

## 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 Convertible Preferred Stock and is currently offering and selling its Series 2 CF Convertible Preferred Stock pursuant to Regulation Crowdfunding under the Securities Act of 1933, as amended and is filing this annual report pursuant to Rule 202 of Regulation Crowdfunding for the fiscal year ended December 31, 2020. A copy of this report may be found on the Company's website at [www.biocurity.com](http://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 management. 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 management'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

BioCurity Pharmaceuticals Inc. is a clinical stage biopharmaceutical company incorporated on February 23, 2015 with a mission to transform the cancer patient journey of radiation therapy by solving the global unmet need of radiation therapy side effects. *Because we believe that fighting cancer is hard enough.* Most people know a friend or family member who has endured the sometimes painful, permanent, or serious side effects from radiation therapy that is prescribed by their physicians for their cancer treatment regimen. Side effects may include skin damage (radiation dermatitis), which results in inflammation, burning, necrosis, and scarring of normal skin. Side effects from radiation therapy also may include damage to internal tissue resulting in pneumonia for lung cancer and other more serious complications.<sup>1,2,3</sup> BioCurity's proprietary technology as demonstrated in preclinical studies is designed to prevent or mitigate damage to normal tissue for a patient receiving radiation therapy, without impairing the effectiveness of the radiation treatment on the patient's cancer cells.


<sup>1</sup>Ryan, Julie. "Ionizing Radiation: The Good, the Bad, and the Ugly." *J Invest Dermatol*. 132 (2012): 985-993.

<sup>2</sup>Bray, Fleta *et al.* "Acute and Chronic Cutaneous Reactions to Ionizing Radiation Therapy." *Dermatol Ther*. 6 (2016): 185-206.

<sup>3</sup>Radvansky, Lauren *et al.* "Prevention and management of radiation-induced dermatitis, mucositis and xerostomia." *Am J Health Syst Pharm*. 12 (2013): 1025-1032.


### BioCurity's Discovery

#### Medical Use of Cerium Oxide Nanoparticles



- **Cancer Patients and Cancer Survivors are suffering from their cancer and serious side effects directly caused by radiation therapy<sup>1</sup>**
- **At an MD Anderson Cancer Center affiliate formerly located on the Orlando Health campus (2005-2010) researchers and physicians discovered a use for cerium oxide nanoparticles to protect normal tissue during radiation**
- **Products for skin and internal tissue were extensively tested in preclinical studies.<sup>2,3,4</sup>**
- **BioCurity completed a Pre-IND filing with the FDA for a topical product for Breast Cancer patients<sup>5</sup>**

See References #1-5 provided under Chart



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<sup>1</sup>Benderitter, Marc *et al.* "Stem Cell Therapies for the Treatment of Radiation-Induced Normal Tissue Side Effects." *Antioxid Redox Signal*. 2 (2014): 338-355.

<sup>2</sup>Colon, Jimmy *et al.* "Protection from radiation-induced pneumonitis using cerium oxide nanoparticles." *Nanomedicine*. 5 (2009): 225-231.

<sup>3</sup>Kuchma, Melissa *et al.* "Phosphate ester hydrolysis of biologically relevant molecules by cerium oxide nanoparticles." *Nanomedicine*. 6 (2010): 738-744.

<sup>4</sup>Manon, Rafael et al. “Harnessing Nanoparticles to Improve Toxicity after Head and Neck Radiation.” *Nanomedicine*. 7 (2012): 1223-1231.

<sup>5</sup>FDA submitted to BioCurity on December 8 2016 the meeting minutes from the Pre-IND meeting held on December 6 2016.

The Company’s breakthrough medical discovery was preclinically tested by the Scientific Co-Founder of BioCurity at an MD Anderson Cancer Center affiliate. The products generated from BioCurity’s technology include a topical formulation for skin and IV formulation (proposed to be delivered by way of an intravenous injection) for internal tissue. Preclinical studies successfully demonstrated prevention or mitigation of damage to normal tissue by radiation in small animal studies. The formulations generated from BioCurity’s technology in preclinical studies were administered before and during radiation treatment in multiple cancers. The cancers tested included breast, head and neck, lung, prostate, and colorectal cancer. The mechanisms of action of the Company’s proprietary technology resulted in multiple peer-reviewed published preclinical animal studies.<sup>4,5,6</sup>

The Company has presented its positive preclinical data and proprietary technology to Key Opinion Leaders at select leading cancer centers in the United States. These Key Opinion Leaders support development of BioCurity’s proposed drug candidates for cancer patients undergoing radiation therapy. Key Opinion Leaders have expressed their interest to perform research collaborations with BioCurity and suggested that clinical studies be performed at their affiliated medical centers.

## **THE PROBLEM - UNMET PATIENT NEED**

Radiation therapy is a standard treatment modality used by physicians in oncology to shrink existing tumors, slow or halt spread of the disease and to reduce pain. The lack of adequate treatment options available to prevent or mitigate the damage to normal tissue causes an unmet global need. Radiation therapy can be delivered prior to surgery, after surgery, or as part of a nonsurgical treatment of cancer. Unfortunately, depending on the sites irradiated, damage to healthy normal tissue on the skin and internal tissue may occur. The side effects experienced by cancer patients receiving radiation therapy can be minimal or severe. The Chart below summarizes the types of cancers and some of the notable clinically reported radiation therapy side effects from the many types of cancers.

## Notable Radiation Therapy Side Effects<sup>1-4</sup>

- **Lung:** Scarring of the lungs (pneumonitis), skin burning, pain
- **Breast:** Scarring of breasts, skin burning, blisters, open wounds, pain
- **Head and Neck:** Drying of mouth, (loss of saliva), difficulty swallowing and other symptoms (xerostomia), skin burning, pain
- **Prostate:** Inflammation of rectum, damage to urinary bladder (frequent painful urination), skin burning, pain
- **Colorectal:** Damage to bowel (bleeding of rectum), skin burning, pain



See References #1-4 provided under Chart



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<sup>1</sup>Ryan, Julie. "Ionizing Radiation: The Good, the Bad, and the Ugly". *J Invest Dermatol.* 132 (2012): 985-993.

<sup>2</sup>Bray Fleta, et al. "Acute and Chronic Cutaneous Reactions to Ionizing Radiation Therapy." *Dermatol Ther.* 6 (2016): 185-206.

<sup>3</sup>Radvansky, Lauren, et al. "Prevention and Management of Radiation-Induced Dermatitis, Mucositis and Xerostomia." *Am J Health Syst Pharm.* 12 (2013): 1025-1032.

<sup>4</sup>Peach, Matthew, et al. "Systematic Review of the Relationship between Acute and Late Gastrointestinal Toxicity after Radiotherapy for Prostate Cancer." *Prostate Cancer.* 15 (2015),1-11.

In 2018, an estimated \$2 Billion was billed by hospitals in the US for in-patient medical care costs to treat radiation dermatitis. The \$2 Billion in costs are associated with treating the skin damaged by radiation therapy to cancers of the breast, lung, head and neck, colorectal, prostate and brain.<sup>7,8</sup> In 2018, an estimated \$1.3 Billion was billed by hospitals in the US for in-patient medical care costs related to head and neck radiation therapy complications.<sup>7,8</sup> Physicians, patients, nonprofit organizations, hospitals, insurance companies and advocates of cancer patient support programs are familiar with the economic costs and wide ranging effects the damage to normal tissue causes patients that are in treatment for their cancer.

<sup>4</sup>Colon, Jimmy *et al.* "Protection from radiation-induced pneumonitis using cerium oxide nanoparticles." *Nanomedicine.* 5 (2009): 225-231.

<sup>5</sup>Kuchma, Melissa *et al.* "Phosphate ester hydrolysis of biologically relevant molecules by cerium oxide nanoparticles." *Nanomedicine.* 6 (2010): 738-744.

<sup>6</sup>Colon, 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.* 6 (2010): 698-705.

<sup>7</sup>"The Web's Free ICD-9-CM Medical Coding Reference." ICD9data.com. ICD9Data, Web. 28 September 2018.

<sup>8</sup>"Healthcare Cost and Utilization Project (HCUP)." *Ahrq.gov.com.* Agency for Healthcare Research and Quality, July 2017. Web. 28 September 2018.

## COMPETITION

BioCurity consultants and the scientific team have researched competitive products to prevent certain side effects caused by radiation therapy to cancer patients. After speaking with radiation oncologists, FDA Advisors and Key Opinion Leaders, options for products are quite limited. The sole drug for damage to internal tissue caused by radiation is known to have side effects as detailed below.

### **Topical Drug for Prevention of Radiation Dermatitis.**

Currently topical steroids, an anti-inflammatory preparation used mainly to control inflamed, itchy, red, cracked, and rough skin has been provided for patients before radiation. As far as preventing radiation dermatitis there is no study that can demonstrate efficacy for topical steroid products either prescribed or over the counter.<sup>9</sup> Over the counter, all-natural topical creams are also available for the prevention and treatment of radiation dermatitis but there is limited evidence in the public domain pertaining to the efficacy of these products. The Company's consultants and Key Opinion Leaders have reinforced the Scientific Co-Founder's review pertaining to the currently available topical drugs for the prevention or mitigation of radiation dermatitis. Patients continue to suffer burns and other side effects causing billions of dollars in medical care.

### **IV Drug for Prevention of Damage to Internal Tissue.**

An FDA approved IV drug, Ethylol (Amifostine) is sometimes administered prior to radiation therapy in patients with head and neck cancers as a way of reducing xerostomia (dry mouth).<sup>10</sup> While Amifostine has clinically proven protective effects against internal normal tissue caused by radiation treatment, Amifostine has been reported to cause adverse reactions, sometimes severe that limit its use with patients for head and neck cancer.<sup>10,11</sup>

## MARKET SIZE

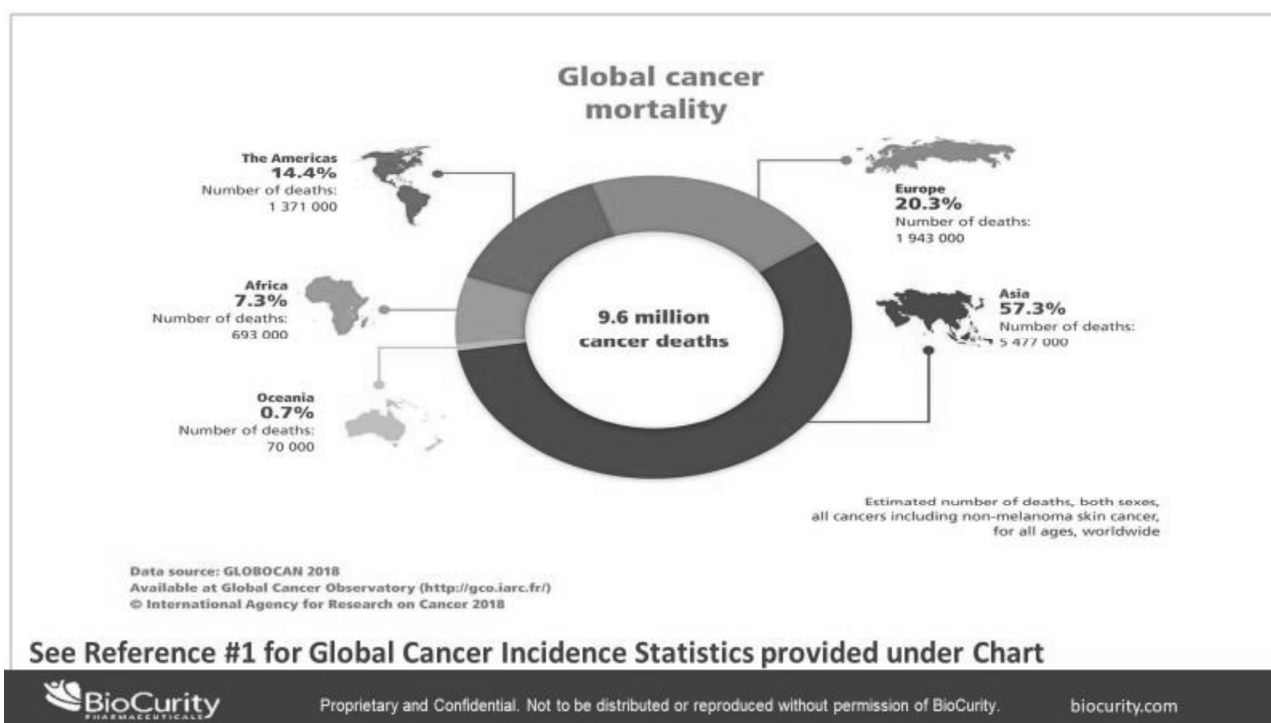
Approximately 18 million cancer patients globally are newly diagnosed annually. Approximately 6 million of these patients receive radiation therapy and 1 million of those cancer patients receive radiation therapy in the United States.<sup>9,12</sup> BioCurity's technology and drug candidates have the potential to significantly reduce radiation therapy toxicity not just for these newly diagnosed patients but also for cancer survivors who receive radiation therapy as part of their ongoing treatment for cancer.

<sup>9</sup>IAEA Report 2017, Radiotherapy in Cancer Care, Facing the Global Challenge.

<sup>10</sup>"ETHYOL Generic Name: Amifostine Brand Name: Ethylol." [www.rxlist.com](http://www.rxlist.com). RxList. 4 March 2019. Web. 9 December 2019.

<sup>11</sup>LABEL: ETHYOL- amifostine injection, powder, lyophilized, for solution." [Dailymed.nlm.nih.gov](http://Dailymed.nlm.nih.gov). NIH US National Library of Medicine, 25 June 2019. Web 9 December 2019.

<sup>12</sup>"All Cancers. Source Globcan: 2018." International Agency for Research on Cancer. March 2019. Web. 23 August 2019.



<sup>14</sup>“All Cancers. Source Globcan: 2018.” International Agency for Research on Cancer. March 2019. Web. 23 August 2020.

