the Company, subject to the rights of any class of preferred stock outstanding. In the event of any liquidation, dissolution or winding-up of the Company (whether voluntary or involuntary), the assets available for distribution to holders of common stock will be in equal amounts per share.

Equity Units

On July 20, 2018, the Company offered up to 266,667 units at a price of \$1.50 per unit (the "\$1.50 Units") in a private placement transaction. During the first quarter of 2019, the Company increased the private offering of \$1.50 Units to 1,000,000 units, on the same terms. Each \$1.50 Unit is comprised of one share of the Company's common stock and two warrants ("\$1.50 Unit Warrants"). Each \$1.50 Unit Warrant is exercisable for one share of the Company's common stock at a price of \$1.00 per share, expires on July 31, 2023, and carries a mandatory exchange feature as described in the relevant warrant subscription agreement. The exercise price is not subject to adjustment, except in the event of stock dividends and stock splits. Further, in the event of a Fundamental Transaction, as defined in the agreement, the holders can participate *pari passu* with common stockholders in the consideration paid by an acquirer for the Company's shares. The Company issued a total of 266,667 \$1.50 Units in 2018 resulting in net proceeds of \$390,930 after issuance costs. The Company received \$24,008 in 2018 relating to 16,005 \$1.50 Units which were subsequently issued in January 2019 following the increase in number of \$1.50 Units offered. The Company recorded

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Stockholders' Equity (continued)

the \$24,008 as an advance deposit on equity units as of December 31, 2018 which was reclassified to equity upon issuance of the applicable \$1.50 Units in January 2019.

During the year ended December 31, 2019, the Company sold an additional 717,328 \$1.50 Units (excluding the 16,005 \$1.50 Units that were issued in January 2019 related to the advance deposits received in 2018 for such \$1.50 Units) resulting in net proceeds of \$1,071,230 after issuance costs.

The holders of the \$1.50 Unit Warrants discussed above have the same rights to receive dividends or other distribution of assets as the holders of common stock. As such, these \$1.50 Unit Warrants are considered participating securities under the two-class method of calculating the net loss per share. The Company has incurred net losses to date, and as the holders of these \$1.50 Unit Warrants are not contractually obligated to share in the losses, there is no impact on the Company's net loss per share calculation for the years presented.

On May 6, 2019, pursuant to the terms of the \$1.50 Unit Warrants, the Company provided a Notice of Trigger Date to the holders of its \$1.50 Unit Warrants informing such holders that the deadline to exercise their \$1.50 Unit Warrants at an exercise price of \$1.00 per share was May 16, 2019 (the "Trigger Date"). Any \$1.50 Unit Warrants not exercised by the Trigger Date will automatically become identical to and of the same class as the warrants to be issued by the Company in the Proposed Public Offering, as more fully described below. A total of 858,855 \$1.50 Unit Warrants were exercised in connection with such notice generating \$858,855 in proceeds for the Company.

On June 11, 2019, the Company offered up to 200,000 units at a price of \$3.00 per unit in a private placement transaction (the "\$3.00 Units"). Each \$3.00 Unit is comprised of one share of the Company's common stock and two warrants ("\$3.00 Unit Warrants"). Each \$3.00 Unit Warrant shall be identical to and be of the same class as the warrants to be issued in the Proposed Public Offering, as more fully described below. Through December 31, 2019, the Company issued 150,169 of the \$3.00 Units resulting in net proceeds of \$330,132 after issuance costs.

Series X Warrants

On December 10, 2019, the Company offered up to 1,000,000 Series X warrants ("X Warrants") at a price of \$0.50 per X Warrant in a private placement transaction ("December 2019 Private Placement"). Through December 31, 2019, the Company issued 500,000 of the X Warrants resulting in net proceeds of \$138,432 after issuance costs. On January 9, 2020, the Company issued an additional 4,000 of the X Warrants and the issuance of these X Warrants resulted in \$2,000 of additional proceeds net of issuance costs.

In April 2020, the Company amended the terms of its December 2019 Private Placement ("Amended Private Placement") to issue convertible promissory notes (the "Notes") in an initial principal amount of up to \$1,000,000 with an annual interest rate of 10% and scheduled maturity on the earlier of July 31, 2021 or a change of control of the Company (the "Maturity Date"). Prior to the Maturity Date, the holder may convert each \$1.00 of initial principal amount of Notes purchased into X Warrants at a conversion price of \$0.50 per X Warrant. In addition, for each \$1.00 of initial principal amount of Notes purchased, investors will receive one X Warrant. As part of the issuance of the Notes, investors who purchased X Warrants in the December 2019 Private Placement prior to the amendment of its terms described herein may elect to surrender two X Warrants for the purchase of \$1.00 initial principal amount of the Notes. Further, the Company issued convertible promissory notes with an aggregate principal amount of \$436,230 and 436,230 X Warrants in a direct offering, on the same terms as the Amended Private Placement (the "Company Direct Offering"), for \$187,500 in cash and the balance as consideration of legal services rendered. An additional 100,000 X Warrants were also issued in connection with such legal services.

