

ANNUAL REPORT

BIOCURITY PHARMACEUTICALS INC.



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In this report, the term “BioCurity,” “we,” “us,” “our” or “the Company” refers to BioCurity Pharmaceuticals Inc. a Delaware corporation and its wholly owned subsidiary, BioCurity, Inc. (a Delaware corporation and successor in interest to BioCurity, Inc., a Florida corporation).

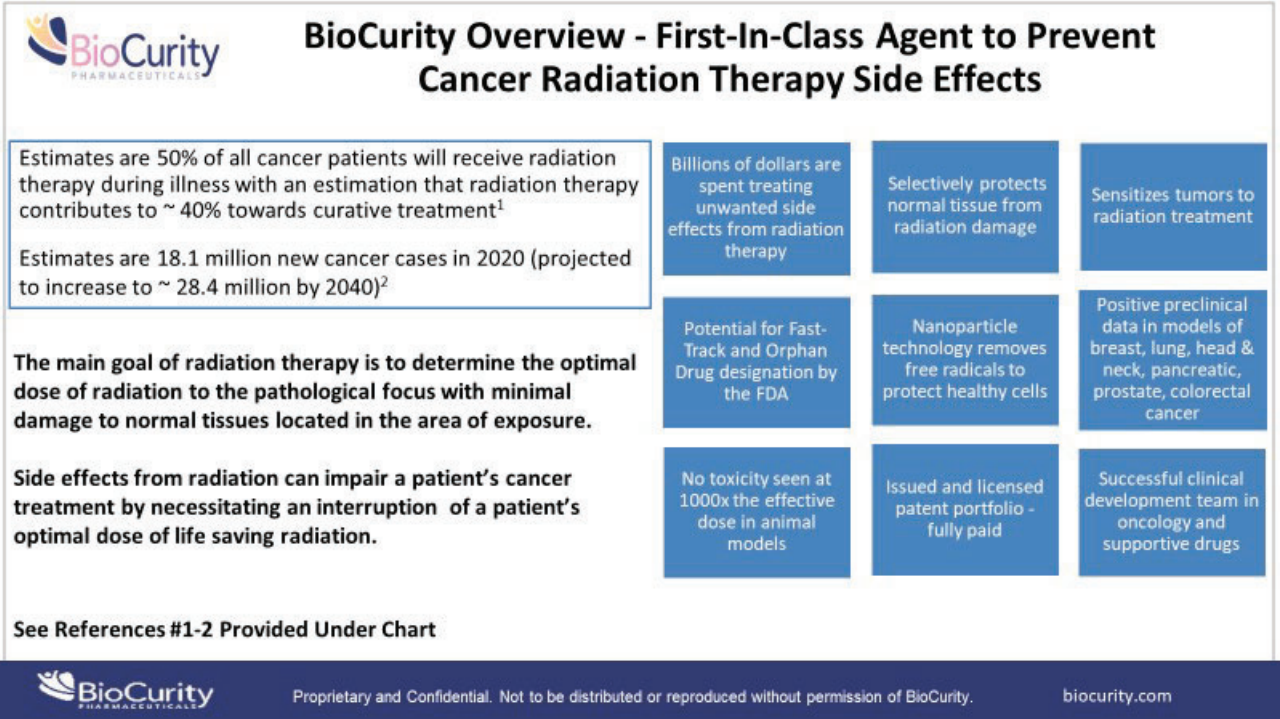
The Company has offered and sold its Series CF and Series 2 CF Convertible Preferred Stock pursuant to Regulation Crowdfunding under the Securities Act of 1933 and is filing this annual report pursuant to Rule 202 of Regulation Crowdfunding for the fiscal year ended December 31, 2022. A copy of this report may be found on the Company's website at www.biocurity.com.

This report may contain forward-looking statements and information relating to, among other things, the Company, its business plan and strategy, and its industry. These forward-looking statements are based on the beliefs of, assumptions made by, and information currently available to the Company’s Board of Directors. When used in this report and the Company’s offering materials, the words “estimate,” “project,” “believe,” “anticipate,” “intend,” “expect,” and similar expressions are intended to identify forward-looking statements. These statements reflect the Company’s Board of Director’s current views with respect to future events and are subject to risks and uncertainties that could cause the company’s action results to differ materially from those contained in the forward-looking statements. Investors are cautioned not to place undue reliance on these forward- looking statements to reflect events or circumstances after such state or to reflect the occurrence of unanticipated even or circumstances after such state or to reflect the occurrence of unanticipated events.

THE COMPANY AND ITS BUSINESS

We are a preclinical biopharmaceutical Company focused on developing proprietary drugs designed to transform radiation therapy by preventing side effects of radiation therapy as well as enhance treatment outcomes and improve the quality of life for cancer patients. We leverage our expertise in novel mechanism-based Cerium oxide nanoparticles intended to prevent normal tissue damage from radiation therapy without interfering with the effectiveness of radiation on the cancerous tissue. We have developed two formulations of Cerium oxide nanoparticle drug product to prevent tissue damage from radiation causing short and long-term side effects. An IV formulation for the protection of normal internal tissue and a topical formulation for the protection of skin tissue.

The drug products have been studied in proof-of-concept animal models of breast, lung, head and neck, pancreatic, prostate, and colorectal cancers. Approximately 50% of all cancer patients will receive radiation therapy at some point in their cancer treatment. With approximately 18 million new cancer patients a year globally, the number of new cancer patients expected to receive radiation is projected to increase. This increase in growth in the use of radiation therapy is also driven by the number of new cancer cases reported annually, patient longevity, lifestyle changes as well as population growth. Fast track and orphan drug designations by the FDA in some indications for our drugs under development is possible. The chart below developed with the assistance of our clinical development team contains information that establishes BioCurity as a First-in-Class Agent to Prevent Radiation Side Effects.



¹Michael Baumann, et al. “What will radiation oncology look like in 2050? A look at a changing professional landscape in Europe and beyond.” *Molecular Oncology* 14:1577–1585, 2020.

²Hyuna Sung, et al. “Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries.” *CA Cancer J Clin.* 71:209-249, 2021.

The short and long-term side effects of radiation therapy to various organs and tissues in humans have been well characterized, can impair a cancer patient's medical treatment plan, and can leave cancer survivors with permanent adverse conditions. These side effects can have a significant impact on a patient's quality of life and contribute to additional healthcare costs. For example, head and neck cancer patients experience a loss in saliva production, resulting in dry mouth, difficulty eating and swallowing and in severe cases malnutrition may require nutrition through a feeding tube. For lung cancer patients, radiation-induced lung scarring and fluid in the lungs can cause persistent coughing and inability to breathe. Burning and blistering and permanent scarring of the skin can also result in cancer patients undergoing radiation therapy.

We believe, if approved, our drug products would be prescribed by and provide physicians with the flexibility and the tools needed for dosing patients properly while ensuring a robust life cycle.

We retain worldwide rights on our drug candidates, with a broad and global patent portfolio on each of the formulations developed providing highly relevant patent coverage with supporting claims to protect our proposed clinical development strategy. Our drug candidate portfolio is protected by US and International issued patents with claims directed to composition of matter and method of use.

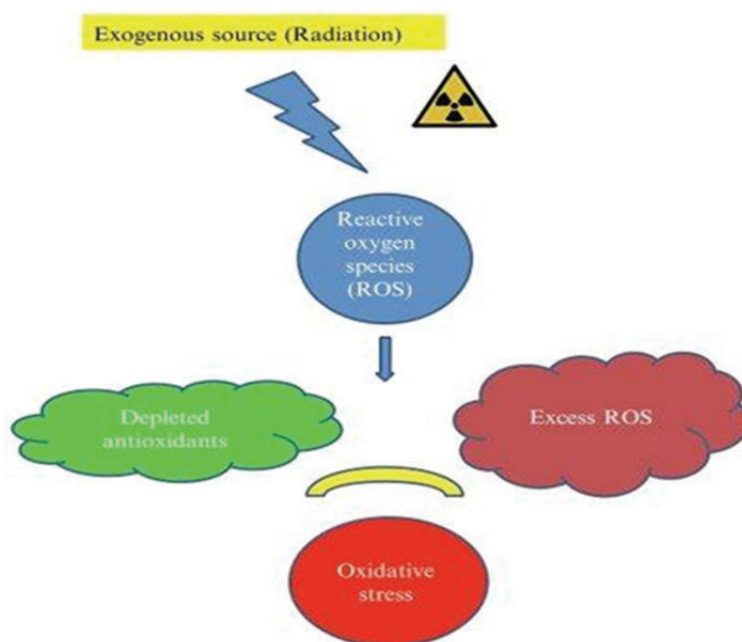
We have an experienced clinical development team led by CSSi LifeSciences (“CSSi”). CSSi offers integrative services to advance drugs from discovery to commercialization. The CSSi staff who will be leading

our drug development have a deep understanding from their previous engagements of the unmet need of radiation therapy side effects. CSSi has an excellent track record in working with small and emerging biopharmaceutical companies to advance their lead drug products to and through commercialization. CSSi has advanced over 60 drugs through the FDA with special designations and have worked on over 500 successful drug programs spanning over three decades of experience. CSSi's preclinical safety, toxicology, drug manufacturing and clinical development strategy and program has been designed to mitigate the costs, the time, and the risk.

We have established a Medical and Scientific Advisory Board, with some of the preeminent leaders in the fields of medical oncology and radiation therapy from the University of Texas MD Anderson Cancer, the University of Chicago Medicine, and the Cleveland Clinic.

THE PROBLEM - UNMET PATIENT NEED

The foundation of BioCurity's discovery is the recognition of the cellular protective and DNA repair mechanisms that fail due to excessive levels of radiation-induced Reactive Oxygen Species (ROS) causing radiation damage. The production of ROS from radiation is a critical function for how radiation damages the DNA of cells of the tissue it passes through. While efficient at reducing and eliminating cancer cells, normal cells in the radiation path, or in close proximity to the treatment target are exposed to harmful ROS. Cellular protective and repair mechanisms are present to block or repair damage caused by ROS; however, the levels of radiation used in cancer therapy can produce levels of ROS that overwhelm the repair processes resulting in death of normal cells as well as cancer cells.



COMPETITION

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, a more established presence in the market, and more expertise in research and development, manufacturing, preclinical studies, and clinical trials, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors.

Large, smaller, or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining highly qualified scientific, sales, marketing and management personnel and

establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our proposed programs.

Our potential commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our potential collaborators may develop. Because our product candidates are designed to reduce normal tissue toxicity from radiotherapy, our potential commercial opportunities could also be reduced or eliminated if radiotherapy methods are improved in a way that reduces normal tissue toxicity or if new therapies are developed which effectively treat cancer with less or without normal tissue toxicity.

Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related products, market acceptance by physicians and patients, the level of generic competition and the availability of reimbursement from government and other third-party payors.

THE SOLUTION

The Company's proprietary technology uses Cerium oxide nanoparticles, which belong to a specific class of compounds known as free radical scavengers. The free radical scavenging ability of Cerium oxide is well established in the chemistry literature and is thought to be a primary driver of its ability to decrease ROS in cells.^{1,2} The Company believes its Cerium oxide nanoparticles deliver beneficial effect by accelerating the breakdown of radiation-induced ROS and free radicals selectively in normal cells.

The Company's Cerium oxide nanoparticles are designed to eliminate radiation-induced charged particles, also known as Reactive Oxygen Species (ROS) that damage the DNA of cells which may be key to preventing side effects of radiation therapy and improve patient outcomes. ROS are highly reactive chemicals formed from molecular oxygen and include but are not limited to hydrogen peroxide and superoxide. The production of ROS from radiation is a critical function for how radiation damages the DNA of cells of the tissue it passes through. While cells possess their own repair mechanisms to prevent DNA damage when encountering ROS, we are focused on reducing the excessive levels of ROS produced during radiation therapy selectively in normal cells without interfering with the effectiveness of radiation on cancer cells.

The preclinical discovery and development of the Company's Cerium oxide nanoparticles were performed at an MD Anderson Cancer Center affiliate hospital (formerly affiliated with the Orlando Health Medical Center campus in Orlando Florida). BioCurity's Scientific Founder, Dr. Cheryl Baker PhD alongside, the radiation, medical and surgical oncologists on staff at MD Anderson Cancer Center Orlando were seeking a solution to serious side effects of radiation therapy for their cancer patients. In collaboration with research scientists at the University of Central Florida the preclinical discovery and development included the preclinically engineering and testing the ability of Cerium oxide nanoparticles to reduce the excessive levels of ROS produced during radiation therapy selectively in normal cells thereby preventing normal tissue DNA damage.

As shown in the chart below, preclinical animal studies demonstrate that the proprietary Cerium oxide nanoparticle proposed IV formulation had no detected toxicity when injected intraperitoneally even at doses at approximately 1,000 times the preclinical protective dose. No long-term adverse effects have been noted in these small animal model studies.³

¹Kim, Jae et al. "Mechanisms of radiation-induced normal tissue toxicity and implications for future clinical trials." *Radiat Oncol J.* 3 (2014): 103-115.

²Xu, Can and Xiaogang Qu. "Cerium oxide nanoparticle: a remarkably versatile rare earth nanomaterial for biological applications." *NPG Asia Materials.* 6 (2014): 1-31.

³Colon, Jimmy et al. "Protection from radiation-induced pneumonitis using cerium oxide nanoparticles." *Nanomedicine.* 5 (2009): 225-231.



BioCurity Science - Can be Transformative for Radiation

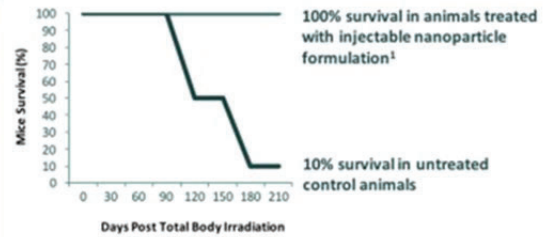
Topical and IV formulations tested in small animal models¹⁻⁴

- **Protection of the skin and internal tissues from radiation-induced damage**
- **Improved survival in animals given high doses of radiation**
- **No detected toxicity at 1000x the effective dose**
- **No interference with effectiveness of radiation on tumors**

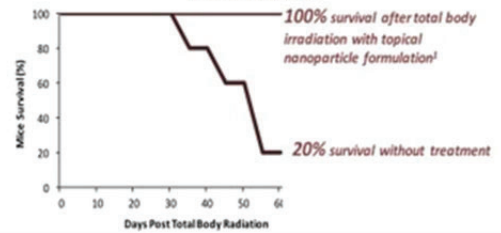
Preclinical studies performed at an MD Anderson Cancer Center affiliated hospital

See References #1-4 Provided Under Chart

IV Treatments Increase Survival in Radiated Mice



Topical Treatments Increase Survival in Radiated Mice



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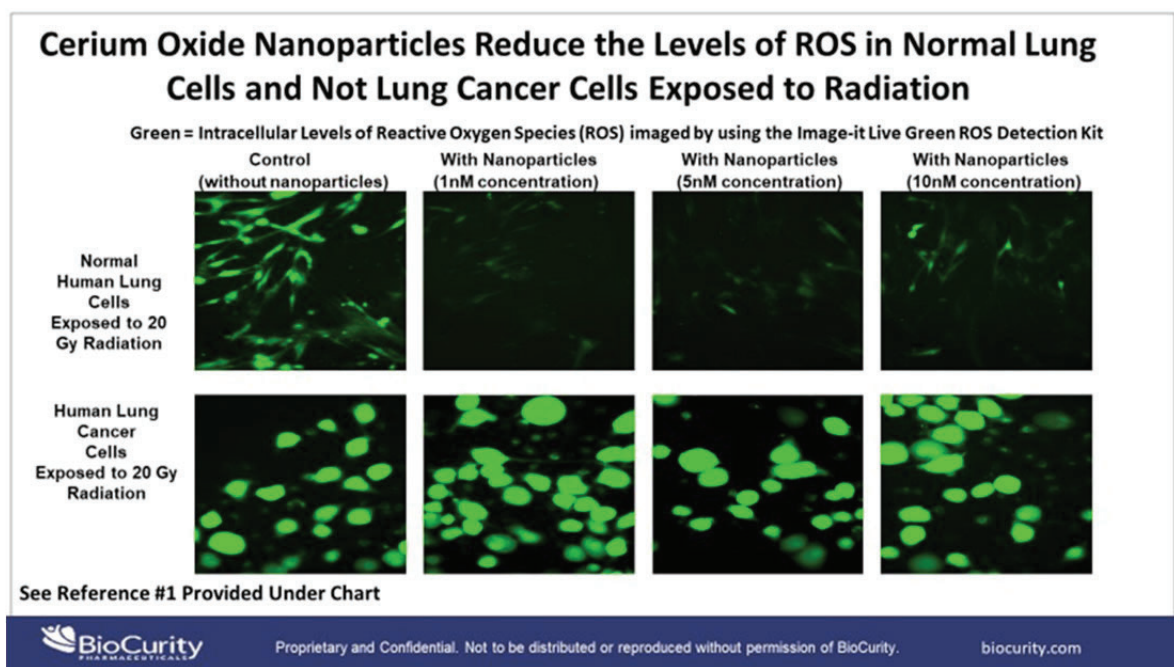
¹Colon, Jimmy et al. "Protection from radiation-induced pneumonitis using cerium oxide nanoparticles." Nanomedicine. (2009): 225-231.

²Manon, Rafael et al. "Harnessing Nanoparticles to Improve Toxicity after Head and Neck Radiation." Nanomedicine. (2012): 1223-1231.

³Colon, Jimmy et al. "Cerium oxide nanoparticles protect gastrointestinal epithelium from radiation-induced damage by reduction of reactive oxygen species and upregulation of superoxide dismutase 2." Nanomedicine. (2010): 698-705.

⁴Wason, Melissa et al. "Sensitization of Pancreatic Cancer Cells to Radiation by Cerium Oxide Nanoparticle-Induced ROS Production." Nanomedicine. (2013): 558-569.


An example of the Company's preclinical studies, as depicted on the chart below shows that the Company's Cerium oxide nanoparticles significantly reduce the levels of ROS in normal lung cells and not in lung cancer cells when exposed to radiation.



¹Colon, Jimmy et al. "Protection from radiation-induced pneumonitis using cerium oxide nanoparticles." Nanomedicine. 5 (2009): 225-231.

Proposed IV Drug for Head and Neck Cancer Patients.

There is a need for more effective, supportive care in head and neck cancer patients undergoing radiation therapy. Head and neck cancer patients undergoing radiation experience a loss in saliva production, resulting in dry mouth, difficulty eating and swallowing, and, in severe cases, malnutrition may require placement of a feeding tube. As shown in the chart below, head and neck cancer represent a growing health care concern globally, with approximately 650,000 new cases diagnosed worldwide and over 66,000 cases annually in the United States. Approximately 60-70% of patients receiving radiotherapy for head and neck cancer will develop severe oral mucositis (SOM), defined by the inability to eat solid food or to drink liquids. An additional \$40,000 in medical expenses is incurred by cancer patients who develop radiation-induced SOM. There is more than \$1B estimated for the market potential in the US for an IV drug like BioCurity's to prevent SOM.



The Reasons for an IV Drug for Head & Neck Cancer as Lead Clinical Indication

>\$1B estimated total market opportunity in US for a drug to prevent severe oral mucositis (Grade Scale 3-4)^{1,2}

- Worldwide 650,000** cases and 330,000 deaths annually³
U.S. 66,000 cases and 14,000 deaths annually
Europe 250,000 cases and 63,500 deaths
- Most radiation patients** with head and neck cancers develop some grade of oral mucositis (Grade Scale 1-4)^{1,2}
- ~60-70% of radiation patients** with head and neck cancers develop severe oral mucositis (Grade Scale 3-4)^{1,2}
- ~ \$40,000 in additional** medical expenses incurred by patients who develop severe oral mucositis (Grade Scale 3-4)^{1,2}

Potential for Fast Track/Orphan Drug Designation

Oral Mucositis Grade Scale				
None	Mild	Moderate	Severe	Life-threatening
0	1	2	3	4
• No mucositis	• Soreness • Redness • Irritation	• Ulcers • Redness • Irritation • Solid foods intolerant with mild pain	• Ulcer patches • Redness • Irritation • Severe pain • Liquid diet only • Severe pain	• Large ulcer patches • Redness • Irritation • Food intake impossible

"Oral Mucositis." Adapted from the World Health Organization (WHO) Oral Mucositis Grading Scale. Mucositis Awareness.org.

See References #1-3 Provided Under Chart

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¹Elting et al. Costs of Oral Complications of Cancer Therapies: Estimates and a Blueprint for Future Study, *JNCI Monographs*. 2019.

²Globocan & US SEER Data in *CA Cancer J Clin*. 2021.

³Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics. *CA Cancer J Clin*. 72, 2022.


IV Drug Development.

Head and neck cancer has been designated by the FDA as an orphan disease. As an orphan disease, BioCurity is able to qualify for registration of their drug as an orphan. Orphan designation has various clinical development benefits to BioCurity, which will further mitigate the time the cost and the risk associated with their drug development program. BioCurity is eligible for additional patent exclusivity and tax credits for the clinical development of BioCurity drug product as an orphan drug. In addition, the FDA has developed clinically meaningful endpoints that will serve as a basis of approval for BioCurity.

Further discussions with the Company’s clinical development lead, CSSi LifeSciences, are required before the clinical development on the proposed IV drug is designed and submitted to the FDA.

Proposed Topical Drug to Prevent Radiation Dermatitis.

The high incidence of skin damage caused by radiation therapy and potential often debilitating ensuing complications makes BioCurity’s topical formulation an ideal drug candidate for prevention of radiation-induced damage to the skin. As shown in the chart below, approximately, 4 million cancer patients in the US receive radiation therapy annually and according to publicly available peer reviewed articles and reports such as but not limited to articles found on the National Institutes of Health, approximately, 85-90% of these patients will experience some form of radiation dermatitis to the skin overlying the targeted cancer. As cited below, a 2022 peer-reviewed article in ‘In Vivo,’ head and neck, lung and breast cancers are the most notable cancers reported to experience some form of radiation dermatitis.



The Reasons for a Topical Formulation to Prevent Radiation Dermatitis


~4 million cancer patients in the US receive radiation therapy annually¹

- **~85-90% of these patients** will experience some form of radiation dermatitis to the skin overlying the targeted cancer - **most notably in head and neck, lung and breast cancer**¹⁻³
- **Within 90 days of radiation treatment** - acute radiation dermatitis may occur (Grades 1-2)²⁻⁴
- **Months to years after completion of radiation** - chronic radiation dermatitis may occur (Grades 3-4)²⁻⁴
- **~20% of patients** receiving radiation experience chronic radiation dermatitis (Grades 3-4)^{1,3}

See References #1-4 Provided Under Chart

Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation mostly confined to skin folds and creases; moderate edema	Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion	Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated	Death

NCI CTCAE: National Cancer Institute Common Terminology Criteria for Adverse Events of Radiation Dermatitis



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¹"Radiation Burns." Cleveland Clinic. <https://my.clevelandclinic.org/health/diseases/21995-radiation-burns>. 21 October 2021.

²Kao YS, et al. "Topical Prevention of Radiation Dermatitis in Head and Neck Cancer Patients: A Network Meta-analysis." *In Vivo*. 36 (2022): 1453-1460.

³Ryan Wolf J, et al. "Radiation Dermatitis." UpToDate. <https://www.uptodate.com/contents/radiation-dermatitis#disclaimerContent>. June 2022.

⁴Manna B, Cooper JS. "Radiation Therapy Induced Skin Ulcer." National Institute of Health, National Cancer for Biotechnology Information. <https://www.ncbi.nlm.nih.gov/books/NBK507719>. August 2022.

Topical Drug Development

BioCurity had planned to develop its topical product in the US for breast cancer patients receiving radiation therapy. However, preliminary discussions with the Company's clinical development lead, CSSi LifeSciences suggest the Company will encounter changes to the first proposed clinical indication of breast cancer to perhaps another clinical indication. No decision has been made as to the clinical indication as of the date of this report hereof. Further discussions with CSSi LifeSciences are required to develop the Company's clinical development plan for its proposed topical product.

Pre-IND meeting with FDA.

In December of 2016, BioCurity participated in a Pre-IND meeting with the FDA on its proposed topical drug for the prevention of radiation dermatitis induced by external beam radiation in breast cancer patients receiving radiotherapy following breast-conserving surgery. The Pre-IND meeting was held to evaluate the suitability of critical development plans for manufacturing with quality control, preclinical toxicology programs and clinical development including a combined Phase 1/2 study with its associated preliminary clinical endpoints and statistical plan.