According to a peer review scientific article published in 2015, radiation therapy is recognized as an essential element of an effective cancer care program throughout the world, regardless of countries’ economic status.<sup>13</sup> A drug that prevents or mitigates radiation damage to normal tissue from radiation therapy, according to radiation oncologists, clinical development consultants and other health experts, could receive widespread support in the global medical community. This is for both a topical and an IV drug in multiple types of cancer.<sup>14</sup>

## THE SOLUTION

As noted above, radiation therapy is one of the most widely utilized modalities for treatment of cancer. 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 ionizing radiation. As with skin, the damage to healthy tissue occurs because ionizing radiation creates free radicals (also known as Reactive Oxygen Species or “ROS”) that disrupt cellular DNA and cause cell death.<sup>15</sup> While cellular protective and repair mechanisms are present to block or repair damage caused by ROS, 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.<sup>16</sup>

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.<sup>15,17</sup> 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 Scientific Co-Founder and consultants agree as, supported by preclinical animal studies that the stability of Cerium oxide nanoparticles will result in the persistence of their protective effects for extended periods of time. The Company’s preclinical animal studies have also shown 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.<sup>18</sup>

<sup>13</sup>Jaffray, David A and Gospodarowicz, Mary K. “Radiation Therapy for Cancer.” Ed. Hellen Gelband, Ed. Prabhat Jha, Ed. Rengaswamy Sankaranarayanan, Ed. Susan Horton. Washington (DC): The International Bank for Reconstruction and Development / The World Bank, 2015. 239-248.

<sup>14</sup>Baskar, Rajamanickam et al. “The diverse and complex roles of radiation on cancer treatment: therapeutic target and genome maintenance.” *Am J Cancer Res.* 4 (2012): 372-382.

<sup>15</sup>Kim, Jae et al. “Mechanisms of radiation-induced normal tissue toxicity and implications for future clinical trials.” *Radiat Oncol J.* 3 (2014): 103-115.

<sup>16</sup>Celardo, Ivana et al. “Pharmacological potential of cerium oxide nanoparticles.” *Nanoscale.* 3 (2011): 1411–1420.

<sup>17</sup>Xu, Can and Xiaogang Qu. “Cerium oxide nanoparticle: a remarkably versatile rare earth nanomaterial for biological applications.” *NPG Asia Materials.* 6 (2014): 1-31.

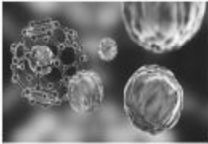
<sup>18</sup>Colon, Jimmy et al. “Protection from radiation-induced pneumonitis using cerium oxide nanoparticles.” *Nanomedicine.* 5 (2009): 225-231.


### How Our Drug Under Development Works

**BioCurity’s proposed drug is intended to eliminate free radicals, PROTECTING the normal skin and internal tissues from the many unwanted side effects of radiation during radiation therapy, without interfering with the radiation treatment<sup>1,2</sup>**

- **Radiation exposure creates free radicals (also known as Reactive Oxygen Species) that disrupt cellular DNA activities and cause cell death in cancer and normal cells<sup>3</sup>**
- **Cerium oxide nanoparticles are free radical scavengers and degrade the free radicals primarily in the normal cells<sup>4,5</sup>**
- **Cancer cells still undergo the desired effect of cell death by the targeted radiation treatment<sup>6</sup>**

**See References #1-6 provided under Chart**





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<sup>1</sup>Colon, Jimmy et al. “Protection from radiation-induced pneumonitis using cerium oxide nanoparticles.” *Nanomedicine.* 5 (2009): 225-231.

<sup>2</sup>Manon, Rafael et al. “Harnessing Nanoparticles to Improve Toxicity after Head and Neck Radiation.” *Nanomedicine.* 7 (2012): 1223-1231.

<sup>3</sup>Kim, Jae et al. “Mechanisms of radiation-induced normal tissue toxicity and implications for future clinical trials.” *Radiat Oncol J.* 3 (2014): 103-115.

<sup>4</sup>Celardo, Ivana et al. “Pharmacological potential of cerium oxide nanoparticles.” *Nanoscale.* 3 (2011): 1411–1420.

<sup>5</sup>Xu, Can and Xiaogang Qu. “Cerium oxide nanoparticle: a remarkably versatile rare earth nanomaterial for biological applications.” *NPG Asia Materials.* 6 (2014): 1-31.

<sup>6</sup>Tarnuzzer, Roy et al. “Vacancy engineered ceria nanostructures for protection from radiation-induced cellular damage.” *Nano Letters.* 12 (2005): 2573-2577.

## PROPOSED TOPICAL DRUG - LEAD PRODUCT

### Proposed Topical Drug for Breast Cancer.

BioCurity plans to develop its lead drug candidate as a topical drug in the United States for breast cancer patients receiving radiation therapy as part of their cancer treatment. Based on discussions with the Company's drug development consultants, the Company believes the advantages of a breast cancer lead product, if approved, would serve a large existing group of cancer patients and prevent skin burns to the breast for breast cancer patients is a priority.

Breast cancer is the leading cancer in the United States for women, and it is estimated that 1 in 8 women in the United States will develop breast cancer over their lifetime.<sup>19</sup> Some form of skin damage has been referenced in the scientific literature to inflict nearly all women with breast cancer who are receiving radiation therapy.<sup>20</sup> Furthermore, expansion of the initial approved indication in breast cancer patients to include additional radiotherapy patients would be desirable. For example, in addition to the frequent use of radiotherapy as adjuvant therapy for breast cancer, radiotherapy is also standardly used to induce shrinkage of tumors, mitigation of locoregional cancer spread and pain management in the treatment of lung cancer, head and neck cancer, colorectal cancer, prostate cancer and brain cancer. Like those seen with breast cancer patients, burning of the skin can occur from the radiotherapy in these cancer patients as well.<sup>21-23</sup>

<sup>19</sup>"Breast Cancer Fact Sheet." ww5komen.org. The Susan G. Komen Breast Cancer Foundation. 30 July 2019. Web. 20 August 2019.

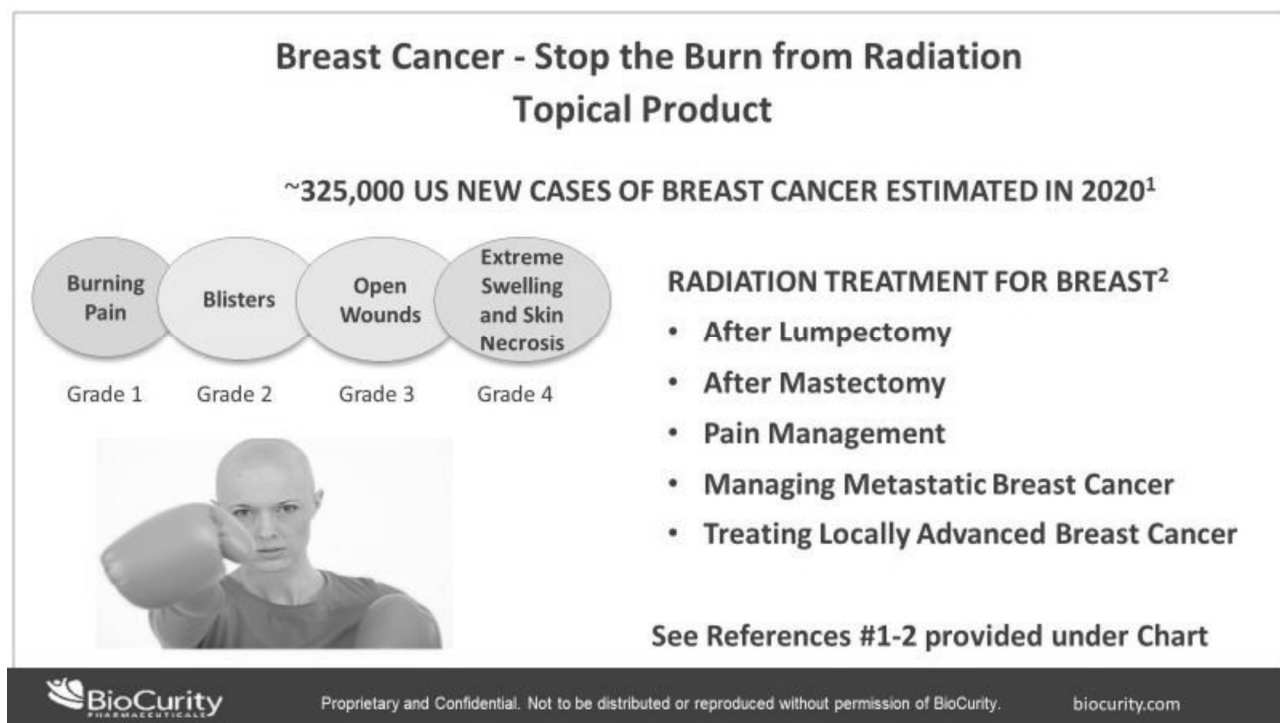
<sup>20</sup>Kole, Adam J et al. "Acute radiation dermatitis in breast cancer patients: challenges and solutions." *Breast Cancer - Targets and Therapy*. 9 (2017): 313-323.

<sup>21</sup>Radvansky, Lauren et al. "Prevention and management of radiation-induced dermatitis, mucositis and xerostomia." *Am J Health Syst Pharm*. 12 (2013): 1025-1032.

<sup>22</sup>Kress, Marie-Adele et al. "Radiation therapy at the end of life: a population-based study examining palliative treatment intensity." *Radiation Oncology*. 15 (2015): 2-9.

<sup>23</sup>Hu, Stephen et al. "Changes in biophysical properties of the skin following radiotherapy for breast cancer." *J. Dermatol*. 12 (2014): 1087-1094.





<sup>1</sup>“U.S. Breast Cancer Statistics.” Breastcancer.org. Breast Cancer.org, 25 June 2020. Web. 11 October 2020.

<sup>2</sup>“When is Radiation Appropriate?” Breastcancer.org. Breast Cancer.org, 28 March 2020. Web. 11 October 2020.

Radiation treatment for breast cancer can be used after lumpectomy, after mastectomy, for pain management, for managing metastatic breast cancer and for treating locally advanced breast cancer.<sup>24</sup> The short term and long-term skin damage associated with radiation therapy for breast cancer patients includes localized burning and blisters that can often be permanent, open wounds, extreme swelling and tenderness of the breast and surrounding lymph nodes, and permanent scars.<sup>25</sup>

### ***Commercial Strategy for Proposed Topical Drug.***

The Company, believes its proposed topical drug is reasonable to manufacture, however, third party analysis of the manufacturing costs of the topical drug have not been performed. Due to the potential to reduce the side effects of radiation and possibly enhance the quality of life for patients, the Company and its consultants believe reimbursement will not present a barrier to access for patients. Independent, third party analysis of the commercialization potential of the Company’s proposed topical drug has not been performed.

### ***Drug Development - Pre-IND Meeting with FDA.***

BioCurity participated in a Pre-IND meeting with the FDA in December 2016 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.

<sup>24</sup>“Radiation Therapy for Breast Cancer.” *mayoclinic.org*. Mayo Clinic. 24 March 2018. Web. 20 August 2019.

<sup>25</sup>Bray, Fleta *et al.* “Acute and Chronic Cutaneous Reactions to Ionizing Radiation Therapy.” *Dermatol Ther.* 6 (2016): 185-206.

BioCurity'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 has been reduced from the Company's Pre-IND submission and cancer patients have been added to participate for the safety portion of the trial.

## BioCurity Lead Product Candidate

### Topical Formulation for Breast Cancer



#### Major Milestones Achieved

- Pre-IND meeting held with FDA resulted in favorable feedback on:
  - *Confirmation of Unmet Clinical Need*
  - *Manufacturing plans for Active Pharmaceutical Ingredient (API) and Topical Product*
  - *IND-Enabling Toxicology Testing Protocols*
  - *Preliminary Clinical Protocol Synopsis for a Phase 1/2 Study\**
  - *Initial Drug Application (IND) Submission Pathway*
- Pilot non-GMP manufacturing of API and topical product has been completed

\*The clinical trial design has been revised subsequent to the Pre-IND meeting



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#### ***Clinical Trial Design Synopsis for Topical Drug.***

The Company's biotech and drug development consultants, who assisted with the clinical design, have decades of combined experience in preclinical and clinical development strategy, regulatory (FDA) protocol development, and clinical trial execution. The proposed Phase 1/2 clinical trial is designed to test the Company's proposed topical drug on a sufficient number of breast cancer patients for safety and efficacy testing.

The proposed Phase 1 (Safety) portion of the proposed Phase 1/2 clinical trial design includes an enrollment total of 18 breast cancer patients receiving radiation therapy. The proposed Phase 2 (Efficacy) portion of the proposed Phase 1/2 clinical trial design includes an enrollment total of 66 breast cancer patients receiving radiation therapy for early-stage breast cancer and as cancer pain management in advanced breast cancer. At the recommendation of the consultants, the total number of participants in the proposed Phase 1/2 clinical trial has been reduced from the Company's Pre-IND submission and cancer patients have been added to participate for the safety portion of the trial. The Company may encounter additional changes to the proposed Phase 1/2 clinical trial design when filed with the FDA at the time of the proposed IND submission.

#### ***Manufacturing of Topical Drug.***

Pilot manufacturing of the API (active pharmaceutical ingredient) and topical drug under non-GMP conditions was completed in Q2 2017. The GMP manufacturing process has not begun as of the date hereof. Several product contract manufacturing organizations (CMOs) appear to have comprehensive GMP manufacturing capabilities for topical dosage form inclusive of creams, gels and ointments. See *Risk Factors* – “We may have significant existing challenges for manufacturing our API with respect to our clinical trials and submission of an IND application in the United States” and “We will rely on relationships with third-party contract manufacturers, which will limit our ability to control the availability of, and manufacturing costs for, our product candidates” for a discussion of risks that the Company may incur with API, selection and reliance on third party service providers such as Contract Research Organizations (CROs) and CMOs.

#### ***Toxicology Studies for Topical Drug.***

Management received and reviewed a detailed quote setting out cost and timing on the proposed IND-enabling toxicology studies required for the filing of an IND from a reputable and global leading company that provides these services for many large and early-stage biotech companies. The Company has not accepted any contract for the toxicology studies or commenced toxicology studies as of the date hereof.

## **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](http://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 the charts below for bios on the CSSi team - Mr. Jim Sergi and Dr. Heidi Nelson-Keherly, PhD.

## The Clinical Development Team - CSSi LifeSciences



### Jim Sergi - President and Founder

- President & Founder of CSSi over 15 years ago to offer turn-key solutions for companies seeking drug development day to day and strategic oversight for drug development
- LifeScience merchant banking experience at Bay Tower Capital (2005 – 2013)
- Founder and CEO of ProED Communications, a healthcare services and drug development company (1991-2005)
- Directly responsible for over 85 New Drug Application approvals and over 250 medical device approvals
- 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
- Serves as scientific reviewer for the NIH SBIR/STTR Programs
- Scientific advisor and board member to numerous nonprofits, private equity and venture backed investment firms
- Master's Degree in Health Care Administration from Cleveland State University and Master's Degree in Nursing from University of Akron



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## The Clinical Development Team - CSSi LifeSciences



### Heidi Nelson - Keherly, PhD - Vice President, Drug Discovery and Development

- Over 20+ years of experience working with small and mid-size pharmaceutical and biotech
- Extensive experience in drug development through Investigational New Drug (IND) submissions
- Directly managed over 300 drug development programs
- Responsible for several multi-therapeutic clinical research sites that participated in over 80 Phase I-IV clinical trials
- Experience assisting companies with development of Scientific Advisory Boards
- PhD in Molecular and Cell Biology, University of Madison-Wisconsin



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### Scientific and Medical Advisory Board.

