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

FORM 10-K

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

For the fiscal year ended December 31, 2022

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

For the transition period from _____ to

Commission File No. 0-51891

INTERNATIONAL STEM CELL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**20-4494098**
(State of other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
9745 Businesspark Ave San Diego, CA	**92131**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number: (760) 940-6383

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

Title of each class	Trading symbol	Name of each exchange on which registered
None	**None**	**None**

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

Common Stock, $0.001 par value per share
(Title of class)

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $1,532,606 based upon the closing price of the common stock on June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter) on the OTC QB Bulletin Board. Shares of common stock held by each officer, director and holder of five percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 27, 2023 there were 8,004,389 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Information from portions of the registrant's definitive Proxy Statement for its Annual Meeting of Stockholders to be held in 2022 is incorporated by reference into Part III of this Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. For example, statements regarding our expected financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about potential markets, future product demand, product development targets and expected timing, expenses, sales and the potential effects of the COVID-19 pandemic are all forward-looking statements. These statements may be found in the items of this Annual Report entitled "Description of Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," as well as in this Annual Report generally. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect," or the negative of such terms or other comparable terminology.

We have based these forward-looking statements on our current expectations and projections about future events. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, research and product development uncertainties, clinical trial results, regulatory policies and approval requirements, competition from other similar businesses, market and general economic factors, the availability of resources and the other risks discussed in Item 1A of this Annual Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this Annual Report.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this Annual Report in the section entitled "Risk Factors" which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this Annual Report. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. We do not undertake, and specifically decline any obligation, to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

PART I

ITEM 1. BUSINESS

Business Overview

International Stem Cell Corporation (sometimes referred to herein as "ISCO", the "Company", "we", "us", or "our") is a clinical stage biotechnology company focused on therapeutic and biomedical product development with multiple long-term therapeutic opportunities and two revenue-generating businesses offering potential for increased future revenue.

We currently have no revenue generated from our principal operations in therapeutic and clinical product development through research and development efforts. We have generated revenue from our two commercial businesses, anti-aging and research products, of a total of $8.2 million and $7.2 million for the years ended December 31, 2022 and 2021, respectively.

Our products are based on multi-decade experience with human cell culture and a proprietary type of pluripotent stem cells, "human parthenogenetic stem cells" ("hpSCs"). Our hpSCs are comparable to human embryonic stem cells ("hESCs") in that they have the potential to be differentiated into many different cells in the human body. However, the derivation of hpSCs does not require the use of fertilized eggs or the destruction of human embryos and also offers the potential for the creation of immune-matched cells and tissues that are less likely to be rejected following transplantation. ISCO scientists have created the first parthenogenetic, homozygous stem cell line that can be a source of therapeutic cells for hundreds of millions of individuals with minimal immune rejection after transplantation. We have facilities and manufacturing processes that we believe comply with the requirements of current Good Manufacturing Practice ("GMP") standards as defined by the U.S. Code of Federal Regulations and promulgated by the Food and Drug Administration ("FDA").

We are developing different cell types from our stem cells that may result in therapeutic products. We focus on applications where cell and tissue therapy are already proven but where there is an insufficient supply of functional cells or tissue. We believe that the most promising potential clinical application of our technology is for neural stem cells (ISC-hpNSC®) for treatment of Parkinson's disease and potentially other central nervous system disorders, such as traumatic brain injury, stroke and Alzheimer's disease.

Our most advanced project is the neural stem cell program for the treatment of Parkinson's disease. In 2013 we published in Nature Scientific Reports the basis for our patent on a new method of manufacturing neural stem cells which is used to produce the clinical-grade cells necessary for future clinical studies and commercialization. In 2014 we completed the majority of the preclinical research establishing the safety profile of neural stem cells ("NSC") in various animal species including non-human primates. In June 2016 we published the results of a 12-month pre-clinical non-human primate study that demonstrated the safety, efficacy and mechanism of action of the ISC-hpNSC®. In 2017, we began our Phase I trial of ISC-hpNSC®, human parthenogenetic stem cell-derived neural stem cells for the treatment of Parkinson's disease. This trial involves three groups, each with four patients, with each group receiving an increasing amount of ISC-hpNSC via intracerebral transplantation. Patients are evaluated for 12 months (active phase of the study) with an additional 5-year observational follow-up period to assess safety. We reported 12-month results from the first cohort and 6-month interim results of the second cohort at the Society for Neuroscience annual meeting (Neuroscience 2018) in November 2018. In April 2019, we announced the completion of subject enrollment, with the 12th subject receiving a transplantation of the highest dose of cells. There have been no safety signals or serious adverse effects seen to date as related to the transplanted ISC-hpNSC® cells. We announced successful completion of the dose escalating phase 1 clinical trial in June 2021. In terms of preliminary efficacy, where scores are compared against baseline before transplantation, we observed a potential dose-dependent response, with an apparent peak effectiveness at our middle dose. The % OFF-Time, which is the time during the day when levodopa medication is not performing optimally and PD symptoms return, decreased an average 47% from the baseline at 12 months post transplantation in cohort 2. This trend continued through 24 months where the % OFF-Time in the second cohort dropped by 55% from the initial reading. The same was true for % ON-Time without dyskinesia, which is the time during the day when levodopa medication is performing optimally without dyskinesia. The % ON-Time increased an average of 42% above the initial evaluation at 12 months post-transplantation in the second cohort.

Each of these product candidates will require extensive preclinical and clinical development and may require specific unforeseen licensing rights obtained at substantial cost before regulatory approval may be achieved and the products sold for therapeutic use.

Additionally, we are subject to various other risks; for example, our business is at an early stage of development and we may not develop therapeutic products that can be commercialized; we have a history of operating losses, do not expect to be profitable in the near future and our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern; and we will need additional capital to conduct our operations and develop our products and our ability to obtain the necessary funding is uncertain. Please see the heading "Risk Factors" beginning on page 14.

Corporate Structure

International Stem Cell Corporation is a Delaware corporation which has four wholly owned subsidiaries: International Stem Cell Corporation, a California corporation ("ISC California"), Lifeline Cell Technology, LLC ("LCT"), Lifeline Skin Care, Inc. ("LSC"), and Cyto Therapeutics.

Cyto Therapeutics was registered in the state of Victoria, Australia on December 19, 2014 and is a limited proprietary company and a wholly-owned subsidiary of the Company. Cyto Therapeutics is a research and development company for the Therapeutic Market, which is conducting clinical trials in Australia for the use of ISC-hpNSC® in the treatment of Parkinson's disease.

Our principal executive offices are located at 9745 Businesspark Ave, San Diego, CA 92131, and our telephone number is (760) 940-6383. Our corporate website address is www.internationalstemcell.com, Lifeline Cell Technology's website address is www.lifelinecelltech.com, and Lifeline Skin Care's website address is www.lifelineskincare.com. Information found on, or accessible through, our websites is not a part of, and is not incorporated into, this Annual Report on Form 10-K. Our common stock is currently quoted on the OTC QB and trades under the symbol "ISCO".

Frequently Asked Questions

What are Stem Cells?

Cells are the basic living units that make up humans, animals, plants and other organisms. Stem cells have two important characteristics that distinguish them from other types of cells. First, they can renew themselves for long periods of time. Second, they are unspecialized and under certain conditions can be induced to become cells with special functions such as metabolically active cells of the liver or transparent and protective cells of the eye. Until recently, scientists have worked with two major kinds of stem cells, *embryonic stem cells* (hESCs) and *adult stem cells* that each has different properties and characteristics. ISCO has developed a third category of stem cells named *parthenogenetic stem cells* (the hpSCs mentioned above) that promise to have significant therapeutic advantages relative to these other types.

What are Pluripotent Stem Cells?

Pluripotent stem cells are able to be differentiated or developed into virtually any other cell made in an organism. Both embryonic and parthenogenetic stem cells are pluripotent. Some scientists are exploring manipulation of adult cells into a potentially pluripotent stage. This type of stem cells is called *induced pluripotent stem cells*.

What are Embryonic Stem Cells?

Embryonic stem cells are derived from embryos at an early stage of development, typically when they are in a structure of a small number of cells called the *blastocyst.* Embryonic stem cells are expanded in a laboratory cell culture process. Once cell lines are established, batches of them can be frozen and shipped to other laboratories for further culture and experimentation.

What are Adult Stem Cells?

An adult stem cell is an undifferentiated cell found among differentiated cells in a tissue or organ. An adult stem cell can renew itself (generally to a lesser degree than can embryonic or parthenogenetic stem cells) and differentiate to a limited number of specialized cell types. These cells can be isolated from different tissues such as the bone marrow, fat tissue, and umbilical cord blood.

Why are Embryonic Stem Cells Important?

Human embryonic stem cells are able to differentiate into virtually any other cell in the body and to reproduce themselves almost indefinitely. In theory, if stem cells can be grown and their development directed in culture, it would be possible to grow cells for the treatment of specific diseases.

An early potential application of human embryonic stem cell technology may be in drug screening and toxicology testing.

The study of human development may also benefit from embryonic stem cell research in that understanding the events that occur at the first stages of development has potential clinical significance for preventing or treating birth defects, infertility and pregnancy loss. The earliest stages of human development have been difficult or impossible to study. Human embryonic stem cells offer insights into developmental events that cannot be studied directly in humans or fully understood through the use of animal models.

What are Parthenogenetic Stem Cells and how are they different?

Parthenogenetic stem cells are pluripotent stem cells created from unfertilized human eggs through a "parthenogenesis" process. Parthenogenesis requires that an unfertilized human egg be "activated" by chemical, physical or other means. Activation results in a non-viable "parthenote" from which pluripotent parthenogenetic stem cell lines can be derived. The cell lines used by ISCO are human parthenogenetic stem cells. Currently, ISCO owns the largest published collection of human parthenogenetic stem cell lines. Our research is based on perfecting proprietary techniques for deriving stem cells through parthenogenesis that result in stem cell lines that have the same capacity to become all cells found in the human body, but do not require use or destruction of a viable human embryo. Furthermore, parthenogenetic stem cells can be produced in a simplified ("homozygous") form that enables each line to be an immunological match for millions of people. We do not obtain stem cells from fetal tissue nor does our technology require the use of discarded frozen human embryos.