The Company's preclinical data, supporting documentation in the form of peer-review published scientific articles, and the Company's proposed clinical design were incorporated into the documentation filed with the FDA. BioCurity received favorable feedback from the FDA where the FDA acknowledged that:

- 1) Active Pharmaceutical Ingredient (API) specifications, including test methods, were acceptable for products entering early phase clinical testing. Both parties agreed that drug product specifications would be modified to increase monitoring of globule size, API stability and product uniformity.
- 2) Pre-clinical toxicology described in a detailed program of GLP-compliant testing was consistent with industry standards and appropriate for the new chemical entity contained within the product candidate.
- 3) The clinical study synopsis describing both Phase 1 (safety/toxicity/PK study) and Phase 2 (blinded, randomized preliminary efficacy study) portions proposed acceptable clinical endpoints and preliminary statistical plans.
- 4) Clinical development plans to seek an indication for prophylaxis of radiodermatitis in breast patients receiving external beam radiotherapy were generally acceptable but subject to additional review at the time of Investigational New Drug (IND) submission. In addition, the clinical trial designs set forth in the Pre-IND were met with suggestions by the FDA to reduce the number of patients initially proposed as well as to include male and female subjects in the breast cancer trial. Subsequent to the Pre-IND meeting and at the recommendation of the Company's consultants, the total number of participants in the proposed Phase 1/2 clinical trial was reduced from the Company's Pre-IND submission and cancer patients were added to participate for the safety portion of the trial.

Further discussion with the Company's clinical development lead, CSSi LifeSciences is required to develop a clinical development plan for the Company's topical drug designed to potentially prevent radiation dermatitis for skin.

Clinical Development Team - from Discovery to Commercialization.

In January of 2021, the Company engaged CSSi LifeSciences ("CSSi") a global contract research organization and consulting group with integrative services to advance drugs from discovery to commercialization to lead the Company's clinical development. See the chart below for why CSSi has been selected as the clinical development lead for the Company.



CSSi LifeSciences Clinical Development Team
(www.cssilifesciences.com)



Why CSSi LifeSciences as Clinical Development Lead for BioCurity

- **A deep bench of services available for regulatory consulting, GMP manufacturing, CRO services, strategic planning and commercialization is available**
- **Outsourcing clinical development is an efficient economic business model for BioCurity**
- **Method of coordinating input of experts and information on clinical development for BioCurity Board members**
- **Experienced in budgeting costs for all phases of clinical development and commercialization**
- **Supportive Oncology Drug development experience by CSSi team members**
- **Well informed on potential exit strategies and the steps necessary for those options**



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The CSSi staff who will be leading the Company's drug development have a deep understanding of the unmet need of radiation therapy side effects the Company's drugs under development are designed to prevent. See below for bios on key members of the CSSi team - Mr. Jim Sergi and Dr. Heidi Nelson-Keherly, PhD.

Mr. Jim Sergi, President, CSSi LifeSciences.

Mr. Sergi is the Founder and President of CSSi LifeSciences, a global drug discovery and technology development company providing fully integrated, specialized regulatory and clinical services for pharmaceutical and medical device companies. Prior to this role, Mr. Sergi was the Founder and Managing Partner of Bay Tower Capital, a life sciences merchant bank and the Founder and CEO of ProED Communications, a healthcare services and drug development company. Mr. Sergi has been responsible for over 85 successful NDA/BLA approvals and over 250 medical device approvals. His academic and medical experience includes Director of Experimental Therapeutics at the Cleveland Clinic Cancer Center, Associate Professor of Medical-Surgical Nursing at the Case Western Reserve University and Lecturer for Oncology at Cleveland State University. Mr. Sergi has authored over 50 peer-reviewed publications and has numerous issued patents. Mr. Sergi serves as a scientific reviewer for the NIH SBIR/STTR Commercial Readiness Program, as well as a mentor to the NIH/NHLBI and the NIH Larta FeedForward programs. Dr. Sergi also serves as a Scientific Advisor and Board Member to numerous nonprofits, private equity and venture backed investment firms, including Defta Partners. Mr. Sergi has an undergraduate degree in nursing from Edinboro University of Pennsylvania and graduate degrees from the University of Akron and Cleveland State University. Mr. Sergi also serves as the General Partner of Tonic Bioventures, a corporate venture formation fund to accelerate and de-risk breakthrough drugs and medical devices to transform patient lives.

Dr. Heidi Nelson-Keherly, PhD., Vice President of Drug Discovery and Development, CSSi LifeSciences.

Dr. Nelson-Keherly is Vice President of Drug Discovery and Development at CSSi. Dr. Nelson-Keherly has over 20 years' experience working with small and mid-size pharmaceutical and biotech companies to develop their drug programs in support of Investigational New Drug (IND) submission. Dr. Nelson-Keherly has managed over 300 drug development programs spanning preclinical lead optimization, pharmacokinetic and safety studies, bioanalysis, process scale up and development, as well as CMC and GMP. During her career, Dr. Nelson-Keherly has been involved with over 1,000 drug development programs. In addition, Dr. Nelson-Keherly was responsible

for several multi-therapeutic clinical research sites that participated in over 80 Phase I-IV clinical trials. Dr. Nelson-Keherly holds a PhD in Molecular Biology from the University of Wisconsin.

Scientific and Medical Advisory Board.

We have established an experienced Medical and Scientific Advisory Board, with some of the preeminent leaders in the fields of medical oncology and radiation therapy. Including Dr. John Heymach, a board-certified medical oncologist from the University of Texas MD Anderson Cancer Center, Dr. Mark Ratain, a board-certified medical oncologist from the University of Chicago Medicine. Dr. Ratain is also the past secretary of the American Society of Clinical Oncology and is regarded like Dr. Heymach as a key international opinion leader in medical oncology. In addition, the advisory board is supported by Dr. Chirag Shah, a board-certified radiation oncologist from the Cleveland Clinic Foundation.

John Heymach, MD, PhD – The University of Texas MD Anderson Cancer Center.

Dr. John Heymach, MD, PhD is the Chair of Thoracic/Head and Neck Medical Oncology at the University of Texas MD Anderson Cancer Center. He holds the David Bruton Endowed Chair in Cancer Research. Dr. Heymach serves as Clinical Lead in Phase I/II clinical trials testing novel therapies for lung cancer and serves as Principal Investigator on numerous NIH grants. Dr. Heymach co-leads the Lung Cancer Moon Shot Program. As a physician-scientist, Dr. Heymach's research focuses on investigating mechanisms of therapeutic resistance to targeted agents, understanding the regulation of angiogenesis in lung cancer, and the development of biomarkers for targeted agents and immunotherapy. Dr. Heymach leads a number of biomarker-directed clinical trials using targeted and immunotherapy agents in lung cancer. Dr. Heymach has directly mentored numerous fellows, including physician-scientists, and serves as chair of the NCI Molecular Cancer Therapeutics-1 study section. Dr. Heymach received his medical degree and doctoral degree from Stanford University and completed his Internship and Residency at Brigham & Women's Hospital/Dana Farber.

Mark Ratain, MD – University of Chicago Medicine.

Dr. Mark Ratain, MD, is Associate Director for Clinical Sciences at the Comprehensive Cancer Center, University of Chicago Medicine. Dr. Ratain is an international leader in Phase I clinical trials, pharmacogenetics, clinical trial methodology and clinical pharmacology of marketed drugs. Dr. Ratain also serves as Director at the Center for Personalized Therapeutics, Chief Hospital Pharmacologist, University of Chicago Medicine. Dr. Ratain is an expert in the use of investigational agents to treat advanced solid tumors in addition to his specialty in the clinical pharmacology of marketed drugs. Dr. Ratain is an international leader in Phase I clinical trials, pharmacogenetics, and clinical trial methodology, and he created the new discipline of interventional pharmacoeconomics. Dr. Ratain's work can be found in more than 500 published articles and book chapters. Dr. Ratain received his medical degree from Yale University and completed his Internship and Residency at Johns Hopkins Medicine.

Chirag Shah, MD – Cleveland Clinic.

Dr. Chirag Shah, MD, is the Director of the Breast Radiation Oncology Department at the Cleveland Clinic. He is also an Associate Professor of the Cleveland Clinic Lerner College of Medicine. Dr. Shah's research focuses on the study and implementation of techniques and methods for limiting short and long-term radiation therapy side effects. Dr. Shah's primary research interests are breast cancer, sarcoma, prostate cancer, lymphoma, and innovative radiation treatment schedules as well as lymphedema. Dr. Shah serves as a reviewer for various medical journals and is a member of various medical societies. Dr. Shah has participated in numerous in-house, pharmaceutical, and cooperative group trials. Dr. Shah has published over 120 peer-reviewed articles and book chapters. Dr. Shah received his medical degree from Northeast Ohio Medical University. He completed his internship, and residency at William Beaumont Hospital.

EMPLOYEES.

As of the date of this annual report, the Company does not have employees – only directors, and consultants, none of which are employees of the Company.

CONSULTANTS.

The Company utilizes high quality consultants with decades of combined biotech industry expertise and successful track records inclusive but not limited to:

- preclinical and clinical development strategy
- product manufacturing oversight
- FDA and global regulatory experience
- clinical trial execution
- licensing deals with public and private pharmaceutical companies

The Company believes the current use of CSSi LifeSciences, a company with a turnkey operation from discovery to commercialization is preferable to hiring full time employees and allows for more efficient use of Company funds and the opportunity to obtain deeper expertise on specific tasks.

PROPERTY

Lease of Regus Space.

The Company entered into an “office agreement” with Regus Management Group, LLC for the occupancy of one office space and use of services from Regus at its property located at 110 Front Street – Suite 300, Jupiter, Florida 33477. The agreement ran for an initial term from February 15, 2017, through May 31, 2018, and was extended until March 31, 2023. The Company terminated its lease effective March 31, 2023, and is currently using a virtual mailbox system.

Corporate Apartments.

The Company entered into lease agreements for two corporate apartments with Casa Mara at 3111 S. Dixie Highway West Palm Beach, Florida 33405. Effective April 4, 2023, the lease for one of the two corporate apartments was terminated and the corporate apartment was vacated. In April 2023, the Company provided notification that it will terminate and vacate the remaining corporate apartment lease effective June 7, 2023.

INTELLECTUAL PROPERTY

BioCurity’s technology is disclosed and claimed in a patent portfolio controlled by BioCurity, including patent rights exclusively licensed from the University of Central Florida Research Foundation, Inc. (“UCFRF” or “Licensor”) effective February 2015 (the “License Agreement”).

Company’s License Agreement.

The License Agreement is a non-royalty, fully paid license that includes 8 issued United States patents. BioCurity has an exclusive license to develop, manufacture, and sell Cerium oxide nanoparticle formulations for preventative, therapeutic, and diagnostic purposes in select fields. The Company’s licensed US patents cover the method of making Cerium oxide nanoparticles and the use of the Company’s Cerium oxide nanoparticle technology for patients with cancer treated with radiation.

There are a number of risks to the Company associated with the License Agreement. The License Agreement limits UCF’s liability. Pursuant to the License Agreement the Company indemnifies UCF and its

affiliates for: (a) material breaches of the License Agreement; (b) the use of the patents underlying the License Agreement on behalf of the Company or its sublicensees; (c) the manufacture, sale, and use of any licensed products under the License Agreement by the Company, its sublicensees, their affiliates and by customers and other end-users; and (d) the death or injury of any person as a result of our actions under subsection (c). UCFRF is not obligated to indemnify the Company for a breach of the License Agreement by either UCFRF or any of its affiliates.

In addition to the risk described above there are risks associated with patents and licenses in general and risks specifically associated with the License Agreement. Both types of risks are described in the “Risk Factors” set forth in this report. Please review “Risk Factors - Company Licensed Patents General Risks.”

Company-Owned Patent Information.

The Company filed International Application No. PCT/US2015/040869, entitled “Treatment of Cancer with a Combination of Radiation, Cerium Oxide Nanoparticles and a Chemotherapeutic Agent,” on July 17, 2015. This invention is directed to methods for the treatment of cancer with a combination of radiation, Cerium oxide nanoparticles and at least one chemotherapeutic agent (“International Patent”). The Company’s International Patent covers the use of the Company’s Cerium oxide nanoparticle technology for patients with certain cancers treated only with radiation combined with chemotherapy. The methods of the invention utilize Cerium oxide nanoparticles to enhance radiation-induced and chemotherapy-induced cancer cell death and also reduce the side effects of radiation therapy. As of the date of this report, select claims in the Company’s International Patent have been issued in Australia, China, Europe, Japan, Hong Kong, Mexico, and the US. and an allowance of claims has been received in Canada. The types of cancers allowed in claims issued for the International Patent is limited in Australia, China, Europe, Hong Kong, Mexico, and US. International Patent applications by the Company are pending in Brazil and Canada. Please review Risk Factors - “Risks related to Company-owned International Patent Portfolio - limitations to cancer types and uses.”

The actual determination of whether to file and prosecute a patent application in each jurisdiction is a function of the Company’s future assessment of the value of continuing to prosecute protection in such jurisdictions, as well as having sufficient funds budgeted to be able to move forward with a patent application. There are no guarantee claims in any of the Company’s pending patents will be allowed to the Company and the Company at any time may decide to abandon any or all pending International Patent applications.

COMPANY’S BOARD OF DIRECTORS

The Company’s Board of Directors consists of three (3) people: Mr. Sam Merchant, Dr. Cheryl Baker, PhD, and Ms. Nancy Cass. They are also the three directors of BioCurity, Inc., the Company’s sole subsidiary. Directors of the Company serve for one-year terms or until the next annual meeting of the stockholders.

Sam Merchant, Co-Founder and Chairman of the Board.

Mr. Merchant is Co-Founder and Chairman of the Board of BioCurity and has served in such capacity since February 2015. Mr. Merchant is also the Co-Founder of MerchantCass Advisors, LLC who served as BioCurity's Interim President and COO until April 10, 2023. Mr. Merchant has been and is structuring and negotiating transactions in the healthcare space through his past business experience.

Mr. Merchant is the founder of The Merchants Financial Group, a privately held company founded in 1982 and headquartered in Atlanta. Merchants Financial Group is focused on identifying and developing international growth opportunities in multiple business sectors including healthcare, biotech, banking, commercial real estate, manufacturing, franchising, and underwriting of traditional and alternative financial products.

Mr. Merchant is Chairman of his Family’s Capital Fund a position he has successfully served since 1986. Mr. Merchant has developed a network that included Fortune 500 companies and businesses local to each region of the world. His family of companies has partnered with global companies in complex business transactions and has been instrumental in the growth of major brands in multiple regions of the world.

As an active resident of Atlanta for many years, Mr. Merchant served on the Atlanta Regional Commission Board for seven years and was a stakeholder board member of Atlanta Vision 20/20. Mr. Merchant, recognized for his effectiveness in Atlanta, served on President George W. Bush's Advisory Board for Economic Development and the Small Business Sub-committee, for an outstanding 6-year tenure. Mr. Merchant has interacted with governments throughout the world at the highest levels and is a well-respected global businessman. Each experience and position held, expanded Mr. Merchant's knowledge, and understanding, thus allowing him to easily adapt and prosper in all industries across the spectrum, including his key advisory roles resolving matters for his local governments and municipalities, on a political level. Mr. Merchant is recognized for his biotech-life sciences experience and served on the World Stem Cell Summit (WSCS), which conducts stem cell and regenerative medicine conferences. In June of 2020, Mr. Merchant was elected and served as Chairman of the Board of Directors to the Regenerative Medicine Foundation until 2021.

Mr. Merchant has been working closely with BioCurity to provide continuous guidance in all business areas of day-to-day operations and is working with all related parties including specifically its auditors, to guide proper financial and corporate governance so essential for emerging growth companies. In furtherance of this: (i) MerchantCass Advisors, LLC an affiliate of Mr. Merchant that had an advisory agreement with the Company, served as Interim President and COO of BioCurity until April 10, 2023; and (ii) Capital & Venture Resources, LLC an affiliate of Mr. Merchant has an advisory agreement with the Company to provide mergers, acquisition, and disposition services to the Company.

Being a co-founder of MerchantCass Advisors, LLC and under the guidance of professional service providers, Mr. Merchant is sufficiently informed on the JOBS Act and capital distribution in the RIA and Broker-Dealer community introduced to him. Mr. Merchant intends to expand his work with early-stage companies by leading quality driven investment opportunities for the retail investor marketplace. He believes it is important to allow access to investment opportunities that to-date have been limited to other family offices, strategic investors, and private equity funds. Making a commitment to economic growth for all is an impact investing commitment whose time has come.

Cheryl Baker, PhD, Scientific Founder, Treasurer, Secretary and Director.

Dr. Cheryl Baker, PhD is Scientific Founder, Secretary/Treasurer, and a Board member of BioCurity. Dr. Baker has been a key member of the team that has performed the BioCurity preclinical studies. Dr. Baker has a deep and extensive understanding of the knowledge and the mechanism of action of BioCurity's science and assisted in writing multiple patents held by the Company internationally, as well as numerous peer reviewed articles on the BioCurity scientific discovery. Dr Baker has conducted cancer related research for over 20 years and has published over 45 peer reviewed manuscripts and articles. From 2005-2010, Dr. Baker served as Director of the Cancer Research Institute of MD Anderson Cancer Center Orlando (formerly on the Orlando Health Medical Center campus in Orlando Florida). During her time at MD Anderson-Orlando, she established and led a team of master and doctoral students, research scientists, physician- scientists and professors in multi-disciplinary cancer research projects. The proprietary Cerium oxide nanoparticle technology supporting BioCurity's mission was preclinically developed and tested by Dr. Baker in collaboration with medical, surgical, radiation oncologists and research staff at MD Anderson-Orlando. With Dr. Baker as lead author, the research in BioCurity's preclinical studies has been published in multiple scientific peer review journals including Nanomedicine, a leading international journal on nanoparticles.

In 2010, Dr. Baker was the recipient of the Medical Marker award given to her by Orlando city Mayor Dyer for 'Advancing Life Sciences in Central Florida.' In 2013, the Rollins College Alumni Association recognized Dr. Baker with a 2013 Alumni Achievement Award for her outstanding career in science.

Dr. Baker received her B.S., cum laude, in Chemistry from Rollins College (Winter Park, Florida) in 1994. In 1999, Dr. Baker received her Ph.D. in Biochemistry from Texas Tech University. Dr. Baker then completed her post-doctoral fellowship in the Department of Cancer Biology at The University of Texas M. D. Anderson Cancer Center in Houston, Texas from 1999-2001. From 2001-2003, Dr. Baker conducted research as an Instructor of Surgery at the Boston Children's Hospital affiliated with Harvard Medical School. Subsequently, Dr. Baker was an Assistant Professor at the University of Texas M.D. Anderson Cancer Center until 2005. From 2005-2013, Dr Baker was appointed to the faculty of the Burnett School of Biomedical Sciences at the University of Central Florida.

Dr. Baker is not employed by or with any other organization. Dr. Baker's focus is on BioCurity.

Nancy J Cass, Director.

Ms. Cass is a Board member of BioCurity and has served in such a capacity since June 2016. Ms. Cass is Co-Founder of MerchantCass Advisors, LLC with Mr. Merchant that served as BioCurity's Interim President and COO until April 10, 2023. Ms. Cass also serves as MerchantCass Advisors, LLC Special Legal Counsel.

Ms. Cass is a licensed attorney in Florida and Illinois and has practiced transactional and securities law for over 20 years. Ms. Cass started her career working in the corporate/securities department of mid-sized law firms where she worked on broker-dealer syndicated offerings, represented borrowers and lenders in complex banking and hedge fund transactions, performed general corporate work and drafted dozens of private offering documents. Ms. Cass has successfully been lead counsel on dozens of financing transactions for early and mid-stage companies.

Ms. Cass also holds Series 79, 24 and 7 FINRA licenses. Over the years Ms. Cass has developed a network of attorneys, accountants and consultants who work with earlier stage companies and entrepreneurs. Ms. Cass was a Managing Director of the Emerging Growth Division of a FINRA member broker dealer. Ms. Cass began her investment banking career at Capitalink, a boutique Miami based investment banking firm that was acquired in 2006 by Ladenburg Thalmann & Co., a New York Stock Exchange member firm. Ms. Cass was licensed at Crescent Securities Group, a FINRA broker from 2015-2020.

Ms. Cass represented public and private issuers, institutional funding sources, banks, and early-stage companies as a banker and attorney. Her proficiency and skill through practicing law and an investment banking background, benefits examining opportunities for financings, strategic partnerships, and other transactions. Ms. Cass is able to interact with the attorneys and bankers on transactions with added insight understanding alternative perspectives and structuring transactions with a keen recognition to avoid hurdles and fashion solutions. In addition to investment banking, she has served as Special Legal Counsel and as an advisor to companies across multiple sectors including biotech, healthcare, real estate, and media during transactions including capital raising.

Ms. Cass is a graduate with distinction of the University of Colorado in Boulder where she received her B.A degree. She received her JD from the University of Denver College of Law where she received awards for academic excellence in course work including an academic scholarship from the law school. Ms. Cass is a member of the ABA and early in her career was active in the Business Law Section of the Florida Bar.

RISK FACTORS

Investing in our securities involves a high degree of risk. In evaluating our business, investors should carefully consider all of the following risk factors. These risk factors contain, in addition to limited historical information, forward-looking statements that involve risks and uncertainties. Our actual results could differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below. The order in which the following risks are presented is not intended to reflect the magnitude of the risks described. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the value of our securities could decline, and you may lose part or all of your investment. References to the "Company," "us" or "we," includes both BioCurity Pharmaceuticals Inc. and its wholly owned subsidiary, BioCurity, Inc. (a Delaware corporation and successor in interest to BioCurity, Inc., a Florida corporation).

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain, subject to change and out of BioCurity's control. We cannot at this time precisely predict what effects COVID-19 will have on our future business, ability to execute business model, results of operations and financial condition, including due to uncertainties relating to the ultimate geographic spread of the virus within the United States and globally, the severity of the disease, the duration of the pandemic and the future governmental responses to the pandemic. As we are in the biotech sector the pandemic may exacerbate difficulties regarding BioCurity's ability to raise capital, execute its business model, obtain strategic partners, and entertain global options.

Financial Risks

The Company has an issued and outstanding Demand Note that is secured by all assets of the Company.

A demand note is a promissory note that becomes payable any time the holder of the note requests payment (“Demand Note” or “Demand Notes”). This differs from promissory notes that are due by a certain date or have a repayment schedule. MerchantCass Advisors, LLC, Capital & Venture Resources, LLC and Mr. Sam Merchant are each holders of a Demand Note in the total amount of \$4,162,454 as of April 30, 2023 (“Holders”). Mr. Sam Merchant and Ms. Nancy Cass, affiliates and members of MerchantCass Advisors, LLC are Directors of the Company and hold two of the three Board seats on the Board of the Company. The debt is a result of years of non-payment by BioCurity pursuant to service agreements entered into by Mr. Sam Merchant, serving in his capacity as Chairman of the Board of the Company, Capital & Venture Resources, LLC, and MerchantCass Advisors, LLC along with accrued interest that is growing on a daily basis. The Company and Dr. Cheryl Baker, PhD individually have executed a full release of MerchantCass Advisors, LLC, and its affiliates, Mr. Sam Merchant, Ms. Nancy Cass and Capital & Venture Resources, LLC, for any claims against the Company regarding the Demand Note and waived all conflicts of interest potential and future, fully indemnified the holders for any claims and waived any and all defenses that may be possible (see “Related Party Transactions”). The Holders can demand immediate payment of the full amount of the Demand Notes at any time and no grace period or notice is required to be provided to the Company. Investors should be aware that the Company does not have the funds to pay the Demand Notes and there is no forbearance of collection on the Demand Notes. The Holders have informed Dr. Cheryl Baker, PhD in writing and orally that they intend to pursue collection on the Demand Notes with their sole and unfettered discretion. Investors should be aware that they risk losing their entire investment if the Holders foreclose on their Demand Note. No settlement discussions are in progress, and it is anticipated collection efforts on the Demand Notes are likely in the near term if the Company remains unwilling to have settlement discussions.

We have never generated any revenue and do not expect to generate revenue in the near future.