Each X Warrant shall automatically become identical to and of the same class as the Series W Warrants to be offered in the Company's Proposed Public Offering, the definitive terms of which will not be established

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Stockholders' Equity (continued)

until the initial issuance of such W Warrants in connection with the Proposed Public Offering. Each W Warrant is expected to be exercisable for one Series B Unit ("Series B Unit") for a five-year period from October 1, 2021 to September 30, 2026 at a price of \$4.00. Each Series B Unit is comprised of one share of the Company's common stock and one Series Z warrant ("Z Warrant"). Each Z Warrant is expected to be exercisable for one share of common stock for a five-year period from July 1, 2022 to June 30, 2027 for a price of \$5.00 per share.

Yissum Warrants

On October 3, 2018, the Company issued a warrant to Yissum, entitling Yissum to purchase up to 450,000 shares ("Warrant Shares") of the Company's common stock at an exercise price of \$1.50 per share of common stock and which warrant expires on October 3, 2025. This warrant was issued as consideration to Yissum in connection with the execution of the MOUs (see Note 5). Upon issuance of this warrant, it was immediately exercisable for 50,000 Warrant Shares. Additional Warrant Shares vest upon the execution of license agreements within a specified number of days upon notice by the Company of its intent to enter into such license agreements. The Company determined that as of December 31, 2018, it was probable that the Company would enter into at least one license agreement. Accordingly, for the year ended December 31, 2018, the Company recognized compensation expense for the 50,000 Warrant Shares that were immediately exercisable upon issuance of the warrant and 50,000 Warrant Shares relating to the probable execution of a license agreement.

Effective March 5, 2019 and August 8, 2019, the Company entered into separate license agreements with Yissum with respect to the results and intellectual property generated from research being conducted at Hebrew University under one of the MOUs (see Note 5). As a result of the first and second license agreements being executed within a specified period after notice, the Company recognized compensation expense in connection with the vesting of an additional 50,000 and 100,000 Warrant Shares, respectively.

The estimated fair value of the Yissum Warrants at grant date was \$0.59 per Warrant Share, calculated using Black-Scholes option pricing model using the following assumptions; fair value of underlying common stock of \$1.00, contractual life of 7 years; risk free interest rate of 3.06%; volatility of 68%, and dividend yield of 0%. There has been no history of dividend payments and there are no expectations of dividend payments during the next several years.

The Company recognized compensation expense related to Warrant Shares of \$89,151 and \$59,434 for the years ended December 31, 2019 and 2018, respectively, which is included in "Research and development" expenses in the accompanying consolidated statements of comprehensive loss.

The table below summarizes all warrant activity for the year ended December 31, 2019:

	Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2018	983,334	\$1.23
Granted	2,267,004	2.06
Exercised	(858,855)	1.00
Forfeited	—	—
Outstanding at December 31, 2019	2,391,483	\$2.10
Warrants exercisable at December 31, 2019	1,391,145	\$1.09

As of December 31, 2019, the remaining contractual term of the outstanding warrants was 6.15 years.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

7. Stock Options

Effective September 24, 2018, the Company approved the Scopus BioPharma Inc. 2018 Equity Incentive Plan (the “Plan”), and reserved 1,000,000 shares of the Company’s common stock, for issuance under the Plan, which, effective as of August 1, 2019, was increased to 2,400,000 shares. The stock options shall be granted at an exercise price per share equal to at least the fair market value of the shares of common stock on the date of grant and generally vest over a three-year period.

The assumptions used to calculate the fair value of stock options granted is as follows:

	Years ended December 31,	
	2019	2018
Weighted average common stock price	\$ 2.00	\$ 1.00
Expected dividend rate	0%	0%
Expected option term (years)	6.0 – 10.0	6.0 – 10.0
Weighted average expected stock price volatility	87%	68%
Risk-free interest rate	1.6% – 2.1%	3.2%

Stock option activity is summarized as follows for December 31, 2019:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Grant Date Fair Value
Outstanding at December 31, 2018	175,000	\$1.50	\$0.70
Granted	425,000	\$3.00	\$1.41
Exercised	—	—	—
Forfeited	—	—	—
Outstanding at December 31, 2019	600,000	2.56	1.21
Vested and exercisable at December 31, 2019	132,138	\$2.17	\$1.43
Unvested at December 31, 2019	467,862	\$2.67	\$1.14

Stock-based compensation associated with vesting options was \$124,498 and \$10,210 for the years ended December 31, 2019 and 2018, respectively, and is included in “General and administrative” expenses in the accompanying consolidated statements of comprehensive loss. As of December 31, 2019, total unrecognized stock-based compensation expense of \$588,331 is expected to be recognized over the remaining weighted-average term of 2.49 years.