Why Not Use Stem Cells Derived from Adults?

There are several approaches now in human clinical trials that utilize adult stem cells. However, these cells have limited availability and limited ability to proliferate in culture as well as risk of genetic mutation. Therefore, obtaining clinically significant amounts of adult stem cells may prove to be difficult.

Why is Stem Cell Research Controversial?

The sources of some types of stem cells cause social and religious controversy. For example, some scientists obtain stem cells from aborted fetal tissue, causing opposition from those opposed to abortion. Another controversial source of stem cells is residual human embryos (from fertilized human eggs) that remain after vitro fertilization procedures and are used to create embryonic stem cell lines.

Is Stem Cell Research Banned in the United States?

Embryonic stem cell research, in general, is not banned in the United States. Work by private organizations is not limited except by the restrictions applicable to all human research. In addition, Proposition 71 in California, which voters approved in November 2004, specifically allows state funds to be used for stem cell research.

Why Not Use the Currently "Approved" Embryonic Stem Cells Lines?

Most, if not all, human embryonic stem cell lines in research now have complex ("heterozygous") immune compositions that are likely to cause the differentiated cells to be rejected by most patients.

Why Not use Adult Cells Reprogrammed to become Pluripotent Cells?

Induced pluripotent cells ("iPSs") benefit from not being derived from human embryos but may face a number of other limitations such as uncertainty as to which genes are turned on and off. Furthermore, like embryonic stem cells, iPSs have complex ("heterozygous") immune compositions that are likely to cause the differentiated cells to be rejected by most patients.

Ethical Issues

The use of embryonic stem cells derived from fertilized human eggs has created an ethical debate in the United States and around the world. However, since no fertilized human eggs are used in creating our stem cells and no human embryo is being created, used or destroyed, we expect that our parthenogenetic stem cells will be more readily accepted in circumstances where there are ethical concerns with using traditional embryonic stem cells.

We also have licensed worldwide rights to use a technology known as Somatic Cell Nuclear Transfer ("SCNT") to create human stem cells. The President's Council on Bioethics, as reported in the publication "Reproduction and Responsibility—The Regulation of New Biotechnologies 2004," has agreed on a series of recommendations for the use of such technology. Countries such as the United Kingdom have made similar recommendations.

Our Platform Technology

We have developed a proprietary process based on parthenogenesis for the creation of a new type of stem cell that has shown to exhibit the pluripotency and proliferative benefits of embryonic stem cells yet avoid the use or destruction of fertilized human eggs or embryos. Furthermore, since parthenogenetic stem cells can be created with immunogenetically identical ("homozygous") chromosome

pairs, each line has potential to be an immune match for tens of millions of patients. If such cells were to be differentiated into functional mature cells they would, theoretically, be universally applicable across a wide range of medical conditions.

We also hold licenses to three other technologies to create human pluripotent stem cells: SCNT technology (as mentioned previously); a technology that may be useful to create induced pluripotent stem cells ("iPS"); and "single blastomere technology" which uses a single cell obtained from a fertilized blastocyst to create an embryonic stem cell line. Each of these technologies has unique cell therapy applications and provides us with a broad base of technologies from which we can operate in the future.

Our Facilities

We have built the capacity to manufacture human cells for research use in our research and development ("R&D") facility in San Diego, California and for preclinical and clinical trials and ultimately for therapeutic use through the completion of our cGMP manufacturing facility in Frederick, Maryland.

Our Products

Therapeutic Product Candidates

We are developing different cell types from our stem cells that may result in therapeutic products. We focus on applications where cell and tissue therapy is already proven but where there is an insufficient supply of functional cells or tissue.

We believe that the most promising potential clinical applications of our technology are Parkinson's disease ("PD"), traumatic brain injury ("TBI"), and stroke. Using our proprietary technologies and know-how, we are creating neural stem cells from hpSCs as a potential treatment of PD, TBI, and stroke.

PD: Our most advanced project is the neural stem cell program for the treatment of Parkinson's disease. In 2013, we published in Nature Scientific Reports the basis for our patent on a new method of manufacturing neural stem cells, which is used to produce the clinical-grade cells necessary for future clinical studies and commercialization. In 2014, we completed the majority of the preclinical research, establishing the safety profile of NSC in various animal species, including non-human primates. In June 2016, we published the results of a 12-month pre-clinical non-human primate study, which demonstrated the safety, efficacy and mechanism of action of the ISC- hpNSC®. In 2017, we dosed four patients in our Phase I trial of ISC-hpNSC®, human parthenogenetic stem cell-derived neural stem cells for the treatment of Parkinson's disease. We reported 12-month results from the first cohort and 6-month interim results of the second cohort at the Society for Neuroscience annual meeting (Neuroscience 2018) in November 2018. In April 2019, we announced the completion of subject enrollment, with the 12th subject receiving a transplantation of the highest dose of cells. There have been no safety signals or serious adverse effects seen to date as related to the transplanted ISC-hpNSC® cells.

We announced a successful completion of the dose escalating phase 1 clinical trial in June 2021. In terms of preliminary efficacy, where scores are compared against baseline before transplantation, we observed a potential dose-dependent response with an apparent peak effectiveness at our middle dose. The % OFF-Time, which is the time during the day when levodopa medication is not performing optimally and PD symptoms return, decreased an average 47% from the baseline at 12 months post transplantation in cohort 2. This trend continued through 24 months where the % OFF-Time in the second cohort dropped by 55% from the initial reading. The same was true for % ON-Time without dyskinesia, which is the time during the day when levodopa medication is performing optimally without dyskinesia. The % ON-Time increased an average of 42% above the initial evaluation at 12 months post-transplantation in the second cohort.

Stroke: In August 2014, we announced the launch of a stroke program, evaluating the use of ISC-hpNSC® transplantation for the treatment of ischemic stroke using a rodent model of the disease. The Company has a considerable amount of safety data on ISC-hpNSC® from the Parkinson's disease program and, as there is evidence that transplantation of ISC-hpNSC® may improve patient outcomes as an adjunctive therapeutic strategy in stroke, having a second program that can use this safety dataset is therefore a logical extension. In 2015, the Company together with Tulane University demonstrated that NSC can significantly reduce neurological dysfunction after a stroke in animal models.

TBI: In October 2016, we announced the results of the pre-clinical rodent study, evaluating the use of ISC-hpNSC® transplantation for the treatment of TBI. The study was conducted at the University of South Florida Morsani College of Medicine. We demonstrated that animals receiving injections of ISC-hpNSC® displayed the highest levels of improvements in cognitive performance and motor coordination compared to vehicle control treated animals. In February 2019, we published the results of the pre-clinical study in Theranostics, a prestigious peer-reviewed medical journal. The publication titled, "Human parthenogenetic neural stem cell grafts promote multiple regenerative processes in a traumatic brain injury model," demonstrated that the clinical-grade neural stem cells used

in our Parkinson's disease clinical trial, ISC-hpNSC®, significantly improved TBI-associated motor, neurological, and cognitive deficits without any safety issues.

Each of these product candidates will require extensive preclinical and clinical development and may require specific unforeseen licensing rights obtained at substantial cost before any regulatory approval may be achieved and the products sold for therapeutic use.

Anti-Aging Skin Care Products

ISCO's wholly owned subsidiary Lifeline Skin Care, Inc. ("LSC") develops, manufactures and sells anti-aging skin care products based on two core technologies: encapsulated extract derived from hpSC and specially selected targeted small molecules. As of December 31, 2022, LSC's products include:

- ProPlus Advanced Defense Complex
- ProPlus Advanced Recovery Complex
- ProPlus Eye Firming Complex
- ProPlus Neck Firming Complex
- ProPlus Advanced Aqueous Treatment
- ProPlus Collagen Booster (Advanced Molecular Serum)
- ProPlus Elastin Booster
- ProPlus Brightening Toner

LSC's products are regulated as cosmetics. LSC's products are sold domestically through a branded website, Amazon, and ecommerce partners.

Research Products

ISCO's LCT subsidiary develops, manufactures and commercializes over 200 human cell culture products. These products include frozen human "primary" cells and stem cells and the reagents (called "media") needed to grow, maintain and differentiate the cells. LCT's scientists have used a technique called basal medium optimization to systematically produce optimized products designed to culture specific human cell types and to elicit specific cellular behaviors. These techniques also produce products that do not contain non-human animal proteins, a feature desirable to research and therapeutic markets. These human cell-based products are used domestically and internationally by research scientists in pharmaceutical, academic and government research organizations to study human disease and basic cell biology. LCT's products eliminate the need for scientists to create their own cells, media and reagents or attempt to adapt "off the shelf" products to match specific experimental needs and they are superior to using animals or non-human animal cells as research tools because they are more relevant to the study of human disease. Strict quality assurance provides a high level of consistency and standardization of these products. LCT offers products that contain no animal products ("called "Xeno-free" products), allowing researchers to have better control of their experiments and to conduct research using products that ultimately can be more appropriate for therapeutic applications.

Often LCT's research customers use our cell-based research products in their clinical research, eventually adapting them for therapeutic applications. If one of our research products is adopted by a successful producer of therapeutic cells, ISCO may become a supplier to the much larger therapeutic market through LCT's products. This is based on the fact that once regulatory product submissions are made to the FDA and similar authorities, the media and reagents used during development cannot be changed easily after approval. These uses of LCT's products bring opportunities to ISCO for future therapeutic products.

LCT products and applications include:

- Human skin cells and associated reagents for the study of skin disease, toxicology or wound healing.
- Human cells from the heart and blood vessels and associated reagents (VascuLife ®), used by researchers to study cardiovascular disease and cancer.
- Human bronchial and tracheal cells for the study of toxicity, cystic fibrosis, asthma and pathogenesis.
- Human mammary epithelial cells for the study of breast cancer, three dimensional culture and carcinogen screening.