Our losses have resulted principally from costs incurred in our discovery, development, and inability to raise capital for general operating activities. We anticipate that we will continue to generate significant losses for the next several years in addition to millions of dollars in accounts payable to service providers. We expect to incur expenses to begin or complete our clinical trial programs for our product candidates including but not limited to building commercial capabilities, engaging, and maintaining costs of consultants, developing our product pipeline, regulatory expenses, patent expenses, and developing a corporate infrastructure.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to predict with certainty the timing or amount of future expenses or when, or if, we will be able to achieve revenue or profitability. We do not expect to generate any revenue for many years as product development is a long-term and uncertain process. We have financed our operations primarily through the sale of equity securities, accrual of fees of service providers including affiliates and the issuance of a line of credit. The size of our future losses is anticipated to increase as development costs grow. Our ability to ever achieve any revenue is dependent on our ability, alone or with others, to raise sufficient capital to enable us to complete the development of our products successfully, obtain the required regulatory approvals, manufacture, and market our proposed products successfully or have such products licensed to and/or manufactured and marketed by others, and gain market acceptance for such products. There can be no assurance as to whether or when we will achieve profitability even if the revenue is achieved.

The Company may not raise the amount of funds needed to continue operations.

Over the last 48 months the Company has been unable to raise the amount of capital to pay most of its operating expenses. This has resulted in a large amount of money in accountants payable for the Company. There is no assurance that the Company will be able to raise needed funds through the sale of securities sufficient to meet the Company’s working capital needs or to bring funds through other methods into the Company on a near-term basis. The failure to raise needed funds has had a material adverse effect on the Company’s business, financial condition, operating results, and prospects, and could result in the loss of your investment in the

Offering. The Company is significantly in debt and creditors have no forbearance preventing them from collecting on the debt immediately.

Investors should be aware that the proceeds from any offering conducted by the Company without an institutional participant is not expected to be sufficient to fund the Company in the near term or make material impact on the ability of the Company to develop its biotech product.

The Company has been unsuccessful in attracting capital from institutional funds and may never obtain a financial interest from an Institutional fund.

The Company has been seeking additional capital on its own for more than four years and in some instances through the efforts of FINRA licensed investment bankers. The Company has not been successful in attracting capital from an institutional fund, strategic partner or investors that are funding other biotech deals with funding sufficient to cover drug development costs. Based upon past experience and the large number of funding sources approached over the last 36 months of more than 100 groups, it is quite possible that the Company may never obtain funding sufficient for drug development. The Company does not have funds to hire investment banking groups willing to take BioCurity as a client and has limited additional groups to contact on its own. Many of the groups BioCurity met with or sent BioCurity materials to have invested in alternative early-stage biotech companies.

Resignation of MerchantCass Advisors LLC - BioCurity has no senior management with business experience.

With the resignation of MerchantCass Advisors, LLC (“MCA”) as Interim President and COO of the Company, the Company is without any Officers or senior staff except for Dr. Cheryl Baker, PhD, who serves as the Secretary and Treasurer of BioCurity. Dr. Cheryl Baker has a PhD in science and no training in accounting, law or business transactions. There are no funds available to pay any staff and therefore, successful recruitment of proficient team members is unlikely at this time. Although affiliates of MCA, Mr. Sam Merchant and Ms. Nancy Cass, serve on and control the BioCurity Board, the affiliates of MCA are not responsible for the day-to-day operations of the Company.

Termination of the MerchantCass Advisors, LLC Agreement and Limitations of Liability for services provided to the Company by MerchantCass Advisors, LLC.

The Company had an Advisory Agreement with MerchantCass Advisors, LLC (“MCA”), an affiliate owned by both the Chairman and a member of the Board of Directors to render financial and business advisory through December 31, 2022. The Company requested services by MCA through April 2023 and continued to accept the benefits of those services pursuant to Forbearance Agreements and extensions thereof. On April 10, 2023, after notification by MCA to the Company on April 5, 2023, of the impending resignation, the services of MCA were terminated. Dr. Cheryl Baker, PhD, on behalf of the Company accepted the resignation of MCA as Interim President and COO of BioCurity (see “Related Party Transactions”).

In no event will MCA or its affiliates, members, successors and assigns have any liability whatsoever to the Company, its shareholders, agents, affiliates, consultants, directors or third party beneficiary or any other entity or individual for any indirect, special, consequential, incidental or punitive damages, including but not limited to loss of anticipated profits or revenue in connection with or arising from anything said, omitted or done, even if either party has been advised of the possibility of such damages (see “Related Party Transactions”). Investors should be aware that there is a limitation of damages and monetary damages for any alleged breach of fiduciary duty by Directors who also control the voting stock of the Company. In addition, the Company is required to indemnify all Directors and Officers.

Fiduciary duty and limitations of liability for services provided to the Company by Capital & Venture Resources, LLC.

The Company has an Advisory Agreement with Capital and Venture Resources LLC, an affiliate of Mr. Sam Merchant (“CVR”). The Advisory Agreement including its addendums state that CVR, its affiliates, members, owners and successors and assigns shall not be liable to the Company or its stockholders for monetary

damages for breach of fiduciary duty as a Director, service provider, shareholders, or in any capacity including personal liability of any member or affiliate of CVR. This is irrevocable and any repeal, modification or prohibition by the Company or its successors and assigns shall not adversely affect any right or protection of CVR including services as a director of the corporation existing at the time of, or increase the liability of CVR or to its affiliates, members, owners, and successors and assigns to the Company with respect to any acts or omissions occurring prior to, such repeal or modification.

In no event will CVR or its affiliates, members, successors and assigns have any liability whatsoever to the Company, its shareholders, agents, affiliates, consultants, directors or third party beneficiary or any other entity or individual for any indirect, special, consequential, incidental or punitive damages, including but not limited to loss of anticipated profits or revenue in connection with or arising from anything said, omitted or done, even if either party has been advised of the possibility of such damages (see “Related Party Transactions”). Investors should be aware that there is a limitation of damages and monetary damages for breach of fiduciary duty by Directors who also control the voting stock of the Company. In addition, the Company is required to indemnify all Directors and Officers.

The Company has a loan of \$147,000 and will be subject to risk of repayment of the loan.

The Company has with Seacoast National Bank a loan (“Loan”) in the amount of \$147,000 collateralized with a CD from the Town of Jupiter, Florida. The Loan payment is for interest only and is secured by a blanket lien on the Company’s assets. The Company has obtained an extension through December 2023 on the outstanding amount under the Loan which was to be due in December 2022. However, the Seacoast National Bank has requested the payoff of the Loan by BioCurity in the near future. The note pursuant to the Loan is secured by substantially all of the personal property and equipment of the Company and an Economic Development Loan Pledge Agreement with the Town of Jupiter, Florida. This includes all of the intellectual property owned by the Company. Should the Company default on its interest payment obligations or be unable to pay the Loan on maturity, the Company is at risk of default with respect to the Loan and loss of all its assets securing the Loan.

There is currently no market for the stock of the Company, there are restrictions on stock transfer, and it is possible that no market will ever develop for shareholders.

The Company is not listed on any exchange, has no plans to list on any exchange, and may never be eligible to be listed on any exchange. In addition, no class of stock of the Company has been registered under the Securities Act, and we are under no obligation to register any class of stock of the Company. There is no market for the Company’s stock and Shareholders will have no liquidity and may never be able to sell their stock.

Our business is subject to risks arising from epidemic diseases, such as the global outbreak of the COVID-19 coronavirus.

An epidemic or pandemic disease outbreak, including the COVID-19 outbreak, could cause significant disruption to our business operations or the operations of our potential third-party manufacturers and retained and/or prospective Contract Research Organizations (“CROs”) upon whom we rely, as well as to our potential clinical trials, including as a result of significant restrictions or bans on travel into and within the countries in which our potential manufacturers may produce our product candidates or where we may conduct our clinical trials. Such disruption could impede, delay, limit or prevent our employees and CROs from commencing and/or continuing research and development activities, the future production, delivery or release of our product candidates to our potential clinical trial sites, as well as potential clinical trial investigators, patients or other critical staff from traveling to or otherwise continuing to participate in our clinical trials, and delay data collection and analysis and other related activities, any of which could impede, delay, limit or prevent completion of our ongoing clinical trials and preclinical studies or commencement of new clinical trials, and ultimately lead to the delay or denial of regulatory approval of our product candidates, which would seriously harm our operations and financial condition and increase our costs and expenses.

The COVID-19 outbreak could also potentially affect the business of the Food and Drug Administration (“FDA”), European Medicines Agency (“EMA”), or other health authorities, which could result in delays in meetings related to planned or completed potential clinical trials and ultimately of reviews and approvals of our product candidates. The COVID-19 outbreak, and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Our business may be disrupted by global and national conditions and events outside of our control.

Business disruptions from COVID-19, global unrest, inflationary trends, and other conditions more likely than not will harm the Company’s financial condition and could delay and materially increase our costs and expenses. Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, war, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions would have an adverse effect on our business, third parties we engage and others we rely on in our industry.

The Company’s Board of Directors will have broad discretion in using the proceeds from any offering including affiliated parties with potential conflicts of interest.

The Company has repeatedly waived conflicts for Board members, and even Holders of the Demand Notes. The Company’s Board of Directors, including those who have potential conflicts of interest and related party transactions will use the proceeds from the sale of equity for general working capital and accrued debt to some of the members of the Board of Directors. Payments from the proceeds from the sale of equity may go directly or indirectly to the Directors of the Board. As such, related parties will have sole discretion in determining the specific uses of the net proceeds it receives as a result of proceeds from any sale of equity by the Company. Investors will not have the opportunity to evaluate the economic, financial, or other information on which the Company bases its decisions on how to use the net proceeds it receives as a result of the sale of equity. Thus, prospective Investors will purchase securities without any assurance that the Company will utilize the proceeds in an effective manner, in a manner with which prospective investors agree or in a manner to meet its ongoing working capital needs.

Secured Debt and Forbearance Agreements with MerchantCass Advisors, LLC, Capital & Venture Resources, LLC and Mr. Sam Merchant.

The Company was not in compliance with the prior Forbearance Agreements with MerchantCass Advisors, LLC, Capital & Venture Resources, LLC or Mr. Sam Merchant (“Noteholders”). In October 2022, the Company entered into a Security Interest and Collateral Agreement in which the existing Note Payable Agreements with the Noteholders are cross-defaulted and were secured with all of the assets of the Company. Investors are urged to carefully review the “Related Party Transactions” which summarizes terms of the conflicts and agreements (see “Related Party Transactions”). Mr. Sam Merchant, an affiliate of and Co-Founder of MerchantCass Advisors, LLC and Capital and Venture, Resources, LLC is the Chairman of the Board of BioCurity. Ms. Nancy Cass, an affiliate and Co-Founder of MerchantCass Advisors, LLC, is also a member of the Board. Investors should be aware of the conflicts that exist prior to making an investment.

Investors are urged to carefully review the “Related Party Transactions” which summarizes terms of the conflicts and agreements (see “Related Party Transactions”). Mr. Sam Merchant, an affiliate of and Co-Founder of MerchantCass Advisors, LLC and Capital & Venture Resources, LLC is the Chairman of the Board of BioCurity. Ms. Nancy Cass, an affiliate and Co-Founder of MerchantCass Advisors, LLC, is also a member of the Board. Investors should be aware of the conflicts that exist prior to making an investment

Major shareholders have a consulting agreement with BioCurity and are the largest creditors of BioCurity.

MerchantCass Advisors, LLC (“MCA”) had a consulting agreement with the Company effective until December 31, 2022. Capital & Venture Resources, LLC (“CVR”) has a consulting agreement with the Company (see “Related Party Transactions”) and, Mr. Sam Merchant, an affiliate of CVR and Co-Founder of MCA, is the beneficial owner of a substantial portion of the Company’s capital stock, warrants and options. Mr. Sam Merchant owns 10 shares of “Super Voting” Series V Preferred Stock that provides Mr. Sam Merchant with voting control over the Company. Ms. Nancy Cass, an affiliate and Co-Founder of MCA, is also a member of the Board and Investors should be aware of the conflicts that exist prior to making an investment. Circumstances may arise where one or more of Dr. Cheryl Baker, PhD, Mr. Sam Merchant, Ms. Nancy Cass, and Capital & Venture Resources, LLC may have interests directly in conflict with shareholders and future investors. Shareholders will have no say and will be entirely relying upon the Board to manage the Company. In addition to their equity ownership, Mr. Sam Merchant and Ms. Nancy Cass, through their ownership in MCA and/or CVR, are the largest creditors of the Company. The funds owed to these entities continue to grow and exceed \$4 million dollars. Future shareholders will need to be aware that these conflicts exist prior to making any investment.

Conflicts of interest-board members.

Board Members have served as consultants or employees of the Company and Mr. Sam Merchant, acting as Chairman together with his affiliates of MerchantCass Advisors, LLC and Capital & Venture Resources, LLC are Noteholders of the Company’s Security Interest and Collateral Agreement entered in October 2022. Ms. Nancy Cass, a Director of BioCurity is an affiliate of MerchantCass Advisors, LLC. Although the Company has engaged the services of independent auditors since 2014, financial and business decisions for the Company are made by the Board and due to the dual roles conflicts of interest are inherent and anticipated, including but not limited to broad advisory services that were provided to the Company by MerchantCass Advisors, LLC and transactional consulting and advisory services provided by Capital & Venture Resources, LLC. For example, BioCurity has agreed to a limitation of damages provision in its agreements with MerchantCass Advisors, LLC and Capital & Venture Resources, LLC. This will limit monetary claims that BioCurity or any shareholder can recover from companies affiliated with Board members for services provided by the Board members (see “Related Party Transactions”).

Voting Control - Mr. Sam Merchant.

Mr. Sam Merchant is the sole owner of the Series V Preferred Stock. The Series V Preferred Stock has less than a \$20 economic interest in BioCurity but holds a majority of common stock voting control. Shareholders must be willing to rely upon the Board and Mr. Sam Merchant for Company control. Investors may receive voting shares in Offerings, but they will not have any control of the Company. The Board has fully indemnified Mr. Sam Merchant and his affiliates waived all conflicts as well as placed limits of damages and reduced the fiduciary duty obligation as allowed by Delaware law. The Company has waived any recourse against Mr. Sam Merchant and any of his affiliates.

There is no guarantee that Capital & Venture Resources, LLC can bring a successful transaction to the Company or will continue to be a service provider of the Company.

Capital & Venture Resources, LLC, (“CVR”) controlled by Mr. Sam Merchant, has been engaged by the Company effective December 1, 2018 (“CVR Agreement”), to use reasonably commercial efforts to assist the Company in engaging in commercial transactions on behalf of the Company. However, as of April 30, 2023, the Company owes \$634,289 to CVR and it is possible that the CVR Agreement will be terminated for breach by BioCurity for non-payment. The ability to attract any such potential transactions and/or successfully consummate them is dependent upon the performance and resources of the Company, which is outside the control of CVR. Given the lack of working capital and financial condition of the Company prospective investors should realize that the past successes of CVR and its affiliates will have negative impacts on the ability of CVR bringing any successful transactions to the Company (see “Related Party Transactions”). In addition, the lack of working capital and financial condition of BioCurity will substantially impact the ability of CVR to bring interested parties to work with BioCurity.

Stock options and dilution.

The Company's officers, directors, or other individuals or entities have and may receive options to purchase stock in the Company, which would result in the dilution of your proportionate ownership interest in the Company. This is an inherent conflict since there is no independent Board Member.

We do not intend to pay dividends on any of the Company stock, so any returns will be limited to the value of our stock.

We do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

Securities in the Series A Plus Preferred Offering ("Offering") are senior to some other classes of our Preferred Stock issued and will Convert to Common Stock under certain circumstances.

The Series A Plus Preferred Stock shares ("Shares") will convert from Preferred to Common Stock automatically upon: (i) twenty (20) business days after a "Stockholder Vote," (ii) the date of the qualification by the Company as a reporting company under the Securities Exchange Act of 1934 ("Exchange Act") through the filing of a Form 8, Form 10 or such other form as may be advisable for the Company to become a publicly reporting Company under the Exchange Act (as determined by the Company's Board of Directors), (iii) a Regulation A Offering which subjects the Company to the reporting requirements under Form I-K or I-SA, or (iv) the listing of the Common Stock of the Company for trading on a national or regional securities exchange of any country in the world, or (v) a debt or equity raise equal to \$5 million at the discretion of the Board. A "Stockholder Vote" for purposes of this paragraph means the affirmative vote of the Holders of not less than 50.1% of the then outstanding shares of Series A Plus Preferred Stock.

The Series A Plus Preferred Stock will rank with respect to rights upon a liquidation event of BioCurity: (i) senior to any "Junior Securities," as they exist on the date hereof or as the Junior Securities may be constituted from time to time; and (ii) junior to any Senior Securities that may be issued from time to time. Once converted, the Shares will become Common Stock and will remain junior to any outstanding Preferred Stock. Therefore, holders of the Shares will have a risk similar to current Common stockholders (including founders, board members and other common stockholders) who many have purchased their stock at a considerably lower price. "Junior Securities" means the shares of Common Stock and the shares of any other class or series of equity securities of the Company which (by the terms of the Certificate of Incorporation or of the instrument by which the Board, acting pursuant to authority granted in the Certificate of Incorporation, as amended from time to time, shall fix the relative rights, preferences and limitations thereof) shall be subordinated or junior to the rights of the Holders upon a Liquidation Event. "Senior Securities" means the shares of any other class or series of equity securities of the Company which (by the terms of the Certificate of Incorporation or of the instrument by which the Board, acting pursuant to authority granted in the Certificate of Incorporation, as amended from time to time, shall fix the relative rights, preferences and limitations thereof) shall be senior to the rights of the Holders upon a Liquidation Event.

The Company may conduct future offerings of securities with rights and preferences that are superior to those of existing stockholders of our Company.

There is no guarantee that the terms of any subsequent offering will not be preferable in control, pricing, or other significant terms to existing investors in our Company. Without the consent of any shareholder, the Company may initiate an offering with a senior class of stock. Many of the terms could result in significant dilution and mandatory rights including liquidation preferences of a new class of shareholders who are currently unknown.

The Company has been unable to raise sufficient capital from the Series A Plus Preferred Offering.

The Company has not been successful in raising sufficient funds to meet its current cash needs. The Company does not have the funds required to hire the staff and professionals required to prepare the

documentation for future capital raises. In addition, the investors in the Offering may experience significant dilution in any future capital raise of debt or equity.

No weighted average anti-dilution protection or preemptive rights - shareholders of Common Stock and Preferred Stock other than shareholders of Series A, Series AA and Series AAA Preferred Stock.

In the event the Board determines in its sole discretion to cause the Company to sell securities at a lower price, shareholders of common stock and Preferred stock other than shareholders of Series A, Series AA and Series AAA Preferred Stock, could be exposed to substantial dilution. Detailed information is available to any investor as to the rights and preferences allocable to their shares on the Certificate of Designation. Investors are encouraged to carefully review the terms of their purchased shares.

Investors holding Series A, Series AA, Series AAA Preferred Stock have received “weighted average” anti-dilution protection based upon the purchase price of each Series with the certain excepted issuances by the Company (i.e., \$1.25, \$1.50 and \$1.70 respectively), including: (i) options, warrants, note conversion rights or other rights to acquire Common Stock or Preferred Stock existing as of the date of their purchase; (ii) any Series AAA, Series AA or Series A Preferred Shares (or underlying Common Stock) issuable in connection with the sale of Series AAA, Series AA and Series A Preferred Shares; (iii) securities issued as consideration for the acquisition of another entity by the Company by merger, or by the purchase of all or substantially all of such other entity’s assets; (iv) securities issued pursuant to an equipment financing lease or similar arrangement; and securities issued other than for cash to strategic partners, banks or lessors of the Company.

In addition, the Series AAA Preferred Stock provides certain preemptive rights in favor of purchasers of 100,000 shares of Series AAA Preferred Stock or more (each a “Large Purchaser”) with respect issuances by the Company of shares of Common Stock, shares of Preferred Stock or any other class of capital stock of the Company, whether or not now authorized, or securities that are convertible into shares of such capital stock by debt instrument (collectively, “New Securities”).

The preemptive rights provide a Large Purchaser with a right within 10 days following delivery of notification by the Company of the New Securities offering to purchase their pro rata share (based on percentage ownership of the Company owned by the Large Holder with respect to their Series AAA Preferred Shares on an as converted to Common Stock basis), provided they deliver notice of acceptance of their preemptive rights within 10 days of such notice, and tender the applicable subscription materials back to the Company together with payment for the New Securities subject to the preemptive rights notice within such 10 day period following delivery of such subscription materials.

The Company is subject to a Stockholder’s Agreement that vests substantial power in the hands of the existing stockholders.

Shareholders in our Company have entered into an agreement (the “Stockholders Agreement”) that places significant limitations on the rights of existing parties for so long as the Stockholders Agreement remains in effect, including: (i) the Company and then the other stockholders party to the agreement have a right of first refusal to purchase a stockholder’s shares of stock in the Company, except for certain limited exempt issuances (ii) the Company has certain drag along rights which can force a stockholder party to the agreement to sell his or her shares on the same terms as the selling shareholders, even if they do not want to sell their shares on such terms; (iii) stockholders who are party to the Stockholders Agreement are required to vote their shares in a manner designed to elect to the Board of Directors each of: (a) Dr. Cheryl Baker, PhD or her designee; and (b) a designee of the Board of Directors is to be comprised of 2 members or such greater number as mutually agreed to between Dr. Cheryl Baker, Mr. Sam Merchant, and/or Ms. Nancy Cass (presently set at a total of three directors), effectively providing them the ability to control the Board of Directors and substantially control the operations of the Company; and (iv) stockholders party to the Stockholders Agreement are required to lock up the sale of their shares of capital stock for a period of 180 days following declaration of effectiveness of a registration statement of capital stock of the Company filed under the Securities Act of 1933, and further provides a power of attorney to the Company to execute any such lock up agreement as is required in connection with such registration, which could significantly impair the marketability of the shares. The termination of the Stockholders Agreement can be affected as agreed to by the Board of Directors along with each of Dr. Cheryl Baker, PhD, Mr. Sam Merchant and/or Ms. Nancy Cass, or under certain other circumstances delineated thereunder, which effectively places its ongoing effectiveness in the control of the aforesaid persons.

Business Risks in Biotech

Risks Relating to Clinical Development and Commercialization of Our Product Candidates.

Loss of Key Team Member - CSSi LifeSciences as Clinical Development Lead.

The Company has signed a contract with CSSi LifeSciences (“CSSi”) for clinical development of its proposed drug. Mr. Jim Sergi, who is Founder and CEO of CSSi is expected to play a key role for the Company as an advisor and service provider. Although CSSi has a significant number of consultants should Mr. Sergi no longer be leading CSSi or if CSSi is unable to perform services for the Company for any reason whatsoever it would be a material loss to the Company. Mr. Sergi has expertise in supportive care oncology drugs as well as working with companies from discovery to commercialization. A loss of his services could seriously impair the Company financially and there is no guarantee the Company could retain the services of another group with his level of expertise or at a price and terms that are acceptable.

The Company has no senior management with experience in drug development.

The Company has no senior management experienced in drug development, including but not limited to Active Pharmaceutical Ingredient (“API”) or drug manufacturing, Investigational New Drug (“IND”) toxicology testing, IND submissions or clinical trials. We will rely on third-party contract research organizations (“CRO”), contract manufacturing organizations (“CMO”), consultants, and advisors, such as the Company’s retained CRO, CSSi LifeSciences for drug development support. However, there is and has not been funding available to pay any consultants with drug development experience or attract any staff with similar experience.

The Company has explored collaborations with academic institutions for drug development.

The Company’s Board of Directors has explored drug development participation with Academic Institutions including a National Cancer Institute Designated Comprehensive Cancer Center. The Company does not have funding available to enter into any of these collaborations. If additional capital is not available, the Company will have to continue to delay drug development and may be forced to cease operations.

Development of our product candidates and general working capital to operate the Company will require substantial additional funds to conduct research and development, bring on FDA and other consultants, additional management, conduct clinical trials, retain legal counsel and other expenditures reasonably necessary, foreseen, and unforeseen, to bring such product candidates to market and to establish manufacturing, marketing, and distribution capabilities. Currently, we have not started clinical trials and there is no guarantee that the Company will ever have the capital required to meet the requirements to file an Initial Drug Application with the FDA or if filed it would be approved to begin clinical trials.

Future capital requirements are required to sustain operations and proceed to drug development.

If the Company is able to proceed with its drug development, we anticipate that we will continue to generate significant losses for the next several years and foreseeable future to commence and complete drug development on our product candidates, commence and complete clinical trial programs for our product candidates, build commercial capabilities, engage consultants, and grow a corporate infrastructure.