8. Related Party Transactions

On September 1, 2017, the Company entered into a management services agreement, as amended, with HCFP/Strategy Advisors LLC (“HCFP/Strategy Advisors”), an affiliated entity, to provide management services to the Company including, without limitation, financial and accounting resources, general business development, corporate development, corporate governance, marketing strategy, strategic development and planning, coordination with service providers and other services as agreed upon between the parties. The Company pays HCFP/Strategy Advisors a monthly management services fee plus related expense reimbursement.

This management services agreement was in effect for a period of one year and was automatically renewable for successive one-year terms unless terminated prior to the end of such term as set forth in the management services agreement.

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

8. Related Party Transactions (continued)

Effective January 9, 2018, HCFP/Strategy Advisors assigned its management services agreement with the Company to HCFP/Portfolio Services LLC (“HCFP/Portfolio Services”), an affiliated entity.

Effective July 1, 2018, the Company amended the management services agreement with HCFP/Portfolio Services to include an additional monthly fee of \$1,500 for the provision of office space and facilities to the Company, which was subsequently increased to \$3,000 effective May 1, 2019. Effective January 1, 2019 the monthly management services fee was increased from \$10,000 to \$25,000 per month and effective July 1, 2019, this fee was increased to \$40,000 per month.

For the years ended December 31, 2019 and 2018, the Company incurred expenses of \$420,000 and \$129,000, respectively, related to this management services agreement which are included in “General and administrative” expenses in the accompanying consolidated statements of comprehensive loss. At December 31, 2019, the amount prepaid to HCFP/Portfolio Services was \$40,000 and is included in “Prepaid expenses” on the accompanying consolidated balance sheets. At December 31, 2018, the amount due to HCFP/Portfolio Services was \$10,000 and is included in “Accounts payable and accrued expenses” on the accompanying consolidated balance sheets.

On September 1, 2017, the Company entered into a management services agreement, as amended, with Clil Medical Ltd. (“Clil”) for Morris C. Laster, M.D., the sole principal of Clil, to serve as the Company’s Chief Executive Officer. The Company shall pay Clil a monthly management services fee, plus related expense reimbursements. This agreement was in effect for a period of one year and is automatically renewable for successive one-year terms unless terminated prior to the end of such term as set forth in the management services agreement. Effective January 1, 2019 the monthly management services fee was increased from \$10,000 to \$25,000 per month. For the years ended December 31, 2019 and 2018, the Company incurred expenses of \$301,442 and \$127,143, respectively, related to this management services agreement which are included in “General and administrative” expenses in the accompanying consolidated statements of comprehensive loss. At December 31, 2019 and 2018, the total amounts due to Clil were \$70,197 and \$17,766, respectively, and are included in “Accounts payable and accrued expenses” on the accompanying consolidated balance sheets.

From time to time, HCFP LLC, an affiliated entity, pays certain expenses on behalf of the Company, which are subsequently reimbursed by the Company. At December 31, 2019 and 2018, the Company had a net payable to this affiliate in the amount of \$645 and \$18,923, respectively, which is included in “Accounts payable and accrued expenses” in the accompanying consolidated balance sheets.

During the year ended December 31, 2019, the Company expensed and paid HCFP/Strategy Advisors an aggregate of \$200,000 for strategy advisory and consulting services related to analyses of the cannabinoid therapeutic industry, including an analysis of the legal and regulatory landscape for cannabis and cannabis-related products including, but not limited to, cannabinoid therapeutics, potential compounds available for licensing opportunities and arrangements, and optimal regulatory pathways, which is included in “General and administrative” expenses in the accompanying consolidated statements of comprehensive loss.

On March 28, 2019, the Company entered into an agreement with HCFP/Capital Markets LLC (“Capital Markets”), an affiliated entity, to serve as the exclusive placement agent in a private offering of the Company’s securities (the \$3.00 Units — see Note 6). For the year ended December 31, 2019, the Company paid Capital Markets \$95,051 for certain documentation and placement fees and a non-accountable expense allowance for such services in accordance with the terms of the related agreement.

On December 10, 2019, the Company entered into an agreement with Capital Markets to serve as the exclusive placement agent in a private offering of the Company’s securities (the December 2019 Private Placement or Amended Private Placement, as the case may be — see Note 6). HCFP/Direct Investments LLC (“Direct Investments”), an affiliated entity, purchased 224,000 X Warrants in the December 2019 Private Placement on the same terms as the non-affiliated investors. The Company shall pay placement agent fees

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

8. Related Party Transactions (continued)

and a non-accountable expense allowance for such services in accordance with the terms of the related agreement. For the year ended December 31, 2019, the Company incurred expenses of \$25,000 in connection with this agreement and paid Capital Markets \$18,500. As of December 31, 2019, the total amount due to Capital Markets was \$6,500 and is included in “Accounts payable and accrued expenses” on the accompanying consolidated balance sheet.