- Adult stem cells (called mesenchymal stem cells) and the reagents necessary to differentiate them into various tissues, including bone, cartilage and fat. These products are valuable for researchers in the emerging field of regenerative medicine.
- Human prostate cells and specialized medium (ProstaLife™) to study prostate disease including cancer.
- Human renal and bladder cells and associated media (RenaLife™) to study renal and bladder diseases.
- Human corneal cells and associated media (OcuLife™) for the study of corneal disease and as a model of toxicology for consumer product testing.
- Human female reproductive system cells (ReproLife™) for the study of cellular physiology of the reproductive tract, cellular response to infectious agents and other areas of female reproductive system research.
- Human Skeletal Muscle Cells (StemLife Sk™) for the study of muscle cell biology, diabetes, insulin receptor studies, muscle metabolism, muscle tissue repair and myotube development.
- An assortment of many other cell culture reagents and supplements for the growth, staining and freezing of human cells.

Each LCT cell product is quality tested for the expression of specific markers (to assure the cells are the correct type), proliferation rate, viability, morphology and absence of pathogens. Each cell system also contains associated donor information and all informed consent requirements are strictly followed.

LCT's research products are marketed and sold by its internal sales force, LCT brand distributors in Europe and Asia and original equipment manufacturing (OEM) partners, which are then re-branded and sold with OEM partners' labels.

Our Markets

Therapeutic Markets

ISCO is currently pursuing a number of scientific development programs designed to lead to the creation of new therapeutic products. We anticipate that, with their superior immune-matching characteristics, our cells will be able to reduce or eliminate the need for immune-suppression drugs and the adverse reactions they trigger in patients.

Parkinson's disease. Parkinson's disease ("PD") is the second most common neurodegenerative disease. According to the Parkinson's Disease Foundation, there are more than one million sufferers in the United States with over $2 billion spent on related medication costs. Currently there is no cure for PD and the improvements in symptoms provided by available PD drugs often diminish with time. Using our proprietary technologies and know-how, we are creating neural stem cells from hpSCs as a potential treatment of PD and potentially other central nervous system disorders, including traumatic brain injury, in order to address this significant market opportunity.

Traumatic Brain Injury. Over 1.7 million people in North America suffer annually from traumatic brain injury, with associated medical costs exceeding $70 billion. According to the World Health Organization, the global incidence for traumatic brain injury is approximately 10 million people annually. According to the CDC, traumatic brain injury is a leading cause of death and disability in the United States, contributing to about 30% of all injury deaths.

Anti-Aging Cosmetic Market

Skin care products play a key role in the daily healthcare routines of many consumers. Greater emphasis on advertising, broader and more integrated distribution networks, raising standards of living in emerging markets, and population aging trends in developed nations are the major factors driving the global demand for skin care products.

The global skin care market is generally comprised of three categories of product -facial care, body care, and special needs products. Top selling products in the facial skincare category include skin brighteners, anti-aging creams and serums, toners, masks, anti-acne and sun protection products.

Facial skincare products that provide anti-aging benefits represent a significant portion of the global skincare market. Increased longevity leads consumers to seek out high quality, technologically advanced skincare products that can help them maintain a youthful appearance. Anti-aging products that are backed by scientific research remain in high demand among sophisticated consumers despite premium prices.

Research Market

The research market for cell systems consists of scientists performing basic and applied research in the biological sciences. Basic research involves the study of cell biology and biochemical pathways. Applied research involves drug discovery, vaccine development, clinical research and cell transplantation. The domestic market can be broken into three segments: (i) academic researchers in universities and privately-funded research organizations; (ii) government institutions such as the National Institutes of Health, the United States Army, the United States Environmental Protection Agency and others; and (iii) industrial organizations such as pharmaceutical companies and consumer product companies. It is estimated that the combined academic and government markets comprise approximately 40% of the total market and that the industrial segment comprises approximately 60%. We believe the following are the main drivers in the research market for commercial cell systems:

- The need for experimental human cells which are more predictive of human biology than are non-human cells or genetically-modified cell lines or living non-human animals.
- The emerging field of stem-cell-based regenerative medicine and the increase in associated grant money to study stem cells is driving the market not only for stem cell products but also for cell culture products in general.
- The desire to lower the cost of drug development in the pharmaceutical industry. We believe that human cell systems may provide a platform for screening toxic drugs early in the development process, thus avoiding late stage failures in clinical trials and reducing costs.
- The need to eliminate animal products in research reagents that may contaminate future therapeutic products.
- The need for experimental control. Serum-free defined media provides the benefit of experimental control because there are fewer undefined components.
- The need for consistency in experiments that can be given by quality-controlled products.
- The need to eliminate in-house formulation of media, obtain human tissue or perform cell isolation.
- The need to reduce animal testing in the consumer products industry.

Intellectual Property

Patents

In 2022, ISCO was issued one patent for technology generated by our R&D team. The patent, issued in the USA, covers the use of Parthenogenic Activation of Human Oocytes. As of December 31, 2022, we held a total of 39 patents. These patents expire from June 2025 through June 2037.

In addition, we have obtained exclusive worldwide licenses to patents and patent applications from Astellas Pharma. We believe that our licensed and internally-generated patents provide the intellectual property rights we need to operate in the pluripotent stem cell field and to progress through the stages of creating a therapeutic stem cell product. These stages include the derivation, isolation, expansion and differentiation of stem cells. The intellectual property available to us enables us to create manufacturing methods that eliminate animal proteins in order to satisfy FDA requirements. In addition, we have rights to sell research products derived through our licensed intellectual property in order to generate income.

The majority of the patents and applications have been filed in the US and in foreign countries through the Patent Cooperation Treaty or by direct country filings in those jurisdictions deemed significant to our operations.

We have protected our research products and branding through both patents and trademarks. Lifeline Skin Care has filed patent applications covering its proprietary core technologies and methods of using stem cells and targeted small molecules to create skin care products. LSC unique product formulas are protected as trade secrets. ISCO, LCT, and LSC have registered trademarks on their company names, logos and various product names to protect their branding investment. Lifeline Cell Technology's reagent formulations are protected as trade secrets.

The patentability of human cells in countries throughout the world reflects widely differing governmental attitudes. In the United States, hundreds of patents covering human embryonic stem cells have already been granted, including those on which we rely. Certain countries in Europe and Asia have taken the position that hES cells themselves are not patentable. ISCO believes that such restrictions are not appropriate as applied to parthenogenetic stem cells and is working with patent legislators in Europe to create exemptions for human parthenogenetic stem cells. As a result, we plan to file internationally wherever feasible and focus our research strategy on cells that best fit the US and foreign country definitions of patentable cells and technologies.

On December 18, 2014 the Court of Justice of the European Union (CJEU), the European Union's highest court ruled that the Company's core technology patent applications are not covered by the prohibition on patenting embryonic stem cells, removing the final barrier to the approval of ISCO's parthenogenetic stem cell patents in the European Union. This final and definitive ruling by the EU's highest court now formally separates parthenogenetic stem cells from embryonic stem cells, and removes the exclusion from patentability on the former while maintaining the ban on the later.

License Agreements

In May 2005, we entered into three exclusive license agreements ("ACT IP," "Infigen IP," and "UMass IP" or collectively "ACTC agreements") with Astellas Pharma Inc. ("Astellas") for the production of therapeutic products in the fields of diabetes, liver disease, retinal disease and the creation of research products in all fields. In February 2013, each of these license agreements was amended and restated, pursuant to which we continue to have rights to Astellas Pharma's human cell patent portfolio and non-exclusive rights to future developments in the area of diabetes and liver disease, as well as certain rights to patents covering Single Blastomere technology. A significant feature of the licensed Single Blastomere technology is a method of ethically obtaining human embryonic stem cells that allows us to isolate and differentiate hES stem cells directly from a "blastocyst" without harming the embryo. Using other licensed technology, the hES cells can be immediately differentiated into stem cells capable of expansion and differentiation into other types of cells. Under the terms of the amendments we have also acquired additional exclusive rights in the area of parthenogenesis and the use of parthenogenetically derived stem cells for treatment of human diseases.

The agreements with Astellas further provide that we are no longer obligated to make milestone payments or to meet any minimum research and development requirements. We will no longer pay any royalties related to the ACT IP or Infigen IP, and our obligation to pay a minimum license fee for the UMass IP has been reduced to $75 thousand annually, payable in two installments to Astellas.

The agreements continue until the expiration of the last valid claim within the licensed patent rights. Either party to each amended and restated license agreement may terminate the agreement for an uncured breach or we may terminate the agreements at any time with a 30-day written notice.

Research Agreements

ISCO actively pursues sponsored research agreements with local and international research organizations and has established research collaborations with collaborators from Yale University, University of South Florida, Tulane University, University of California, San Diego, The Scripps Research Institute (La Jolla), and the Sanford Burnham Preby Medical Discovery Institute. We are in frequent negotiations to develop collaborative research agreements with additional domestic and international research organizations from both the public and private sector. These agreements allow us to team up with nationally and internationally known research scientists to study stem cell technologies developed or licensed by ISCO for possible use in therapeutic or research fields. In addition to the research collaborations mentioned above, we provide our stem cell lines to researchers at many universities and other research facilities. Ordinarily, the stem cell lines are provided without charge, but we retain the right to either an exclusive or non-exclusive right to use any technology that may be developed that is necessary in order for us to make therapeutic products based on the research that uses our cells.

Competition

The development of therapeutic and diagnostic agents for human disease is intensely competitive. Pharmaceutical companies currently offer a number of pharmaceutical products to treat Parkinson's disease, diabetes, liver diseases, and other diseases for which our technologies may be applicable. Many pharmaceutical and biotechnology companies are investigating new drugs and therapeutic approaches for the same purposes, which may achieve new efficacy profiles, extend the therapeutic window for such products, alter the prognosis of these diseases, or prevent their onset. We believe that our therapeutic products, when and if successfully developed, will compete with these products principally on the basis of improved and extended efficacy and safety and their overall economic benefit to the health care system. We believe that our most significant competitors will be fully integrated pharmaceutical companies and more established biotechnology companies. Smaller companies may also be significant competitors, particularly through collaborative arrangements with large pharmaceutical or biotechnology companies.

Some of our primary competitors in the development of stem cell therapies are BioTime, SanBio, BlueRock Therapeutics, and ReNeuron. Our primary competitors in the skin care market are Obagi, ZO Skin Health, Skinceuticals, SkinMedica (now owned by Allergan), and Murad. In the field of research products, our primary competitors for human cells, media and reagents are Lonza, EMD Millipore, Life Technologies (now owned by Thermo Fisher Scientific), StemCell Technologies, Zen-bio, PromoCell, and Specialty Media. In each of these areas many of our competitors have substantially greater resources and experience than we do.