There is a risk of delay or failure at any stage of developing a product candidate, and the time required, and costs involved in successfully accomplishing our objectives cannot be accurately predicted. Actual drug research and development costs as well as general working capital needs could substantially exceed budgeted amounts, which could force us to delay, reduce the scope of or eliminate one or more of our research or development programs, commercializing approved product candidates. If any of these events occur, our business could be materially harmed, and the value of our securities would decline.

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

- the scope, rate of progress, results, and costs of our preclinical and non-clinical studies;

- clinical trials, which have not yet begun due to funding shortfalls;
- once initiated the scope, rate of progress and costs of our manufacturing, development, and commercial manufacturing activities;
- the cost, timing, and outcomes of regulatory proceedings, including but not limited to U.S. FDA, and other regulatory costs both national and international the costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims;
- the costs associated with commercializing a drug candidate if clinical trials begin and if the drugs development receive regulatory approval;
- the cost and timing of establishing sales and marketing capabilities;
- expenses for international strategy;
- cost of management, consultants, and general working capital expenses;
- competing technological efforts and market developments;
- revenues received from any future products, if any; and
- payments received under any future strategic collaborations, if any.

We have no experience as a Company in conducting clinical trials.

The Company does not have the funding, nor has it completed testing to apply to conduct a clinical trial. The Company will not be able to commence material steps toward a clinical trial until sufficient funds are available. In part because of the lack of experience conducting clinical trials, we cannot be certain that our proposed preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, contract research organizations (CROs) and consultants. Relying on third-party clinical investigators, CROs and consultants may force us to encounter delays that are outside of our control.

If approved to commence clinical trials we also will compete with other clinical stage companies and institutions for clinical trial participants, which could reduce our ability to recruit participants for our clinical trials. Any delay in recruiting clinical trial participants could materially adversely affect our ability to bring a product to market prior to our competitors.

We may face delays in initiating and completing our clinical trials and may not be able to complete or initiate them at all. Clinical trials necessary to support an application for approval to market any product candidates have not been initiated. We may need to conduct more clinical trials than we currently anticipate. We may experience delays due to a number of factors, some of which may not be in control of the Company, such as the COVID -19 pandemic and other foreseeable and unforeseeable risks.

Our future proposed clinical trials may be delayed, unsuccessful, never initiated, or terminated as a result of many factors, including:

- delays in designing an appropriate clinical trial protocol and reaching agreement on trial design with investigators and regulatory authorities;
- governmental or regulatory delays, failure to obtain regulatory approval or changes in regulatory requirements, policy, or guidelines;
- adding new clinical trial sites;
- reaching agreement on acceptable terms with contract research organizations, (“CROs”), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the actual performance of CROs and clinical trial sites in ensuring the proper and timely conduct of our clinical trials;
- developing and validating companion diagnostics on a timely basis;

- adverse effects experienced by subjects in clinical trials;
- manufacturing sufficient quantities of product candidates for use in clinical trials;
- delays in achieving study endpoints and completing data analysis for a trial; and
- risks by using a CRO outside of the United States.

In addition to these factors, if clinical trials are ever initiated our trials may be delayed, unsuccessful or terminated because:

- regulators or Institutional Review Boards (“IRBs”), may not authorize us to commence a clinical trial;
- regulators or IRBs may suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or concerns about patient safety;
- we may suspend or terminate our clinical trials if we believe that they expose the participating patients to unacceptable health risks;
- patients may not complete clinical trials due to safety issues, side effects, such as injection site discomfort, a belief that they are receiving placebo instead of our product candidates, or other reasons;
- patients with serious diseases included in our clinical trials may die or suffer other adverse medical events for reasons that may not be related to our product candidates;
- in those trials where our product candidate is being tested in combination with one or more other therapies, deaths may occur that may be attributable to the other therapies;
- we may have difficulty in maintaining contact with patients after treatment, preventing us from collecting the data required by our study protocol;
- product candidates may demonstrate a lack of efficacy during clinical trials; and
- personnel conducting clinical trials may fail to properly administer our product candidates.

We could encounter delays if our clinical trials after initiation are suspended or terminated by us, by IRBs of the institutions in which such trials are being conducted, by the data safety monitoring boards for such trials or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including potential for unacceptable safety risks to patients, inspection of the clinical trial operation or trial site, changes in government regulations or administrative actions.

We will rely on CROs and perhaps other consultants to perform our data management and analysis. They may not provide these services as required or in a timely or compliant manner, and we may be held legally responsible for any or all of their performance failures or inadequacies. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. In addition, any delays in completing or initiating our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also lead to the denial of regulatory approval of our product candidates.

If we encounter difficulties obtaining approval for clinical trials and enrolling patients in our clinical trials, our clinical trials if approved could be delayed or otherwise adversely affected.

If we have difficulty enrolling a sufficient number or diversity of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business. Patient enrollment is affected by factors including:

- severity of the disease under investigation;

- design of the trial protocol;
- the size and nature of the patient population;
- eligibility criteria for the study in question;
- lack of a sufficient number of patients who meet the enrollment criteria for our clinical trials;
- delays required to characterize tumor types to allow us to select the proper product candidates;
- which may lead patients to seek to enroll in other clinical trials or seek alternative treatments;
- perceived risks and benefits of the product candidate under study;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- scheduling conflicts with participating clinicians;
- patient referral practices of physicians;
- protocols due to the COVID-19 pandemic which could impede the clinical trials in unforeseen ways
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our product candidates are based on a novel technology - this is a large risk.

Our product candidates are based on our novel technology platform. There can be no assurance that development problems related to our novel technology will not arise in the future that cause delays or that we are not able to resolve. Regulatory approval of novel product candidates such as ours can be more expensive and take longer than for other, more well-known, or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of our platform may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. The Company may decide to proceed with an IV product instead of the topical product or may proceed simultaneously with a topical and an IV product, but no decision has been made as of the date of this annual report. The nature of our product candidates may also mean that fewer people are trained in or experienced with product candidates of this type, which may make it difficult to find, hire and retain capable personnel, particularly for research, development, commercial and manufacturing positions. If we are unable to hire as employees or consultants or retain the necessary personnel, the rate and success at which we can develop and commercialize product candidates will be limited. Any such event would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition, and results of operations.

We have not developed an acceptable toxicity profile for our product candidates.

In order to move a product candidate into human clinical trials, we must first demonstrate an acceptable toxicity profile in preclinical testing. Furthermore, in order to obtain approval, we must also demonstrate safety in various non-clinical tests. For example, we plan to conduct preclinical testing in anticipation of filing an Investigational New Drug (IND) application, subject to obtaining additional funding. We may not have conducted or may not conduct the types of nonclinical testing required by regulatory authorities, or future non-clinical tests may indicate that our product candidates are not safe for use. Preclinical and non-clinical testing is expensive, time-consuming and has an uncertain outcome. In addition, success in initial non-clinical testing does not ensure that later non-clinical testing will be successful.

We may experience numerous unforeseen events during, or as a result of, the non-clinical testing process, which could delay or prevent our ability to develop or commercialize our product candidates, including:

- our preclinical and non-clinical testing may produce inconclusive or negative safety results, which may require us to conduct additional non-clinical testing or to abandon product candidates;
- our product candidates may have unfavorable pharmacology or toxicity characteristics;
- our product candidates may cause undesirable side effects such as negative immune responses that lead to autoimmune complications;
- our enrolled patients may have yeast allergies that lead to complications after treatment; and
- the FDA or other regulatory authorities may determine that additional safety testing is required.

Any such event would increase our costs and could delay or prevent our ability to commercialize our product candidates, which could adversely impact our business, financial condition, and results of operations.

Results of early-stage studies and clinical trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, and it may be because we have not selected the best first product candidate. This could require the Company to repeat steps which are costly and will take time. The results of preclinical studies and/or early clinical trials of our product candidates may not be predictive of the design or results of later-stage clinical trials. Statistical significance is a statistical term that means that an effect is unlikely to have occurred by chance. In order to be approved, product candidates must demonstrate that their effect on patients' diseases in the trial is statistically significant. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Early clinical trials frequently enroll patient populations that are different from the patient populations in later trials, resulting in different outcomes in later clinical trials from those in earlier stage clinical trials. In addition, adverse events may not occur in early clinical trials and emerge in larger, late-stage clinical trials or after commercialization. A number of companies in the biopharmaceutical industry have suffered significant setbacks and incurred loss of value to security holders in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials.

If later stage clinical trials do not demonstrate efficacy and safety of our product candidates, we will not be able to market them, and our business will be materially harmed.

We may be required to suspend, repeat, or terminate a future clinical trial.

We are not currently in any clinical trials and have not filed the paperwork or performed the tests to gain approval to do so. Clinical trials must be conducted in accordance with FDA regulations governing clinical studies, or other applicable foreign government guidelines, and are subject to oversight by the FDA, other foreign governmental agencies, and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced under Good Manufacturing Practices ("GMP") and may require large numbers of test subjects.

Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- the time required to determine whether the product candidate is effective may be longer than expected;
- deaths or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies;

- the quality or stability of the product candidate may fall below acceptable standards; and
- insufficient quantities of the product candidate might be available to complete the trials.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial. Due to these and other factors, our product candidates could take longer to gain regulatory approval than we expect, or we may never gain approval for any product candidates, which could reduce or eliminate our revenue by delaying or terminating the commercialization of our product candidates. There is no assurance that the Company would have the capital available to pay for any alterations required for clinical trials or be able to fund the trials as required.

Regulatory authorities may not approve our product candidates even if they meet safety and efficacy endpoints in clinical trials.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

We plan, if reasonably possible to have discussions with and will attempt to obtain guidance from regulatory authorities regarding certain aspects of our clinical development activities. These discussions, if possible, are not binding commitments on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. A regulatory authority may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Prior to regulatory approval, a regulatory authority may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under a regulatory authority review. In the United States, these outside experts are convened through the FDA's Advisory Committee process, which would report to the FDA and make recommendations that may differ from the views of the FDA. Should an Advisory Committee be convened, it would be expected to lengthen the time for obtaining regulatory approval, if such approval is obtained at all. The FDA and foreign regulatory agencies may delay, limit, or deny marketing approval for many reasons, including:

- a product candidate may not be considered safe or effective;
- our manufacturing processes or facilities may not meet the applicable requirements;
- changes in the agencies' approval policies or adoption of new regulations may require;
- different divisions of the FDA are reviewing different product candidates and those divisions may have different requirements for approval; and
- changes in regulatory law, FDA or foreign regulatory agency organization, or personnel may result in different requirements for approval than anticipated.

Any delay in or failure to receive or maintain approval for any of our product candidates could prevent us from ever generating revenues and could result in the closing of the business.

Any product candidate could be subject to restrictions, withdrawal, and unanticipated problems with our products, when and if any of them are approved.

Any product candidate that we obtain marketing approval for, along with the manufacturing processes, post-approval clinical data, labeling, advertising, and promotional activities for such product, will be subject to continual requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a

product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use. If we market our products outside of their approved indications, we will be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with these products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products, fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approval;
- refusal to permit the import or export of our products; and
- product seizure and injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, any marketing approval that was obtained could be lost, which would adversely affect our business, prospects, and ability to achieve or sustain profitability.

We may encounter substantial regulatory, funding, and other challenges with the production of our product.

Before obtaining marketing approval from regulatory authorities for the sale of our current product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing.

Any inability to successfully initiate and/or complete preclinical studies, manufacturing materials and clinical trials could result in additional costs to us and/or impair our ability to ever meet regulatory milestones permitting the Company to obtain an approved product. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions which will cause delays and cost additional funds that the Company may not have.

Before receiving approval to commercialize a drug candidate, we must demonstrate to the FDA and other regulatory agencies, with substantial evidence from well controlled clinical trials, that the drug candidate is both safe and effective. If these trials or future clinical trials are unsuccessful, our business and reputation would be harmed. Clinical failure or a lack of funding to perform the testing can occur at any stage of clinical development. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Because of these regulatory risks, the research and development efforts of an API manufacturer may not result in any commercially viable products. There is no guarantee that this will ever occur. If a portion of these

development efforts is not successfully completed such as retaining a compliant API manufacturer or, if other required regulatory approvals are not obtained by our vendors and service providers, we are not likely to meet further milestones or obtain any approved products.

Risks associated with obtaining foreign regulatory approvals.

Sales of our products outside the United States will be subject to foreign regulatory requirements governing clinical trials, marketing approval, intellectual property issues, manufacturing, product licensing, pricing, and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. In addition, due to the limited funding of the Company, it may lack the funds necessary to obtain regulatory approval in foreign jurisdictions, which could result in a lapse of applications, if submitted.

Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA and foreign regulatory authorities could require additional testing. Failure to comply with these regulatory requirements or obtain required approvals could impair our ability to develop foreign markets for our products.

Material negative impact of undesirable side effects of product candidates.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Our product candidates are intended to protect the normal tissue from radiation-induced damage. As a result of any side effects, our clinical trials, if commenced at all, could be suspended, or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development, or deny approval, of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; and
- we may be sued and held liable for harm caused to patients; and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We have no sales and marketing team to distribute products that may be approved.

We do not have a sales and marketing infrastructure or any experience in the sales, marketing, or distribution of pharmaceutical products. We plan to seek third-party collaborators for the commercialization of our product candidates. In the future, we may choose to build a focused sales and marketing infrastructure to market or co-promote some of our product candidates if and when they are approved, which would be expensive and time-consuming. Alternatively, we may elect to outsource these functions to third parties. Either approach carries significant risks. For example, recruiting and training a sales force is expensive and time-consuming and, if done improperly, could delay a product launch and result in limited sales. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses.

This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, manage and retain adequate numbers of effective sales and marketing personnel;
- the inability of marketing personnel to develop effective marketing materials;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We may develop third-party collaborations to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into additional arrangements with third parties to sell and market our product candidates or doing so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates.

The availability and amount of reimbursement for our product candidates, if approved, and the manner, if any, in which government and private payers may reimburse for any potential products, are uncertain.

In both the United States and foreign markets, sales of any products will depend in part on the availability of reimbursement from third-party payers such as government health administration authorities, private health insurers and other organizations. The future magnitude of our revenues and profitability may be affected by the continuing efforts of governmental and third-party payers to contain or reduce the costs of health care. We cannot predict the effect that private sector or governmental health care reforms may have on our business, and there can be no assurance that any such reforms will not have a material adverse effect on our business, financial condition, and results of operations.

In addition, in both the United States and elsewhere, sales of prescription drugs are dependent in part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. The ability to obtain reimbursement of our products from these parties is a critical factor in the commercial success of any of our products. Failure to obtain appropriate reimbursement could result in reduced or no sales of our products.

Third-party payers are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved health care products. There can be no assurance that our products will be considered cost effective, or that adequate third-party reimbursement will be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Legislation and regulations affecting the pricing of pharmaceuticals may change before any of our products are approved for marketing. Adoption of such legislation could further limit reimbursement for medical products and services. We, or our collaborators, may elect not to market future products in certain markets.

We have limited resources and cannot develop multiple drug products simultaneously.

Because we have limited, uncertain and vulnerable financial and managerial resources, we focus on research programs and product candidates for the indications that we believe are the most scientifically and commercially promising. Our resource allocation decisions may cause us to fail to capitalize on viable scientific or commercial products or profitable market opportunities. In addition, we may spend valuable time and limited managerial and financial resources on research programs and product candidates for specific indications that ultimately do not yield any scientifically or commercially viable products. If we do not accurately evaluate the scientific and commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in situations where it would have been more advantageous for us to retain sole rights to development and commercialization.

Risks Relating to Manufacturing Activities

We have no experience manufacturing our product candidates or supervising the manufacturing of our product candidate by others.

The Company has not performed any Good Manufacturing Practices (“GMP”) of the Company’s Active Pharmaceutical Ingredient (“API”) or product candidates. There will be ongoing regulatory significant and material requirements for manufacturing a product which is essential for the Company to proceed to drug development. We currently plan to rely on Contract Manufacturing Organizations (CMOs) for our API and product candidates. Failure to find and maintain satisfactory commercial-scale fill and finish contractors with the appropriate regulatory licenses could impair our ability to supply product for clinical and commercial needs. Additionally, we plan to outsource product manufacturing activities to a third party CMO. The Company will be dependent upon the information provided by advisors, such as the Company’s retained CRO, CSSi LifeSciences, to oversee the selection process for a CMO and engage a CMO for product manufacturing, since there is no senior management and Dr. Cheryl Baker, PhD is not experienced in manufacturing drug products.

Failure of any of these contractors to maintain compliance with GMPs and other regulatory and legal requirements could result in government actions that would limit or eliminate toxicology testing, clinical trials, and commercial product supply. Under any agreement with a CMO, we would have less control over the timing and quality of manufacturing than if we were to perform such manufacturing ourselves. A CMO would be manufacturing other pharmaceutical products in the same facilities as our product candidates, increasing the risk of cross product contamination. Further, there is no guarantee that any CMO will continue ongoing operations, causing potential delays in product supply, reduced revenues, and other liabilities for us. The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of equipment, systems, and processes.

We may be subject to lengthy delays and expense in conducting validation studies if we can meet the requirements at all. If we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in our manufacturing processes or our relationships with other manufacturers, our preclinical and clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, we or our contract manufacturers must supply all necessary documentation in support of our regulatory approval applications on a timely basis and must adhere to current Good Manufacturing Practices (“GMP”) regulations enforced by the FDA and other regulatory bodies through their facilities inspection programs. As such, we will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any non-disclosure agreement, biologics license application (“BLA”) or marketing authorization application (“MAA”).

If the manufacturing facilities cannot pass a pre-approval plant inspection, the approval by the FDA or other regulatory bodies of the products will not be granted. If the FDA or a comparable foreign regulatory authority does not approve facilities and processes for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to correct the issues or find alternative manufacturing facilities, if available at all, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Accordingly, we and our collaborators and suppliers must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. In the event that our manufacturing source(s) fail to comply with applicable regulatory requirements, this could delay our ability to generate the products necessary for completion of clinical trials, or if approved, to generate production of products to serve our markets. Any such delays could be deleterious to the Company.

We will rely on relationships with third-party contract manufacturers.

Problems with any of our contract manufacturers’ or raw material suppliers’ facilities or processes, could prevent or delay the production of adequate supplies of finished product. This could delay preclinical testing, clinical

trials or delay and reduce commercial sales in the event of approval of any product and materially harm our business. Any prolonged delay or interruption in the operations of our collaborators' facilities or contract manufacturers' facilities could result in cancellation of shipments, loss of components in the process of being manufactured or a shortfall in availability of a product candidate or products. A number of factors could cause interruptions, including:

- the inability of a supplier to provide raw materials;
- equipment malfunctions or failures at the facilities of our collaborators or suppliers;
- high process failure rates;
- damage to facilities due to natural or man-made disasters;
- changes in regulatory requirements or standards that require modifications to our or our collaborators' and suppliers' manufacturing processes;
- action by regulatory authorities or by us that result in the halting or slowdown of production of components or finished product at our facilities or the facilities of our collaborators or suppliers;
- problems that delay or prevent manufacturing technology transfer to another facility, contract manufacturer or collaborator with subsequent delay or inability to start up a commercial facility;
- a contract manufacturer or supplier going out of business, undergoing a capacity shortfall, or otherwise failing to produce product as contractually required;
- employee or contractor misconduct or negligence;
- shipping delays, losses, or new US or global regulations or long-term interruptions;
- circumstances due to global conditions outside the control of the Company;
- other similar factors; and
- international related manufacturing issues.

Because manufacturing processes are complex and are subject to a lengthy regulatory approval process, alternative qualified production capacity and sufficiently trained or qualified personnel may not be available on a timely or cost-effective basis or at all. Difficulties or delays in our contract manufacturers' production of drug substances could delay or prevent our preclinical work, clinical trials and increase our costs.

Further, if our contract manufacturers are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We and our contract manufacturers are subject to significant regulation with respect to the manufacturing of our products.

All entities involved that may be retained in the preparation of a product candidate for clinical trials or commercial sale, including our manufacturing facility and our contract manufacturing organizations used for filling and finishing of our bulk product, are subject to extensive regulation. Components of a finished product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. The facilities and quality systems of some or all of our third-party contractors must pass a preapproval inspection for compliance with the applicable regulations as a condition of any regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third-party contractors or raw material suppliers. If any such inspection or audit identifies a failure to comply and even

be able to meet with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of preclinical activities, a clinical trial or commercial sales or the temporary or permanent closure of a facility. Our third-party contractors or raw material suppliers may refuse or be unable to implement remedial measures required by regulatory authorities. Any failure to comply with applicable manufacturing regulations or failure to implement required remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

During the course of the product life cycle provided a product is approved for sale, we may make process changes that can negatively impact us.

In the event that manufacturing process changes are necessary for the further development of a product candidate, we may not be able to reach agreement with regulatory agencies on the criteria for demonstrating comparability to the original product, which would require us to repeat clinical studies performed with the original product. This could result in lengthy delays in implementing the new process or site and substantial lost sales as a result of our inability to meet commercial demand. If we reach agreement with regulatory agencies on the criteria for establishing comparability, we may not be able to meet these criteria or may suffer lengthy delays in meeting these criteria. This may result in significant lost sales due to inability to meet commercial demand with the original product. Furthermore, studies to demonstrate comparability, or any other studies on the new process or site such as validation studies, may uncover findings that result in regulatory agencies delaying or refusing to approve the new process or site.

Risks Relating to Regulation of Our Industry

The biopharmaceutical industry is subject to significant, evolving regulation and oversight in the United States, in addition to approval of products for sale and marketing.

In addition to FDA restrictions on marketing of biopharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the biopharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal health care 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 health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory 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, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

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. Several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free products to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws, which could have a material adverse effect on our business, financial condition, and results of operations. Rules and regulations are constantly evolving and subject to unanticipated material changes without sufficient notice. Certain factors are out of control of the Company.

We may be subject, directly, or indirectly, to challenging federal and state healthcare fraud and abuse laws and health information privacy and security laws.

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act and its implementing regulations, which impose certain requirements relating to the privacy, security, and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Misconduct or other improper activities by affiliates may cause harm to the Company.

We are exposed to the risk of fraud or other misconduct by employees, advisers, agents, and affiliates. Misconduct by related parties could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. 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. It is not always possible to identify and deter misconduct of related parties, and the precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Health care reform measures could adversely affect our business.

In the United States and foreign jurisdictions, there have been and continue to be multiple legislative and regulatory changes to the healthcare system that could affect materially affect our ability to develop the technology of the Company and other aspects of the Company's operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs. Most recently, in March 2010 the Patient Protection and Affordable Health Care Act, ("PPACA") as amended by the Health Care and

Education Affordability Reconciliation Act, or collectively the PPACA, was enacted, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, that began in 2011;
- new requirements to report certain financial arrangements with physicians and others, including reporting any “transfer of value” made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, began in 2014, and has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending that began on Jan. 1, 2011.

Many of the details regarding the implementation and continuation of the PPACA are uncertain and therefore the effect that the PPACA has on our business remains unclear. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA to our product candidates. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product. The FDA has issued several guidance documents, but no implementing regulations on biosimilars and no biosimilar applications have yet been approved. It is not certain that we will receive 12 years of biologics marketing exclusivity for any of our products. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way we conduct our business and may require us to change current strategies.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payers or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition, and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to generate revenue. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on our ability to profitably price our products, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. We might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which

could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Risks Relating to Competitive Factors

We compete in an industry characterized by extensive research and development efforts and rapid technological progress.

New developments occur and are expected to continue to occur at a rapid pace in our industry, and there can be no assurance that discoveries or commercial developments by our competitors will not render some or all of our potential products obsolete or non-competitive. Many of the companies we will compete with have established successful track records, substantially greater financial, research and development, other companies may have grant resources or support from major medical facilities and/or academic institutions, manufacturing abilities, management expertise, industry contacts, marketing experience. These companies represent substantial long-term competition for us that could eliminate the Company's projected market. Such companies may succeed in discovering and developing pharmaceutical products more rapidly than we do or pharmaceutical products that are safer, more effective and/or less costly than any that we may develop. Such companies also may be more successful than we are in manufacturing, sales, and marketing. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Academic institutions, governmental agencies and other public and private research organizations also conduct clinical trials, seek patent protection, and establish collaborative arrangements for the development of product candidates. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, reimbursement coverage, price, and patent position. There can be no assurance that our competitors will not develop safer and more effective products, commercialize products earlier than we do, or obtain patent protection or intellectual property rights that limit our ability to commercialize our products.