We have assembled a Scientific and Medical Advisory Board currently comprised of three members, Dr. Chirag Shah, MD, radiation oncologist affiliated with the Cleveland Clinic, Dr. John Heymach, MD, PhD, medical oncologist affiliated with the University of Texas MD Anderson Cancer Center, Dr. Mark Ratain, MD,

medical oncologist affiliated with the University of Chicago Medicine, and Dr. Chirag Shah, MD, radiation oncologist affiliated with the Cleveland Clinic, who are scientific and clinical experts and key opinion leaders in the fields of radiation and medical oncology, clinical research on methods for preventing radiation therapy-induced side effects, clinical trial strategy and clinical trial execution.

***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. He received his undergraduate degree from Harvard University and his MD/PhD from Stanford. He completed his Internship and Residency at Brigham and Women's Hospital and his fellowship in Medical Oncology from the Dana Farber/Mass General Brigham 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. His research has led to new therapeutic approaches for KRAS mutant lung cancer, small cell lung cancer (SCLC), EGFR mutant non-small cell lung cancer (NSCLC), adenoid cystic carcinoma, and oligometastatic NSCLC, many of which are now considered standard of care regimens or undergoing clinical testing. He serves as PI on 4 R01 awards investigating molecular subsets of lung cancer, and on an U01 focused on SCLC. He serves as the MDACC PI for the SU2C-ACS Lung Cancer Dream Team targeting KRAS mutant lung cancers, as the leader of the Lung CCSG Program, and the co-leader of the Lung Cancer Moon Shot. He is also the co-PI and project leader of the Lung SPORE.

As a clinical investigator, he leads a number of biomarker-directed clinical trials using targeted and immunotherapy agents in lung cancer. He has directly mentored numerous fellows, including physician-scientists, and serves as chair of the NCI Molecular Cancer Therapeutics-1 study section.

***Mark Ratain, MD – University of Chicago Medicine.***

Dr. Mark Ratain, MD, 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 has an interest in the clinical development of new oncology drugs, and more recently, his research focused on the use of pharmacogenomics to guide personalized prescribing and interventional pharmacoeconomics. Through this research, he is aiming to decrease prescribing costs through the use of lower dosages, less frequent dosing, shorter duration of treatment, and/or therapeutic substitution.

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. His work can be found in more than 500 published articles and book chapters.

Dr. Ratain also received several awards/recognitions for his dedication to improving medicine. In 2015, Dr. Ratain received the Award in Excellence in Clinical Pharmacology from the Pharmaceutical Research and Manufacturers of America Foundation. In 2016 he was the nominee (Scientific Advances), from the Giants of Cancer, OncLive and in 2019 Dr. Ratain presented the Gruber Lectureship at Thomas Jefferson University.

***Chirag Shah, MD – Cleveland Clinic.***

Dr. Chirag Shah, MD, is Associate Staff in the Department of Radiation Oncology and Director of Clinical Research in the Department of Radiation Oncology at the Cleveland Clinic. Dr. Shah received his Bachelor's degree from Youngstown State University and his Medical degree from Northeast Ohio Medical University. He completed his internship, and residency at William Beaumont Hospital from 2007 to 2012 and joined the Cleveland Clinic Staff in 2015.

Dr. Shah serves as a reviewer for various medical journals and is a member of various medical societies. His primary research interests are breast cancer, sarcoma, prostate cancer, lymphoma, and innovative radiation

treatment schedules as well as lymphedema. He has participated in numerous in-house, pharmaceutical, and cooperative group trials.

## **PROPOSED IV DRUG - PROTECTION OF INTERNAL TISSUE**

### ***Proposed IV Drug.***

As set out above, damage to internal tissue during radiation therapy is an unmet clinical need for cancer patients. The Company believes there is a strong value proposition for an IV drug preventing or mitigating side effects of radiation therapy for multiple cancers. Some of the side effects from radiation therapy can contribute to life-threatening complications. While radiation therapy is considered one of the most common treatment strategies for lung and head and neck cancer, the normal lung and tissues in the head and neck are highly sensitive to radiation and these cancer patients often face long-term radiation-induced side effects.<sup>26,27</sup>

For example, in patients with lung cancer treated with radiation therapy, the radiation may cause inflammation and scarring of the normal lung, resulting in difficulty with breathing, chest pain, and pneumonia (which may require hospitalization).<sup>26</sup> For head and neck cancer patients treated with radiation therapy, these patients may have difficulties with eating, speaking, tasting, and dry mouth as a result of radiation-induced damage to the internal salivary glands.<sup>27</sup> Worldwide, lung cancer remains the leading cause of cancer incidence and mortality, with 2.1 million new lung cancer cases and 1.8 million deaths estimated in 2018.<sup>28</sup> As reported in 2018, in the United States, every year, approximately 200,000 patients are diagnosed with lung cancer and each year an estimated 150,000 patients diagnosed with lung cancer die.<sup>29</sup> The annual occurrence rate of newly diagnosed head and neck cancer patients, as reported in 2018, is approximately 63,000 cases in the United States.<sup>30</sup>

### ***IV Drug Development.***

Further discussions with the Company's drug development and clinical trial consultants and the Company's regulatory advisors are required before the clinical development on the proposed IV drug is designed and submitted to the FDA. The Company has had preliminary discussions with strategic funding groups for its proposed IV drug development and there appears to be interest in the proposed IV drug.

<sup>26</sup>Lierova, Anna et al. "Cytokines and radiation-induced pulmonary injuries." *Journal of Radiation Research*. 59 (2018): 709–753.

<sup>27</sup>Radvansky, Lauren et al. "Prevention and Management of Radiation-Induced Dermatitis, Mucositis and Xerostomia." *Am J Health Syst Pharm*. 12 (2013): 1025-1032.

<sup>28</sup>Bray, Freddie et al. "Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries." *CA: A Cancer Journal for Clinicians*. 68 (2018): 394-424.

<sup>29</sup>"Lung Cancer Is the Biggest Cancer Killer in Both Men and Women – Infographic." *cdc.gov*. Centers for Disease Control and Prevention. 19 July 2018. Web. 5 September 2019.

<sup>30</sup>Head and Neck Cancer Market Research Report - Forecast to 2023. Herald Keeper Report, 1 August 2018. Web. 5 September 2019.

### **Employees.**

As of the date of this annual report, the Company does not have employees – only executive officers, directors, and consultants, none of which are employees of the Company. All members of the Company's team work virtually due to the COVID-19 pandemic.

### **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 consultants as opposed to hiring full time employees to support these key areas when needed allows for more efficient use of Company funds.

## **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 has been extended until August 31, 2021.

## **INTELLECTUAL PROPERTY**

BioCurity’s technology is disclosed and claimed in a patent portfolio controlled by BioCurity, including patent rights wholly or jointly owned by the Company, as well as patent rights exclusively licensed from the University of Central Florida Research Foundation, Inc. (“UCFRF” or “Licensor”) effective February 2015 (the “License Agreement”). The Company’s issued patent portfolio (in addition to the Company’s pending patent applications) provides highly relevant coverage with supporting claims to protect the Company’s proposed clinical efforts.

### ***Company’s License Agreement.***

The License Agreement is a non-royalty, fully paid license that includes 7 issued United States patents. BioCurity has an exclusive license to develop, manufacture, and sell cerium oxide nanoparticle formulations for preventative, therapeutic, diagnostic purposes in select fields.

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 (e) UCFRF is not obligated to indemnify the Company for a breach of the License Agreement by either UCFRF or any of its affiliates.

There are a number of risks to the Company. associated with the License Agreement. 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. The Company’s international patent covers the use of the Company’s cerium oxide nanoparticle technology for patients with cancer 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 toxicity associated with radiation therapy and chemotherapy. In January 2017, this application entered the National Phase and patent protection is being sought in the following countries: Australia, Brazil, Canada, China, Hong Kong, Japan, Mexico, New Zealand, Europe and USA. As of the date of this report, the Company's international patent has issued in Australia, China, Europe, Japan and Hong Kong. The types of cancers allowed in claims issued is limited. Patent applications are pending, some of which include countries the Company holds issued patents. Please review *Risk Factors* – “*Risks related to Company-owned International Patent Portfolio.*”

The Company believes that by seeking international patent protection, if successful, it will enhance the value of the Company's intellectual property portfolio. The actual determination of whether to file and prosecute the 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 the applications. There is no guarantee pending claims will be allowed to the Company and the Company at any time, may decide to abandon pending applications. See Charts below for the Company's licensed patents and Company's international patents.

<b>Licensed US Patent*</b>	<b>Type</b>	<b>Expires</b>	<b>Owned</b>
<b>7 Issued Patents</b>	Composition of Matter & Method of Use US Patents	2025 - 2032	Exclusive License
<b>2 Pending Patent Applications</b>	Composition of Matter & Method of Use US Patent	Estimated 2030	Exclusive License

**\*THE COMPANY'S LICENSED PATENTS COVER THE USE OF THE COMPANY'S CERIUM OXIDE NANOPARTICLE TECHNOLOGY FOR PATIENTS WITH CANCER TREATED WITH RADIATION.**

<b>International Patents*</b>	<b>Type</b>	<b>Expires</b>	<b>Owned</b>
<b>5 Issued Patents</b>	Method of Use US and International Patent	Estimated 2035	BioCurity Owned
<b>Pending Patent Application</b>	Method of Use US and International Patent	Estimated 2035	BioCurity Owned

**\*THE COMPANY’S INTERNATIONAL PATENTS COVER THE USE OF THE COMPANY’S CERIUM OXIDE NANOPARTICLE TECHNOLOGY FOR PATIENTS WITH CANCER TREATED ONLY WITH RADIATION COMBINED WITH AT LEAST ONE CHEMOTHERAPEUTIC AGENT.**

**THE COMPANY IS PURSUING PATENT COVERAGE IN: AUSTRALIA, BRAZIL, CANADA, CHINA, HONG KONG, EUROPE, JAPAN, MEXICO, NEW ZEALAND, AND THE USA. A PATENT HAS BEEN ISSUED IN AUSTRALIA, CHINA, EUROPE, JAPAN, AND HONG KONG.**

**THE TYPES OF CANCERS ALLOWED IN CLAIMS ISSUED IS LIMITED.**

## **MANAGEMENT OF THE COMPANY**

The Company is managed by its Board of Directors, which presently consists of three (3) persons: Dr. Cheryl Baker, PhD, Aslam S “Sam” Merchant and Nancy Cass. They also are 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.

### **Management Team**

#### ***Sam Merchant, Chairman of the Board of Directors.***

Sam Merchant serves as Chairman of the Board of BioCurity and has served in such capacity since February 2015. Mr. Merchant is the founder of The Merchants Financial Group, a privately held capital investment 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 the family’s projects and equities fund a position he has successfully served since 1986. Mr. Merchant has developed a network that includes Fortune 500 companies and businesses local to each region of the world. He has partnered with global companies in complex business transactions and been instrumental in the growth of major franchise 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. This expanded his knowledge of addressing and solving problems of governments and municipalities. Mr. Merchant, recognized for his effectiveness in Atlanta, served for six years on President George W. Bush’s Advisory Board for Economic Development and the Small Business Sub-committee. Mr. Merchant has interacted with governments throughout the world at the highest levels and is a well-respected global businessman. In June of 2019, Mr. Merchant was elected to serve as Chairman of the Board of Directors to the Regenerative Medicine Foundation. In addition to this position, he continues to serve as the financial team lead of the World Stem Cell Summit, one of the largest international conferences of its kind.

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, an affiliate of Mr. Merchant that has an advisory agreement with the Company, serves as interim President and COO of BioCurity; and (ii) Capital and 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.

Mr. Merchant is well informed on the JOBS Act and capital distribution in the RIA and Broker- Dealer community. 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.

Mr. Merchant has been a citizen of the United States since 1986. He is a resident of South Florida and often travels to his corporate headquarters in Atlanta. In his academic achievements, he obtained his B.Sc and BBA prior to attending Georgia State University. Mr. Merchant's graduate level academic interests and course work included, but was not limited to, physics, math, economics, and business with an emphasis on accounting and information systems technology while attending Georgia State University.

***Cheryl Baker, PhD, Scientific Co-Founder and Director.***

Dr. Cheryl Baker, PhD is Scientific Co-Founder and a Board member of BioCurity. Dr. Baker received her B.S., cum laude, in Chemistry from Rollins College (Winter Park, Florida) in 1994. In 1999, she received her Ph.D. in Biochemistry from Texas Tech University. She 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, she conducted research as an Instructor of Surgery at the Boston Children's Hospital affiliated with Harvard Medical School. Subsequently, she was an Assistant Professor at the University of Texas M.D. Anderson Cancer Center until 2005.

During 2006-2010, Dr. Baker served as Director of the Cancer Research Institute of MD Anderson Cancer Center Orlando (formerly affiliated with Orlando Health). 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. Dr. Baker has conducted cancer related research for over 20 years and is the recipient of research funding from local, state, and government agencies. Dr. Baker has published over 45 peer-reviewed manuscripts, book chapters and articles.

Dr. Baker assisted BioCurity's 3rd party FDA advisors with product development activities for the Pre-IND submission and assists patent counsel on the scientific content for BioCurity's US and international patent applications.

Dr. Baker is not employed by any other organizations. Dr. Baker also serves as Secretary and Treasurer for BioCurity.

***Nancy J Cass, Director.***

Ms. Cass is a Director of BioCurity and has served in such capacity since June 2016. Ms. Cass is a corporate/securities attorney and a licensed investment banker at Crescent Securities Group, Inc., where she has worked since January 2016. Ms. Cass uses her depth of experience in transactional and securities law to provide added value for investment banking clients. Ms. Cass at the outset of her legal career worked at mid-sized law firms in Chicago and Miami from 1982-1986. Early in her career, Ms. Cass represented public and private issuers, institutional funding sources, banks and early-stage companies. Her proficiency and skill through practicing law benefits examining opportunities for financings, strategic partnerships, and other transactions. Her evaluations are frequently comprehensive, and Ms. Cass is able to interact with the attorneys on transactions, review documents and conduct due diligence with added insight from her legal and securities training. She joined the Company as a director in June 2016.