Sales and Marketing

To date, sales of our research products have been derived primarily through our in-house sales force and via OEM partners and LCT brand distributors in Europe and Asia. Approximately 45% of our total product sales in 2022 were from one customer.

LSC phased out its retail product line in 2019, with the exception of select cleanser products that were offered to both professional and retail customers. LSC is now offering its ProPLUS product line through its branded website — www.lifelineskincare.com, as well as through a network of select online retailers and a limited number of professional accounts, such as dermatologists, and plastic surgeons. Domestically, we plan to increase distribution of our products through increasing brand awareness, strategic partnerships, and sales promotions.

Government Regulation

Regulation by governmental authorities in the United States and other countries is a significant factor in development, manufacture and marketing of our proposed therapeutic and skin care products and in our ongoing research and product development activities. The nature and extent to which such regulation applies to us will vary depending on the nature of any products that we may develop. We anticipate that many, if not all, of our proposed therapeutic products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous pre-clinical and clinical testing and other approval procedures of the FDA, and similar regulatory authorities in European and other countries. Various governmental statutes and regulations also govern or influence testing, manufacturing, safety, labeling, storage and recordkeeping related to such products and their marketing. The process of obtaining these approvals and the subsequent compliance with appropriate statutes and regulations require the expenditure of substantial time and money, and there can be no guarantee that approvals will be granted.

We have made extensive progress in obtaining the necessary regulatory approvals of research protocols, informed consent documents and donor protection procedures to obtain oocytes in the United States for the production of our parthenogenetic stem cell bank. These approvals include: federally mandated Institutional Review Board (IRB) and State of California required Stem Cell Research Oversight (SCRO) committee.

FDA Approval Process

Prior to commencement of clinical studies involving humans, pre-clinical testing of new pharmaceutical products is generally conducted on animals in the laboratory to evaluate the potential efficacy and safety of the product candidate. The results of these studies are submitted to the FDA as a part of an Investigational New Drug ("IND") application, which must become effective before clinical testing in humans can begin. Typically, human clinical evaluation involves a time-consuming and costly three-phase process. In Phase I, clinical trials are conducted with a small number of people to establish safety pattern of drug distribution and metabolism within the body. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, possible dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary efficacy and preliminary safety and patterns of drug metabolism and distribution, in which case it is referred to as a Phase I/II trial. In Phase III, large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease in order to provide enough data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing; and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the patient. Monitoring of all aspects of the study to minimize risks is a continuing process. All adverse events must be reported to the FDA.

The results of the pre-clinical and clinical testing on a non-biologic drug and certain diagnostic drugs are submitted to the FDA in the form of a New Drug Application ("NDA") for approval prior to commencement of commercial sales. In the case of vaccines or gene and cell therapies, the results of clinical trials are submitted as a Biologics License Application ("BLA"). In responding to a NDA or BLA, the FDA may grant marketing approval, request additional information or refuse to approve if the FDA determines that the application does not satisfy its regulatory approval criteria. There can be no assurance that approvals will be granted on a timely basis, if at all, for any of our proposed products.

In November 2014, in an important ruling the FDA cleared ISCO's human parthenogenetic stem cells line for investigational clinical use. This was a necessary step in the process of eventually advancing stem cell therapies based on ISCO's core technology into clinical development. Although the Phase I trial for the Parkinson's Disease program is anticipated to be conducted in Australia, and therefore not subject to FDA oversight, any future studies will likely be carried out in the United States where this approval is necessary.

In recognition of the challenges that accompany development of cellular therapy (CT) products, the FDA has recently initiated an expedited review and approval process for promising investigational CTs. The first step in the pathway is submission of a request for Regenerative Medicine Advanced Therapy (RMAT) designation by the sponsor to the FDA, either at the same time as the initial IND

filing or by amendment to an active IND (prior to the end-of-phase 2 meeting). Upon grant of RMAT designation by the FDA, the sponsor receives access to a number of benefits, the most advantageous of which is early interactions with senior FDA managers for the purpose of discussing potential surrogate or intermediate clinical endpoints to support accelerated approval requirements. Consideration for accelerated approval, heretofore unavailable to regenerative medicine products, represents a major regulatory advance because it would enable ISCO to market ISC-hpNSC earlier than would be possible through the traditional approval process.

European and Other Regulatory Approval

Whether or not FDA approval has been obtained, approval of a product by comparable regulatory authorities in Europe and other countries will likely be necessary prior to commencement of marketing the product in such countries. The regulatory authorities in each country may impose their own requirements and may refuse to grant an approval, or may require additional data before granting it, even though the relevant product has been approved by the FDA or another authority. As with the FDA, the regulatory authorities in the European Union ("EU"), Australia and other developed countries have lengthy approval processes for pharmaceutical products. The process for gaining approval in particular countries varies, but generally follows a similar sequence to that described for FDA approval. In Europe, the European Committee for Proprietary Medicinal Products provides a mechanism for EU-member states to exchange information on all aspects of product licensing. The EU has established a European agency for the evaluation of medical products, with both a centralized community procedure and a decentralized procedure, the latter being based on the principle of licensing within one member country followed by mutual recognition by the other member countries.

In Australia, the approval process for commencing Phase 1 and 2 clinical trials resides with Therapeutic Goods Administration (TGA) and the Human Research Ethics Committee, (HREC). Prior to commencing a clinical trial, a sponsor must submit to TGA a CTX or CTN application and must submit to the HREC a study protocol, an investigator brochure and a template informed consent for such clinical trial. The HREC approval process generally takes four to eight weeks.

Other Regulations

We are also subject to various United States federal, state, local and international laws, regulations and recommendations relating to the treatment of oocyte donors, the manufacturing environment under which human cells for therapy are derived, safe working conditions, laboratory and manufacturing practices and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. We cannot accurately predict the extent of government regulation which might result from future legislation or administrative action.

Other Regulations for Lifeline Skin Care

The Federal Food, Drug and Cosmetic Act ("FFDCA") and the Fair Packaging and Labeling Act ("FPLA") provide the regulatory framework for selling cosmetics. The FFDCA oversees the safety of cosmetics. The FPLA ensures that the labeling is not false or misleading and includes all relevant information in a prominent and conspicuous manner.

Safety and efficacy testing of the products is performed by independent third party testing organization.

Information about our Executive Officers

For information concerning our executive officers, see Part III, Item 10 of this Annual Report on Form 10-K.

Human Capital

As of December 31, 2022, including our 2 executive officers, we had 29 full-time employees, and 2 part-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements.

The Company considers its diverse and innovative workforce to be one of its most valuable resources. In recognition of our employees' contributions to the Company's business objectives and long-term research and business success, we strive to provide a dynamic, safe, and inclusive work environment that enables each employee to develop professionally as part of the team, as well as be rewarded for individual initiative. In order to achieve this goal, we focus on the following aspects of human capital management:

Corporate Values and Ethics

The key elements of our corporate value system are described in our Code of Business Conduct Policy (the "Business Code"), which provides uniform guidance to all our employees regarding expectations for proper workplace behavior and ethical decision

making. Our Board of Directors adopted and regularly reviews the Code of Business Conduct, which applies to all of our employees, officers and directors of the Company.

The values outlined in the Business Code, including personal honesty, professional integrity, and organizational transparency, are vital to achieving our business and research objectives, as well as to serving our stakeholders. We have established a reporting hotline that enables employees to file anonymous reports of any suspected violations of the Business Code or other policies.

Workplace Diversity and Inclusion

As a truly international team, we value and celebrate unique talents, backgrounds and perspectives each employee contributes to achieving our corporate and research objectives. As an equal opportunity employer, we strive to ensure we evaluate a diverse group of candidates for every role with the goal of identifying the best possible candidates to fill open positions within the Company.

Compensation & Benefits

Our compensation and benefits programs, with oversight from the Compensation Committee of our Board of Directors, are designed to attract, retain and reward employees through competitive salaries, incentive bonus and stock option grant eligibility, a 401(k) Plan, healthcare and insurance benefits, paid time off, family leave, and employee assistance programs.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below as well as other information provided to you in this document, including information in the section of this document entitled "Forward Looking Statements". If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized.

Our business is at an early stage of development. We do not have any products in late stage clinical trials. We are still in the early stages of identifying and conducting research on potential therapeutic products. Our potential therapeutic products will require significant research and development and pre-clinical and clinical testing prior to regulatory approval in the United States and other countries. We may not be able to obtain regulatory approvals, enter new and later stage clinical trials for any of our product candidates, or commercialize any products. Our product candidates may prove to have undesirable and unintended side effects or other characteristics adversely affecting their safety, efficacy or cost effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits, or achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production.

We have a history of operating losses, do not expect to be profitable in the near future.

We have not generated any profits since our entry into the biotechnology business and have incurred significant operating losses. We expect to incur additional operating losses for the foreseeable future and we expect our operating losses to increase significantly. Our commercial businesses have not generated revenues in amounts to support our research and development efforts, and we may not achieve that level of revenues in the foreseeable future.

We have expended substantial funds to develop our technologies, products and product candidates. Based on our financial condition, recurring losses and projected spending, which raise substantial doubt about our ability to continue as a going concern. If we were unable to continue as a going concern, the values we receive for our assets on liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements.

We will need additional capital to conduct our operations and develop our products and our ability to obtain the necessary funding is uncertain.

During the year ended December 31, 2022, we used a significant amount of cash to finance our continued operations, and we need to obtain significant additional capital resources in order to develop products going forward. We may not be successful in maintaining our normal operating cash flow and the timing of our capital expenditures may not result in cash flows sufficient to sustain our operations through the next twelve months. If financing is not sufficient and additional financing is not available or available only on terms that are detrimental to our long-term survival, it could have a major adverse effect on our ability to pursue our clinical research and product development programs, and could ultimately affect our ability to continue to function. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying the estimates for capital needs in 2023 and beyond;
- the extent that revenues from sales of LSC and LCT products cover the related costs and provide capital;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with pre-clinical development and clinical trials;
- the extent to which third party interest in Company's research and commercial products can be realized through effective partnerships;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the number and type of product candidates that we pursue; and

- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the current and future impact of it and COVID-19 on our business operations and funding requirements.