Competitive products for prevention and treatment of radiation-induced damage - competitors may develop and market products that are less expensive and superior to ours.

The biopharmaceutical industry is highly competitive. There are many public and private biopharmaceutical companies, public and private universities and research organizations actively engaged in the discovery and research and development of products for cancer and radiation protection. Given the current significant unmet patient need for new therapies, oncology is a sector of focus for large and small companies as well as research institutions. As a result, there is and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products. It is possible that competitors may develop products superior to the Company's products, which could render the Company's products not to be commercially viable.

Many of our competitors, either alone or with their strategic collaborators, have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of drugs, obtaining FDA and other regulatory approvals, and the commercialization of those products. Some competitors may obtain funding from government grants and other programs which are intended to expedite their development of products. Accordingly, our competitors may be more successful in obtaining approval for drugs and achieving widespread market acceptance. Further, it is possible that we may initiate a clinical trial or trials for these product candidates, only to find that data from competing products, including over the counter products, make it impossible for us to complete enrollment in these trials, resulting in our inability to file for marketing approval with regulatory agencies. Even if our products are approved for marketing in a particular indication or indications, they may have limited sales due to particularly intense competition in these markets.

Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the significant expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

We also compete with other clinical-stage companies and institutions for clinical trial participants, which could reduce our ability to recruit participants for our clinical trials. Any delay in recruiting clinical trial participants could materially adversely affect our ability to bring a product to market prior to our competitors. Research and discoveries by others may result in breakthroughs that render our product candidates obsolete even before they begin to generate any revenue.

In addition, our competitors may obtain patent protection and/or FDA and other regulatory approval and have resources to develop and commercialize products more rapidly than we do, which may impact future sales of any of our product candidates that receive marketing approval. If the FDA approves the commercial sale of any of our product candidates, we expect to be forced to compete in areas in which we have limited or no experience including but not limited to manufacturing and marketing. We expect competition among products will be based on a number of issues including product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payers, and patent position. Our financial position will suffer in spite of receiving regulatory approval but cannot compete effectively in the marketplace.

If any of our product candidates are approved and commercialized, we may face competition from biosimilars. The route to market for biosimilars was established with the passage of the PPACA in March 2010, providing 12 years of marketing exclusivity for reference products and an additional six months of exclusivity if pediatric studies are conducted. In Europe, the European Medicines Agency has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the United States or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

Our product candidates may not be accepted in the marketplace; therefore, we may not be able to generate significant revenue, if any.

Even if our product candidates are approved for sale, physicians and the medical community may not ultimately use them or may use them only in applications more restricted than we expect. Our product candidates, if successfully developed, will compete with a number of traditional products manufactured and marketed by major pharmaceutical and other biotechnology companies. Our product candidates will also compete with new products currently under development by such companies and others. Physicians will prescribe a product only if they determine, based on experience, clinical data, side effect profiles, reimbursement for their patients and other factors, that it is beneficial as compared to other products currently in use. Many other factors influence the adoption of new products, including marketing and distribution restrictions, course of treatment, adverse publicity, product pricing, the views of thought leaders in the medical community and reimbursement by government and private third-party payers. For our products that are developed in combination with other therapies, changes in standard of care or use patterns could make those combinations obsolete.

Risks Relating to Our Arrangements with Third Parties

We will be highly dependent on third parties for all aspects of our clinical development.

We plan to rely on third parties, such as CROs, CMOs, medical institutions, academic institutions, clinical investigators, and contract laboratories, to conduct our non-clinical studies, and clinical trials. We are responsible for confirming that our preclinical studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA as well as other regulatory groups require us to comply with Good Laboratory Practice ("GLP") for conducting and recording the results of our preclinical studies and GLP, for conducting, monitoring, recording, and reporting the results of clinical trials, to ensure that data and reported results are accurate and that the clinical trial participants are

adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with GLP, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be more costly than expected or budgeted, extended, delayed or terminated or may need to be repeated, and we may not be able to obtain the funding for this or regulatory approval for or commercialize the product candidate being tested in such trials. Further, if our CMOs are not in compliance with regulatory requirements at any stage, including post-marketing approval, we may be fined, forced to remove a product from the market and/or experience other adverse consequences, including delays, which could materially harm our business.

We may explore strategic collaborations that may never materialize or may fail.

We may, in the future, periodically explore and expend substantial resources on a variety of possible strategic collaborations on behalf of the Company. At the current time, we cannot predict what form such a strategic collaboration might take, and we do not have the capital to pursue strategic collaborations. If capital were available, we are likely to face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all and this could result in expending capital which could hinder other opportunities for the Company. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the lack of capital, numerous risks and uncertainties associated with establishing strategic collaborations.

Risks Relating to Protecting Our Intellectual Property

Our success depends on our ability to protect our intellectual property.

Our success depends on our ability to obtain and maintain patent protection for products developed utilizing our technologies, in the United States (US) and in other countries, and to enforce these patents. The patent positions of pharmaceutical firms, including us, are generally uncertain and involve complex legal and factual questions. Notwithstanding our licensing of US patents related to our technologies, there is no assurance that any of our existing and potential future patent claims are sufficiently broad enough for our proposed products, will be held valid and enforceable against third-party infringement, or that our products will not infringe any third-party patent or intellectual property. Moreover, any patent claims relating to our technologies may not be sufficiently broad to protect our products. In addition, issued patent claims or licensed patent claims may be challenged, potentially invalidated or potentially circumvented and patent litigation is extremely costly, with no assurances that we would have adequate capital to engage in protracted patent litigation. Our patent claims may not afford us protection against competitors with similar technology or permit the commercialization of our products without infringing third-party patents or other intellectual property rights.

Company licensed patents general risks.

There can be no assurance that we will discover or develop patentable products or processes. The Company has entered into a license agreement (“License Agreement”) with the University of Central Florida Research Foundation (“UCFRF”) regarding the licensing of certain technology (the “Licensed Technology”), the terms of which create a series of risks for the Company. The Company has entered into a subscription agreement with UCFRF and tendered common stock of the Company and there is no obligation for UCFRF to return such shares if the License Agreement is terminated even if UCFRF is in breach of its obligations under the License Agreement. The License Agreement contained options for patent applications, some of which were exercised by the Company but have now expired. The patents that the Company did not exercise and could be licensed by other parties may compete with the Company. The Company is required to fully indemnify UCFRF and UCFRF is not liable for damages to the Company under any circumstances. In the event of an infringement on any of the Licensed Technology, there are obligations that must be followed pursuant to the License Agreement which could result in additional expense to the Company and/or loss of control of the defense of or prosecution of the Licensed Technology. In the event of development of new technology which draws upon any of the Licensed Technology, there can be questions as to whether such technology is subject to the License Agreement and who has the obligation to prosecute the protection of such intellectual property. Prospective investors are urged to review the

summary of the License Agreement included in this report to get a fuller appreciation of the associated risks of the License Agreement.

Potential competitors or other researchers in the field have filed patent applications, issued patents, published articles, or otherwise created prior art that could restrict, or block our efforts to obtain patents that are significant to the Company's product. There also can be no assurance that the UCF issued patents will not be challenged, invalidated, rendered unenforceable or circumvented or that the rights granted hereunder will provide us with proprietary protection or competitive advantages. Our patent rights may also depend on our compliance with technology and our intentions to license patents upon which our patent rights are based and upon the validity of assignments of patent rights from consultants and other inventors that were, or are, not employed by us.

In addition, competitors may manufacture and sell our potential products in those foreign countries where we or UCF have not filed for patent protection or where patent protection may be unavailable, not obtainable, or ultimately not enforceable. In addition, even where patent protection is obtained, third-party competitors may challenge our patent claims or the patent claims of UCF in the various patent offices, for example via opposition in the European Patent Office or inter partes review or reexamination proceedings in the United States Patent and Trademark Office, or USPTO. The ability of such competitors to sell such products in the United States or in foreign countries where we or UCF have obtained patents is usually governed by the patent laws of the countries in which the product is sold.

Risks related to Company-owned international patent portfolio - limitations to cancer types and uses.

The Company filed an international patent application in July 2015 and in January 2017, the patent application entered the National Phase. This invention is directed to methods for the use of the Company's Cerium oxide nanoparticle technology for the treatment of patients with cancer treated only with radiation combined with at least one chemotherapeutic agent. The types of cancers allowed in the claims issued are limited, which may not sufficiently protect our products. This limitation may substantially reduce the economic value of the Company, exit strategies, and coverage of the products under development.

As of the date of this report, the Company's International Patent has been issued in Australia, China, Europe, Hong Kong, Japan, Mexico, and US. The Company has received allowance of claims in Canada. Furthermore, we have only received claim coverage for patients with lung cancer and pancreatic cancer treated only with radiation combined with at least one chemotherapeutic agent in Australia, China, Europe, Hong Kong, Mexico, and US.

We anticipate incurring significant expenses in maintaining, expanding, and investigating issues regarding and defending our patent portfolio.

There can be no assurances that we will have sufficient resources to fund the cost of moving such applications through approval, or that even if we have sufficient funding, that we will be able to obtain approval for any of such patent applications. Even if we are successful in obtaining patent approval in foreign countries, the cost of enforcing such patents against infringers could be expensive or uneconomical, and we risk that in any such enforcement action, the competitor may seek to challenge the validity of the patent(s) granted in such jurisdiction.

Should we lack the funds to file patents, maintain a patent portfolio if issued or to enforce future rights against infringers, we could be adversely impacted. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend. In addition, the Company may incur expenses associated with actual dispute resolution regarding infringement of its licensed patents and matters related to patent ownership by others. The Company is presently examining at least one circumstance in the United States and has requested information to ascertain the facts of the situation for its legal counsel to review and advise. Should the Company determine with legal counsel it is in the best interests of the Company to pursue any such matter, it may incur significant expense in doing so and there is no guarantee that such actions will materially benefit the Company. If the Company were to seek to license its technology or sell the Company or enter into a joint venture or seek other financing a legal opinion of counsel may be required and there is no guarantee that the Company would have the funds available or could ever obtain such an opinion, or that if obtained that: (i) it would remain valid with the passage of time and changing landscape of patent rights; or (ii) the opinion accurately lays out a path of non-infringement that is commercially viable for the Company; or (iii) others would be accepting of the existence of such opinion, as frequently such opinions contain privileged communications and are not shared with third parties. For more information regarding

this patent information, prospective investors will be required to execute a confidentiality agreement in form and content satisfactory to the Company.

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own, claim to own or have exclusively licensed;
- we or our licensors or strategic collaborators, if any, might not have been the first to make the inventions covered by the issued patents that we own or have exclusively licensed;
- we or our licensors or strategic collaborators if any, might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- issued patents that may become necessary to secure our Intellectual Property and that we seek to license may not be available or feasible to license;
- issued patents that we may have, own in the future, or have licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our current or future competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any or some of these events occur or partially occur, some threats may exist that are out of our control or unanticipated cause damage, they could significantly harm our business, results of operations and prospects.

We may be subject to litigation with respect to the ownership and use of intellectual property that will be costly to defend or pursue and uncertain in its outcome.

Our success also will depend, in part, on our refraining from infringing patents or otherwise violating intellectual property owned or controlled by others. Pharmaceutical companies, biotechnology companies, universities, research institutions and others may have filed patent applications or have received, or may obtain, issued patents in the United States or elsewhere relating to aspects of our technology. It is uncertain whether the issuance of any third-party patents will require us to alter our products or processes if approved, obtain licenses, or cease certain activities. Some third-party applications or patents may conflict with our issued patents. Any such conflict could result in a significant reduction of the scope or value of our issued or licensed patents. In addition, if patents issued to other companies contain blocking, dominating or conflicting claims and such claims are ultimately determined to be valid, we may be required to obtain licenses to these patents or to develop or obtain alternative non-infringing technology and cease practicing those activities, including potentially manufacturing or selling any products deemed to infringe those patents. If any licenses are required, there can be no assurance that we will be able to obtain any such licenses on commercially favorable terms, if at all, and if these licenses are not obtained, we might be prevented from pursuing the development and commercialization of certain of our potential products.

Our failure to obtain a license for any technology that we may require to commercialize our products on favorable terms may have a material adverse impact on our business, financial condition, and results of operations. Litigation, which could result in substantial costs to us (even if determined in our favor), may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of the proprietary rights of

others. The FDA has only recently published draft guidance documents for implementation of the Biologics Price Competition and Innovation Act (“BPCIA”) under the PPACA, related to the development of follow-on biologics (biosimilars), and detailed guidance for patent litigation procedures under this act has not yet been provided. If another company files for approval to market a competing follow-on biologic, and/or if such approval is given to such a company, we may be required to promptly initiate patent litigation to prevent the marketing of such biosimilar version of our product prior to the normal expiration of the patent. There can be no assurance that our issued or licensed patents would be held valid by a court of competent jurisdiction or that any follow-on biologic would be found to infringe our patents.

In addition, if our competitors file or have filed patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings to determine priority of invention. These proceedings, if initiated by the USPTO, could result in substantial costs to us, even if the eventual outcome is favorable to us. Such proceedings can be lengthy, are costly to defend and involve complex questions of law and fact, the outcomes of which are difficult to predict. Moreover, we may have to participate in post-grant proceedings or third-party *ex parte* or *inter parte* proceedings under the USPTO. An adverse outcome with respect to a third-party claim or in an interference proceeding could subject us to significant liabilities, require us to license disputed rights from third parties, or require us to cease using such technology, any of which could have a material adverse effect on our business, financial condition, and results of operations.

We also may rely on trade secrets to protect technology, especially where patent protection is not believed to be appropriate or obtainable or where patents have not been issued. For example, our manufacturing process may involve a number of trade secret steps, processes, and conditions. We intend to attempt to protect our proprietary technology and processes, in part, with confidentiality agreements and assignment of invention agreements with our employees and confidentiality agreements with our consultants and certain contractors. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. We may fail in certain circumstances to obtain the necessary confidentiality agreements, or their scope or term may not be sufficiently broad to protect our interests.

If our trade secrets or other intellectual property become known to our competitors, it could result in a material adverse effect on our business, financial condition, and results of operations. To the extent that we or our consultants or research collaborators use intellectual property owned by others, disputes may also arise as to the rights to related or resulting know-how and inventions.

The patent protection and patent prosecution for some of our product candidates is dependent or may be dependent in the future on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when platform technology patents or product-specific patents that relate to our product candidates may be controlled by our licensors. In addition, any licensors and/or licensees may have back-up rights to prosecute patent applications in the event that we do not do so or choose not to do so, and our licensees may have the right to assume patent prosecution rights after certain milestones are reached. If any of our licensing collaborators fails to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products.

Risks Relating to Our Exposure to Litigation

We are exposed to potential product liability or similar claims, and insurance against these claims may not be available to us at all, in sufficient amounts or cost the Company can afford.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, and marketing of human therapeutic products. Clinical trials involve the testing of product candidates on human subjects or volunteers under a research plan and carry a risk of liability for personal injury or death to patients due to unforeseen adverse side effects, improper administration of the product candidate, or other factors. Many of these patients may be already seriously ill and are therefore particularly vulnerable to further illness or death. We plan to carry clinical trial liability insurance but there can be no assurance that we will be able to obtain such insurance or that the amount of such insurance will be adequate to cover claims. We could be materially and adversely affected

if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance. In addition, there can be no assurance that insurance will continue to be available on terms acceptable to us, if at all, or that if obtained, the insurance coverage will be sufficient to cover any potential claims or liabilities. Due to lack of capital, the Company has recently lost its Product Liability, Commercial/Auto and Cyber insurance policies that were set to be renewed in April of 2023. Similar risks would exist upon the commercialization or marketing of any products by us or our collaborators. Regardless of their merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial volunteers;
- costs of litigation;
- distraction of management; and
- substantial monetary awards to plaintiffs.

Should any of these events occur, it could have a material adverse effect on our business and financial condition.

Claims for indemnification by our directors, key employees, officers, consultants, and others.

Our certificate of incorporation provides that we will indemnify our officers and directors to the fullest extent permitted by Delaware law:

- we will indemnify our directors and executive officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law;
- Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify other officers, employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and executive officers in connection with defending a proceeding, except that such directors or executive officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by our Board of Directors, (iii) such indemnification is provided by us, in our sole discretion, pursuant to the powers vested in the corporation under applicable law or (iv) such indemnification is required to be made pursuant to our amended and restated bylaws;
- we may be obligated to indemnify consultants even though they may contribute to the event triggering the indemnification;
- we may be obligated to indemnify licensors and will be unable to recoup under expenses from the licensor even if the licensor was grossly negligent or intentionally caused the harm; and
- the rights conferred in our bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees, and agents and to obtain insurance to indemnify such persons.

As a result, if we are required to indemnify one or more of our directors or executive officers, it may reduce our available funds to satisfy successful third-party claims against us, may reduce the amount of money available to us and may have a material adverse effect on our business and financial condition. We may not be able to meet our indemnification obligations that will place us in default of multiple agreements.

The Company is significantly in debt and may be unable to remain in operation.

The Company is significantly in debt and the creditors have no forbearance preventing them from collecting on the debt immediately. The Company's failure to raise sufficient capital to pay most of its operating expenses over 4 years has put a significant strain on the Company and its business. Due to lack of capital, the Company has been unable to proceed with drug development and any potential future growth has and will be materially adversely affected.

There are other unidentified risks.

The risks set forth above are not a complete list of the potential risks facing us. We realize that there may exist significant risks yet to be recognized or encountered to which we may not be able to effectively respond. There can be no assurance that we will be successful in addressing these risks or future potential risks, and any failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

OWNERSHIP AND CAPITAL STRUCTURE; RIGHTS OF THE SECURITIES

The Company's Securities.

The authorized capital stock of the Company consists of: (i) 100,000,000 shares of Common Stock, par value \$0.00001 per share (ii) 20,000,000 shares of Preferred Stock, of which: (A) 1,620,000 shares have been designated as Series A Preferred Stock; (B) 300,000 shares have been designated Series AA Preferred Stock; (C) 400,000 shares have been designated Series AAA Preferred Stock; (D) 500,000 shares have been designated Series AAAA Preferred Stock (E) 300,000 shares have been designated Series AAAAA Preferred Stock, (F) 100,000 shares have been designated Series AAAAAA Preferred Stock; (G) 200,000 shares have been designated Series 7A Preferred Stock (H) 20 shares have been designated "Super Voting" Series V Preferred Stock; and (I) 200,000 shares have been designated Series A Plus Preferred Stock. As of April 30, 2023 the Company had 5,853,411 issued and outstanding shares of capital stock comprised of 4,025,445 shares of Common Stock, 510,615 shares of Series A Preferred Stock, 300,000 shares of Series AA Preferred Stock, 160,000 shares of Series AAA Preferred Stock and 232,500 shares of Series AAAA Preferred Stock, 300,000 shares of Series AAAAA Preferred Stock, 100,000 shares of Series AAAAAA Preferred Stock, 124,494, shares of Series 7A Preferred Stock), 10 shares of "Super Voting" Series V Preferred Stock and 100,348 shares of Series A Plus Preferred Stock. As of April 30, 2023, the Company had 6,625,376 outstanding common stock options and 1,187,000 outstanding common stock warrants. The Company had 13,665,787 issued and outstanding shares on a fully diluted basis, assuming exercise of all options and warrants and before giving effect to any stock or options issuable following April 30, 2023.

Ownership.

The following tables set forth certain information regarding the beneficial ownership of the Company's holders of 20% or more of any class of voting securities as of April 30, 2023. Except pursuant to applicable marital property laws, the persons named below have sole voting and investment power with respect to the shares beneficially owned by such persons.

<u>Stockholder Name</u>	Number of Securities	Percentage of Voting
	<u>Owned</u>	<u>Power (4)</u>
Cheryl H. Baker, PhD(1)	289,836	1.83% (4)
Sam Merchant(2)	484,057	66.14% (4)
Nancy J. Cass(3)	484,056	3.05% (4)

- (1) All holdings are in the name of Dr. Cheryl Baker, PhD. In addition to the shares of Common Stock set forth above, Dr. Cheryl Baker, PhD was granted at various times options to purchase Common Stock, exercisable in each instance during the 10-year period to exercise from each date of issuance. Options are comprised of options to purchase up to 155,000 shares exercisable at \$2.00 per share.
- (2) All holdings are in the name of Mr. Sam Merchant and are all Common Stock. In addition to the shares of Common Stock set forth above, Mr. Sam Merchant was granted at various times options and warrants to purchase Common Stock exercisable in each instance during the 10-year period to exercise from each date of issuance. Options are comprised of options to purchase up to 994,556 shares exercisable at \$1.30 per share and up to 4,597,753 shares exercisable at \$2.00 per share. Warrants are comprised of warrants to purchase up to 375,000 shares at \$0.40 per share and up to 437,000 shares at \$0.69 per share.
- (3) All holdings are in the name of Ms. Nancy Cass. In addition to the shares of Common Stock set forth above, Ms. Nancy Cass was granted at various times options and warrants to purchase Common Stock, exercisable in each instance during the 10-year period from the date of issuance. Options are comprised of options to purchase up to 311,139 shares exercisable at \$1.30 per share and up to 414,340 shares exercisable at \$2.00 per share. One warrant is outstanding to purchase up to 375,000 shares at \$0.40 per share.

- (4) As of April 30, 2023, the Company had 5,853,411 shares of capital stock issued and outstanding including 10 shares of “Super Voting” Series V Preferred Stock held by Mr. Sam Merchant, which votes together with Common Stock on the basis of 1,000,000 votes per share; accordingly after accounting for the 10,000,000 votes allocable to the Series V Voting Preferred Stock there are 15,853,411 votes for all matters based upon Common Stock and all classes of preferred stock voting together as a single class (except for specific class votes related to each class of preferred stock). Accordingly, the above table shows voting power based on cumulative votes inclusive of those votes allocable to the Series V Preferred Stock. Each such share of the Series V Preferred Stock has a nominal liquidation value.

Common Stock.

On July 1, 2020, and July 1, 2021, all of the shares of Series CF Convertible Preferred Stock issued to investors in our November 2019 Regulation Crowdfunding offering were converted into Common Stock. On July 1, 2021, all of the shares of the Series 2 CF Convertible Preferred Stock issued to investors in our July 2020 Regulation Crowdfunding Offering were converted into Common Stock. The number of shares of Common Stock received upon conversion was convertible on a 1:1 basis as the conversion rate per share, subject to equitable adjustment to the conversion rate to account for subdivisions, forward or reverse stock splits, stock dividends or other extraordinary corporate events as specified in the Company’s Certificate of Incorporation. As such, all investors in our Regulation Crowdfunding offerings are now holders of our Common Stock, the material terms of which are set forth below.

Voting Rights.

Each share of Common Stock is entitled to one vote. The Certificate of Incorporation does not provide for cumulative voting. Therefore, stockholders do not have the right to aggregate their votes for the election of directors.

Dividend Rights.

The holders of Common Stock are entitled to receive such dividends as declared by the Board out of assets legally available.

Liquidating Distributions and Change of Control.

The holders of Common Stock are entitled to share ratably with other holders of Common Stock in the assets of the Company available upon liquidation.

Rights and Preferences.

There are no preemptive, subscription, conversion or redemption rights pertaining to the shares of Common Stock.

Preferred Stock.

The Company’s Preferred Stock is currently comprised of Series A Preferred Stock, Series AA Preferred Stock, Series AAA Preferred Stock, Series AAAA Preferred Stock, Series AAAAA Preferred Stock, Series AAAAAA Preferred Stock, Series 7A Preferred Stock, Series V Preferred Stock, and the Series A Plus Preferred Stock. The Series A through Series 7A Convertible Preferred and Series A Plus Preferred shares convert on 1:1 basis to Common Stock, subject to equitable adjustment in the event of stock splits, stock dividends, or extraordinary corporate transactions that alter the capital structure.

Voting Rights.

The holders of Preferred Stock shall vote together with the holders of the Common Stock, and not as a separate class. The Certificate of Incorporation does not provide for cumulative voting. Therefore, stockholders do not have the right to aggregate their votes for the election of directors.

Dividend Rights.

The holders of Series A through Series 7A and Series A Plus Preferred Stock are entitled to receive such dividends as declared by the Board out of assets legally available.

Liquidation Preferences of our Series A Plus Preferred Stock.