Ms. Cass co-founded MerchantCass Advisors with Sam Merchant in 2012 ([www.merchantcass.com](http://www.merchantcass.com)). Prior to co- founding MerchantCass Advisors she 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. Most recently, Ms. Cass was licensed at Crescent Securities Group, a FINRA broker, from 2015-2020.

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. Ms. Cass will participate in the interim executive services provided to BioCurity through MerchantCass Advisors.

She maintains an active license to practice law in Florida and Illinois. Ms. Cass holds FINRA Series 24, 7, 79 and 63 licenses.

## 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 global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. 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.

### Financial Risks

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

Our losses have resulted principally from costs incurred in our discovery, development, and operating activities. We anticipate that we will continue to generate significant losses for the next several years and foreseeable future as we incur expenses to complete our clinical trial programs for our product candidates, build commercial capabilities, engage consultants, develop our product pipeline and grow a corporate infrastructure.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain profitability. We do not expect to generate any revenue for many years as product development is a long-term 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.

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

An epidemic or pandemic disease outbreak, including the recent 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 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 FDA, 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 events outside of our control.***

Business disruptions could seriously harm our future revenue and financial condition and 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, 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.

***The Company has a loan of \$350,000 and will be subject to risk of repayment of the Loan.***

As noted in the description of the \$350,000 line of credit that the Company has with Seacoast National Bank and collateralized with a CD from the Town of Jupiter, Florida, as the Company draws down on that line of credit, it will be indebted for borrowed money, which is secured by a blanket lien on the Company's assets. In December 2020, the Company obtained an extension on the note allowing for additional 12 monthly interest only payments and any remaining balance due in December 2021 of less than \$150,000 must be paid in full by December 21, 2021. The Company may not have the resources to repay it. 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. While the Company has the right to prepay such loan at any time, should the Company default on its interest payment obligations or be unable to pay the loan on maturity, the Company is at risk for default with respect to the loan and loss of all its assets securing the loan.

***The Company may not raise the needed amount of funds.***

There is no assurance that the Company will sell an amount of securities sufficient to meet the Company's working capital needs on a near term basis. Investors should be aware that the proceeds from any Regulation Crowdfunding (CF) Offering are not sufficient to fund the Company in the near term or make material impact on the development of the Company's biotech product. The Company has been seeking additional capital from institutional sources and not yet been successful. If funds are not sufficient to sustain operations, the Company may have to cease operations. Lack of capital is a high risk and investors should be prepared to lose their entire investment due to the Company's inability to raise capital.

***The Company Management will have broad discretion in using the proceeds from any Offering including affiliated parties with potential conflicts of interest.***

The Company's management including those who have potential conflicts of interest and related party transactions will use the proceeds from the Offering for general working capital, expenses related to future capital raises, intellectual property development, professional fees to consultants, attorneys, accountants, and others. Payments from the proceeds of the Offering may go to officers, directors, and affiliated parties of the Company in accordance with written agreements. As such, related parties will have sole discretion in determining the specific uses of the net proceeds it receives as a result of the Offering. 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 Offering. 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.

***Board Members and Major Shareholders have Consulting Agreements with BioCurity.***

Each of MerchantCass and Capital and Venture Resources, LLC has a consulting agreement with the Company (see “*Related Party Transactions*”) 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, through BioCurity Controlling Shares, Inc. owns 10 shares of “Super Voting” Series V Preferred Stock that provides Mr. Merchant voting control over the Company. Circumstances may arise where one or more of Dr. Baker, Mr. Merchant, MerchantCass and Capital and 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 the terms of the conflicts and agreements.

***A small group of stockholders, who also control the Board, have the ability to exert significant influence on the Company’s board of directors and its business and the interests of these stockholders may conflict with yours.***

Certain 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 Cheryl H. Baker and of MerchantCass Advisors, LLC. Each of MerchantCass Advisors and Capital and Venture Resources LLC has a consulting agreement with the Company (see “*Related Party Transactions*”) and, together with their Affiliates are the beneficial owners of a substantial portion of the Company’s capital stock, warrants and options. Sam Merchant, through BioCurity Controlling Shares, Inc. owns 10 shares of “Super Voting” Series V Preferred Stock that provides Mr. Merchant voting control over the Company. Circumstances may arise where one or more of Dr. Baker, Mr. Merchant, MerchantCass and Capital and 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 the terms of the conflicts and agreements.

***Conflicts of Interest-Board Members.***

Given that BioCurity has a limited operating team, Board Members serve as consultants or employees of the Company. 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 provided to the Company by MerchantCass Advisors, and transactional consulting and advisory services provided by Capital and Venture Resources LLC. For example, BioCurity has agreed to a limitation of damages provision in its contracts with MerchantCass Advisors and Capital and Venture Resources. 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 – BioCurity Controlling Shares, Inc. Affiliate of Sam Merchant***

BioCurity Controlling Shares, Inc., an affiliate of Mr. Merchant is the sole owner of the Company’s outstanding shares and issued shares of Series V Preferred Stock. The Series V Preferred Stock has less than a \$20 economic interest in BioCurity but provides Mr. Merchant with voting control of the Company. Shareholders

must be willing to rely upon the Board and BioCurity Controlling Shares, Inc. for the management of the Company. Investors may receive voting shares in the Offering, but they will not have any control of the Company. Mr. Merchant is Chairman of the Board of BioCurity as well as a consultant to the Company through his affiliates Capital and Venture Resources and MerchantCass Advisors. The Board has fully indemnified Sam Merchant and his affiliates.

***Forbearance Agreement and Accrued Fees.***

As described above, the Company is seeking capital raising from sources other than from investors in the Offering. Further delays in this capital raising may require the Company to accrue more fees to MerchantCass Advisors, LLC (“MCA”) and their affiliates. As of the date of this annual report, these accrued fees are more than \$2 million dollars. In addition, the delay in capital raising may require other creditors of the Company to forbear funds owed by the Company. An accrual of more fees may make our capital raising efforts more challenging. On December 21, 2020, the Company entered into Notes Payable agreements with MCA and its affiliates (see “*Related Party Transactions*”). On January 25, 2021, the Company entered into Forbearance Agreements with MCA and its affiliates (see “*Related Party Transactions*”) which expires on April 25, 2021. The Forbearance Agreements are expected to be extended and may require additional terms such as corporate housing and stock options to be paid by 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, upon exercise, 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. MCA under its existing Advisory Agreement, as amended, is entitled to receive options to purchase an additional 1% of the Company fully diluted as of the end of each calendar quarter through the calendar quarter ended December 31, 2022, as well as additional options if the Company is not current with respect to its payment obligations to MCA. In addition, it is anticipated additional Stock Options will be issued. Investors should be aware of the effects of such issuances on their shareholdings prior to investing in the Company.

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

***No Guarantee that Capital and Venture Resources LLC Can Bring a Successful Transaction to the Company.***

Capital and Venture Resources LLC, controlled by Sam Merchant, has been engaged by the Company to use its best efforts to assist the Company in engaging in commercial transactions on behalf of the Company. However, the ability to attract any such potential transactions and/or successfully consummate them is dependent upon the performance of the Company, which is outside the control of Capital and Venture Resources LLC. Accordingly, prospective investors should realize that there can be no guarantee that the past successes of Capital and Venture Resources LLC and its affiliates will result in Capital and Venture Resources LLC bringing any successful transactions to the Company (see “*Related Party Transactions*”).

## **Business Risks**

### ***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.

***We will require substantial additional capital in the foreseeable future. If additional capital is not available, we will have to delay 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. 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 and other research and development activities;
- 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 our product candidates, if they receive regulatory approval;
- the cost and timing of establishing sales and marketing capabilities;
- expenses for international strategy;
- cost of management, consultant 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 anticipate that we will continue to generate significant losses for the next several years and foreseeable future as we incur expenses to complete our clinical trial programs for our product candidates, build commercial capabilities, engage consultants, develop our product pipeline and grow a corporate infrastructure.

There can be no assurance that our revenue and expense forecasts if any, will prove to be accurate, and changes in the foregoing assumptions are likely and could require us to obtain additional financing earlier than anticipated. 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.

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. Our future clinical trials may be delayed, unsuccessful, 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; and
- delays in achieving study endpoints and completing data analysis for a trial.
- risks by using a CRO outside of the United States.

In addition to these factors, 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 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.

We may not be able to enroll a sufficient number of patients, or those with required or desired characteristics, in a timely manner. 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;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

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.

***Our product candidates are based on a novel technology, which may raise development issues we may not be able to resolve, regulatory issues that could delay or prevent approval, or personnel issues that may keep us from being able to develop our product candidates.***

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. Although we have currently chosen to proceed with a topical product there is no guarantee that is the correct decision. 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 events 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 no experience as a Company in conducting clinical trials.***

We have no experience as a Company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies will be completed on time or if the planned 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.

***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. A topical formulation may in the end take longer than an IV formulation to develop. Failure can occur at any time during the clinical trial process, and it is possible 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 on 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.

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

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.

Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies 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.

Any delay in or failure to receive or maintain approval for any of our product candidates could prevent us from ever generating revenues or achieving profitability.

***We may be required to suspend, repeat or terminate our clinical trials, provided we initiate clinical trials, if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, or the trials are not well designed.***

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 current Good Manufacturing Practices ("cGMP") 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.

***Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience 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 have risks associated with clinical trials including risks possible if clinical trials are to be conducted in a foreign country.***

Identifying and qualifying patients to participate in clinical studies, if and when such trials are performed by the Company of our pharmaceutical products, is critical to our success. The timing of our clinical studies depends upon many factors including but not limited to, the speed at which we can recruit patients to participate in testing our pharmaceutical products, the ability to produce an adequate formulation and the funding necessary to pay for such trials. We may experience delays due to a number of factors some of which may not be in control of the Company. If patients are unwilling to participate in our clinical studies because of negative publicity from adverse events in the biopharmaceutical industries or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting patients, conducting studies, and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical studies altogether.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by the FDA or other regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical study in any foreign country is subject to numerous risks some of which may be unique to conducting business in a foreign country, including:

- difficulty in establishing or managing relationships with competent contract research organizations and physicians;
- different standards for the conduct of clinical studies and logistical difficulties of conducting business outside of the United States;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business.

***We may encounter substantial regulatory, funding and other challenges with production of our product in a foreign country.***

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. This is further complicated by the fact that our proposed API may be manufactured in a foreign country and/or the United States. Our API manufacturer(s) will be required to comply with both US FDA requirements as well as with European pharmaceutical regulatory standards.

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.

***We may have significant existing challenges for manufacturing our API with respect to our clinical trials and submission of an IND application in the United States.***

The active pharmaceutical ingredients (“API”) for our initial topical product may be manufactured in both the United States and in a foreign country. There has not been any GMP API manufactured and there are limited potential manufacturing sources for our API globally. Therefore, we are subject to the risks associated with being dependent initially upon a sole source or limited source for the API, which may be further complicated by the challenges of doing business with a manufacturer situated in a foreign country. In the event of approval of our initial product for sale in the United States, there will be ongoing regulatory significant and material requirements for manufacturing a product which is essential to the Company moving forward in its timeline toward clinical trials.

Manufacturers and manufacturing facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices (“cGMP”) regulations. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any non-disclosure agreement, biologics license application (“BLA”) or marketing authorization application (“MAA”). 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.

***If we are unable to comply with foreign regulatory requirements or obtain foreign regulatory approvals, our ability to develop foreign markets for our products, should the Company decide to make a foreign market for its product could be hindered or not reasonably plausible.***

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 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.

***Competitive products for prevention and treatment of radiation-induced damage exist and there may be more competition in the future.***

The clinical and commercial landscape for prevention and treatment of radiation-induced damage is constantly changing. New data from commercial and clinical-stage products continue to emerge. It is possible that these data may alter current standards of care, completely precluding us from further developing our product candidates, or getting them approved by regulatory agencies. 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 these products are approved for marketing in a particular

indication or indications, they may have limited sales due to particularly intense competition in these markets. It is also possible that competitors may develop products superior to the Company's products, which could render the Company's products to not be commercially viable.

***We will need to develop or acquire additional manufacturing and distribution capabilities in order to commercialize any product candidates that obtain marketing approval, and we may encounter unexpected costs and other difficulties in doing so.***

If we independently develop and commercialize one or more of our product candidates, we will need to invest in acquiring or building additional capabilities and effectively manage our operations and facilities to successfully pursue and complete future research, development, and commercialization efforts. We will require additional investment and validation process development in order to qualify our commercial-scale manufacturing process to manufacture clinical trial materials and commercial material if any of our products are approved for marketing. This investment and validation process development may be expensive and time-consuming, and could be highly dilutive to existing investors, even if adequate financing could be obtained. We will require additional personnel with experience in commercial-scale manufacturing, managing of large-scale information technology systems and managing a large-scale distribution system. We will need to add personnel and expand our capabilities, which may strain our existing managerial, operational, regulatory compliance, financial and other resources. To do this effectively, we must:

- recruit, hire, train, manage and motivate a growing employee base;
- accurately forecast demand for our products;
- assemble and manage the supply chain to ensure our ability to meet demand; and
- expand existing operational, manufacturing, financial and management information systems.

We may seek regulatory approval in the United States and elsewhere for our production process and facilities simultaneously with seeking approval for sale of our product candidates. Should we not complete the development of adequate capabilities, including manufacturing capacity, or fail to receive timely approval of our manufacturing process and facilities, our ability to supply clinical trial materials for planned clinical trials or supply products following regulatory approval for sale could be delayed, which would further delay our clinical trials or the period of time when we would be able to generate revenues from the sale of such products, if we are even able to obtain approval or generate revenues at all. Additionally, we will outsource all of our manufacturing activities to third party commercial manufacturing organizations ("CMO"). 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. Any such events 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.

***Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

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.

***If we cannot demonstrate an acceptable toxicity profile for our product candidates in non-clinical studies, we will not be able to initiate or continue clinical trials or obtain approval for any 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 application, (IND), 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 events 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.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are 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, including possibly using the network some of whom may be affiliates of Capital and Venture Resources, LLC who have been involved in the sale of medical products and/or services domestically and abroad. 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 U.S. 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 for 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 may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

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, and there can be no assurance that our product candidates can be manufactured in compliance with U.S. and other countries' regulations.***

We currently plan to rely on CMOs for sterile fill and finish of our products. 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 no one on the Management team is 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 trial 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 cGMP regulations enforced by the FDA and other regulatory bodies through their facilities inspection programs. Currently our anticipated manufacturer has additional regulatory hurdles for compliance. If these 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.