Additional financing through strategic collaborations, public or private equity or debt financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to our stockholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all. Further, if we obtain additional funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we might otherwise seek to develop and commercialize on our own. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or product development initiatives, any of which could have a material adverse effect on our financial condition or business prospects.

We have limited clinical testing and regulatory capabilities, and human clinical trials are subject to extensive regulatory requirements, very expensive, time-consuming and difficult to design and implement. Our products may fail to achieve necessary safety and efficacy endpoints during clinical trials, which may limit our ability to generate revenues from therapeutic products.

Due to the relatively early stage of our therapeutic products and stem cell therapy-based systems, we have not yet invested significantly in internal clinical testing and regulatory capabilities, including for human clinical trials. We cannot assure you that we will be able to invest or develop resources for these capabilities successfully or as expediently as necessary. In particular, human clinical trials can be very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be affected by several factors, including:

- unforeseen safety issues;
- determination of dosing issues;
- inability to demonstrate effectiveness during clinical trials;
- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- competitive developments, including changes in the standard of care treatment for an indication;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- developments related to the coronavirus outbreak and impact of it and COVID-19 on the costs and timing associated with the conduct of our clinical trials and other related activities.

In addition, we or the FDA (or other applicable regulatory agency) may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or other regulatory agency finds deficiencies in our submissions or the conduct of these trials.

Patents held by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products.

A number of pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapy, stem cells, and other technologies potentially relevant to or required by our expected products. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware that a number of companies have filed applications relating to stem cells. We are also aware of a number of patent applications and patents claiming use of stem cells and other modified cells to treat disease, disorder or injury.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make and use our potential products and such claims are ultimately determined to be valid, we might not be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop some products commercially. We may be required to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. An adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease using such technology.

The outcome of pre-clinical, clinical and product testing of our products is uncertain, and if we are unable to satisfactorily complete such testing, or if such testing yields unsatisfactory results, we may be unable to sell our proposed products.

Before obtaining regulatory approvals for the commercial sale of any potential human products, our products will be subjected to extensive pre-clinical and clinical testing to demonstrate their safety and efficacy in humans. The clinical trials of our prospective products, or those of our licensees or collaborators, may not demonstrate the safety and efficacy of such products at all, or to the extent necessary to obtain appropriate regulatory approvals. Similarly, the testing of such prospective products may not be completed in a timely manner, if at all, or only after significant increases in costs, program delays or both, all of which could harm our ability to generate revenues. In addition, our prospective products may not prove to be more effective for treating disease or injury than current therapies. Accordingly, we may have to delay or abandon efforts to research, develop or obtain regulatory approval to market our prospective products. The failure to adequately demonstrate the safety and efficacy of a therapeutic product under development could delay or prevent regulatory approval of the product and could harm our ability to generate revenues, operate profitably or produce any return on an investment in us.

Even if we are successful in developing a therapeutic application using our cell technologies, it is unclear whether cell therapy can serve as the foundation for a commercially viable and profitable business.

Stem cell technology is rapidly developing and could undergo significant change in the future. Such rapid technological development could result in our technologies becoming obsolete. While our product candidates appear promising, they may fail to be successfully commercialized for numerous reasons, including, but not limited to, competing technologies for the same indications. There can be no assurance that we will be able to develop a commercially successful therapeutic application for our stem cell technologies.

Moreover, advances in other treatment methods or in disease prevention techniques could significantly reduce or entirely eliminate the need for our cell therapy services, planned products and therapeutic efforts. There is no assurance that cell therapies will achieve the degree of success envisioned by us in the treatment of disease. Additionally, technological or medical developments may materially alter the commercial viability of our technology or services and require us to incur significant costs to replace or modify programs in which we have a substantial investment. We are focused on cell therapy, and if this field is substantially unsuccessful, this could jeopardize our success or future results. The occurrence of any of these factors may have a material adverse effect on our business, operating results and financial condition.

Our competition includes fully integrated biotechnology and pharmaceutical companies that have significant advantages over us.

The market for therapeutic stem cell products is highly competitive. We expect that our most significant competitors will be fully integrated and more established pharmaceutical and biotechnology companies. These companies are developing stem cell-based products and they have significantly greater capital resources and research and development, manufacturing, testing, regulatory compliance, and marketing capabilities. Many of these potential competitors are further along in the process of pharmaceutical product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop uneconomic or obsolete.

If competitors develop and market products that are more effective, safer, or less expensive than our product candidates or offer other advantages, our commercial prospects will be limited.

Our cell therapy development programs face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates.

As a general matter, we also face competition from many companies that are researching and developing cell therapies. Many of these companies have financial and other resources substantially greater than ours. In addition, many of these competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals, and marketing and selling. If we ultimately obtain regulatory approval for any of our product candidates, we also will be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial-scale experience. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of our technologies and greater availability of capital for investment in these fields.

Restrictive and extensive government regulation could slow or hinder our production of a cellular product.

The research and development of stem cell therapies is subject to and restricted by extensive regulation by governmental authorities in the United States and other countries. The process of obtaining FDA and other necessary regulatory approvals is lengthy, expensive and uncertain. We may fail to obtain the necessary approvals to continue our research and development, which would hinder our ability to manufacture or market any future product.

The development and commercialization of our product candidates is subject to extensive regulation by the FDA and other regulatory agencies in the United States and abroad, and the failure to receive regulatory approvals for our product candidates would likely have a material and adverse effect on our business and prospects.

The process of obtaining FDA and other regulatory approvals is expensive, generally takes many years and is subject to numerous risks and uncertainties, particularly with complex and/or novel product candidates such as our product candidates. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application or may make it easier for our competitors to gain regulatory approval to enter the marketplace. Ultimately, the FDA and other regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional pre-clinical, clinical or other studies. In addition, varying agency interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any of the following factors, among others, could cause regulatory approval for our product candidates to be delayed, limited or denied:

- the product candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be filed with the FDA and other regulatory authorities;
- data obtained from pre-clinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing;
- negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us to delay or terminate development efforts for a product candidate; and/or
- FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials;
- a pandemic, epidemic or outbreak of a contagious disease, such as the ongoing global pandemic of the novel coronavirus COVID-19 may refocus the FDA and other regulatory authorities to clinical trials that are of the utmost need.

Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales, and could make any search for a collaborative partner more difficult.

Research in the field of embryonic stem cells is currently subject to strict government regulations, and our operations could be restricted or outlawed by any legislative or administrative efforts impacting the use of nuclear transfer technology or human embryonic material.

Significant portions of our business are focused on human cell therapy, which includes the production of human differentiated cells from stem cells and involves human oocytes. Although our focus is on parthenogenetic stem cells derived from unfertilized oocytes, certain aspects of that work may involve the use of embryonic stem cells. Research utilizing embryonic stem cells is controversial, and currently subject to intense scrutiny, particularly in the area of the use of human embryonic material.

Federal law is not as restrictive regarding the use of federal funds for human embryonic cell research, commonly referred to as hES cell research as it once was. However, federal law does prohibit federal funding for creation of parthenogenetic stem cells. Our operations may also be restricted by future legislative or administrative efforts by politicians or groups opposed to the development of hES cell technology, parthenogenetic cell technology or nuclear transfer technology. Further, future legislative or administrative restrictions could, directly or indirectly, delay, limit or prevent the use of hES technology, parthenogenetic technology, or nuclear transfer technology, the use of human embryonic material, or the sale, manufacture or use of products or services derived from nuclear transfer technology or hES or parthenogenetic technology.

We may be unsuccessful in our efforts to comply with applicable federal, state and international laws and regulations, which could result in loss of licensure, certification or accreditation or other government enforcement actions or impact our ability to secure regulatory approval of our product candidates.

Although we seek to conduct our business in compliance with applicable governmental healthcare laws and regulations, these laws and regulations are exceedingly complex and often subject to varying interpretations. The cell therapy industry is the topic of significant government interest, and thus the laws and regulations applicable to our business are subject to frequent change and/or reinterpretation. As such, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all such healthcare laws and regulations. Failure to comply with such healthcare laws and regulations, as well as the costs associated with such compliance or with enforcement of such healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

Our manufacture of certain cellular therapy products triggers additional FDA requirements applicable to hESCs which are regulated as a drug, biological product, or medical device. FDA's GMP regulations govern the manufacture, processing, packaging and holding of cell therapy products regulated as drugs. FDA's Quality System Regulation, or QSR, similarly governs the manufacture, processing, packaging and holding of cell therapy products regulated as medical devices. We must comply with GMP or QSR requirements including quality control, quality assurance and the maintenance of records and documentation for certain products. We may be unable to comply with these GMP or QSR requirements and with other FDA, state and foreign regulatory requirements. These requirements may change over time and we or third-party manufacturers may be unable to comply with the revised requirements.

We will continue to be subject to extensive FDA regulation following any product approvals, and if we fail to comply with these regulations, we may suffer a significant setback in our business.

Even if we are successful in obtaining regulatory approval of our product candidates, we will continue to be subject to the requirements of and review by, the FDA and comparable regulatory authorities in the areas of manufacturing processes, post-approval clinical data, adverse event reporting, labeling, advertising and promotional activities, among other things. In addition, any marketing approval we receive may be limited in terms of the approved product indication or require costly post-marketing testing and surveillance. Discovery after approval of previously unknown problems with a product, manufacturer or manufacturing process, or a failure to comply with regulatory requirements, may result in actions such as:

- warning letters or other actions requiring changes in product manufacturing processes or restrictions on product marketing or distribution;
- product recalls or seizures or the temporary or permanent withdrawal of a product from the market; and
- fines, restitution or disgorgement of profits or revenue, the imposition of civil penalties or criminal prosecution.

The occurrence of any of these actions would likely cause a material adverse effect on our business, financial condition and results of operations.

Health care companies have been the subjects of federal and state investigations, and we could become subject to investigations in the future.