At any time prior to conversion any Series of our Series A Plus Preferred Stock to Common Stock, in the event of: (i) any voluntary or involuntary liquidation, dissolution or winding up of the Company, (ii) a sale, lease transfer or conveyance of all or substantially all of the assets of the Company; (iii) a consolidation of the Company with, or merger of the Company with or into, another corporation or other business entity in which the stockholders of the Company immediately prior to such consolidation or merger own less than 50% of the voting power of the surviving entity immediately after such consolidation or merger; or (iv) any transaction or series of related transactions to which the Company is a party in which in excess of 50% of the Company's voting power is transferred, excluding any consolidation or merger effected exclusively to change the domicile of the Company and/or an effective change of the number of issued and outstanding shares of the Company (any of such events being a "Liquidation Event"), and further excluding any of the issuances of capital stock with respect to any of the transactions contemplated in the Offering, the holders of the following Series of Preferred Stock shall be entitled to receive, an amount in cash, or to the extent cash is not available, property, the Stated Value per Preferred Share, and shall be subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations and the like, the "Original Issue Price"). Alternatively, the holders of the Preferred shares shall be entitled to convert their Preferred shares to Common Stock.

On liquidation, certain classes of Preferred shares are senior to other classes of stock of the Company. The following is a summary of each Series of Preferred Stock's liquidation preferences, as well as their Original Issue Price.

Pre-Emptive Rights and Weighted Average Anti-Dilution Rights.

The Series A, Series AA, Series AAA Preferred Stock have "weighted average" anti-dilution protection based upon the purchase price of each Series with the certain excepted issuances by the Company (i.e., \$1.25, \$1.50 and \$1.70 respectively), including: (i) options, warrants, note conversion rights or other rights to acquire Common Stock or Preferred Stock existing as of the date of purchase; (ii) any Series AAA, Series AA or Series A Preferred Shares (or underlying Common Stock) issuable in connection with the sale of Series AAA, Series AA and Series A Preferred Shares; (iii) securities issued as consideration for the acquisition of another entity by the Company by merger, or by the purchase of all or substantially all of such other entity's assets; (iv) securities issued pursuant to an equipment financing lease or similar arrangement; and securities issued other than for cash to strategic partners, banks or lessors of the Company.

In addition, the Series AAA Preferred Stock provides certain preemptive rights in favor of purchasers of 100,000 shares of Series AAA Preferred Stock or more (each a "Large Purchaser") with respect issuances by the Company of shares of Common Stock, shares of Preferred Stock or any other class of capital stock of the Company, whether or not now authorized, or securities that are convertible into shares of such capital stock by debt instrument (collectively, "New Securities").

The preemptive rights provide a Large Purchaser with a right within 10 days following delivery of notification by the Company of the New Securities offering to purchase their pro rata share (based on percentage ownership of the Company owned by the Large Holder with respect to their Series AAA Preferred Shares on an as converted to Common Stock basis), provided they deliver notice of acceptance of their preemptive rights within 10 days of such notice, and tender the applicable subscription materials back to the Company together with payment for the New Securities subject to the preemptive rights notice within such 10 day period following delivery of such subscription materials.

The preemptive rights do not extend to:

- (1) issuances of capital stock in connection with (i) conversion of existing (and Series AAA) preferred stock to Common Stock; (ii) shares of stock reserved for issuance to employees, directors, providers of financing, consultants and sales representatives pursuant to a stock option plan; (iii) shares of stock issued in exchange for assets, services, financing and the like; (iv) warrants or stock options issued in connection with employees or other service providers, including in connection with placement of securities; and (v) shares issued in connection with exercise of any of the rights enumerated herein;

- (2) securities offered pursuant to a registration statement under the Securities Act of 1933 as amended; or
- (3) securities issued to a single purchaser, or such single purchaser issued together with its affiliates in an amount of \$2,000,000 or more.

Series V “Super Voting” Preferred Stock.

Each share of Series V “Super Voting” Preferred Stock is accorded 1,000,000 votes. The Company has issued 10 shares of “Super Voting” Series V Preferred Stock to Mr. Sam Merchant; each such share has a nominal liquidation value, but is accorded 1,000,000 votes, providing it effective voting control over the Company.

Series A Plus Preferred Stock.

Voting Rights.

The holders of the Series A Plus Preferred shares shall vote together with the holders of the Common Stock, and not as a separate class, on all matters presented to the stockholders of the Company, except as specifically provided in the Certificate of Designations or as otherwise required by law, provided that the rights, preferences and privileges of the Series A Plus Preferred Stock shall not be altered or impaired without the consent of the holders of the Series A Plus Preferred Stock, voting as a separate class. Each Series A Plus Preferred Share shall have a number of votes equal to the number of shares of Common Stock then issuable upon conversion of such Share.

Subscription Agreement.

Each investor in the Company’s Series A Plus Preferred Stock is expected to be required to execute the Subscription Agreement and Stockholders Agreement. The Subscription Agreement places significant limitations on the rights of the parties thereto and each prospective Investor is urged to review the agreement carefully. Included in these restrictions are the following that apply for so long as the Stockholder’s Agreement remains in effect: (i) a beneficial ownership limitation that prohibits transfer any of the Series A Plus Preferred Shares by an investor in the Offering to a purchaser who individually or together with his, her or its affiliates holds 3% or more of the issued and outstanding shares of capital stock of the Company without the prior written consent of the Company; (ii) a drag along rights provision which can force a stockholder to sell his or her Series A Plus Preferred Shares on the same terms as the selling stockholders, even if they do not want to sell their shares on such terms; and (iii) stockholders party to the Subscription Agreement are required to lock up the sale of their Series A Plus Preferred Shares for a period of time not to exceed 180 days determined by the Board of Directors of the Company upon advice of its managing underwriter, from and after the effective date of any registration statement with respect to common stock of the Company unless the Board of Directors of the Company authorizes the release of any of such Stockholder Stock from the lock-up restrictions, and further provides a power of attorney to the executive officers of the Company to execute any such lock up agreement as is required in connection with such registration, which could significantly impair the marketability of the shares. The termination of the Subscription Agreement can be affected as agreed to by the Company and the Investor, which effectively places its ongoing effectiveness in the control of the aforesaid persons.

It should be noted that the Company has issued 10 shares of “Super Voting” Series V Preferred Stock to Mr. Sam Merchant; each such share has a nominal liquidation value, but is accorded 1,000,000 votes, providing it effective voting control over the Company. This summary is qualified in its entirety by the terms of the Subscription Agreement.

Dividend Rights.

The holders of our Series A Plus Preferred shares shall be entitled to receive cumulative dividends, only when and if declared by the Board. If the Board declares a dividend or other distribution on the Common Stock, the Shares would also be entitled to participate in such dividend or distribution with the holders of the Common Stock, pro rata, on an as-if converted to Common Stock basis. In general, it is not contemplated that dividends will be declared or paid.

Conversion Rights of Series A Plus Preferred.

Elective Conversion.

Each Holder shall have the right to convert at any time and from time to time, each of his, her or its shares of Series A Plus Preferred Stock into the number of fully paid and non-assessable shares of Common Stock, free and clear of any liens, claims, preemptive rights, or encumbrances imposed by or through the Company (the “Conversion Shares”), as is computed in accordance with the terms hereof (a “Conversion”).

Mandatory Conversion.

On the first to occur of (i) twenty (20) business days after a “Stockholder Vote” (as defined above), (ii) the date of the qualification by the Company as a reporting company under the Securities Exchange Act of 1934 (“Exchange Act”) through the filing of a Form 8, Form 10 or such other form as may be advisable for the Company to become a publicly reporting Company under the Exchange Act (as determined by the Company’s Board of Directors), (iii) a Regulation A Offering which subjects the Company to the reporting requirements under Form I-K or I-SA, or (iv) the listing of the Common Stock of the Company for trading on a national or regional securities exchange of any country in the world, or (v) a raise debt or equity equal to 5 million dollars at the discretion of the Board (the “Mandatory Conversion Date”), the remaining shares of Series A Plus Preferred Stock then held by each Holder together with, in the Company’s sole discretion, any accrued and unpaid dividends shall be automatically converted (a “Mandatory Conversion”) as follows:

(i) the shares of Series A Plus Preferred Stock shall be automatically converted into the number of shares of Common Stock equal to the product of the number of shares of Series A Plus Preferred Stock held by each Holder times the Conversion Rate in effect at the time; and

(ii) the accrued and unpaid dividends on the shares of Series A Plus Preferred Stock shall be automatically converted into the number of shares of Common Stock equal to: (a) the amount of such accrued and unpaid dividends, divided by the Stated Value; times (b) the Conversion Rate in effect at the time.

1. Series A Preferred Stock

Original Issue Price: \$1.25

Senior to: Common Stock

On Parity with: Series AA, AAA, AAAA, AAAAA, AAAAAA and 7A preferred stock of the Company.

Junior to: None.

2. Series AA Preferred Stock

Original Issue Price: \$1.50

Senior to: Common Stock

On Parity with: Series A, AAA, AAAA, AAAAA, AAAAAA and 7A preferred stock of the Company.

Junior to: None.

3. Series AAA Preferred Stock

Original Issue Price: \$1.70

Senior to: Common Stock

On Parity with: Series A, AA, AAAA, AAAAA, AAAAAA and 7A preferred stock of the Company.

Junior to: None.

4. Series AAAA Preferred Stock

Original Issue Price: \$2.00

Senior to: Common Stock

On Parity with: Series A, AA, AAA, AAAAA, AAAAAA and 7A preferred stock of the Company.

Junior to: None.

5. Series AAAAA Preferred Stock

Original Issue Price: \$3.20

Senior to: Common Stock

On Parity with: Series A, AA, AAA, AAAA, AAAAAA and 7A preferred stock of the Company.

Junior to: None.

6. Series AAAAAA Preferred Stock

Original Issue Price: \$3.20

Senior to: Common Stock

On Parity with: Series A, AA, AAA, AAAA, AAAAA, and 7A preferred stock of the Company.

Junior to: None.

7. Series 7A Preferred Stock

Original Issue Price: \$4.00

Senior to: Common Stock

On Parity with: Series A, AA, AAA, AAAA, AAAAA, and AAAAAA preferred stock of the Company.

Junior to: None.

8. Series A Plus Preferred Stock

Original Issue Price: \$4.50

Senior to: Common Stock

On Parity with: None.

Senior to: Series A, AA, AAA, AAAA, AAAAA, AAAAAA and 7A preferred stock of the Company.

9. Series V Preferred Stock

Original Issue Price: \$0.01

Senior to: Common Stock

On Parity with: None.

Junior to: All other classes of Preferred Stock of the Company.

Stockholders Agreement.

Except for the holders of the Series V Preferred Stock, shareholders in our Company have entered into an agreement (the “Stockholders Agreement”) that contains certain provisions that restrict the rights of existing parties to such agreement, including: (i) a right of first refusal in favor of the Company in connection with transfers of shares except to certain designated permitted transferees; (ii) a drag along provision which requires stockholders to participate in certain sales of shares approved by certain selling stockholders; and (iii) an obligation to vote shares in a manner to elect one designee to the Board as selected by each of Dr. Cheryl Baker, PhD and of Mr. Sam Merchant or Ms. Nancy Cass. MerchantCass Advisors, LLC had an advisory agreement with the Company effective until December 31, 2022. Capital & Venture Resources, LLC has a consulting agreement with the Company and, together with their affiliates, are the beneficial owners of a substantial portion of the Company’s capital stock, warrants and options. Mr. Sam Merchant owns 10 shares of “Super Voting” Series V Preferred Stock that provides Mr. Sam Merchant with voting control over the Company. Circumstances may arise where one or more of Dr. Cheryl Baker, PhD, Mr. Sam Merchant, and Capital & Venture Resources, LLC may have interests directly in conflict with the investors. Investors will have no say and will be entirely relying upon the Board to manage the Company. Investors should be aware that these conflicts exist prior to making any investment. Investors are urged to carefully review the “Related Party Transactions” which summarizes terms of the conflicts and agreements.

Stock Option Plan and Warrants.

The Company established a 2015 Stock Option and Grant Plan (“2015 Plan”) as an incentive to its employees, officers, directors, and consultants. The 2015 Plan originally called for the issuance of stock options, stock grants or other equity incentives to purchase the equivalent of up to 1,000,000 shares of Common Stock, to be granted over a period of up to 10 years from the date of the 2015 Plan, and was amended in January 2017 to call for the issuance of up to 4,000,000 shares of Common Stock options to purchase 2,534,375 of the shares subject to the 2015 Plan have been granted and remain outstanding as of December 31, 2020. In March 2021, the Company adopted a 2021 Stock Option and Grant Plan calling for the issuance of up to 9,000,000 shares of Common Stock. The Board of Directors serves as the stock option committee for purposes of administering the 2021 Stock Option and Grant Plan, including determining the number of shares subject to either outright grant, or grant of purchase option and the terms of such option grants (including vesting schedule, exercise period, strike price and other terms and conditions). It is anticipated additional Stock Options will be issued.

Presently there are: (i) warrants outstanding that were issued in 2015 to purchase up to 1,187,000 shares of Common Stock, with: (a) warrants for 750,000 of those shares exercisable at \$0.40 per share; and warrants for 437,000 of those shares exercisable at \$0.69 per share; and (ii) options to purchase up to 6,625,376 shares of Common Stock, all exercisable at prices ranging from \$1.30 per share to \$2.00 per share.

These warrants and options are held by Mr. Sam Merchant and Ms. Nancy Cass except for options to purchase 307,588 shares of Common Stock by other individuals.

Delaware Antitakeover Law.

The Delaware Antitakeover Law prohibits certain “business combinations” between a Delaware corporation, whose stock is generally publicly-traded or held by more than 2,000 stockholders, and an “interested stockholder” of the corporation for a three-year period following the date that such stockholder became an interested stockholder, unless: (i) the corporation has elected, in its certificate of incorporation, not to be governed by the Delaware Antitakeover Law (the Company has not made such an election); (ii) the business combination was approved by the board of directors of the corporation before the other party to the business combination became an interested stockholder; (iii) upon consummation of the transaction which resulted in the stockholder

becoming an interested stockholder, the interested stockholder owned at least eighty-five percent (85%) of the voting stock of the corporation outstanding at the commencement of the transaction (excluding voting stock owned by directors who are also officers or held in employee benefit plans in which the employees do not have a confidential right to tender or vote stock held by the plan); or (iv) the business combination was approved by the board of directors of the corporation and ratified by 66% of the voting stock which the interested stockholder did not own. The three-year prohibition also does not apply to certain business combinations proposed by an interested stockholder following the announcement or notification of certain extraordinary transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation's directors or who became an interested stockholder prior to the amendment to the corporation's certificate of incorporation to subject the corporation to the Delaware Anti-takeover Law. The term "business combination" is defined generally to include mergers or consolidations between a Delaware corporation and an interested stockholder, transactions with an interested stockholder involving the assets or stock of the corporation or its majority-owned subsidiaries, and transactions which increase an interested stockholder's percentage ownership of stock. The term "interested stockholder" is defined, generally, as those stockholders who become beneficial owners of fifteen percent (15%) or more of a Delaware corporation's voting stock.

These provisions could delay or frustrate the removal of incumbent directors or a change in control of the Company. These provisions also could discourage, impede, or prevent a merger, tender offer, or proxy contest, even if such an event would be favorable to the interests of the stockholders.

What it means to be a Minority Holder.

As a minority holder of the Series A Plus Preferred Stock of the Company, investors will have limited rights in regard to the corporate actions of the Company, including additional issuances of securities, Company repurchases of securities, a sale of the Company or its significant assets, or Company transactions with related parties. Further, investors in the offering have rights less than those of other investors and will have limited influence on the corporate actions of the Company.

DILUTION

Investors should understand the potential for dilution. The investor's stake in a company could be diluted due to the company issuing additional shares. In other words, when the company issues more shares, the percentage of the company that you own will go down, even though the value of the company may go up. You will own a smaller piece of a larger company. This increase in number of shares outstanding could result from a stock offering (such as an initial public offering, another crowdfunding round, a venture capital round, angel investment), employees exercising stock options, or by conversion of certain instruments (e.g., convertible bonds, preferred shares, or warrants) into stock.

If the Company decides to issue more shares, an investor could experience value dilution, with each share being worth less than before, and control dilution, with the total percentage an investor owns being less than before. There may also be earnings dilution, with a reduction in the amount earned per share (though this typically occurs only if the company offers dividends, and most early-stage companies are unlikely to offer dividends, preferring to invest any earnings into the company).

The type of dilution that hurts early-stage investors most occurs when the company sells more shares in a "down round," meaning at a lower valuation than in earlier offerings. An example of how this might occur is as follows (numbers are for illustrative purposes only):

- In June 2017 Jane invests \$20,000 for shares that represent 2% of a company valued at \$1 million.
- In December, the company is doing very well and sells \$5 million in shares to venture capitalists on a valuation (before the new investment) of \$10 million. Jane now owns only 1.3% of the company but her stake is worth \$200,000.
- In June 2018, the company has run into serious problems and in order to stay afloat it raises \$1 million at a valuation of only \$2 million (the "down round"). Jane now owns only 0.89% of the company and her stake is worth only \$26,660.

This type of dilution might also happen upon conversion of convertible notes into shares. Typically, the terms of convertible notes issued by early-stage companies provide that in the event of another round of financing, the holders of the convertible notes get to convert their notes into equity at a “discount” to the price paid by the new investors, i.e., they get more shares than the new investors would for the same price. Additionally, convertible notes may have a “price cap” on the conversion price, which effectively acts as a share price ceiling. Either way, the holders of the convertible notes get more shares for their money than new investors. In the event that the financing is a “down round” the holders of the convertible notes will dilute existing equity holders, and even more than the new investors do, because they get more shares for their money. Investors should pay careful attention to the amount of convertible notes that the company has issued (and may issue in the future, and the terms of those notes.

If you are making an investment expecting to own a certain percentage of the Company or expecting each share to hold a certain amount of value, it is important to realize how the value of those shares can decrease by actions taken by the Company. Dilution can make drastic changes to the value of each share, ownership percentage, voting control, and earnings per share.

TRANSFERABILITY OF SECURITIES

Under Regulation Crowdfunding, for a year after purchase, the securities can only be resold:

- In an IPO;
- To the Company;
- To an accredited investor; and
- To a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance.

In addition, investors in the Offering enter into the Subscription Agreement, which contains a “Lock-Up” provision whereby the investor agrees not to offer, sell, or otherwise dispose of any of Series A Plus Preferred Stock during the period of time (not to exceed 180 days) determined by the Board of Directors of the Company, from the effective date of any registration statement with respect to the Common Stock of the Company unless the Board of Directors of the Company authorizes such transfer. The Subscription Agreement also contains a drag along provision which requires stockholders to participate in certain sales of shares approved by certain selling stockholders, as well as a beneficial ownership limitation that prohibits transfer any of the Shares by an investor in the Offering to a purchaser who individually or together with his, her or its affiliates holds 3% or more of the issued and outstanding shares of capital stock of the Company without the prior written consent of the Company.

RECENT OFFERINGS OF SECURITIES

We have made the following issuances of securities within the last three years.

Date of Commencement of Offering (MM/YYYY)	Offering Exemption Relied Upon	Securities Offered	Final Amount Sold	Final Proceeds	Use of Proceeds
02/2018	Rule 506(b) of Regulation D under the Securities Act	Series 7A Preferred	80,000	\$320,000	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company

12/2018	Rule 506(b) of Regulation D under the Securities Act	Fixed Term Preferred	36,250	\$145,000	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
04/2019	Rule 506(b) of Regulation D under the Securities Act	Fixed Term Preferred	66,666.67	\$200,000	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
09/2019	Rule 506(b) of Regulation D under the Securities Act	Fixed Term Preferred	77,500	\$310,000	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
12/2019	Regulation Crowdfunding	Series CF Convertible Preferred Stock	93,461 ¹	\$407,445.52	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
7/2020	Regulation Crowdfunding	Series 2 CF Convertible Preferred Stock	56,806 ²	\$239,596.46	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
5/2021	Rule 506(c) of Regulation D under the Securities Act	Series A Plus Preferred Stock	6,720	\$25,200	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
8/2021	Rule 506(b) of Regulation D under the Securities Act	Series A Plus Preferred Stock	39,200	\$176,400	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
3/2022	Rule 506(b) of Regulation D under the Securities Act	Series A Plus Preferred Stock	35,156	\$151,402	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company

11/2022	Rule 506(b) of Regulation D under the Securities Act	Series A Plus Preferred Stock	19,272 ³	\$93,475 ³	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company
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¹Does not include 1,827 shares issued to the Regulation Crowdfunding portal, StartEngine.

²Does not include 1,075 shares issued to Regulation Crowdfunding portal, StartEngine.

³This includes the shares issued and sold as of April 30, 2023.

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Financial statements.

Our financial statements for the years ending December 31, 2022, and 2021 can be found in Exhibit A to this report.

Financial Condition.

You should read the following discussion and analysis of our financial condition and results of our operations together with our financial statements and related notes appearing at the end of this report. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the section entitled “Risk Factors” and elsewhere in this report.

Results of Operations.

Year Ended December 31, 2022, Compared to the Year Ended December 31, 2021

Revenues.

To date, the Company has not generated any revenue.

Operating Expenses.

Total operating expenses for the twelve months ended December 31, 2022, was \$2,507,565 as compared to \$5,311,502 for the twelve months ended December 31, 2021.

General and administrative expenses were \$1,028,615 for the twelve months ended December 31, 2022; a 4% decrease compared to \$1,072,913 for the twelve months ended December 31, 2021. The decrease in our general and administrative expenses from December 31, 2021, to December 31, 2022, is primarily the result reduced consultant expenses, and reduced expenses for capital raising as a result of the Company concluding its Regulation Crowdfunding offerings in 2021. Share-based compensation totaled \$1,464,670 for the twelve months ended December 31, 2022, as compared to \$4,224,269 for the twelve months ended December 31, 2021. Share-based compensation decreased primarily due to a decrease in option grants to officers and directors of the Company during the twelve months ended December 31, 2022.

All options issued during 2022 and 2021 were fully vested upon issuance. The weighted average estimated fair value of the options granted during 2022 and 2021 were \$1.41 and \$1.38, respectively per share.

Other Expenses.

“Other Expenses” were \$206,700 for the twelve months ended December 31, 2022; a 5% increase compared to \$138,099 for year ended December 31, 2021. The increase in our other expenses from December 31, 2021, to December 31, 2022, is primarily the result of the Company’s notes payable agreements executed in December 2020 with MerchantCass Advisors, LLC, Capital & Venture Resources, LLC and Mr. Sam Merchant. The notes are due on demand and accrue interest at 5% per annum, which was increased to 8% in September

2022. As of December 31, 2022, the Company had paid \$42,122.64 to MerchantCass Advisors, LLC and accrued \$290,756 interest in 2022.

Interest expense incurred for the Company's note payable with Seacoast National Bank was \$2,967 for the year ended December 31, 2022.

Net Loss.

As a result of the foregoing, the Company had a net loss of \$2,714,265 for the twelve months ended December 31, 2022, as compared to \$5,449,601 for the twelve months ended December 31, 2021.

Plan of Operations.

Dr. Cheryl Baker, PhD, on behalf of the Company is currently seeking an investment from investors who are willing to invest in BioCurity which will include their willingness to negotiate the repayment of the Company's debt, including the Seacoast Loan and debt owed to MerchantCass Advisors, LLC and affiliates. If Dr. Cheryl Baker, PhD, is unsuccessful, the Company will likely not continue.

Liquidity and Capital Resources.

As of December 31, 2022, our primary sources of liquidity consisted of cash and cash equivalents of \$60,228. The Company's cash and cash equivalents as of December 31, 2021, were \$79,363. The decrease in our cash and cash equivalents from December 31, 2021, to December 31, 2022, is primarily due to an increase in cash needed for operating expenses, in 2022 compared to 2021.

As of December 31, 2021, the Company has a negative working capital of \$4,437,863, and an accumulated deficit of \$19,770,016.

In November 2019, the Company authorized the issuance of up to 305,882 shares of Series CF Convertible Preferred Stock with a par value of \$0.00001 per share through an offering under Regulation Crowdfunding under the Securities Act. The Company's Series CF Convertible Preferred Stock offering commenced on December 16, 2019, and closed on June 30, 2020. The Company issued 95,288 shares of Series CF Convertible Preferred Stock for a total of \$407,445.52 gross proceeds.