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

All entities involved 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.

***We will rely on relationships with third-party contract manufacturers, which will limit our ability to control the availability of, and manufacturing costs for, our product candidates.***

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 results 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 interruptions; and

- other similar factors
- 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.

***During the course of the product life cycle provided a product is approved for sale, we may make process changes to scale up manufacturing to commercial manufacture or transfer the production to alternate sites or other contract manufacturers. Our ability to successfully implement these changes will depend on our ability to demonstrate, to the satisfaction of the FDA and other regulatory agencies that the product made by the new process or at the new site is comparable to the original product.***

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 product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of 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 federal and state healthcare fraud and abuse laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various federal and state fraud and abuse laws, including, without limitation, the federal anti-kickback statute. 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.

***Our employees or agents may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.***

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 revenues. 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 discoveries or commercial developments by our competitors could render our potential products obsolete or non-competitive.***

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, which could have discoveries through The recent funding passed in December 2016 by the United States of billions of dollars specifically for cancer research may increase competition and reduce the timeframe for competitors to get to market and increase grant funding of groups that may resolve the unmet need of the Company's product. 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.

***Our competitors may develop and market products that are less expensive, more effective, safer or reach the market sooner than our product candidates, which may diminish or eliminate the commercial success or ability to obtain financing of any products we may commercialize or develop.***

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 are and will likely continue to be extensive research and substantial financial resources invested in the discovery and development of new oncology products.

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 program 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. 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.

Further, 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 rely on third parties to conduct our non-clinical studies and some of our clinical trials. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our product candidates, or we may be delayed in doing so.***

We plan to rely on third parties, such as CROs, 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 for conducting and recording the results of our preclinical studies and Good Clinical Practices, or GCP, 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 GCP, 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 in an effort to gain access to additional product candidates and/or resources. At the current time, we cannot predict what form such a strategic collaboration might take. 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. We are unable to predict when, if ever, we will enter into any additional strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic collaborations.

## **Risks Relating to Protecting Our Intellectual Property**

***If we are unable to protect our proprietary rights or to defend against infringement claims, we may not be able to compete effectively or operate profitably.***

Our success will depend, in part, on our ability to obtain patents, license technology on acceptable terms, operate without infringing the proprietary rights of others and maintain trade secrets, both in the United States and other countries. Patent matters in the biotechnology and pharmaceutical industries can be highly uncertain and involve complex legal and factual questions. Accordingly, the validity, breadth and enforceability of our patents and the existence of potentially blocking patent rights of others cannot be predicted, either in the United States or in other countries.

### ***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 our pending patent applications (and pending patent applications of UCFRF comprising a portion of the Licensed Technology), if issued, and 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. We have filed patent applications with respect to one patent in numerous countries.

#### ***Risks related to Company-owned International Patent Portfolio.***

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 nanoparticle technology for the treatment of patients with cancer treated only with radiation combined with at least one chemotherapeutic agent. Unlike the licensed patents, there is no guarantee that these patents will be issued or that if issued they will provide a commercially viable product. In addition, the international patent is more restrictive.

As of the date of this report, the Company's international patent has issued in Australia, China, Europe, Japan and Hong Kong. The types of cancers allowed in claims issued is limited which may not sufficiently protect our products. Patent applications in these same countries are pending which include additional cancers but there is no guarantee the Company will receive claim allowance for these cancers.

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.

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

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 (i) the opinion accurately lays out a path of non-infringement that is commercially viable for the Company; or (ii) 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 patent or pending patent application 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;
- it is possible that our pending patent applications will not lead to issued patents;
- 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.

***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 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 U.S. patents related to our technologies, there is no assurance that any

of our patent claims in our other pending non-provisional and provisional patent applications relating to our technologies will issue or if issued, that any of our existing and 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.

***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 or pending applications. 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 to 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 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 in work for us, 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 are 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. 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 licensors may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to the Company.***

Our certificate of incorporation provides that we will indemnify our 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.

**Risks Relating to the Company's Current Series 2 CF Convertible Preferred Offering (the "Offering") set to expire on April 30, 2021.**

***The Proceeds from the current Series 2 CF Convertible Preferred Offering will not sustain Company operations and will provide capital for a short amount of time.***

The Target Offering Amount is low and will not contribute to sustaining the Company's operations. The Company will require additional financing if the Company only raises the Target Offering Amount in the Offering. The Company cannot be certain that additional capital or financing will be available to it on favorable terms when required, if available at all. The failure to raise needed funds, including a successful current offering, could have a material adverse effect on the Company's business, financial condition, operating results and

prospects, and could result in the loss of your entire investment in the Offering. The Series 2 CF Convertible Preferred Offering is expected to terminate on April 30, 2021.

***Securities in the Series 2 CF Convertible Preferred Offering are junior to some other classes of our Preferred Stock issued and will Convert to Common Stock at or prior to July 1, 2021.***

The Series 2 CF Convertible Preferred Stock shares will convert from Preferred to Common Stock prior to July 1, 2021. Once converted, the Shares will become Common Stock and will remain junior to any outstanding Preferred Stock. The Shares are junior in liquidation preference to all presently issued and outstanding Preferred Stock of the Company. Therefore, investors 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.

***The Company may conduct future offerings of securities with rights and preferences that are superior to those of the Series 2 CF Convertible Preferred stock being sold in the Offering.***

The Company may extend its current Series 2 CF Convertible Preferred Offering or initiate a new CF or Regulation D offering. There is no guarantee that the terms of any subsequent offering will not be preferable in control, pricing, or other significant terms. 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 of a new class of shareholders who are currently unknown. The Company has engaged a FINRA broker-dealer to assist with introductions for an institutional raise but there is no guarantee that they will be successful in bringing an interested party to the Company or that the parties would be able to agree to terms.

***Dilution and Subsequent Preferred Stock with Preferable Terms.***

The Company intends to raise additional capital after the Offering or possibly during some or all of the term of the Offering, which may be in the form of Preferred stock, which may be senior in liquidation and in other respects to the Shares to be issued from the Offering. The Company may sell other series of preferred stock in the future that may be entitled to dividends, warrants, liquidation preferences or other benefits and preferences not being offered to the purchasers of the Shares. The Company is currently seeking institutional funding and may seek funding by way of a Regulation D 506(c) and/or another Regulation Crowdfunding Offering. Any such offering will probably be on terms dilutive to existing stockholders of the Company or have other terms adverse to them, including but not limited to one or more of the following: lower cost per share, warrant coverage (in addition to share issuance), anti-dilution rights, liquidation preferences and dividend rights (with possible associated equity conversion rights).

***There Can Be No Assurances that the Company will be able to Raise Sufficient Capital from the Offering or to Raise Additional Capital After the Offering.***

There can be no assurances that the Company will be able to raise sufficient monies in the Offering to meet its current cash needs. The Company intends to raise funds from a subsequent offering, either pursuant to Regulation A or Regulation CF – but it may not have the funds required to hire the staff and professionals required to prepare offering materials to commence a future Regulation A or Regulation CF offering. If the Company does file an Offering Statement for a Regulation A Offering, there is no guarantee that such Offering Statement will ever be qualified by the SEC of that the Company will ever be able to sell any shares pursuant to such offering. If the Regulation A Offering is qualified by the SEC, there is no guarantee that any underwriter(s) engaged by the Company in connection with such an offering will be successful in selling the Company securities and generating capital for the Company. In addition, the investors in this Offering may experience significant dilution in any future capital raise of debt or equity.

***No Weighted Average Anti-Dilution Protection or Preemptive Rights for Convertible Preferred Shares.***



The conversion price of the Shares is not subject to “weighted average” anti-dilution protection which typically provides for an adjustment to the applicable conversion price in the event that the Company issues additional equity securities at a purchase price less than the conversion price of the Series 2 CF Convertible Preferred Shares. In the event the Board determines in its sole discretion to cause the Company to sell securities at a lower price, purchasers of the Series 2 CF Preferred Convertible Preferred shares 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 for the Series 2 CF Convertible Preferred Stock.

Investors holding Series 2 CF Convertible Preferred shares do not have weighted anti-dilution protection. 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 Offering price in any financing may not necessarily bear any relationship to established criteria for value.***

The Offering price that may be selected by the Company will be based on evaluation of a number of factors, including certain of the Company’s empirical financial data and that of comparable companies’ institutions, general market conditions, the anticipated market demand and our prospects for the future. The Offering price may not necessarily bear any relationship to the value of the Company’s assets, future cash flows, future earnings, financial condition, or any other established criteria for value. We do not anticipate obtaining any valuation opinion from outside financial advisors or investment bankers in connection with establishing the Offering price. Investors are urged to make their own investigation as to valuation prior to making an investment and should not rely upon anyone at the Company or working with the Company including, its advisors, attorneys, officers or directors for valuation matters.

***There is currently no market for the stock of the Company, and it is possible that no market will develop in the future.***

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 Shares and the Shares are subject to the terms of the Subscription Agreement, which imposes additional restrictions on its transfer. In the event the Company is successful in conducting a Regulation A or other Offering

it is still likely there will not be a liquid market for the Company's stock. All investors should have no need for liquidity of this investment and be able to bear the entire loss of their investment.

***The Company will not have a tax opinion with respect to the consequences of an investment in the Shares.***

The Company makes no representations as to the possible tax consequences, adverse or otherwise, of any features of an investment in the Shares, including, without limitation, any features of the Shares. You should consult with your own tax advisor prior to an investment about the impact of an investment in the Shares on your own particular situation.

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

The holders of a substantial majority of the capital stock of the Company are subject to a Stockholders Agreement. The Stockholders Agreement places significant limitations on the rights of the parties thereto. Included in these restrictions are the following that apply for so long as the Stockholder's Agreement remains in effect: (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) Cheryl Baker or her designee; and (b) a designee of MerchantCass Advisors, LLC, and the Board of Directors is to be comprised of 2 members or such greater number as mutually agreed to between Cheryl Baker and MerchantCass Advisors (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 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 Stockholders Agreement can be affected as agreed to by the Board of Directors along with each of Cheryl Baker and MerchantCass Advisors, or under certain other circumstances delineated thereunder, which effectively places its ongoing effectiveness in the control of the aforesaid persons.

***Investors must enter into a Subscription Agreement that will restrict the transferability of the Shares purchased in any CF Offering.***

Each Investor in our Shares is expected to be required to execute the Subscription 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 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 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 Shares for a period of time not to exceed 180 days following declaration of effectiveness of a registration statement of capital stock of the Company filed under the Securities Act of 1933 and following qualification of an offering statement of capital stock of the Company filed under Regulation A, 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.

***The Company may be unable to efficiently manage its growth.***

The Company's current plans contemplate a period of costly product development that may place a significant strain on the Company's financial, managerial, and other resources. If the Company's executives are unable to manage growth effectively, the Company's business, operating results, financial condition, and prospects could be materially adversely affected.

***We have not retained independent professionals for subscribers.***

We have not retained any independent professionals to review or comment on the Offering or otherwise protect the interests of the subscribers. Although the Company has retained its own law firms, neither such firms nor any other firm has made any independent examination of any factual matters herein, and purchasers of the Shares issued in the Offering should not rely on the firms so retained with respect to any matters herein described. Counsel to the Company does not represent the investors. In addition, certain counsel to the Company may also serve as counsel to MerchantCass Advisors or its affiliates (and may hereafter also perform certain services on behalf of Cheryl Baker or her affiliates) with respect to matters unrelated to the Company which may be deemed to constitute a conflict of interest, and prospective investors should consider the impact of such separate representation on the impact of their relationships to the Company.

***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 (G) 20 shares have been designated "Super Voting" Series V Preferred Stock; and (H) 1,411,765 shares have been designated Series 2 CF Convertible Preferred Stock.

As of December 31, 2020, the Company had 5,728,159 issued and outstanding shares of capital stock comprised of 3,964,440 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 242,500 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, 26,100 shares of Series 2 CF Preferred Stock. As of December 31, 2020, the Company had 2,534,375 outstanding common stock options and 1,187,000 outstanding common stock warrants. The Company had 9,449,534 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 December 31, 2020).

### **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 December 31, 2020. 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.

<b><u>Stockholder Name</u></b>	<b><u>Number of Securities</u></b>	<b><u>Percentage of Voting</u></b>
	<b><u>Owned</u></b>	<b><u>Power (3)</u></b>
Cheryl H. Baker, PhD(1)	289,836	1.94% (4)
Sam Merchant(2)	484,057	70.32% (4)
Nancy J. Cass(3)	476,556	3.20% (4)

- (1) All holdings are in the name of Cheryl Baker, PhD. In addition to the shares of Common Stock set forth above, Cheryl Baker 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 105,000 shares exercisable at \$2.00 per share.
- (2) All holdings are in his affiliate, Merchants Capital Trust, LLC, and are all Common Stock, with the exception of 10 shares of “Super Voting” Series V Preferred Stock in the case of BioCurity Controlling Shares, Inc. In addition to the shares of Common Stock set forth above, Merchants Capital Trust, LLC 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 810,852 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 her Affiliate, Pierce Family Ventures, LLC. In addition to the shares of Common Stock set forth above, Pierce Family Ventures, LLC 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 160,240 shares exercisable at \$2.00 per share. One warrant is outstanding to purchase up to 375,000 shares at \$0.40 per share.
- (4) The Company has 5,728,159 shares of capital stock issued and outstanding including 10 shares of “Super Voting” Series V Preferred Stock held by an Affiliate of Sam Merchant, BioCurity Controlling Shares, Inc., 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 14,909,531 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 the Series V Preferred Stock. Each such share of the Series V Preferred Stock has a nominal liquidation value.

## **Common Stock.**

### ***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 2 CF Convertible Preferred Stock. The Series A through Series 7A Convertible 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 2 CF Preferred Stock are entitled to receive such dividends as declared by the Board out of assets legally available.