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of health care companies, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, have made it easier for private parties to bring "*qui tam"* (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. The Federal False Claims Act provides, in part, that an action can be brought against any person or entity that has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. The government has taken the position that claims presented in violation of the federal anti-kickback law, Stark Law or other healthcare-related laws, including laws enforced by the FDA, may be considered a violation of the Federal False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false claims provision. Any future investigations of our business or executives could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation.

Restrictions on the use of human stem cells, and the ethical, legal and social implications of that research, could prevent us from developing or gaining acceptance for commercially viable products in these areas.

Although our stem cells are derived from unfertilized human eggs through a process called "parthenogenesis" that can produce cells suitable for therapy, but are believed to be incapable of producing a human being, such cells are nevertheless often incorrectly referred to as "embryonic" stem cells. Because the use of human embryonic stem cells gives rise to ethical, legal and social issues regarding the appropriate use of these cells, our research related to human parthenogenetic stem cells could become the subject of adverse commentary or publicity and some political and religious groups may still raise opposition to our technology and practices. In addition, many research institutions, including some of our scientific collaborators, have adopted policies regarding the ethical use of human embryonic tissue, which, if applied to our procedures, may have the effect of limiting the scope of research conducted using our stem cells, thereby impairing our ability to conduct research in this field. In some states, use of embryos as a source of stem cells is prohibited.

To the extent we utilize governmental grants in the future, the governmental entities involved may retain certain rights in technology that we develop using such grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established government guidelines.

Certain of our licensors' research have been or are being funded in part by government grants. Our research may also be government-funded in the future. In connection with certain grants, the governmental entity involved retains various rights in the technology developed with the grant. These rights could restrict our ability to fully capitalize upon the value of this research by reducing total revenues that might otherwise be available since such governmental rights may give the government the right to practice the invention without payment of royalties if we do not comply with applicable requirements.

We rely on parthenogenesis, cell differentiation and other stem cell technologies that we may not be able to successfully develop, which may prevent us from generating revenues, operating profitably or providing investors any return on their investment.

We have concentrated our research on our parthenogenesis, cell differentiation and stem cell technologies, and our ability to operate profitably will depend on being able to successfully implement or develop these technologies for human applications. These are emerging technologies with, as yet, limited human applications. We cannot guarantee that we will be able to successfully implement or develop our nuclear transfer, parthenogenesis, cell differentiation and other stem cell technologies or that these technologies will result in products or services with any significant commercial utility. We anticipate that the commercial sale of such products or services, and royalty/licensing fees related to our technology, would be an additional source of revenues.

If we are unable to keep up with rapid technological changes in our field or compete effectively, we will be unable to operate profitably.

We are engaged in activities in the biotechnology field, which is characterized by extensive research efforts and rapid technological progress. If we fail to anticipate or respond adequately to technological developments, our ability to operate profitably could suffer. Research and discoveries by other biotechnology, agricultural, pharmaceutical or other companies may render our technologies or potential products or services uneconomical or result in products superior to those we develop. Similarly, any technologies, products or services we develop may not be preferred to any existing or newly developed technologies, products or services.

We may not be able to protect our proprietary technology, which could harm our ability to operate profitably.

The biotechnology, cosmetic, and pharmaceutical industries place considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, to a substantial degree, on our ability to obtain and enforce patent protection for our products, preserve any trade secrets and operate without infringing the proprietary rights of others. We cannot assure you that:

- we will succeed in obtaining any patents, obtain them in a timely manner, or that the breadth or degree of protection that any such patents will protect our interests;
- the use of our technology will not infringe on the proprietary rights of others;
- patent applications relating to our potential products or technologies will result in the issuance of any patents or that, if issued, such patents will afford adequate protection to us or will not be challenged, invalidated or infringed; or
- patents will not be issued to other parties, which may be infringed by our potential products or technologies.

We are aware of certain patents that have been granted to others and certain patent applications that have been filed by others with respect to nuclear transfer and other stem cell technologies. The fields in which we operate have been characterized by significant efforts by competitors to establish dominant or blocking patent rights to gain a competitive advantage, and by considerable differences of opinion as to the value and legal legitimacy of competitors' purported patent rights and the technologies they actually utilize in their businesses.

Considerable research in the areas of stem cells, cell therapeutics and regenerative medicine is being performed in countries outside of the United States, and a number of our competitors are located in those countries. The laws protecting intellectual property in some of those countries may not provide adequate protection to prevent our competitors from misappropriating our intellectual property.

Our business is highly dependent upon maintaining licenses with respect to key technology.

Although our primary focus relates to intellectual property we have developed internally, some of the patents we utilize are licensed to us by Astellas Pharma, which has licensed some of these from other parties, including the University of Massachusetts ("UMass"). These licenses are subject to termination under certain circumstances (including, for example, our failure to make minimum royalty payments). The restriction or loss of any of such licenses, or the conversion of such licenses to non-exclusive licenses, could adversely affect our operations and/or enhance the prospects of our competitors.

Although our licenses with Astellas allow us to cure any defaults under the underlying licenses to them and to take over the patents and patents pending in the event of default by Astellas, the cost of such remedies could be significant and we might be unable to adequately maintain these patent positions. If so, such inability could have a material adverse effect on our business. Some of these licenses also contain restrictions (e.g., limitations on our ability to grant sublicenses) that could materially interfere with our ability to generate revenue through collaborative relationships or other transactions that involve the licensing or sale to third parties of important and valuable technologies that we have, for strategic reasons, elected not to pursue directly. In the future we may require further licenses to complete and/or commercialize our proposed products. We may not be able to acquire any such licenses on a commercially-viable basis.

We have experienced in the past and may experience in the future network or system failures, or service interruptions, including cybersecurity attacks, or other technology risks. Our inability to protect our systems and data against such risks could harm our business and reputation.

Our ability to provide uninterrupted and high levels of service depends upon the performance of our internal network, systems and related infrastructure, and those of our third-party vendors. Any significant interruptions in, or degradation of, the quality of the services, including infrastructure storage and support, that these third parties provide to us could severely harm our business and reputation and lead to the loss of customers and revenue. Our internal network, systems, and related infrastructure, in addition to the networks, systems, and related infrastructure of our third-party technology vendors, may be vulnerable to computer viruses and other malware that infiltrate such systems and networks, as well as physical or electronic security breaches, natural disasters, and similar disruptions. They have been and may continue to be the target of attempts to identify and exploit network and system vulnerabilities, penetrate or bypass security measures in order to interrupt or degrade the quality of the services we receive or provide, or otherwise gain unauthorized access to our networks and systems or those of our third-party vendors. These vulnerabilities or other attempts at access may result from, or be caused by, human error or technology failures, however, they may also be the product of malicious actions by third parties intending to harm our business. The methods that may be used by these third parties to cause interruptions or failures or to obtain unauthorized access to information change frequently, are difficult to detect, evolve rapidly, and are increasingly sophisticated and hard to defend against. Although we have not incurred material losses or liabilities as a result of security breaches or attempted security breaches and continue to invest in security measures, we cannot be certain that our defensive measures, and those employed by our third-party vendors, will be sufficient to defend against all such current and future methods.

Our careful vetting of third parties to provide technology services and the contractual requirements related to the security that we impose on our third-party vendors who have access to this data may not be sufficient to protect us from network or system failures or service interruptions.

Any actual or perceived security breach, whether experienced by us or a third-party vendor; the reporting or announcement of such an event, or reports of perceived security vulnerabilities of our systems or the systems of our third-party service providers whether accurate or not; or our failure or perceived failure to respond or remediate an event or make adequate or timely disclosures to the public, regulatory or law enforcement agencies following any such event may be material and lead to harm to our financial condition, business reputation, and prospects of future business due to, among other factors: loss of customer confidence arising from interruptions or outages, delays, failure to meet contractual obligations, and loss of data or public release of confidential data; increase regulatory scrutiny on us; compromise our trade secret and intellectual property; expose us to costly uninsured liabilities such as material fines, penalties, liquidated damages, and overall margin compression due to renegotiation of contracts on less favorable terms or loss of business; liability

for claims relating to misuse of personal information in violation of contractual obligations or data privacy laws; and potential theft of our intellectual property.

A security breach could occur and persist for an extended period of time without detection. We expect that any investigation of a security breach could take a substantial amount of time, and during such time we may not necessarily know the extent of the harm or how best to remediate it, and certain errors or actions could be repeated or compounded before they are discovered and remediated, all of which could further increase the costs and consequences of such a breach. Further, detecting and remediating such incidents may require specialized expertise and there can be no assurance that we will be able to retain or hire individuals who possess, or otherwise internally develop, such expertise. Our remediation efforts therefore may not be successful. The inability to implement, maintain, and upgrade adequate safeguards could have a material and adverse impact on our business, financial condition and results of operations. Moreover, there could be public announcements regarding any data security-related incidents and any steps we take to respond to or remediate such incidents.

The occurrence of any such failure may also subject us to costly lawsuits, claims for contractual indemnities, as well as divert valuable management, research and development, information technology, and marketing resources toward addressing these issues and delay our ability to achieve our strategic initiatives. In addition, we gather, as permitted by law, non-public, personally-identifiable financial information from customers, such as names, addresses, telephone numbers, bank and credit card account numbers and financial transaction information, and the compromise of such data, which may subject us to fines and other related costs of remediation.

Certain of our technology may not be subject to protection through patents, which leaves us vulnerable to theft of our technology.

Certain parts of our know-how and technology are not patentable or are trade secrets. To protect our proprietary position in such know-how and technology, we intend to require all employees, consultants, advisors and collaborators to enter into confidentiality and invention ownership agreements with us. These agreements may not provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, in the absence of patent protection, competitors who independently develop substantially equivalent technology may harm our business.

We depend on our collaborators to help us develop and test our proposed products, and our ability to develop and commercialize products may be impaired or delayed if collaborations are unsuccessful.

Our strategy for the development, clinical testing and commercialization of our proposed products requires that we enter into collaborations with corporate partners, licensors, licensees and others. We are dependent upon the subsequent success of these other parties in performing their respective responsibilities and the continued cooperation of our partners. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to our research and development activities related to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

Under agreements with collaborators, we may rely significantly on such collaborators to, among other things:

- design and conduct advanced clinical trials in the event that we reach clinical trials;
- fund research and development activities with us;
- pay us fees upon the achievement of milestones; and
- market with us any commercial products that result from our collaborations.