In July 2020, the Company authorized the issuance of up to 1,411,765 shares of Series 2 CF Convertible Preferred Stock with a par value of \$0.00001 per share through an offering under Regulation Crowdfunding under the Securities Act. The Company's Series 2 CF Convertible Preferred Stock offering commenced on July 29, 2020, and closed on April 30, 2021. The Company issued 57,881 shares of Series 2 CF Convertible Preferred Stock for a total of \$239,596.46 gross proceeds. During 2022, the Company issued 353 shares of Series CF Convertible Preferred Stock to the Crowdfunding portal in connection with services provided.

On July 1, 2021, all of the shares of the Series CF and Series 2 CF Convertible Preferred Stock were converted into Common Stock.

In 2021, the Company commenced an offering pursuant to Regulation D in which it offered shares of its Series A Plus Preferred Stock (the "Offering"). As of December 31, 2022, the Company has received \$436,352 in proceeds from the sale of 91,378 shares of this Offering. As of the date of this report, the Company has received \$446,477 in proceeds from the sale of 93,628 shares of its Series A Plus Preferred Stock pursuant to the Offering.

The funds from the Offering are critical to our Company's operations, and our viability as a Company. Apart from those listed above, we have no other capital resources available to us.

Indebtedness.

Loan Agreement with Seacoast National Bank and Town of Jupiter Florida.

On December 21, 2016, the Company entered into a non-revolving note payable agreement with Seacoast National Bank, for the principal sum of \$350,000 at a fixed rate of 4% interest. The Company can draw on the line for the first 24 months of the agreement. Payments during this period are monthly interest only payments. Following the first 24-month period, the Company was required to pay equal monthly payments of principal and interest based on a 10-year amortization period. In December 2022, the Company obtained an extension on the note allowing for additional 12 monthly interest only payments and any remaining balance due in December 2023 must be paid in full by December 21, 2023. The loan balance may be prepaid without penalty. The note is secured

by substantially all of the personal property and equipment of the Company and an Economic Development Loan Pledge Agreement with the Town of Jupiter, Florida.

As of December 31, 2022, the note balance, net of unamortized debt issuance costs of \$2,387, is \$141,965. As of December 31, 2021, the note balance is \$147,210. Future maturities on the note payable consist of \$141,965 during the year ending December 31, 2023.

RELATED PARTY TRANSACTIONS

BioCurity's breach of MerchantCass Advisors, LLC Agreement for non-payment.

The Company acknowledged in January 2023, that there was an ongoing material breach of the services agreement and all amendments thereto, entered into by BioCurity with MerchantCass Advisors, LLC ("MCA Service Agreement"), whereby MCA has since December 2018, served as Interim President and COO of BioCurity. The breach by the Company is due to non-payment to MCA in the amount of \$3,119,762 which was the outstanding balance, including interest owed to MCA by the Company as of April 30, 2023. There was also a failure by the Company to subsequently cure the material breach of the Service Agreement.

Due to the breach of the MCA Service Agreement, MCA is no longer an Officer in BioCurity. Effective as of April 10, 2023, Dr. Cheryl Baker, PhD, on behalf of the Company accepted the resignation of MerchantCass Advisors, LLC ('MCA') as Interim President and COO of BioCurity.

Mr. Sam Merchant and Ms. Nancy Cass, both affiliates of MCA, remain as members of the Board of BioCurity. Mr. Sam Merchant serves as Chairman of the Board and Ms. Nancy Cass serves as a Director. Although Mr. Sam Merchant and Ms. Nancy Cass, as affiliates of MCA serve on and control the BioCurity Board, Mr. Sam Merchant and Ms. Cass are not responsible for the day-to-day operations of the Company.

Secured Debt and Forbearance Agreements with MerchantCass Advisors, LLC, Capital & Venture Resources, LLC and Mr. Sam Merchant.

The Company's Forbearance Agreements with MerchantCass Advisors, LLC, ("MCA"), Capital & Venture Resources, LLC ("CVR"), or Mr. Sam Merchant ("Chairman of the Board"), were defaulted on by the Company. The Company's debt owed to MCA, CVR and Chairman of the Board, in the amount of \$4,162,454 as of April 30, 2023, is the result of years of non-payment by BioCurity pursuant to service agreements entered into by MCA, CVR and Chairman of the Board, along with accrued interest that is growing on a daily basis.

The debt owed to MCA, CVR and Chairman of the Board, were collateralized with a Security Agreement. Given the Company's breach of its Forbearance Agreements with MCA, CVR and Chairman of the Board, these creditors are holders of a Demand Note ("Holders") that are enforceable at the discretion of the Holders and secured by all assets of the Company.

As of April 30, 2023, the accrued expenses including interest and Demand Notes payable to MCA, CVR and Chairman of the Board were \$3,119,762, \$634,289, and \$408,403, respectively.

Mr. Sam Merchant and Ms. Nancy Cass are affiliates and members of MCA. CVR is an affiliate of Mr. Sam Merchant. The Company and Dr. Cheryl Baker, PhD individually have executed a full release of MCA and its affiliates, Mr. Sam Merchant, Ms. Nancy Cass and CVR for any claims against the Company regarding the Demand Note and waived all conflicts of interest potential and future, fully indemnified the Holders for any claims and waived any and all defenses that may be possible. The Holders can demand immediate payment of the full amount of the Demand Note at any time and no grace period or notice is required to be provided to the Company.

Mr. Sam Merchant, affiliate of MCA and CVR and Ms. Nancy Cass, affiliate of MCA are the beneficial owners of a substantial portion of the Company's capital stock, warrants and options. Mr. Sam Merchant owns 10 shares of "Super Voting" Series V Preferred Stock that provides Mr. Sam Merchant with voting control over the Company.

Limitations of Liability for Services provided to the Company by MerchantCass Advisors, LLC and Capital & Venture Resources, LLC that survive termination of the MCA Agreement.

MCA and CVR, its affiliates, members, owners, and successors and assigns shall not be liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director, service provider, shareholder or in any capacity including personal liability of any member or affiliate of MCA or CVR. This is irrevocable and any repeal or modification or prohibition by the Company or its successors and assigns shall not adversely affect any right or protection of MCA or CVR, including services as a director of the corporation existing at the time of, or increase the liability of MCA or CVR to its affiliates, members, owners, and successors and assigns to the Company with respect to any acts or omissions occurring prior to, such repeal or modification.

In no event will MCA or CVR, its affiliates, members, successors and assigns have any liability whatsoever to the Company, its shareholders, agents, affiliates, consultants, directors or third party beneficiary or any other entity or individual for any indirect, special, consequential, incidental or punitive damages, including but not limited to loss of anticipated profits or revenue in connection with or arising from anything said, omitted or done, even if either party has been advised of the possibility of such damages.

Capital & Venture Resources, LLC Agreement.

The Company entered into an Advisory Agreement dated as of December 1, 2018, with Capital & Venture Resources, LLC, an affiliate of Mr. Sam Merchant (“CVR”) to use reasonably commercial efforts to assist the Company in engaging in commercial transactions on behalf of the Company, with the provision of financial advisory services, including strategic transactions, joint ventures, licensing, and M&A transactions (the “CVR Agreement”).

However, as of April 30, 2023, the Company owes \$634,289 to CVR and it is possible that the CVR Agreement will be terminated for breach by BioCurity for non-payment. The ability to attract any such potential transactions and/or successfully consummate them is dependent upon the performance and resources of the Company, which is outside the control of CVR.

The CVR Agreement calls for payment of a base fee of \$10,000 per month plus a 10% administrative fee. The CVR Agreement provides that in the event that BioCurity, or one of its affiliates engages in a sale, merger, or other associated transaction during the term of the Agreement, CVR is entitled to a fee of 6% of the transaction consideration, and further provides that in the event of a break-up fee, a judgment or settlement in favor of the Company or some other fee regarding an aborted transaction, then CVR is to receive one half of the proceeds from such fee or other payment. It also provides for a tail of 24 months following termination in which the Company agrees to either continue to fund the average monthly payments during the tail period or not enter into a transaction with persons introduced to the Company by CVR without CVR’s prior written consent. It also contains an indemnification provision and a prohibition against using contacts introduced by CVR or MCA to the Company without CVR’s consent, except in instances where failure to use such contacts could result in breach of contract with such contact.

REGULATORY INFORMATION

Disqualification

No disqualifying events have been recorded with respect to the Company or its officers or directors.

Ongoing Reporting

The Company has previously been subject to the ongoing reporting requirements of Regulation Crowdfunding and, as such, has complied with the requirements of Rule 202.

SIGNATURES

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C-AR and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

BioCurity Pharmaceuticals Inc.

/s/ Cheryl Baker

By: Cheryl Baker

Title: Principal Executive Officer

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), this Form C-AR has been signed by the following persons in the capacities and on the dates indicated.

/s/ Cheryl Baker

By: Cheryl Baker

Title: Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer and Director

Date: May 31, 2023

/s/ Nancy Cass

By: Nancy Cass

Title: Director

Date: May 31, 2023

/s/ Sam Merchant

By: Sam Merchant

Title: Director

Date:

EXHIBIT A TO FORM C
FINANCIAL STATEMENTS AND INDEPENDENT ACCOUNTANT'S REVIEW

BioCurity Pharmaceuticals Inc.

Consolidated Financial Statements

December 31, 2022 and 2021

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INDEPENDENT AUDITOR'S REPORT

To the Board of Directors and Shareholders
BioCurity Pharmaceuticals Inc.
Jupiter, Florida

Opinion

We have audited the accompanying consolidated financial statements of BioCurity Pharmaceuticals Inc. (the "Company"), which comprise the consolidated balance sheets as of December 31, 2022 and 2021, and the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the years then ended, and the related notes to the consolidated financial statements.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of their operations and their cash flows for the years then ended in accordance with accounting principles generally accepted in the United States.

Basis for Opinion

We conducted our audits in accordance with auditing standards generally accepted in the United States. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Consolidated Financial Statements section of our report. We are required to be independent of the Company and to meet our other ethical responsibilities in accordance with the relevant ethical requirements relating to our audits. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Emphasis of Matter - Uncertainty Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and is dependent upon future issuance of equity or other financing to fund ongoing operations, both of which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Responsibilities of Management for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is required to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are available to be issued.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with generally accepted auditing standards will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements, including omissions, are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the consolidated financial statements.

In performing an audit in accordance with generally accepted auditing standards, we:

- Exercise professional judgment and maintain professional skepticism throughout the audit.
- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, and design and perform audit procedures responsive to those risks. Such procedures include examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, no such opinion is expressed.
- Evaluate the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluate the overall presentation of the consolidated financial statements.
- Conclude whether, in our judgment, there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for a reasonable period of time.

We are required to communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit, significant audit findings, and certain internal control related matters that we identified during the audit.

May 2, 2023
Glen Allen, Virginia

BioCurity Pharmaceuticals Inc.
Consolidated Balance Sheets
December 31, 2022 and 2021

	<u>Assets</u>	
	<u>2022</u>	<u>2021</u>
Current assets:		
Cash and cash equivalents	\$ 60,228	\$ 79,363
Equipment, net	-	40
Intangible assets, net	107,518	121,758
Total assets	<u>\$ 167,746</u>	<u>\$ 201,161</u>
<u>Liabilities and Stockholders' Deficit</u>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 703,095	\$ 455,788
Notes payable - related parties	3,653,031	2,915,423
Notes payable, net	141,965	147,210
Total current liabilities	<u>4,498,091</u>	<u>3,518,421</u>
Stockholders' deficit:		
Preferred stock, 20,000,000 shares authorized,		
Series A Stock, par value \$0.00001; 510,615 shares issued and outstanding at December 31, 2022 and 2021	5	5
Series AA Stock, par value \$0.00001; 300,000 shares issued and outstanding at December 31, 2022 and 2021	3	3
Series AAA Stock, par value \$0.00001; 160,000 shares issued and outstanding at December 31, 2022 and 2021	2	2
Series AAAA Stock, par value \$0.00001; 242,500 shares issued; 232,500 shares outstanding at December 31, 2022 and 2021	2	2
Series AAAAA Stock, par value \$0.00001; 300,000 shares issued and outstanding at December 31, 2022 and 2021	3	3
Series AAAAAA Stock, par value \$0.00001; 100,000 shares issued and outstanding at December 31, 2022 and 2021	1	1
Series 7A Stock, par value \$0.00001; 124,494 shares issued and outstanding at December 31, 2022 and 2021	1	1
Series V Stock, par value \$0.00001; 10 shares issued and outstanding at December 31, 2022 and 2021	-	-
Series CF Stock, par value \$0.00001; 0 shares issued and outstanding at December 31, 2022 and 2021	-	-
Series 2 CF Stock, par value \$0.00001; 0 shares issued and outstanding at December 31, 2022 and 2021	-	-
Series A Plus Stock, par value \$0.00001; 98,098 and 45,920 shares issued and outstanding at December 31, 2022 and 2021, respectively	1	-
Common stock, par value \$0.00001; 100,000,000 shares authorized; 4,025,445 and 4,025,092 shares issued; 3,325,445 and 3,325,092 shares outstanding at December 31, 2022 and 2021, respectively	40	40
Additional paid-in capital	15,441,328	13,740,149
Treasury stock, 710,000 shares at December 31, 2022 and 2021	(7)	(7)
Accumulated deficit	(19,771,724)	(17,057,459)
Total stockholders' deficit	<u>(4,330,345)</u>	<u>(3,317,260)</u>
Total liabilities and stockholders' deficit	<u>\$ 167,746</u>	<u>\$ 201,161</u>

See accompanying notes to the consolidated financial statements.

BioCurity Pharmaceuticals Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2022 and 2021

	<u>2022</u>	<u>2021</u>
Revenues	\$ -	\$ -
Cost of sales	<u>-</u>	<u>-</u>
Gross profit	<u>-</u>	<u>-</u>
Operating expenses:		
General and administrative	1,028,615	1,072,913
Share based compensation	1,464,670	4,224,269
Amortization	14,240	14,240
Depreciation	40	80
Total operating expenses	<u>2,507,565</u>	<u>5,311,502</u>
Operating loss	<u>(2,507,565)</u>	<u>(5,311,502)</u>
Other income (expense):		
Interest expense	<u>(206,700)</u>	<u>(138,099)</u>
Net loss	<u>\$ (2,714,265)</u>	<u>\$ (5,449,601)</u>

See accompanying notes to the consolidated financial statements.

BioCurity Pharmaceuticals Inc.
Consolidated Statements of Changes in Stockholders' Deficit
For the Years Ended December 31, 2022 and 2021

	Preferred Stock Series		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value	Shares	Value			
Balance, January 1, 2021	1,763,719	\$ 17	3,964,440	\$ 40	710,000	\$ (7)	\$ 9,173,504	\$ (11,607,858)	\$ (2,434,304)
Issuance of convertible preferred stock Series CF	2,771	-	-	-	-	-	11,780	-	11,780
Conversion of preferred stock Series CF to common stock	(2,771)	-	2,771	-	-	-	-	-	-
Issuance of convertible preferred stock Series 2 CF	31,781	-	-	-	-	-	128,996	-	128,996
Conversion of preferred stock Series 2 CF to common stock	(57,881)	-	57,881	-	-	-	-	-	-
Issuance of preferred stock Series A Plus	45,920	-	-	-	-	-	201,600	-	201,600
Share based compensation	-	-	-	-	-	-	4,224,269	-	4,224,269
Net loss	-	-	-	-	-	-	-	(5,449,601)	(5,449,601)
Balance, December 31, 2021	1,783,539	17	4,025,092	40	710,000	(7)	13,740,149	(17,057,459)	(3,317,260)
Issuance of convertible preferred stock Series CF	353	-	-	-	-	-	1,708	-	1,708
Conversion of preferred stock Series CF to common stock	(353)	-	353	-	-	-	-	-	-
Issuance of preferred stock Series A Plus	52,178	1	-	-	-	-	234,801	-	234,802
Share based compensation	-	-	-	-	-	-	1,464,670	-	1,464,670
Net loss	-	-	-	-	-	-	-	(2,714,265)	(2,714,265)
Balance, December 31, 2022	1,835,717	\$ 18	4,025,445	\$ 40	710,000	\$ (7)	\$ 15,441,328	\$ (19,771,724)	\$ (4,330,345)

See accompanying notes to the consolidated financial statements.

BioCurity Pharmaceuticals Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2022 and 2021

	<u>2022</u>	<u>2021</u>
Cash flows from operating activities:		
Net loss	\$ (2,714,265)	\$ (5,449,601)
Adjustment to reconcile net loss to net cash used in operating activities:		
Amortization expense	14,240	14,240
Depreciation expense	40	80
Amortization of debt issuance costs	-	2,981
Share based compensation for stock options	1,464,670	4,224,269
Share based compensation for services provided	-	12,461
Decrease in assets:		
Other current assets	-	24,008
Increase in liabilities:		
Accounts payable and accrued expenses	984,915	870,957
Net cash used in operating activities	<u>(250,400)</u>	<u>(300,605)</u>
Cash flows from financing activities:		
Advances (payments) on note payable	(5,245)	481
Proceeds from issuance of preferred stock, net of issuance costs	236,510	329,915
Net cash provided by financing activities	<u>231,265</u>	<u>330,396</u>
Change in cash and cash equivalents	(19,135)	29,791
Cash and cash equivalents, beginning of year	<u>79,363</u>	<u>49,572</u>
Cash and cash equivalents, end of year	<u>\$ 60,228</u>	<u>\$ 79,363</u>
Supplemental cash flow information:		
Cash paid for interest	<u>\$ 12,967</u>	<u>\$ 35,002</u>
Non-cash financing activities:		
Conversion of accounts payable to notes payable - related parties	<u>\$ 737,608</u>	<u>\$ 808,523</u>

See accompanying notes to the consolidated financial statements.

Note 1 - Description of the Business and Summary of Significant Accounting Policies

Organization and Nature of Operations

BioCurity Pharmaceuticals Inc., a Delaware corporation, was incorporated on February 25, 2015, and is a biotechnology company developing a patent protected nanoparticle drug candidate designed to protect and treat normal tissue (both skin and internal tissue) from damage caused by radiation therapy. The Company has not yet realized any revenues from its planned operations.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of BioCurity Pharmaceuticals Inc. and its wholly owned subsidiary, BioCurity, Inc. (collectively, the "Company"). All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates in Preparation of Financial Statements

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Amounts on deposit with financial institutions are classified as cash and cash equivalents. Accounts maintained at commercial banks are insured by the Federal Deposit Insurance Corporation ("FDIC") for up to \$250,000 per financial institution. Balances in these accounts may, at times, be in excess of the FDIC limits. The Company has not experienced any losses in such accounts.

Equipment

Equipment is stated at cost, less accumulated depreciation. Depreciation is computed over the estimated useful lives of the assets using the straight-line method. The estimated useful life for computer equipment is 5 years. Expenditures for maintenance and repairs are charged against earnings in the year incurred. The cost and accumulated depreciation of assets sold or retired are removed from the respective accounts and any gain or loss is reflected in earnings.

Intangibles

Intangible assets are stated at cost less accumulated amortization. Amortization is computed over the estimated useful lives of the assets using the straight-line method. The estimated useful life for patents and patent licenses is 15 years.

Fair Value Measurements

The fair value of the Company's financial instruments reflects the amounts that the Company estimates to receive in connection with the sale of an asset or paid in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The fair value hierarchy that prioritizes the use of inputs used in valuation techniques is as follows:

Note 1 - Description of the Business and Summary of Significant Accounting Policies, continued

Fair Value Measurements, continued

Level 1 quoted prices in active markets for identical assets and liabilities;

Level 2 observable inputs other than quoted prices in active markets, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data;

Level 3 unobservable inputs reflect management's assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The determination of where an asset or liability falls in the hierarchy requires significant judgment and considers factors specific to the instrument.

Income Taxes

The Company uses the asset and liability method in accounting for income taxes. Under this method, deferred tax assets and liabilities are recorded for temporary differences between the tax basis of assets and liabilities and their reported amounts in the consolidated financial statements, using statutory rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the results of operations in the period that includes the enactment date. A valuation allowance is recorded to reduce the carrying amounts of deferred tax assets unless it is more likely than not those assets will be realized.

The Company applies the provisions of ASC 740-10-05, "Accounting for Uncertainty in Income Taxes", which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements. ASC 740-10-05 prescribes a two-step process for evaluating tax positions taken, or expected to be taken, on a tax return. Step one is a determination as to whether it is more likely than not that a tax position will be sustained, based upon the technical merits, upon examination by the taxing authorities. If the tax position is expected to meet the more likely than not criteria, the benefit recorded for the tax position equals the largest amount that is greater than 50% likely to be realized upon ultimate settlement of the respective tax position. Uncertain tax positions require determinations and estimated liabilities to be made based on provisions of the tax law which may be subject to change or varying interpretation. If the Company's determinations and estimates prove to be inaccurate, the resulting adjustments could be material to the Company's future financial results. The Company is not currently under audit by any tax jurisdictions.

The Company records interest and penalties related to income tax matters in its provision for income taxes in the accompanying consolidated statements of operations.

Note 1 - Description of the Business and Summary of Significant Accounting Policies, continued

Recent Accounting Pronouncements

Preferred Stock: In August 2020, the FASB issued new guidance to simplify accounting for convertible instruments. Consequently, more convertible debt instruments will be reported as a single liability instrument and more convertible preferred stock as a single equity instrument with no separate accounting for embedded conversion features. The new guidance removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify. The new guidance is effective for the Company for the year ending December 31, 2024, with early adoption permitted. The Company is evaluating the effect this new guidance will have on its financial statements.

Leases: In February 2016, the FASB issued a new accounting standard for leases that requires the recognition of right-of-use ("ROU") assets and lease liabilities on the balance sheet for all leases that extend beyond a one-year time period. The Company adopted the standard effective January 1, 2022, which did not have a material impact on its consolidated financial statements. The Company has elected, for all underlying classes of assets, to not recognize right-of-use assets and lease liabilities for short-term leases that have a lease term of 12 months or less at lease commencement, and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. Lease cost associated with short-term leases is recognized on a straight-line basis over the lease term.

Note 2 – Going Concern

As of December 31, 2022, the Company has negative working capital of \$4,437,863. The Company also incurred operating losses totaling \$2,714,265 and \$5,449,601 for the years ended December 31, 2022 and 2021, respectively, and has an accumulated deficit of \$19,771,724 at December 31, 2022. In order to meet its current obligations, management plans to raise additional capital during 2023 to fund operations.

This uncertainty raises substantial doubt about the ability of the Company to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis which assumes continuity of operations and realization of assets and liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

Note 3 – Equipment

Equipment consists of the following as of December 31, 2022 and 2021:

	2022	2021
Computer equipment	\$ 8,576	\$ 8,576
Accumulated depreciation	(8,576)	(8,536)
Total	\$ -	\$ 40

Depreciation expense for the years ended December 31, 2022 and 2021 was \$40 and 80, respectively.

Note 4 – Intangibles

Intangible assets consist of the following as of December 31, 2022 and 2021:

	2022	2021
Patents and patent licenses	\$ 213,574	\$ 213,574
Accumulated amortization	(106,056)	(91,816)
Total	\$ 107,518	\$ 121,758

Amortization expense for the next 5 years approximates \$14,238 each year.

Note 5 – Notes Payable

The Company has a note payable agreement with Seacoast National Bank at a fixed rate of 4% interest. Interest only payments are due monthly with any remaining balance due in December 2023. The Company obtained an extension on the note allowing for additional 12 monthly interest only payments and any remaining balance due in December 2023. The loan balance may be prepaid without penalty. The note is secured by substantially all of the personal property and equipment of the Company and an Economic Development Loan Pledge Agreement with the Town of Jupiter, Florida.

At December 31, 2022 and 2021, the note balance is \$141,965 and \$147,210, respectively. Future maturities on the note payable consist of \$141,965 during the year ending December 31, 2023.

The Company has notes payable due to related parties, which are due on demand and bear interest at 8% per annum. In 2021 and 2022, the Company converted outstanding payables with related parties into additional notes payable. At December 31, 2022 and 2021, the balance of notes payable to related parties is \$3,653,031 and \$2,915,423, respectively. See Note 8 for additional information on the related party notes payable.

Note 6 – Stockholders’ Equity and Stock-Based Compensation

Common Stock

The Company has authorized the issuance of up to 100,000,000 shares of common stock with a par value of \$0.00001 per share. There were 4,025,445 shares issued and 3,325,445 shares outstanding at December 31, 2022. There were 4,025,092 shares issued and 3,325,092 shares outstanding at December 31, 2021.