In January and February 2020, Direct Investments advanced a total of \$47,430 to the Company. On February 26, 2020, the Company repaid such advances in full in an amount equal to \$47,698, including \$268 in interest.

On April 9, 2020, one of the Company’s directors invested \$7,500 in the convertible promissory notes issued as part of the Company Direct Offering.

9. Income Taxes

The components of the income tax benefit are as follows:

	For the years ended December 31,	
	2019	2018
Current:		
Federal, State, and Foreign	\$ —	\$ —
Deferred:		
Federal	519,147	143,858
State and local	253,681	93,172
Foreign	66,458	18,692
Total taxes deferred	839,286	255,722
Valuation allowance	(839,286)	(255,722)
Net deferred tax	\$ —	\$ —

The reconciliation of the provision for income taxes at the federal statutory rate of 21% to the actual tax expense or benefit for the applicable years were as follows:

	For the years ended December 31,	
	2019	2018
Statutory Federal tax	\$(564,889)	\$(144,053)
Meals and entertainment	10,909	195
Stock-based compensation	11,585	—
Non-deductible expenses	28,424	—
State and local taxes	(252,605)	(93,172)
Foreign taxes	(71,475)	(18,692)
Other	(1,235)	—
Change in valuation allowance	839,286	255,722
Income tax expense (benefit)	\$ —	\$ —

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Income Taxes (continued)

Deferred tax assets and liabilities consist of the following:

	December 31,	
	2019	2018
Deferred tax assets:		
Start-up costs	\$ 33,848	\$ 36,451
Patents	71,585	59,176
Non-qualified stock options	78,920	24,093
Net operating losses	908,401	208,437
OCI – Unrealized foreign exchange loss	11,573	3,308
Foreign research costs	29,610	8,683
Foreign net operating loss	55,540	10,009
Total deferred tax assets	1,189,477	350,159
Deferred tax liabilities		
Fixed assets	(32)	—
Valuation allowance	(1,189,445)	(350,159)
Net deferred tax assets	\$ —	\$ —

The Company has available approximately \$11,000 of U.S. net operating loss carryovers which expire by 2037, and \$2,853,000 and \$241,500 of Federal US and foreign net operating losses carryovers, respectively, with indefinite lives. In addition, the Company has available approximately \$2,863,000 of state net operating loss carryovers that begin to expire in 2037. ASC 740 requires a “more likely than not” criterion be applied when evaluating the realization of a deferred tax asset. Management does not expect that it is more likely than not that the Company will generate sufficient taxable income in future years to utilize the deferred tax assets. Accordingly, the Company has recorded a full valuation allowance against the deferred tax assets.

As of December 31, 2019, the fiscal tax years 2017 through 2018 remain open to examination by the Internal Revenue Service. There are currently no federal tax examinations in progress.

Under the provisions of Section 382 of the Internal Revenue Code, net operating loss and other tax attributes may be subject to limitation if there has been a significant change in ownership of the Company, as defined by the Internal Revenue Code. Future owner or equity shifts, including an IPO, could result in limitations on net operating loss and credit carryforwards. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company’s formation due to the significant complexity and cost associated with such study and because there could be additional changes in control in the future. As a result, the Company is not able to estimate the effect of the change in control, if any, on the Company’s ability to utilize net operating loss carryforwards.

10. Subsequent Events

The Company has evaluated subsequent events through May 15, 2020, which is the date the consolidated financial statements were available to be issued. Any material subsequent events that occurred during this time have been properly recognized or disclosed in the consolidated financial statements and accompanying notes (see Note 6).

The Company has also considered the spread of the COVID-19 coronavirus outbreak, which the World Health Organization has declared a “Public Health Emergency of International Concern.” The COVID-19 outbreak is disrupting supply chains and affecting production and sales across a range of industries. The

SCOPUS BIOPHARMA INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

10. Subsequent Events (continued)

extent of the impact of COVID-19 on the Company's operational and financial performance will depend on certain developments, including the duration and spread of the outbreak and its impact on the Company's employees and vendors, all of which are uncertain and cannot be predicted. At this point, the extent to which COVID-19 may impact the Company's financial condition or results of operations is uncertain.

1,000,000 Shares



Common Stock

Sole Bookrunning Manager

The Benchmark Company

Co-Manager

Joseph Gunnar & Co., LLC

January 26, 2021