The development and commercialization of potential products will be delayed if collaborators fail to conduct these activities in a timely manner, or at all. In addition, our collaborators could terminate their agreements with us and we may not receive any development or milestone payments. If we do not achieve milestones set forth in the agreements, or if our collaborators breach or terminate their collaborative agreements with us, our business may be materially harmed.

Contractual arrangements with licensors or collaborators may require us to pay royalties or make other payments related to the development of a product candidate, which would adversely affect the level of our future revenues and profits.

Even if we obtain all applicable regulatory approvals and successfully commercialize one or more of our cell therapy candidates, contractual arrangements between us and a licensor, collaborator or other third party in connection with the respective product may require that we make royalty or other payments to the respective third party, and as a result we would not receive all of the revenue derived from commercial sales of such product.

Our reliance on the activities of our non-employee consultants, research institutions, and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our proposed products.

We rely extensively upon and have relationships with scientific consultants at academic and other institutions, some of whom conduct research at our request, and other consultants with expertise in clinical development strategy or other matters. These consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these consultants and, except as otherwise required by our collaboration and consulting agreements to the extent they exist, can expect only limited amounts of their time to be dedicated to our activities. These research facilities may have commitments to other commercial and non-commercial entities. We have limited control over the operations of these laboratories and can expect only limited amounts of time to be dedicated to our research goals.

We may not be able to obtain third party patient reimbursement or favorable product pricing, which would reduce our ability to operate profitably.

Our ability to successfully commercialize certain of our proposed products in the human therapeutic field may depend to a significant degree on patient reimbursement of the costs of such products and related treatments at acceptable levels from government authorities, private health insurers and other organizations, such as health maintenance organizations. Reimbursement in the United States or foreign countries may not be available for any products we may develop, and, if available, may be decreased in the future. Also, reimbursement amounts may reduce the demand for, or the price of, our products with a consequent harm to our business. We cannot predict what additional regulation or legislation relating to the health care industry or third party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on our business. If additional regulations are overly onerous or expensive, or if health care related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans or completely abandon our business model.

Our products may be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them.

Our products may be significantly more expensive to manufacture than other therapeutic products currently on the market today. We hope to substantially reduce manufacturing costs through process improvements, development of new methods, increases in manufacturing scale and outsourcing to experienced manufacturers. If we are not able to make these, or other improvements, and depending on the pricing of the product, our profit margins may be significantly less than that of other therapeutic products on the market today. In addition, we may not be able to charge a high enough price for any cell therapy product we develop, even if they are safe and effective, to make a profit. If we are unable to realize significant profits from our potential product candidates, our business would be materially harmed.

We presently lack sufficient manufacturing capabilities to produce our therapeutic product candidates at commercial scale quantities and do not have an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the product.

We expect that we would need to significantly expand our manufacturing capabilities to meet potential demand for our therapeutic product candidates, if approved. Such expansion would require additional regulatory approvals. Even if we increase our manufacturing capabilities, it is possible that we may still lack sufficient capacity to meet demand.

We do not presently have any alternate supply for our products. If our facilities where our products are currently being manufactured or equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity, including if such facilities are deemed not in compliance with current Good Manufacturing Practice ("GMP") requirements, future clinical studies and commercial production for our products would likely be significantly disrupted and delayed. It would be both time consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with the regulatory requirements.

Ultimately, if we are unable to supply our products to meet commercial demand, whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could dramatically increase and sales of the product and its long-term commercial prospects could be significantly damaged.

To be successful, our proposed products must be accepted by the health care community, which can be very slow to adopt or unreceptive to new technologies and products.

Our proposed products and those developed by our collaborative partners, if approved for marketing, may not achieve market acceptance since hospitals, physicians, patients or the medical community in general may decide not to accept and utilize these products.

The products that we are attempting to develop represent substantial departures from established treatment methods and will compete with a number of more conventional therapies manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any of our developed products will depend on a number of factors, including:

- our establishment and demonstration to the medical community of the clinical efficacy and safety of our proposed products;
- our ability to create products that are superior to alternatives currently on the market;
- our ability to establish in the medical community the potential advantage of our treatments over alternative treatment methods; and
- reimbursement policies of government and third-party payers.

If the healthcare community does not accept our products for any of the foregoing reasons, or for any other reason, our business would be materially harmed.

Our business is based on novel technologies that are inherently expensive, risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.

The clinical development, commercialization and marketing of cell and tissue-based therapies are at an early-stage, substantially research-oriented, and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize a stem cell product. In general, stem cell products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. Furthermore, the number of people who may use cell or tissue-based therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a significant market for cell- and tissue-based therapies and our ability to capture a share of this market with our product candidates.

Our development efforts with our therapeutic product candidates are susceptible to the same risks of failure inherent in the development and commercialization of therapeutic products based on new technologies. The novel nature of cellular therapeutics creates significant challenges in the areas of product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, the United States FDA has relatively limited experience regulating therapies based on cells, and there are few approved treatments utilizing cell therapy.

During the year ended December 31, 2022, we derived approximately 45% of our revenues from one customer.

During the year ended December 31, 2022, one customer accounted for 45% of our consolidated revenues. To the extent that this significant customer reduces or delays its purchases from us or terminate its relationship with us, our revenues would decline significantly, and our financial condition and results of operations would suffer substantially.

We depend on key personnel for our continued operations and future success, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.

Because of the specialized nature of our business, we are highly dependent on our ability to identify, hire, train and retain highly qualified scientific and technical personnel for the research and development activities we conduct or sponsor. The loss of one or more key executive officers, or scientific officers, would be significantly detrimental to us. In addition, recruiting and retaining qualified scientific personnel to perform research and development work is critical to our success. Our anticipated growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing, will require the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities. Accordingly, we may not be able to continue to attract and retain the qualified personnel, which would adversely affect the development of our business.

We may not have sufficient product liability insurance, which may leave us vulnerable to future claims we will be unable to satisfy.

The testing, manufacturing, marketing and sale of human therapeutic products entail an inherent risk of product liability claims. We currently have a limited amount of product liability insurance, which may not be adequate to meet potential product liability claims. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses. Adequate insurance coverage may not be available in the future on acceptable terms, if at all. If available, we may not be able to maintain any such insurance at sufficient levels of coverage and any such insurance may not provide adequate protection against potential liabilities. Whether or not

a product liability insurance policy is obtained or maintained in the future, any product liability claim could harm our business or financial condition.

Many of the key materials in our products and packaging, and manufacturing services for certain of our other products, are obtained from a single or limited number of suppliers. Thus, we are at risk of shortages, price increases, tariffs, changes, delay, or discontinuation of key materials and manufacturing services, which could disrupt and materially and adversely affect our business.

Many of the key materials used to manufacture or package our LCT products come from limited or single sources of supply. In addition, in some cases primarily for our LSC products, we rely only on one manufacturer or a limited number of contract manufacturers to fill and finish, test, and package our products. In general, our contract manufacturers fabricate or procure certain materials and packaging on our behalf, subject to certain approved procedures or supplier lists. We do not have firm commitments from many of these suppliers and manufacturers to provide all materials and services, or to provide them in quantities and on timelines that we may require.

Due to our reliance on the key materials provided by suppliers and services provided by contract manufacturers, we are subject to the risk of shortages and long lead times or other disruptions in the supply of certain materials or services. For example, our ability to ship LCT products has recently been adversely affected by shortages in plastic resin that is used to make the packaging containers for those products. Our ongoing efforts to identify alternative suppliers (for many of the single-sourced or limited-sourced materials used in our products) and alternative contract manufacturers (for the assembly of our LSC products) may not be successful. We are subject to the risk that our suppliers may discontinue or modify the materials they provide to us, or that the materials may cease to be available on commercially reasonable terms, or at all. We have in the past experienced, and may in the future experience, materials shortages or delays or other problems in product assembly, and the availability of these materials or services may be difficult to predict. For example, our suppliers or manufacturers may experience temporary or permanent disruptions in their manufacturing operations due to equipment breakdowns, labor strikes or shortages, natural disasters, the occurrence of a contagious disease or illness, such as COVID-19, component or material shortages, cost increases, acquisitions, insolvency, bankruptcy, business shutdowns, trade restrictions, changes in legal or regulatory requirements, or other similar problems. In particular, the current COVID-19 pandemic has caused disruptions in our supply chain. To the extent COVID-19 pandemic continues and results in continuing restrictions, disruptions in our supply chain may continue and cause shortages of our ability to sell products, which could materially and adversely impact our financial results.

Additionally, various sources of supply-chain risk, including strikes or shutdowns at delivery ports or loss of or damage to our products while they are in transit or storage, intellectual property theft, losses due to tampering, third-party vendor issues with quality or sourcing control, failure by our suppliers to comply with applicable laws and regulation, potential tariffs or other trade restrictions, or other similar problems, could limit or delay the supply of our products or harm our reputation. In the event of a shortage or supply interruption from suppliers or contract manufacturers, we may not be able to develop alternate sources quickly, cost-effectively, or at all. Any interruption or delay in material supply or manufacturing, any increases in material or manufacturing costs, or the inability to obtain these materials or services from alternate sources at acceptable prices and within a reasonable amount of time, would harm our ability to provide our products on a timely basis. This could materially and adversely affect our business.

Economic uncertainties and unfavorable economic conditions could adversely affect our business, financial condition, results of operations or our access to capital.

Our business, financial condition, results of operations or prospects could be adversely affected by general economic conditions and uncertainties, including in the financial markets. Negative economic conditions, both in the United States and abroad, including the effects of changes in economic growth and expectations, labor shortages, supply chain disruptions, inflationary pressures, financial and credit market fluctuations, international trade relations and/or the imposition of trade tariffs, political turmoil, natural catastrophes, regional or global outbreaks of contagious diseases, such as the ongoing COVID-19 pandemic, terrorist attacks and warfare (such as the Russia – Ukraine conflict and any resulting sanctions imposed), as well as related governmental or regulatory responses, could cause a decrease or deferral in spending by our customers and otherwise negatively affect our business. A severe or prolonged economic downturn or economic uncertainties from these or other factors could also adversely affect our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruptions. Any such disruptions may also magnify the impact of other risks described in this Annual Report on Form 10-K.