Preferred Stock

The Company has authorized the issuance of up to 20,000,000 shares of preferred stock with a par value of \$0.00001 per share. Preferred Stockholders are entitled to receive, prior and in preference to any distribution of assets or surplus funds of the Company to any holders of common stock, an amount equal to all declared but unpaid dividends. In the event of any Liquidation Event, the holders of Preferred Stock shall be entitled to be paid, before any distribution or payment is made upon any common stock or any other class or series of capital stock of the Company designated to be junior to the Preferred Stock, and subject to the liquidation rights and preferences of any future class or series of Preferred Stock designated to be senior to, or on parity with, the Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend. The issued and outstanding classes of preferred stock are as set forth below.

Series A Through 7A Convertible Preferred Stock

Of the 20,000,000 shares of authorized preferred stock, 1,620,000 shares have been designated as Series A Convertible Preferred Stock, 300,000 shares have been designated as Series AA Convertible Preferred Stock, 400,000 shares have been designated as Series AAA Convertible Preferred Stock, 500,000 shares have been designated as Series AAAA Convertible Preferred Stock, 300,000 shares have been designated as Series AAAAA Convertible Preferred Stock, 100,000 shares have been designated as Series AAAAAA Convertible Preferred Stock and 200,000 shares have been designated as Series 7A Convertible Preferred Stock (all of such classes of stock are hereinafter collectively referred to as the “Senior Securities”).

Each share of the Company’s Senior Securities is convertible into shares of common stock at the option of the holder. The number of shares of common stock to be received upon conversion is calculated as convertible initially on a 1:1 basis at a per share price from \$1.25 to \$4.00, subject to equitable adjustment to the conversion rate to account for subdivisions, forward or reverse stock splits, stock dividends or other extraordinary corporate events as specified in the Company’s Certificate of Incorporation. The conversion of the Senior Securities to common stock is automatic upon: (i) the closing of a qualified public offering or (ii) the vote or written consent of holders of at least a majority of the shares of the respective Series of Preferred Stock then outstanding.

Each share of the Company’s Senior Securities shall be entitled to the number of votes equal to the number of shares of common stock into which each share is convertible using the record date for determining the conversion rate.

Senior Securities Stockholders are also entitled to receive dividends on the Senior Securities, whenever funds are legally available and when and as declared by the Board. Dividends on the Senior Securities are not cumulative and will accrue only if declared by the Board.

Note 6 – Stockholders' Equity and Stock-Based Compensation, continued

Series A Through 7A Convertible Preferred Stock, continued

Each Senior Security is on parity with the each of the other Senior Securities as to proceeds from a Liquidation Event.

Fixed Term Convertible Preferred Stock

The Company has authorized the issuance of up to 500,000 shares of Fixed Term Convertible Preferred Stock, divided into 3 series: FT-1 Shares (up to 187,500 shares to be issued), FT-2 Shares (up to 312,500 shares to be issued) and FT-3 Shares (up to 100,000 shares to be issued) with a par value of \$0.00001 per share. There are no outstanding shares of Fixed Term Convertible Preferred Stock as of December 31, 2022 and 2021.

In the event of any Liquidation Event, the Senior Securities are senior to the Fixed Term Convertible Preferred Stock, which in turn is senior to the common stock.

Series CF and Series 2 CF Convertible Preferred Stock

The Company has authorized the issuance of up to 305,882 shares of Series CF Convertible Preferred Stock and 1,411,765 shares of Series 2 CF Convertible Preferred Stock with a par value of \$0.00001 per share through an offering under Regulation Crowdfunding under the Securities Act. During the year ended December 31, 2022, 353 shares of Series CF Convertible Preferred Stock were issued. During the year ended December 31, 2021, 944 and 30,706 shares of Series CF Convertible Preferred Stock and Series 2 CF Convertible Preferred Stock were issued, respectively. Subscriptions, which are revocable by investors, are held in escrow by the Crowdfunding portal prior to a closing. During the years ended December 31, 2022 and 2021, \$1,708 and \$128,315, respectively, of proceeds, net of expenses charged by the Crowdfunding portal and related service providers, from subscriptions were disbursed to the Company.

During 2022, the Company issued 353 shares of Series CF Convertible Preferred Stock to the Crowdfunding portal in connection with services provided. During 2021, the Company issued 1,827 shares of Series CF Convertible Preferred Stock and 1,075 shares of Series 2 CF Convertible Preferred Stock to the Crowdfunding portal in connection with services provided. The services were valued based on the respective value of the shares issued. For the year ended December 31, 2021, the Company recognized \$12,461 in share-based compensation expense in connection with the issuance of preferred stock for the services provided.

Each share of the Company's Series CF and Series 2 CF Convertible Preferred Stock is convertible into shares of Common Stock at the option of the holder. The number of shares of Common Stock to be received upon conversion is calculated as convertible initially on a 1:1 basis as the conversion rate per share, subject to equitable adjustment to the conversion rate to account for subdivisions, forward or reverse stock splits, stock dividends or other extraordinary corporate events as specified in the Company's Certificate of Incorporation. The conversion of Series CF and Series 2 CF Convertible Preferred Stock is automatic upon: (i) the closing of a qualified public offering, (ii) the vote or written consent of holders of at least a majority of the shares of the Series CF or Series 2 CF Convertible Preferred Stock then outstanding, or (iii) automatically on July 1, 2021. In July 2021, all of the shares of Series CF and Series 2 CF Convertible Preferred Stock were converted into Common Stock.

Note 6 – Stockholders’ Equity and Stock-Based Compensation, continued

Series CF and Series 2 CF Convertible Preferred Stock, continued

Each share of the Company’s Series CF and Series 2 CF Convertible Preferred Stock is entitled to the number of votes equal to the number of shares of common stock into which each share is convertible using the record date for determining the conversion rate.

Series CF and Series 2 CF Convertible Preferred Stockholders are also entitled to receive dividends on the Series CF and Series 2 CF Convertible Preferred Stock, whenever funds are legally available and when and as declared by the Board. Dividends on the Series CF and Series 2 CF Convertible Preferred Stock are not cumulative and will accrue only if declared by the Board.

In the event of any Liquidation Event, the Senior Securities are senior to the Series CF and Series 2 CF Convertible Preferred Stock, which in turn is senior to the common stock. The Fixed Term Convertible Preferred Stock are all on parity with the Series CF and Series 2 CF Convertible Preferred Stock as to proceeds from a Liquidation Event (all of such classes of stock, including the Fixed Term Convertible Preferred Stock are hereinafter collectively referred to as the “Parity Securities”).

Series A Plus Preferred Stock

In May 2021, the Company authorized the issuance of up to 200,000 shares of Series A Plus Preferred Stock with a par value of \$0.00001 per share. In May 2021, the Company issued 6,720 shares of Series A Plus Preferred Stock for \$25,200. During the years ended December 31, 2022 and 2021, the Company issued an additional 52,178 and 39,200 shares of Series A Plus Preferred Stock for \$234,802 and \$176,400, respectively, for which each share of Series A Plus Preferred Stock is senior to the Company’s prior offering of Series A Plus Preferred issued.

Each share of the Company’s Series A Plus Preferred Stock is convertible into shares of Common Stock at the option of the holder. The number of shares of Common Stock to be received upon conversion is calculated as convertible initially on a 1:1 basis into common stock at \$4.50 per share, subject to equitable adjustment to the conversion rate to account for subdivisions, forward or reverse stock splits, stock dividends or other extraordinary corporate events as specified in the Company’s Certificate of Incorporation. The conversion of Series A Plus Preferred Stock to Common Stock is automatic upon: (i) twenty (20) business days after a “Stockholder Vote,” (ii) the date of the qualification by the Company as a reporting company under the Securities Exchange Act of 1934 (“Exchange Act”) through the filing of a Form 8, Form 10 or such other form as may be advisable for the Company to become a publicly reporting Company under the Exchange Act (as determined by the Company’s Board of Directors), (iii) a Regulation A Offering which subjects the Company to the reporting requirements under Form I-K or I-SA, or (iv) the listing of the common stock of the Company for trading on a national or regional securities exchange of any country in the world, or (v) a debt or equity raise equal to \$5 million at the discretion of the Board.

Note 6 – Stockholders’ Equity and Stock-Based Compensation, continued

Series A Plus Preferred Stock, continued

Each share of the Company’s Series A Plus Preferred Stock shall be entitled to the number of votes equal to the number of shares of Common Stock into which each share is convertible using the record date for determining the conversion rate. Series A Plus Preferred Stockholders are also entitled to receive dividends on the Series A Plus Preferred Stock, whenever funds are legally available and when and as declared by the Board. Dividends on the Series A Plus Preferred Stock are not cumulative and will accrue only if declared by the Board.

In the event of any Liquidation Event, the Series A Plus Preferred Stock will rank with respect to rights upon a Liquidation Event: (i) senior to any Junior Securities, as they exist on the date hereof or as the Junior Securities may be constituted from time to time; and (ii) junior to the Senior Securities that may be issued from time to time.

Series V Preferred Stock

The Company has authorized the issuance of up to 20 shares of Series V Preferred Stock with a par value of \$0.00001 per share, of which 10 shares were issued to BioCurity Controlling Shares Inc., a Delaware corporation owned by Sam Merchant. The Series V Preferred Stock was transferred to Sam Merchant from BioCurity Controlling Shares, Inc. in December 2021. Each share of Series V Preferred Stock shall be entitled to cast one million (1,000,000) votes per share. The holders of Series V Preferred Stock shall not be entitled to receive dividends. The Series V Preferred Stock shall rank junior to all other classes of Preferred Stock and senior to the Common Stock of the Company.

Warrants Issued to Purchase Common Stock

The Company has outstanding warrants that were issued to Pierce Family Ventures, LLC (“Pierce”) and Merchants Capital Trust, LLC (“MCT”), as designees of MerchantCass Advisors, LLC (“MCA”), in connection with the consulting agreement between the Company and MCA. Pierce and MCT are affiliates of Nancy Cass and Sam Merchant, respectively, both of whom serve on the board of directors of the Company. The warrants owned by MCT were transferred to Sam Merchant in 2021 and the warrants owned by Pierce were transferred to Nancy Cass. Under these warrants, each of Sam Merchant and Nancy Cass have the right to purchase, at any time during the warrant exercise term, up to 375,000 shares of common stock of the Company (up to 750,000 shares in the aggregate), at a per share exercise price of \$0.40. The exercise price of these warrants is subject to a “down-round” anti-dilution adjustment if the Company issues or is deemed to have issued securities at a price lower than the then applicable exercise price of the warrants.

The Company also has outstanding warrants that were issued to MCT in connection with the undertaking of Sam Merchant to serve as Chairman of the Board of Directors of the Company. In 2021 these warrants were transferred to Sam Merchant. Under these warrants, Sam Merchant has the right to purchase, at any time during the warrant exercise term, up to 437,000 shares of additional common stock, of the Company, at a per share exercise price of \$0.69.

Based on the Company’s evaluation of the warrants under ASC 480 and ASC 815, all outstanding warrants are classified as equity and are recorded at fair value at the grant date. There were no warrants issued, exercised or cancelled during the years ended December 31, 2022 and 2021. The weighted average exercise price was \$0.52 per share at December 31, 2022 and 2021.

Note 6 – Stockholders’ Equity and Stock-Based Compensation, continued

Stock Incentive Plan

The Company has a stockholder-approved stock-based compensation plan, the 2021 Stock Option and Grant Plan (the “Plan”), which provides for the grant of share options and shares for up to 9,000,000 shares of Common Stock.

During the years ended December 31, 2022 and 2021, the Company granted new options to purchase 1,039,099 and 3,051,902 shares, respectively, of common stock at an exercise price of \$2.00 per share over a 10-year term.

The Company uses the Black-Scholes valuation model to estimate the fair value of stock options at grant date. This valuation model requires the use of highly subjective inputs and assumptions that determine the fair value of stock-based awards, including the expected price volatility of the Company’s stock, the expected period during which the stock options will be outstanding, and the estimated fair value of the Company’s common shares.

In estimating the fair value of the Company’s common stock for use in the Black-Scholes pricing model, the Company considers several factors, including (i) the most recently completed arms-length sale of the Company’s stock, (ii) achievement of milestones set by the Company, (iii) market capitalizations of similar publicly traded companies, (iv) precedent transactions, (v) financial projections and (vi) discounted cash flows. Other valuation assumptions and other inputs include the following:

- Expected stock price volatility: There is no active market for the Company’s common stock providing a basis to estimate the expected volatility of the Company’s stock prices for the purpose of valuing stock options granted. Alternatively, the Company uses the historical volatility of three publicly traded peer companies that represents the primary industry sector within which the Company operates. When selecting its industry peer companies, the Company considers the size, stage in the life cycle, type of products being sold, and financial leverage of the peer companies in comparison to the Company.
- Expected term of stock options: The expected term of stock options represents the period of time stock options are expected to be outstanding. The Company has concluded that its historical experience does not provide a sufficient basis to estimate expected term and has chosen to use the simplified method under ASC 718 for computing the expected term. Under the simplified method, the expected option term is the average of the vesting period and the original contractual term.
- Risk-free interest rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the expected option term.
- Expected annual dividends: The estimate for annual dividends is zero because the Company has not historically paid and does not intend to pay dividends on its common stock in the foreseeable future.

Note 6 – Stockholders’ Equity and Stock-Based Compensation, continued

Stock Incentive Plan, continued

The Company determined the grant date fair value of the options granted using the following assumptions:

	2022	2021
Volatility	90.00%	90.00%
Risk Free Rate	2.42 - 4.06%	0.44 - 1.26%
Expected Term	5 Years	5 Years

The Company recognized share-based compensation expense of \$1,464,670 and \$4,224,269 during the years ended December 31, 2022 and 2021, respectively. All options issued during 2022 and 2021 were fully vested upon issuance. The weighted average estimated fair value of the options granted during 2022 and 2021 were \$1.41 and \$1.38, respectively, per share.

The following is a summary of the Company’s stock option activity for the years ended December 31, 2022 and 2021:

	Number of Options	Weighted Average Exercise Price
Outstanding Balance at January 1, 2021	2,534,375	\$ 1.62
Granted	3,051,902	2.00
Forfeited	-	-
Exercised	-	-
Outstanding Balance at December 31, 2021	5,586,277	1.83
Granted	1,039,099	2.00
Forfeited	-	-
Exercised	-	-
Outstanding Balance at December 31, 2022	6,625,376	\$ 1.86

At December 31, 2022, the Company had 2,374,624 shares available for future option awards.

Note 7 – Commitments and Contingencies

The Company is subject to various claims and assessments in the ordinary course of business. Management believes that resolution of any such matters will not have a material effect on the Company's financial position, results of operations or cash flows.

The Company is subject to various federal, state and local regulations in the normal course of conducting its business. The Company conducts an ongoing monitoring and compliance program and records provisions for expected costs. Management is not aware of any matters related to such regulations that it believes would have a material adverse effect on the Company's financial position, results of operations or cash flows.

Office Lease

The Company has a lease agreement for office space in Jupiter, Florida through March 2023 for \$1,079 per month. The Company also has lease agreements for two corporate apartments that extend through June 2023 with monthly rent totaling \$7,550. Total rent expense was \$95,726 and \$69,292 for the years ended December 31, 2022 and 2021, respectively.

Note 8 – Related Party Transactions

MCA Agreement

The Company has an agreement with MerchantCass Advisors, LLC ("MCA"), an affiliate owned by both the Chairman and a member of the Board of Directors and stockholders of the Company, to render financial and business advisory services through December 31, 2022. The services include, but are not limited to, advice and assistance with due diligence, working with the University of Central Florida, assembly of a management team, assisting with business strategy, working with auditors, and assistance with preparation of documentation, business plans and term sheets. Under the agreement, the Company pays \$350 per hour for services provided by MCA's principals, Sam Merchant and Nancy Cass, with a lesser hourly rate if other service providers are used, plus a 10% administrative fee. In the event that the hours exceed 120 hours per month, MCA may increase such rate to \$400 per excess hour. The Company is also subject to late fees and interest on the outstanding balance due MCA. Advisory service and administrative fees incurred under the MCA agreement amounted to \$544,347 and \$554,400 during the years ended December 31, 2022 and 2021, respectively. Advisory service fees payable to MCA were \$3,007,950 and \$2,317,624 as of December 31, 2022 and 2021, respectively, and are included in accrued expenses and notes payable – related parties in the accompanying consolidated balance sheets.

Note 8 – Related Party Transactions, continued

MCA Agreement, continued

Compensation under the MCA Agreement includes stock options which are fully earned and vested when granted. The agreement included an initial grant to purchase one million shares of the Company's common stock at \$1.30 per share. In addition, MCA is entitled to receive options to purchase 1% of the "Base Amount" of the capital of the Company per calendar quarter for the term of the agreement (each option comprised of 1% of the sum of: (i) issued and outstanding Common Stock; plus (ii) the as converted to Common Stock shares with respect to convertible preferred stock outstanding; plus (iii) outstanding warrants and options to purchase common stock, exercisable at the fair market value of the Common Stock of the Company from time to time as set by the Board of Directors of the Company. The MCA Agreement further provides that if as of the end of any calendar quarter, the Company is at least two months in arrears as to its obligations to MCA, then an additional like amount of options as was granted for such calendar quarter (*i.e.*, another 1% of the Company issued and outstanding capital stock, options and warrants) shall be issued to MCA in consideration for its services.

In 2022 and 2021, the Company issued options to designees of MCA for the purchase of 1,039,099 and 3,001,902 shares, respectively, exercisable at \$2.00 per share for 10 years following the date of grant to MCA's designees for the aforesaid 1% amount.

Capital and Venture Resources, LLC Agreement

The Company has entered into an advisory agreement with Capital and Venture Resources LLC, an affiliate of Sam Merchant ("CVR"), for the provision of financial advisory services, including strategic transactions, joint ventures, licensing and M&A transactions (the "CVR Agreement"). It calls for the provision of not more than 20 hours per month of services and has a term ending December 31, 2024. It calls for payment of a base fee of \$10,000 per month. Any services in excess of the maximum monthly amount are to be provided only if mutually agreed to by the parties, and then, to be provided on mutually agreeable rates of compensation. The CVR Agreement provides that in the event that the Company or one of its affiliates engages in a sale, merger or other associated transaction during the term of the Agreement, CVR is entitled to a fee of 6% of the transaction consideration, and further provides that in the event of a break-up fee, a judgment or settlement in favor of the Company or some other fee regarding an aborted transaction, then CVR is to receive one half of the proceeds from such fee or other payment. It also provides for a tail of 24 months following termination in which the Company agrees to either continue to fund the average monthly payments during the tail period or not enter into a transaction with persons introduced to the Company by CVR without CVR's prior written consent. It also contains an indemnification provision and a prohibition against using contacts introduced by CVR or MCA to the Company without CVR's consent, except in instances where failure to use such contacts could result in breach of contract with such contacts. The Company is also subject to late fees and interest on the outstanding balance due CVR. Financial advisory service fees incurred under the CVR Agreement amounted to \$128,200 and \$132,000 during the years ended December 31, 2022 and 2021, respectively. Financial advisory service fees payable to CVR were \$570,286 and \$413,137 as of December 31, 2022 and 2021, respectively, and are included in accrued expenses and notes payable – related parties in the accompanying consolidated balance sheets.

Note 8 – Related Party Transactions, continued

Notes Payable – Related Parties

The Company has Notes Payable Agreements with the following related parties, MerchantsCass Advisors, LLC (“MCA”), Capital and Venture Resources, LLC (“CVR”) and Mr. Sam Merchant (“Chairman”). All of the notes are due on demand and accrue interest at 5% per annum, which was increased to 8% in September 2022. During the years ended December 31, 2022 and 2021, the Company entered into Forbearance Agreements with MCA, CVR and Chairman, in which MCA, CVR and Chairman agreed to forbear from exercising its rights to demand payment on the Amended and Restated Notes Payable Agreements, not to increase their respective fees and to accrue its fees through September 30, 2022. In addition, the Company agreed to waive the requirement of a minimum number of hours per week to be provided by MCA and CVR through September 30, 2022 and to raise a certain amount of capital on a monthly basis. Pursuant to the Forbearance Agreements with CVR and Chairman, the Company granted stock options to CVR and Chairman for the purchase of 750,000 shares each of Common Stock, which have been issued to Sam Merchant. In October 2022, the Company entered into a Security Interest and Collateral Agreement in which the Note Payable Agreements are cross-defaulted and secured by all assets of the Company. The Company was not in compliance with the Forbearance Agreements as of December 31, 2022.

The note balances as of December 31, 2022, amounted to \$2,793,770 due to MCA; \$524,198 due to CVR; and \$335,063 due to Chairman. The note balances as of December 31, 2022 are presented inclusive of overage, penalties and delinquency fees. Interest payable on the related party note balances amounted to \$290,756 as of December 31, 2022 and is presented within accounts payable and accrued expenses on the accompanying consolidated balance sheet. The note balances as of December 31, 2021, amounted to \$1,986,300, not inclusive of overage, interest, penalties, or delinquency fees due to MCA; \$341,000, not inclusive of overage, late fees, interest, or penalties due to CVR; and \$232,000, not inclusive of late fees due to Chairman. Total overage, penalties and delinquency fees amounted to \$356,123 as of December 31, 2021. Interest payable on the related party note balances amounted to \$97,022 as of December 31, 2021 and is presented within accounts payable and accrued expenses on the accompanying consolidated balance sheet.

Note 9 – Income Taxes

The components of the provision for income taxes for the years ended December 31, 2022 and 2021 are as follows:

	<u>2022</u>	<u>2021</u>
Current		
Federal	\$ -	\$ -
State	-	-
Total Current	<u>-</u>	<u>-</u>
Deferred		
Federal	569,793	1,142,605
State	226,181	191,620
Total Current	<u>795,974</u>	<u>1,334,225</u>
Change in Valuation Allowance	(795,974)	(1,334,225)
Provision for Income Taxes	<u>\$ -</u>	<u>\$ -</u>

Note 9 – Income Taxes, continued

Net deferred tax assets consist of the following components as of December 31, 2022 and 2021:

	<u>2022</u>	<u>2021</u>
Deferred Tax Assets		
Net operating loss carryforwards	\$ 1,454,485	\$ 1,350,429
Accrued expenses	948,513	678,891
Stock compensation	1,802,236	1,384,538
Other	4,705	106
Total Deferred Tax Assets	<u>4,209,939</u>	<u>3,413,964</u>
Valuation Allowance	<u>(4,209,939)</u>	<u>(3,413,964)</u>
Net Deferred Tax Assets	<u>\$ -</u>	<u>\$ -</u>

The Company has federal tax net operating loss carryforwards of approximately \$5,892,000 as of December 31, 2022 and Florida net operating loss carryforwards of approximately \$4,996,000 as of December 31, 2022. The net operating loss carryforwards generated prior to January 1, 2018, if not used to reduce taxable income in future periods, will begin to expire in 2034, for both federal and state tax purposes. The net operating loss carryforwards generated after December 31, 2017 will never expire for federal tax purposes but can only reduce 80% of taxable income in future years.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the future generation of taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and taxing strategies in making this assessment. Based on this assessment, management has established a full valuation allowance against all of the net deferred tax assets for each period, since it is more likely than not that all of the deferred tax assets will not be realized. The valuation allowance for the years ended December 31, 2022 and 2021 increased by approximately \$796,000 and \$1,334,000, respectively.

Note 10 – Subsequent Events

Effective March 31, 2023, the Company's Jupiter office lease was terminated and the Company began using a virtual mailbox system. Effective April 4, 2023, the lease for one of the two Company corporate apartment leases was terminated and the corporate apartment was vacated. In April 2023, the Company provided notification that it will terminate and vacate the remaining corporate apartment lease, effective June 7, 2023.

In April 2023, the Company issued 2,250 shares of Series A Plus Preferred Stock for \$10,125.

Effective April 10, 2023, Dr. Cheryl Baker, PhD, as a Director of the Company, accepted the resignation of MCA as Interim President and COO of the Company. The Company acknowledged that there is a material breach of the forbearance agreement signed by the Company and MCA and a material breach of the services agreement and all amendments thereto, entered into by the Company with MCA ('Service Agreement'). There was also a failure by the Company to subsequently cure the material breach of the Service Agreement. Sam Merchant and Nancy Cass, both affiliates of MCA, will remain as members of the Board of the Company. Sam Merchant will serve as Chairman of the Board and Nancy Cass will serve as a Director.

Management has evaluated subsequent events through May 2, 2023, the date the consolidated financial statements were available for issuance and has determined that other than events disclosed above there are no additional subsequent events that required disclosure.