### ***Liquidation Preferences of our Series A Preferred Stock.***

At any time prior to conversion any Series of our Series A 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 to 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 BioCurity Controlling Shares, Inc., a company owned by 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 2 CF Convertible Preferred Stock.**

#### ***Voting Rights.***

The holders of the Series 2 CF Convertible 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 2 CF Convertible Preferred Stock shall not be altered or impaired without the consent of the holders of the Series 2 CF Convertible Preferred Stock, voting as a separate class. Each Series 2 CF Convertible 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 Offering must enter into a Subscription Agreement. The Subscription Agreement contains certain provisions that restrict the rights of existing parties to such agreement, including: (i) a drag along provision which requires stockholders to participate in certain sales of shares approved by certain selling stockholders; (ii) 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; (iii) a lock-up provision which restricts the right of investors to sell the Shares purchased in the Offering 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 executive officers of the Company to execute any such lock up agreement as is required in connection with such registration and (iv) a lock-up provision which restricts the right of investors to sell the Shares purchased in the Offering for a period of 180 days following qualification of an offering statement of capital stock of the Company filed under Regulation A, and, in the case of (iii) and (iv) further provides a power of attorney to the executive officers of the Company to execute any such lock-up agreements as is required in connection with any such registration statement or offering statement. It should be noted that the Company has issued 10 shares of “Super Voting” Series V Preferred Stock to BioCurity Controlling Shares, Inc., a company owned by 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 2 CF Convertible 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 2 CF Convertible Preferred.***

#### ***Elective Conversion.***

Each of the holders of our Series 2 CF Convertible Preferred shares shall have the right, at his, her or its sole election, to convert each share held by such holder and all accrued and unpaid dividends thereon (if any) into such number of 1 share of Common Stock for each Series 2 CF Convertible Preferred Share outstanding (subject to equitable adjustment to account for forward and reverse stock splits, consolidations and other extraordinary corporate events (as provided in Certificate of Designations)).

#### ***Mandatory Conversion.***

Each Series 2 CF Convertible Preferred Share will automatically convert into Common Stock on June 30, 2021 on a 1:1 basis (subject to adjustment as noted in “Elective Conversion” above) in the event that the Company has not received a notification of qualification of a Regulation A offering. In the event a Regulation A offering has received a notification of qualification on or before June 30, 2021, then the Series 2 CF Convertible Preferred shares shall automatically convert to Common Stock at that time on the same basis.

## **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 2 CF Convertible Preferred Stock

*Original Issue Price:* \$4.25

*Senior to:* Common Stock

*On Parity with:* None.

*Junior 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

Except for the holders of the Series V Preferred Stock and Series 2 CF Preferred Stock, the holders of each other class of the Company's securities are subject to a Stockholders Agreement. The Stockholders' Agreement contains a number of provisions relating to the transfer rights and voting rights of the holders of securities subject to the Stockholders Agreement, such as (i) the Company and then the other stockholders 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 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) Cheryl Baker or her designee; and (b) a designee of MerchantCass Advisors, LLC, and the Board of Directors is to be comprised of 2 members or such greater number as mutually agreed to between Cheryl Baker and MerchantCass Advisors (presently set at a total of three directors); 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 executive officers of the Company to execute any such lock up agreement as is required in connection with such registration.

### **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 (see "*Related Party Transactions - MerchantCass Agreement*" for a discussion of options issuable to it). In March 2021, the Company adopted a 2021 Stock Option and Grant Plan calling for the issuance of up to 5,000,000 shares of Common Stock, which replaced the 2015 Plan. 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 2,534,375 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 affiliates of MerchantCass Advisors except for options to purchase 257,588 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 2 CF Convertible 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’s 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, 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 2 CF 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.

<b>Date of Commencement of Offering (MM/YYYY)</b>	<b>Offering Exemption Relied Upon</b>	<b>Securities Offered</b>	<b>Final Amount Sold</b>	<b>Final Proceeds</b>	<b>Use of Proceeds</b>
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 <sup>1</sup>	\$403,434	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	46,624 <sup>2</sup>	\$187,250.25 <sup>2</sup>	Working capital inclusive of payments to service providers and payments to officers, directors, consultants, some of who are affiliates of the Company

<sup>1</sup>Does not include 2,372 shares issued to the Regulation Crowdfunding portal, StartEngine, in January 2021.

<sup>2</sup>This includes the shares issued and sold as of the date of this report. The Company expects to issue additional shares and receive additional proceeds from its Series 2 CF Convertible Preferred Stock Offering prior to its termination date expected April 30, 2021.

## FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Financial statements.

Our financial statements for the years ending December 31, 2020 and 2019 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, 2020 Compared to the Year Ended December 31, 2019*

#### *Revenues.*

To date, the Company has not generated any revenues.

#### *Operating Expenses.*

Total operating expenses for the twelve months ended December 31, 2020 was \$2,177,773 as compared to \$2,180,808 for the twelve months ended December 31, 2019. General and administrative expenses were \$1,619,839 for the twelve months ended December 31, 2020; a 20.5% increase compared to \$1,287,994 for the twelve months ended December 31, 2019. This was primarily the result of increased marketing and consulting costs incurred in connection with this Offering, as we sought to increase our social media presence online, as well as drive investments in our Company. Offering costs also included legal, accounting, and other offering costs. Share-based compensation totaled \$543,616 for the twelve months ended December 31, 2020 as compared to \$878,260 for the twelve months ended December 31, 2019. Share-based compensation decreased primarily due to decreased option grants to management during the twelve months ended December 31, 2020.

All options issued during 2020 and 2019 were fully vested upon issuance. The weighted average estimated fair value of the options granted during 2020 and 2019 were \$1.38 and \$1.63 per share, respectively.

#### *Other Expenses.*

“Other Expenses” for the year ended December 31, 2020 is \$12,911 as compared to \$10,252 for year ended December 31, 2019. Interest expense incurred for the Company’s note payable with Seacoast Bank was \$2,758.70 for year ended December 31, 2020.

#### *Net Loss.*

As a result of the foregoing, the Company had a net loss of \$ 2,164,862 for the twelve months ended December 31, 2020 as compared to \$2,191,060 for the twelve months ended December 31, 2019.

### Liquidity and Capital Resources.

As of December 31, 2020, our primary sources of liquidity consisted of cash and cash equivalents of \$49,57. The Company’s cash and cash equivalents as of December 31, 2019 were \$62,2154. The reduction in our cash and cash equivalents from December 31, 2019 to December 31, 2020 is primarily the result of increased operating expenses, from consulting fees, and accounts payable, in 2020 compared to 2019, which reduced our

cash reserves. As of December 31, 2020, the Company has a negative working capital of \$2,570,422, and an accumulated deficit of \$11,607,858.

In 2020, the Company commenced an offering pursuant to Regulation Crowdfunding in which it offered shares of its Series 2 CF Convertible Preferred Stock (the “Offering”). As of December 31, 2020, the Company has received \$104,125 in proceeds from the sale of 26,100 shares of this Offering. As of the date of this report, the Company has received \$172,919.75 in proceeds from the sale of 43,087 shares of its Series 2 CF Convertible 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. If we raise the Maximum Offering Amount of \$599,998 from the Offering, we estimate we will be able to continue our operations for 6 months. As of April 20, 2021, the Company has raised approximately \$210,000 in gross proceeds from the Offering.

## **Indebtedness.**

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

On December 21, 2016, the Company entered 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 2020, the Company obtained an extension on the note allowing for additional 12 monthly interest only payments and any remaining balance due in December 2021 must be paid in full by December 21, 2021. 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, 2020, the note balance, net of unamortized debt issuance costs of \$2,981, was \$143,748.

## **RELATED PARTY TRANSACTIONS**

The Company and/or BioCurity, Inc., as applicable, have entered into the agreements outlined below (as to certain but not all key provisions), which are qualified in their entirety by the full terms of such agreements. Copies of all of such agreements are available upon request after execution of a confidentiality agreement acceptable to the Company.

### **MerchantCass Agreement.**

The Company entered into a second amended and restated advisory agreement with MerchantCass Advisors, LLC (“MCA”) dated as of December 1, 2018, which amends and restates in its entirety the amended and restated advisory agreement dated as of January 1, 2017, which in turn amended and restated the original advisory agreement with MCA dated as of April 1, 2014 as amended (“MCA Agreement”). In March 2021, the Company entered into an Addendum which has been added to the December 1 2018 MCA Agreement as part of Exhibit A which is fully incorporated into the MCA Agreement. The MCA Agreement inclusive of the Addendum calls for the provision of advisory services by MCA through December 31, 2022, including acting as interim COO and President of BioCurity.. The rate of compensation is \$350 per hour for services provided by its principals Sam Merchant and Nancy Cass (lesser hourly rate if other service providers used), plus a 10% administrative fee. The Company is also subject to late fees and interest on the outstanding balance due to MCA.

Compensation under the MCA Agreement includes stock options received as set out in the capitalization table (covering the period from January 1, 2017 through the quarter ended June 30, 2019) which are fully earned and vested. Going forward 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 its agreement, commencing with the quarter ended December 31, 2018 (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 outstanding; plus (iii)

outstanding warrants and options to purchase Common Stock, exercisable 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). It further provides that if as of the end of any calendar quarter commencing with the date of the second amendment and restatement of the agreement 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.

Advisory service and administrative fees incurred under the MCA agreement amounted to \$692,900 during the years ended December 31, 2020 and 2019. Advisory service and administrative fees payable to MCA were \$1,662,900 and \$970,000 as of December 31, 2020 and 2019, respectively.

In 2020, the Company issued options to designees of MCA for the purchase of 339,774 shares, exercisable at \$2.00 per share for 10 years following the date of grant to MCA's designees for the aforesaid 1% amount. In February 2021, the Company issued options to designees of MCA for the purchase of 577,670 shares of Common Stock, 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 entered into an advisory agreement dated as of December 1, 2018 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"). In March 2021, the Company entered into an Addendum which has been added CVR Agreement as part of Exhibit A which is fully incorporated into the CVR Agreement as well as Section 2 B of the CVR Agreement. The CVR Agreement inclusive of the Addendum, calls for the provision of not more than 20 hours per month of services and has a term ended 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 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 contacts.

Financial advisory service fees incurred under the CVR Agreement amounted to \$132,000 during the years ended December 31, 2020 and 2019. Financial advisory service fees payable to CVR were \$264,000 and \$132,000 as of December 31, 2020 and 2019, respectively.

### **Addendum to MerchantCass Advisors, LLC and Capital and Venture Resources, LLC Agreements.**

In March 2021, the Company entered into an Addendum into the second amended and restated advisory agreement with MerchantCass Advisors, LLC ("MCA") dated as of December 1, 2018 and the advisory agreement dated as of December 1, 2018 with Capital and Venture Resources LLC, an affiliate of Sam Merchant ("CVR"). The Addendum states that 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 (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.

#### **Notes Payable and Forbearance Agreements.**

In December 2020, the Company entered into notes payable agreements with the following related parties, MCA, CVR and Sam Merchant.

As of December 31, 2020, the note balances amounted to \$1,662,900 due to MCA, \$264,000 due to CVR and \$180,000 due to Sam Merchant. All of the notes are due on demand and accrue interest at 5% per annum. In January 2021, the Company entered into Forbearance Agreements with MCA and its affiliates which expires on April 25, 2021. The Forbearance Agreements are expected to be extended and may require additional terms such as corporate housing and stock options to be paid by BioCurity.

### **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.

#### **UPDATES**

Updates on the status of the Offering may be found at: <https://www.startengine.com/biocurity>

## SIGNATURE

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/ MerchantCass Advisors, LLC

By: MerchantCass Advisors, LLC

Title: President, Principal Executive Officer, and COO

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/ MerchantCass Advisors, LLC

By: MerchantCass Advisors, LLC

Title: President, Principal Executive Officer, and COO

Date: April 23, 2021

/s/ Nancy Cass

By: Nancy Cass

Title: Director

Date: April 23, 2021

/s/ Cheryl H. Baker

By: Cheryl Baker

Title: Director, Principal Accounting Officer, and Controller

Date: April 23, 2021

**EXHIBIT A TO FORM C**

**FINANCIAL STATEMENTS AND INDEPENDENT ACCOUNTANT'S REVIEW**

# **BioCurity Pharmaceuticals Inc.**

## **Consolidated Financial Statements**

**December 31, 2020 and 2019**

## BioCurity Pharmaceuticals Inc.

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## **REPORT OF INDEPENDENT ACCOUNTANTS**

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

### **Report on the Consolidated Financial Statements**

We have audited the accompanying consolidated financial statements of BioCurity Pharmaceuticals Inc. (the "Company"), which comprise the consolidated balance sheets as of December 31, 2020 and 2019, 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.

### **Management's Responsibility 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.

### **Auditor's Responsibility**

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements 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 entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

## **Opinion**

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioCurity Pharmaceuticals Inc. as of December 31, 2020 and 2019, 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.

## **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 of 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.

A handwritten signature in black ink, appearing to read "Keita", with a long horizontal flourish extending to the right.

March 8, 2021  
Glen Allen, Virginia

**BioCurity Pharmaceuticals Inc.**  
**Consolidated Balance Sheets**  
**December 31, 2020 and 2019**

	<u>Assets</u>	
	<u>2020</u>	<u>2019</u>
Current assets:		
Cash and cash equivalents	\$ 49,572	\$ 62,215
Other current assets	24,008	9,960
Total current assets	<u>73,580</u>	<u>72,175</u>
Equipment, net	120	200
Intangible assets, net	<u>135,998</u>	<u>150,236</u>
Total assets	<u>\$ 209,698</u>	<u>\$ 222,611</u>
	<u>Liabilities and Stockholders' Deficit</u>	
Current liabilities:		
Accounts payable and accrued expenses	\$ 393,354	\$ 1,365,118
Notes payable - related parties	2,106,900	-
Notes payable, net	143,748	159,212
Total current liabilities	<u>2,644,002</u>	<u>1,524,330</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, 2020 and 2019	5	5
Series AA Stock, par value \$0.00001; 300,000 shares issued		
and outstanding at December 31, 2020 and 2019	3	3
Series AAA Stock, par value \$0.00001; 160,000 shares issued		
and outstanding at December 31, 2020 and 2019	2	2
Series AAAA Stock, par value \$0.00001; 242,500 shares issued		
and outstanding at December 31, 2020 and 2019	2	2
Series AAAAA Stock, par value \$0.00001; 300,000 shares issued		
and outstanding at December 31, 2020 and 2019	3	3
Series AAAAAA Stock, par value \$0.00001; 100,000 shares issued		
and outstanding at December 31, 2020 and 2019	1	1
Series 7A Stock, par value \$0.00001; 124,494 shares issued		
and outstanding at December 31, 2020 and 2019	1	1
Series FT-1 Stock, par value \$0.00001; 0 and 15,000 shares issued		
and outstanding at December 31, 2020 and 2019, respectively	-	-
Series FT-2 Stock, par value \$0.00001; 0 and 62,500 shares issued		
and outstanding at December 31, 2020 and 2019, respectively	-	1
Series FT-3 Stock, par value \$0.00001; 0 and 66,667 shares issued		
and outstanding at December 31, 2020 and 2019, respectively	-	1
Series V Stock, par value \$0.00001; 10 shares issued		
and outstanding at December 31, 2020 and 2019	-	-
Series 2 CF Stock, par value \$0.00001; 26,100 and 0 shares issued		
and outstanding at December 31, 2020 and 2019, respectively	-	-
Common stock, par value \$0.00001; 10,000,000 shares authorized;		
3,964,440 and 3,727,756 shares issued; 3,264,440 and 3,027,756		
shares outstanding at December 31, 2020 and 2019, respectively	40	37
Additional paid-in capital	9,173,504	8,141,228
Treasury stock, 700,000 shares at December 31, 2020 and 2019	(7)	(7)
Accumulated deficit	(11,607,858)	(9,442,996)
Total stockholders' deficit	<u>(2,434,304)</u>	<u>(1,301,719)</u>
Total liabilities and stockholders' deficit	<u>\$ 209,698</u>	<u>\$ 222,611</u>

See accompanying notes to the consolidated financial statements.



**BioCurity Pharmaceuticals Inc.**  
**Consolidated Statements of Operations**  
**For the Years Ended December 31, 2020 and 2019**

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	<u>2020</u>	<u>2019</u>
Revenues	\$ -	\$ -
Cost of sales	<u>-</u>	<u>-</u>
Gross profit	<u>-</u>	<u>-</u>
Operating expenses:		
General and administrative	1,619,839	1,287,994
Share based compensation	543,616	878,260
Amortization	14,238	14,238
Depreciation	80	316
Total operating expenses	<u>2,177,773</u>	<u>2,180,808</u>
Operating loss	<u>(2,177,773)</u>	<u>(2,180,808)</u>
Other income (expense):		
Other income	23,556	-
Interest expense	<u>(10,645)</u>	<u>(10,252)</u>
	<u>12,911</u>	<u>(10,252)</u>
Net loss	<u><u>\$(2,164,862)</u></u>	<u><u>\$(2,191,060)</u></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, 2020 and 2019**

	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, 2019	1,737,609	\$ 17	3,727,756	\$ 37	700,000	\$ (7)	\$ 6,814,170	\$ (7,251,936)	\$ (437,719)
Issuance of preferred stock Series FT-1	15,000	-	-	-	-	-	60,000	-	60,000
Issuance of preferred stock Series FT-2	62,500	1	-	-	-	-	249,999	-	250,000
Issuance of preferred stock Series FT-3	66,667	1	-	-	-	-	199,999	-	200,000
Issuance of preferred stock Series V	10	-	-	-	-	-	-	-	-
Issuance costs of preferred stock	-	-	-	-	-	-	(61,200)	-	(61,200)
Share based compensation	-	-	-	-	-	-	878,260	-	878,260
Net loss	-	-	-	-	-	-	-	(2,191,060)	(2,191,060)
Balance, December 31, 2019	1,881,786	19	3,727,756	37	700,000	(7)	8,141,228	(9,442,996)	(1,301,719)
Issuance of convertible preferred stock Series CF	92,517	1	-	-	-	-	384,535	-	384,536
Conversion of preferred stock Series FT-1 to common stock	(15,000)	-	15,000	-	-	-	-	-	-
Conversion of preferred stock Series FT-2 to common stock	(62,500)	(1)	62,500	1	-	-	-	-	-
Conversion of preferred stock Series FT-3 to common stock	(66,667)	(1)	66,667	1	-	-	-	-	-
Conversion of preferred stock Series CF to common stock	(92,517)	(1)	92,517	1	-	-	-	-	-
Issuance of convertible preferred stock Series 2 CF	26,100	-	-	-	-	-	104,125	-	104,125
Share based compensation	-	-	-	-	-	-	543,616	-	543,616
Net loss	-	-	-	-	-	-	-	(2,164,862)	(2,164,862)
Balance, December 31, 2020	1,763,719	\$ 17	3,964,440	\$ 40	700,000	\$ (7)	\$ 9,173,504	\$ (11,607,858)	\$ (2,434,304)

See accompanying notes to the consolidated financial statements.

**BioCurity Pharmaceuticals Inc.**  
**Consolidated Statements of Cash Flows**  
**For the Years Ended December 31, 2020 and 2019**

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	<u>2020</u>	<u>2019</u>
Cash flows from operating activities:		
Net loss	\$(2,164,862)	\$(2,191,060)
Adjustment to reconcile net loss to net cash used in operating activities:		
Amortization expense	14,238	14,238
Depreciation expense	80	316
Amortization of debt issuance costs	1,290	1,291
Share based compensation	543,616	878,260
Forgiveness of PPP loan	(18,556)	-
(Increase) decrease in assets:		
Other current assets	(14,048)	253
Increase in liabilities:		
Accounts payable and accrued expenses	1,135,136	757,334
Net cash used in operating activities	<u>(503,106)</u>	<u>(539,368)</u>
Cash flows from financing activities:		
Proceeds from SBA PPP loan	18,556	-
Payments on note payable	(16,754)	(14,498)
Proceeds from issuance of preferred stock, net of issuance costs	488,661	448,800
Net cash provided by financing activities	<u>490,463</u>	<u>434,302</u>
Change in cash and cash equivalents	(12,643)	(105,066)
Cash and cash equivalents, beginning of year	62,215	167,281
Cash and cash equivalents, end of year	<u>\$ 49,572</u>	<u>\$ 62,215</u>
<u>Supplemental cash flow information:</u>		
Cash paid for interest	<u>\$ 6,755</u>	<u>\$ 7,134</u>
<u>Non-cash financing activities:</u>		
Conversion of preferred stock Series FT to common stock	<u>\$ 236,684</u>	<u>\$ -</u>
Conversion of accounts payable to notes payable - related parties	<u>\$ 2,106,900</u>	<u>\$ -</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**

**Leases:** In February 2016, the FASB issued a new accounting standard for leases that will impact both lessees and lessors. Under the new standard, lessees will recognize lease assets and lease liabilities on the balance sheet for all leases that extend beyond a one-year time period and that lessors will recognize the majority of leases as sales type or direct financing leases for any lease that relinquishes control of the leased asset to the lessee. The Company plans to adopt the new standard for the year ending December 31, 2022, and does not expect that this pronouncement will have a material impact on its consolidated financial statements.

**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.

**Note 2 – Going Concern**

As of December 31, 2020, the Company has negative working capital of \$2,570,422. The Company also incurred operating losses totaling \$2,164,862 and \$2,191,060 for the years ended December 31, 2020 and 2019, respectively, and has an accumulated deficit of \$11,607,858 at December 31, 2020. In order to meet its current obligations, management plans to raise additional capital during 2021 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.

**BioCurity Pharmaceuticals Inc.**  
**Notes to Consolidated Financial Statements**

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**Note 3 – Equipment**

Equipment consists of the following as of December 31, 2020 and 2019:

	<b>2020</b>	<b>2019</b>
Computer equipment	\$ 8,576	\$ 8,576
Accumulated depreciation	(8,456)	(8,376)
<b>Total</b>	<b>\$ 120</b>	<b>\$ 200</b>

Depreciation expense for the years ended December 31, 2020 and 2019 was \$80 and \$316, respectively.

**Note 4 – Intangibles**

Intangible assets consist of the following as of December 31, 2020 and 2019:

	<b>2020</b>	<b>2019</b>
Patents and patent licenses	\$ 213,574	\$ 213,574
Accumulated amortization	(77,576)	(63,338)
<b>Total</b>	<b>\$ 135,998</b>	<b>\$ 150,236</b>

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. The Company was required to pay equal monthly payments of principal and interest based on a 10 year amortization period, with the remaining balance payable in full in December 2020. In December 2020, the Company obtained an extension on the note allowing for additional 12 monthly interest only payments and any remaining balance due in December 2021. 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. The Company incurred \$2,981 in loan costs to obtain the extension.

At December 31, 2020, the note balance, net of unamortized debt issuance costs of \$2,981, is \$143,748. At December 31, 2019, the note balance, net of unamortized debt issuance costs of \$1,290, is \$159,212. Future maturities on the note payable consist of \$146,729 during the year ending December 31, 2021.

In May 2020, the Company obtained a Paycheck Protection Program (PPP) loan under the Coronavirus Aid, Relief and Economic Security Act enacted March 27, 2020 (the CARES Act) in the amount of \$18,556. The Company applied for and was granted forgiveness of the loan, which was spent on payroll costs, rent and utilities in 2020 as calculated in accordance with the requirements of the PPP and the CARES Act. The forgiveness amount is included in other income on the accompanying statements of operations.

**Note 5 – Notes Payable, continued**

In December 2020, the Company converted outstanding payables with related parties into notes payable. The notes are due on demand and bear interest at 5% per annum. At December 31, 2020, the balance of notes payable to related parties is \$2,106,900.

**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 3,964,440 shares issued and 3,264,440 shares outstanding at December 31, 2020. There were 3,727,756 shares issued and 3,027,756 shares outstanding at December 31, 2019.

**Treasury Stock**

Pursuant to a common stock purchase agreement on October 29, 2018, Dr. Cheryl Baker sold 700,000 shares of common stock to the Company for nominal consideration.

**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. The issued and outstanding classes of preferred stock are as set forth below.

**Series A Convertible Preferred Stock**

During 2015, the Company issued 344,000 shares of Series A Convertible Preferred Stock ("Series A Preferred Stock") for \$430,000, net of stock issuance costs of \$51,600. Certain holders exercised their warrants to purchase Series A Preferred shares during 2015 and 2016, including 85,000 shares in 2015 for \$110,500, and 81,615 shares in 2016 for \$106,100.

Each share of the Company's Series A 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 \$1.25 per share for those shares purchased directly from the Company and at \$1.30 per share for those shares purchased pursuant to exercise of warrants issued by the Company with a \$1.30 exercise price, 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 Preferred Stock 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 Series A Preferred Stock then outstanding.

Each share of the Company's Series A 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.



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

**Series A Convertible Preferred Stock, continued**

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

Series A Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of 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 the Series A 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 Series A 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 Series A Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend. The Series AA Preferred Stock, Series AAA Preferred Stock, Series AAAA Preferred Stock, Series AAAAA Preferred Stock, Series AAAAAA Preferred Stock and Series 7A Preferred Stock are all on parity with the Series A Preferred Stock as to proceeds from a Liquidation Event (all of such classes of stock, including the Series A Preferred Stock are hereinafter collectively referred to as the “Senior Securities”).

**Series AA Preferred Convertible Stock**

During 2016, the Company issued 300,000 shares of Series AA Convertible Preferred Stock (“Series AA Preferred Stock”) for \$450,000. Each share of the Company’s Series AA 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 at \$1.50 per share, subject to equitable adjustment to the conversion rate to account for subdivisions, forward or reverse splits, stock dividends or other extraordinary corporate events as specified in the Company’s Certificate of Incorporation. The conversion of Series AA Preferred Stock is automatic upon the: (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 Series AA Preferred Stock then outstanding.

Each share of the Company’s Series AA 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 AA Preferred Stock holders are also entitled to receive dividends on the Series AA Preferred Stock, whenever funds are legally available and when and as declared by the Board. Dividends on the Series AA Preferred Stock are not cumulative and will accrue only if declared by the Board.

Series AA Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of surplus funds of the Company to any holders of common stock, an amount equal to all declared but unpaid dividends.

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

**Series AA Preferred Convertible Stock, continued**

In the event of any Liquidation Event, the holders of the Series AA 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 Series AA 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 Series AA Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend.

**Series AAA Preferred Convertible Stock**

During 2016, the Company issued 160,000 shares of Series AAA Convertible Preferred Stock ("Series AAA Preferred Stock") for \$272,000.

Each share of the Company's Series AAA 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 at \$1.70 per share, subject to equitable adjustment to the conversion rate to account for subdivisions, forward or reverse splits, stock dividends or other extraordinary corporate events as specified in the Company's Certificate of Incorporation. The conversion of Series AAA Preferred 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 Series AAA Preferred Stock then outstanding.

Each share of the Company's Series AAA 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 AAA Preferred Stock holders are also entitled to receive dividends on the Series AAA Preferred, whenever funds are legally available and when and as declared by the Board. Dividends on the Series AAA Preferred Stock are not cumulative and will accrue only if declared by the Board.

Series AAA Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of 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 the Series AAA 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 Series AAA 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 Series AAA Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend.

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

**Series AAAA Preferred Convertible Stock**

During 2016, the Company issued 242,500 shares of Series AAAA Convertible Preferred Stock (“Series AAAA Preferred Stock”) for \$485,000.

Each share of the Company’s Series AAAA 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 at \$2.00 per share, subject to equitable adjustment to the conversion rate to account for subdivisions, forward or reverse splits, stock dividends or other extraordinary corporate events as specified in the Company’s Certificate of Incorporation. The conversion of Series AAAA Preferred 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 Series AAAA Preferred Stock then outstanding.

Each share of the Company’s Series AAAA 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 AAAA Preferred Stock holders are also entitled to receive dividends on the Series AAAA Preferred, whenever funds are legally available and when and as declared by the Board. Dividends on the Series AAAA Preferred Stock are not cumulative and will accrue only if declared by the Board.

Series AAAA Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of 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 the Series AAAA 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 Series AAAA 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 Series AAAA Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend.

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

**Series AAAAA Preferred Convertible Stock**

During 2017, the Company issued 300,000 shares of Series AAAAA Convertible Preferred Stock (“Series AAAAA Preferred Stock”) for \$960,000.

Each share of the Company’s Series AAAAA 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 at \$3.20 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 AAAAA Preferred 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 Series AAAAA Preferred Stock then outstanding.

Each share of the Company’s Series AAAAA 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 AAAAA Preferred Stock holders are also entitled to receive dividends on the Series AAAAA Preferred, whenever funds are legally available and when and as declared by the Board. Dividends on the Series AAAAA Preferred Stock are not cumulative and will accrue only if declared by the Board.

Series AAAAA Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of 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 the Series AAAAA 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 Series AAAAA 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 Series AAAAA Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend.

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

**Series AAAAAA Preferred Convertible Stock**

During 2017, the Company issued 100,000 shares of Series AAAAAA Convertible Preferred Stock (“Series AAAAAA Preferred Stock”) for \$320,000.

Each share of the Company’s Series AAAAAA 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 at \$3.20 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 AAAAAA Preferred 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 Series AAAAAA Preferred Stock then outstanding.

Each share of the Company’s Series AAAAAA 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 AAAAAA Preferred Stock holders are also entitled to receive dividends on the Series AAAAAA Preferred, whenever funds are legally available and when and as declared by the Board. Dividends on the Series AAAAAA Preferred Stock are not cumulative and will accrue only if declared by the Board.

Series AAAAAA Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of 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 the Series AAAAAA 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 Series AAAAAA 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 Series AAAAAA Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend.

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

**Series 7A Preferred Convertible Stock**

During 2017, the Company issued 44,493.65 shares of Series 7A Convertible Preferred Stock (“Series 7A Preferred Stock”) for \$177,975. During 2018, the Company issued 80,000 shares of Series 7A Preferred Stock for \$320,000.

Each share of the Company’s Series 7A 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 at \$4.00 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 7A Preferred 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 Series 7A Preferred Stock then outstanding.

Each share of the Company’s Series 7A 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 7A Preferred Stock holders are also entitled to receive dividends on the Series 7A Preferred Stock, whenever funds are legally available and when and as declared by the Board. Dividends on the Series 7A Preferred Stock are not cumulative and will accrue only if declared by the Board.

Series 7A Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of 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 the Series 7A 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 Series 7A 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 Series 7A Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend.

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

**Fixed Term Convertible Preferred Stock**

In December 2018, the Company authorized the issuance of up to 500,000 shares of Fixed Term Convertible Preferred Stock, divided into 2 series: FT-1 Shares (up to 187,500 shares to be issued) and FT-2 Shares (up to 312,500 shares to be issued) with a par value of \$0.00001 per share. In April 2019, the Company authorized the issuance of up to 100,000 shares of Series FT-3 Convertible Preferred Stock with a par value of \$0.00001 per share. During 2019, the Company issued 15,000 shares of Series FT-1 Fixed Term Convertible Preferred Stock for \$60,000, 62,500 shares of FT-2 Fixed Term Convertible Preferred Stock for \$250,000 and 66,667 shares of FT-3 Fixed Term Convertible Preferred Stock for \$200,000. In June 2020, the 15,000 shares of Series FT-1 Fixed Term Convertible Preferred Stock, the 62,500 shares of Series FT-2 Fixed Term Convertible Preferred Stock and the 66,667 shares of FT-3 Fixed Term Convertible Preferred Stock issued and outstanding were converted into 144,167 shares of Common Stock on a 1:1 basis.

Each share of the Company’s Fixed Term 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 into common stock at \$4.00 per share in the case of FT-1 and FT-2 Shares and \$3.00 per share in the case of FT-3 Shares, 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 amended to date (the “Certificate of Incorporation”). The conversion of Fixed Term Convertible Preferred Stock to Common Stock is automatic upon: (i) the closing of a qualified public offering (a “Public Offering”); (ii) the vote or written consent of holders of at least a majority of the shares of the Fixed Term Convertible Preferred Stock then outstanding; or (iii) in the event that the conditions to subparagraph (i) above are not met by June 30, 2020. The number of shares converted in the event the conditions to subparagraph (i) are met is equal to the product of 4 times the conversion rate then in effect divided by 85% of the price per share offered in the Public Offering in the case of FT-1 Shares and by 75% of the price per share in the case of FT-2 Shares. In the case of FT-3 Shares, the number of shares converted in the event the conditions to subparagraph (i) are met is equal to the product of 3 times the conversion rate then in effect divided by 50% of the price per share offered in the Public Offering. Any other conversion to common stock would be at the original issue price for the Fixed Term Convertible Shares, namely \$4.00 per share of FT-1 and FT-2 Fixed Term Convertible Preferred Stock and \$3.00 per share of FT-3 Fixed Term Convertible Preferred Stock.

Each share of the Company’s Fixed Term Convertible 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.

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

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

**Fixed Term Convertible Preferred Stock, continued**

Fixed Term Convertible Preferred Stock shareholders are entitled to receive, prior and in preference to, any distribution of assets of 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 the Series Fixed Term Convertible 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 Fixed Term Convertible 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 Fixed Term Convertible Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend. The “Senior Securities” defined above are senior to the Fixed Term Convertible Preferred Stock, which in turn is senior to the common stock.

**Series CF Convertible Preferred Stock and Series 2 CF Convertible Preferred Stock**

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. As of December 31, 2020, 92,517 shares of Series CF Convertible Preferred Stock had been issued. Subscriptions, which are revocable by investors, are held in escrow by the Crowdfunding portal prior to a closing. An additional 2,372 shares were issued to the Regulation Crowdfunding portal, StartEngine, in 2021. As of December 31, 2020, \$384,536 of proceeds, which is net of expenses charged by the Crowdfunding portal and related service providers, from subscriptions were disbursed to the Company. There is an additional \$18,898 held in escrow for the benefit of the Company from the Series CF Convertible Preferred Stock Offering as of December 31, 2020.

Each share of the Company’s Series CF Convertible Preferred Stock is converted 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. In July 2020, all of the shares of CF Convertible Preferred Stock were converted to common stock.

Each share of the Company’s Series 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 Convertible Preferred Stock holders are also entitled to receive dividends on the Series CF Convertible Preferred Stock, whenever funds are legally available and when and as declared by the Board. Dividends on the Series CF Convertible Preferred Stock are not cumulative and will accrue only if declared by the Board.



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

**Series CF Convertible Preferred Stock and Series 2 CF Convertible Preferred Stock, continued**

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. As of December 31, 2020, 26,100 shares of Series 2 CF Convertible Preferred Stock had been issued. As of December 31, 2020, 26,100 shares of Series 2 CF Convertible Preferred Stock Subscriptions, which are revocable by investors, were held in escrow by the Crowdfunding portal prior to a closing. As of December 31, 2020, approximately \$104,125 of proceeds, which is net of expenses charged by the Crowdfunding portal and related service providers, from subscriptions were disbursed to the Company.

Each share of the Company’s 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 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 2 CF Convertible Preferred Stock then outstanding, or (iii) automatically on July 1, 2021.

Each share of the Company’s Series 2 CF Convertible 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 2 CF Convertible Preferred Stock holders are also entitled to receive dividends on the Series 2 CF Convertible Preferred Stock, whenever funds are legally available and when and as declared by the Board. Dividends on the 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 holders of the Series 2 CF Convertible 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 Series 2 CF Convertible 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 Series 2 CF Convertible Preferred Stock, an amount of consideration equal to the stated value of each share, plus any unpaid dividend. The “Senior Securities” defined above are senior to the 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 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”).

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

**Series V Preferred Stock**

In November 2019, the Company authorized the issuance of up to 20 shares of Series V Preferred Stock with a par value of \$0.00001 per share. During 2019, the Company issued 10 shares of Series V Preferred Stock for \$0.10. The Series V Preferred Stock was issued to BioCurity Controlling Shares Inc., a Delaware corporation owned by Sam Merchant. 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. Under these warrants, each of Pierce and MCT 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. Under these warrants, MCT 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, 2020 and 2019. The weighted average exercise price was \$0.52 per share at December 31, 2020 and 2019.

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

**Warrants Issued to Purchase Common Stock, continued**

The Company uses the Black-Scholes valuation model to estimate the fair value of warrants 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 warrants 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 warrants 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 warrants: The expected term of warrants represents the period of time stock warrants 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.

**Stock Incentive Plan**

The Company has a stockholder-approved stock-based compensation plan, the 2015 Stock Incentive Plan (the "Plan"), which provides for the grant of share options and shares for up to 4,000,000 shares of Common Stock.

During the years ended December 31, 2020 and 2019, the Company granted new options to purchase 394,774 and 540,016 shares, respectively, of common stock at an exercise price of \$2.00 per share over a 10-year term.

**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 Black Scholes Method with the following assumptions:

	<b>2020</b>	<b>2019</b>
Volatility	90.00%	80.00%
Risk Free Rate	0.36%	1.92%
Expected Term	5 Years	10 Years

The Company recognized share-based compensation expense of \$543,616 and \$878,260 during the years ended December 31, 2020 and 2019, respectively. All options issued during 2020 and 2019 were fully vested upon issuance. The weighted average estimated fair value of the options granted during 2020 and 2019 were \$1.38 and \$1.63 per share, respectively.

The following is a summary of the Company’s stock option activity for the years ended December 31, 2020 and 2019:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding Balance at January 1, 2019	1,599,585	\$ 1.69
Granted	540,016	2.00
Forfeited	-	-
Exercised	-	-
Outstanding Balance at December 31, 2019	2,139,601	1.56
Granted	394,774	2.00
Forfeited	-	-
Exercised	-	-
Outstanding Balance at December 31, 2020	<u>2,534,375</u>	<u>\$ 1.62</u>

At December 31, 2020, the Company had options for 1,465,625 shares available for future 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 May 2021 for \$689 per month. The Company also has a lease agreement for a corporate apartment that extends through July 2021 and requires monthly rent of \$2,990. Total rent expense was \$52,916 and \$46,356 for the years ended December 31, 2020 and 2019, respectively.

### **Note 8 – Related Party Transactions**

#### **Baker Employment Agreement**

The Company had an employment agreement ("Employment Agreement") through September 2020 with Dr. Cheryl Baker, PhD ("Cheryl Baker") which provided for her to serve as CEO or such other title as the Board of Directors shall determine from time to time. At the present time her role is as Founder and Chief Scientific Research Officer. Under the Employment agreement, base compensation is set by the Board of Directors for an amount not greater than \$80,000 per annum. She is entitled to a performance bonus in the discretion of the Board of Directors of up to 50% of her base salary. The Employment agreement calls for disability payments of up to 90 days from the onset of disability. In the event that the Company elects not to renew the Employment Agreement upon expiration of its initial or any renewal term, then Cheryl Baker would be entitled to one month of severance for each full year of employment time served, subject to execution of a general release to the Company. As of July 5, 2020, Cheryl Baker's employment with the Company was terminated pursuant to a Separation Agreement dated June 29, 2020 ("Agreement"). In consideration for Cheryl Baker to agreeing and adhering to the terms and conditions of the Agreement, inclusive of full and complete general release and waiver of all rights and claims against the Company by her, the Company provided a payment of a severance equal to fifteen days of her then current base salary, less taxes, and other applicable withholding amounts. Cheryl Baker also received 5,000 stock options at a strike price of the stock option price for all employees or consultants at the time of execution of the Agreement ("Severance Stock Options"). In addition, Cheryl Baker agreed to convert all outstanding accrued salary due to her under the Employment Agreement in return for a stock option grant to purchase 50,000 shares of common stock in the Company at a strike price of the stock option price for all employees at the effective date of this Agreement for a five year period. The Severance Stock Options are to vest upon 180 days after execution of the Agreement so long as Cheryl Baker is not in violation of the Employment Agreement or the Agreement.

**Note 8 – Related Party Transactions, continued**

**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 \$692,900 during the years ended December 31, 2020 and 2019. Advisory service and administrative fees payable to MCA were \$1,662,900 and \$970,000 as of December 31, 2020 and 2019, respectively.

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 2020 and 2019, the Company issued options to designees of MCA for the purchase of 339,774 and 390,016 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.

**Note 8 – Related Party Transactions, continued**

**Placement Agent Agreement**

The Company had an exclusive placement agent agreement with Crescent Securities Group, Inc., a FINRA member (the “Placement Agent”), and MerchantCass Advisors, LLC through November 2021 (“Placement Agent Agreement”). The Placement Agent Agreement was terminated on December 31, 2020 as Nancy Cass, an affiliate of MerchantCass Advisors, LLC, is no longer a registered representative with the Placement Agent. The Company has agreed to pay the Placement Agent a cash fee equal to 12% of the gross proceeds of equity or equity-linked securities, and a cash fee equal to 5% of the gross proceeds raised from debt securities, as placed during the term of the Placement Agent Agreement. It provides for a 24-month tail following termination of the Placement Agreement with respect to subsequent debt or equity financings raised by the Company from entities introduced to it by the Placement Agent during the term of the Agreement. The Placement Agent Agreement has customary language whereby the Company agrees to maintain responsibility for its disclosures in connection with securities offerings and provides broad indemnification to MCA and the Placement Agent with respect to matters other than due to their willful misconduct or fraud. Placement fees incurred under the Placement Agent Agreement amounted to \$61,200 during 2019. There were no placement fees during 2020, and no placement fees payable to the Placement Agent as of December 31, 2020 and 2019.

**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 30 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 \$132,000 during the years ended December 31, 2020 and 2019. Financial advisory service fees payable to CVR were \$264,000 and \$132,000 as of December 31, 2020 and 2019, respectively.

**Notes Payable – Related Parties**

As disclosed in note 5, in December 2020, the Company entered into notes payable agreements with the following related parties, MCA, CVR and Sam Merchant. At December 31, 2020, the note balances amounted to \$1,662,900 due to MCA, \$264,000 due to CVR and \$180,000 due to Sam Merchant. All of the notes are due on demand and bear interest at 5% per annum.

**Note 9 – Income Taxes**

The components of the provision for income taxes for the years ended December 31, 2020 and 2019 are as follows:

	<b>2020</b>	<b>2019</b>
Current		
Federal	\$ -	\$ -
State	-	-
<b>Total Current</b>	<u>-</u>	<u>-</u>
Deferred		
Federal	458,489	459,413
State	76,871	40,919
<b>Total Current</b>	<u>535,360</u>	<u>500,332</u>
Change in Valuation Allowance	(535,360)	(500,332)
Provision for Income Taxes	<u><u>\$ -</u></u>	<u><u>\$ -</u></u>

Net deferred tax assets consist of the following components as of December 31, 2020 and 2019:

	<b>2020</b>	<b>2019</b>
Deferred Tax Assets		
Net operating loss carryforwards	\$ 1,264,774	\$ 1,143,109
Accrued expenses	464,931	\$ 185,712
Stock compensation	348,670	215,365
Other	1,363	192
<b>Total Deferred Tax Assets</b>	<u>2,079,738</u>	<u>1,544,378</u>
Valuation Allowance	(2,079,738)	(1,544,378)
Net Deferred Tax Assets	<u><u>\$ -</u></u>	<u><u>\$ -</u></u>

The Company has federal tax net operating loss carryforwards of approximately \$5,287,000 as of December 31, 2020 and Florida net operating loss carryforwards of approximately \$4,389,000 as of December 31, 2020. 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, 2020 and 2019 increased by approximately \$535,000 and \$500,000, respectively.



**Note 10 – Subsequent Events**

Management has evaluated subsequent events through March 8, 2021, the date the consolidated financial statements were available for issuance. Management has determined that the following subsequent events required disclosure in the accompanying consolidated financial statements. In January 2021, the Company received \$3,407 in net proceeds from the sale of 944 shares of Series CF Convertible Preferred Stock. In January 2021, the Company received \$18,898 which had been held in escrow for the benefit of the Company from the Series CF Convertible Preferred Stock Offering.