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

The outbreak of the coronavirus, COVID-19, which has been declared by the World Health Organization to be a pandemic has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, customers, suppliers, third party shipping carriers, government and other partners may be prevented from or limited in their ability to conduct business activities for an indefinite period of time, including due to the spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. The impact that COVID-19 could have on our business, the continued spread of COVID-19 and the measures taken by the governments

of states and countries affected could disrupt, among other things, the supply chain and the manufacture or shipment of our products. Our laboratory operations, including laboratory employees, may be subject to closure or shut down due to the spread of the disease within these individuals, or as part of a larger scale government recommendation or mandate. Any disruption in our laboratory operations would have a material adverse effect on our business and would impede our ability to manufacture and ship products to our customers in a timely manner, or at all. Additionally, the demand for our skincare products may continue to significantly decline as COVID-19 continues to spread, including as a result of prioritization of customer financial resources toward essential household items or government-imposed quarantines that impede the ability of our customers to purchase our professional skincare product line through spas and medical offices that may not be considered essential businesses and are mandated to close for an indefinite amount of time. The occurrence of any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations. The COVID-19 outbreak and mitigation measures 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. The extent to which the COVID-19 outbreak continues to affect 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.

Risks Related to the Securities Markets and Our Capital Structure

Stock prices for biotechnology companies have historically tended to be very volatile.

Stock prices and trading volumes for many biotechnology companies fluctuate widely for a number of reasons, including but not limited to the following factors, some of which may be unrelated to their businesses or results of operations:

- clinical trial results;
- the amount of cash resources and such company's ability to obtain additional funding;
- announcements of research activities, business developments, technological innovations or new products by competitors;
- entering into or terminating strategic relationships;
- changes in government regulation;
- disputes concerning patents or proprietary rights;
- changes in revenues or expense levels;
- public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed;
- development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the current and future impact of it and COVID-19 to the financial market;
- reports by securities analysts;
- activities of various interest groups or organizations;
- media coverage; and
- status of the investment markets.

This market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock.

Two of our executive officers and directors can significantly influence our direction and policies, and their interests may be adverse to the interests of our other stockholders.

As of December 31, 2022, Dr. Andrey Semechkin, Chief Executive Officer and Co-Chairman of the Board of Directors, and Dr. Russell Kern, Executive Vice President and Chief Scientific Officer and a director, beneficially own approximately 64% of our outstanding shares of common stock, including shares issuable upon conversion of the outstanding shares of our Series D, Series G, and Series I-2 Preferred Stock and shares issuable upon exercise of options that they hold and that are exercisable within 60 days of December 31, 2022. As a result of their holdings and the rights, preferences and privileges of those series of preferred stock, Dr. Andrey Semechkin and Dr. Russell Kern may appoint and remove two of our four directors, and propose candidates for nomination of up to two additional directors, and therefore will be able to significantly influence the election of our Board of Directors. They may also prevent corporate transactions (such as a merger, consolidation, a sale of all or substantially all of our assets or a financing transaction) that may be favorable from the standpoint of our other stockholders or they may cause a transaction that our other stockholders may view as unfavorable.

The rights of holders of our common stock are subordinate to significant rights, preferences and privileges of our existing five series of preferred stock, and to any additional series of preferred stock created in the future.

Under the authority granted by our Certificate of Incorporation, our Board of Directors has established four separate series of outstanding preferred stock, Series B, Series D, Series G and Series I-2 Preferred Stock, which have various rights and preferences senior to the shares of common stock. Shares of some series of our existing preferred stock are also entitled to enhanced voting rights and liquidation preferences. As a result of the various voting rights, the holders of our existing preferred stock may be able to block the proposed approval of various corporate actions, which could prevent us from achieving strategic or other goals dependent on such actions. As a result of the liquidation preferences, in the event that we voluntarily or involuntary liquidate, dissolve or windup our affairs (including as a result of a merger), the holders of our preferred stock would be entitled to receive stated amounts per share, including any accrued and unpaid dividends, before any distribution of assets or merger consideration is made to holders of our common stock. Additionally, these shares of preferred stock may be converted, at the option of the holders, into common stock at rates that may be adjusted, for the benefit of holders of preferred stock, if we sell equity securities below the then existing conversion prices. Any such adjustments would compound the potential dilution suffered by holders of common stock if we issue additional securities at prices below the current conversion prices (ranging from $0.39 to $9.69 per share as of December 31, 2022). Additionally, subject to the consent of the holders of our existing preferred stock, our Board of Directors has the power to issue additional series of preferred stock and to designate, as it deems appropriate (subject to the rights of the holders of the current series of preferred stock), the special dividend, liquidation or voting rights of the shares of those additional series. The creation and designation of any new series of preferred stock could adversely affect the voting power, dividend, liquidation and other rights of holders of our common stock and, possibly, any other class or series of stock that is then in existence.

The market price for our common stock has been and may continue to be particularly volatile given our status as a relatively unknown company with a limited operating history and lack of profits, which could lead to wide fluctuations in our share price. The price at which stockholders purchase shares of our common stock may not be indicative of the price of our common stock that will prevail in the trading market.

The market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our stock price could continue to be more volatile than a seasoned issuer for the indefinite future. The potential volatility in our share price is attributable to a number of factors. First, there has been limited trading in our common stock. As a consequence of this lack of liquidity, any future trading of shares by our stockholders may disproportionately influence the price of those shares in either direction. Second, we are a speculative or "risky" investment due to our limited operating history and lack of profits to date, and uncertainty of future market acceptance for our potential products. As a consequence of this enhanced risk, more risk averse investors may, under the fear of losing all or most of their investment in the event of negative news or lack of progress, be more inclined to sell their shares on the market more quickly and at greater discounts than would be the case with the stock of a seasoned issuer. Many of these factors will be beyond our control and may decrease the market price of our common stock, regardless of our operating performance. We cannot make any predictions or projections as to what the prevailing market price for our common stock will be at any time or as to what effect that the sale of shares or the availability of shares for sale at any time will have on the prevailing market price.

In addition, the market price of our common stock could be subject to wide fluctuations in response to:

- quarterly variations in our revenues and operating expenses;
- announcements of new products or services by us;
- fluctuations in interest rates;
- significant sales of our common stock;
- the operating and stock price performance of other companies that investors may deem comparable to us; and
- news reports relating to trends in our markets or general economic conditions.

Certain provisions of our Certificate of Incorporation and Delaware law may make it more difficult for a third party to affect a change-in-control.

Our Certificate of Incorporation authorizes the Board of Directors to issue up to 20,000,000 shares of preferred stock and our Board of Directors has created and issued shares of four series of preferred stock that remain outstanding, Series B, Series D and Series I-2 Preferred Stock. The terms of various series of Preferred Stock include, among other things, voting rights on particular matters (for example, with respect to the Series D Preferred Stock, restricting our ability to undergo a change in control or merge with, or sell assets to, a third-party), preferences as to dividends and liquidation, and conversion rights. These preferred stock rights diminish the rights of holders of our common stock, and therefore could reduce the value of such common stock. In addition, as long as shares of our Series

B, Series D and Series G Preferred Stock remain outstanding, or if our Board creates and issues additional shares of preferred stock in the future with rights that restrict our ability to merge with, or sell assets to, a third party, it could make it more difficult, delay, discourage, prevent or make it more costly to acquire the Company or affect a change-in-control.

The application of the "penny stock" rules to our common stock could limit the trading and liquidity of our common stock, adversely affect the market price of our common stock and increase stockholder transaction costs to sell those shares.

While we are currently exempt from the "penny stock" rules, as long as the trading price of our common stock is below $5.00 per share, the open market trading of our common stock would be subject to the "penny stock" rules, if we otherwise do not continue to qualify for an exemption from the "penny stock" definition. The "penny stock" rules impose additional sales practice requirements on certain broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $1 million or annual income exceeding $200 thousand or $300 thousand together with their spouse). These regulations, if they apply, require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. Under these regulations, certain brokers who recommend such securities to persons other than established customers or certain accredited investors must make a special written suitability determination regarding such a purchaser and receive such purchaser's written agreement to a transaction prior to sale. These regulations may have the effect of limiting the trading activity of our common stock, reducing the liquidity of an investment in our common stock and increasing the transaction costs for sales and purchases of our common stock as compared to other securities.

The sale or issuance of a substantial number of shares may adversely affect the market price for our common stock.

The future sale of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could significantly and negatively affect the market price for our common stock. We expect that we will likely issue a substantial number of shares of our capital stock in financing transactions in order to fund our operations and the growth of our business. Under these arrangements, we may agree to register the shares for resale soon after their issuance. We may also continue to pay for certain goods and services with equity, which would dilute our current stockholders. Also, sales of the shares issued in this manner could negatively affect the market price of our stock.

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

We have incurred substantial tax losses during our history. Subject to various limitations, we may carryforward unused taxable losses, including those generated in the future, and other available credits to offset any future taxable income until the unused losses or credits expire. Federal and state tax laws impose restrictions on the utilization of net operating loss ("NOL") and tax credit carryforwards in the event of an "ownership change" as defined by Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382"). Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically, three years). Under Section 382 and Section 383, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post change income may be limited. Because of the cost and complexity involved in the analysis of a Section 382 ownership change and the fact that we do not have any taxable income to offset, we have not undertaken a study to assess whether an "ownership change" has occurred or whether there have been multiple ownership changes since we became a "loss corporation" as defined in Section 382. Future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change." In addition, future equity offerings or acquisitions that have equity as a component of the purchase price could result in an "ownership change." If an "ownership change" has occurred or does occur in the future, our ability to utilize our NOL carryforwards or other tax attributes may be limited, which could result in an increased future tax liability to us.

Limitations on director and officer liability and indemnification of our officers and directors by us may discourage stockholders from bringing suit against a director.

Our certificate of incorporation and bylaws provide, with certain exceptions as permitted by governing state law, that a director or officer shall not be personally liable to us or our stockholders for breach of fiduciary duty as a director, except for acts or omissions which involve intentional misconduct, fraud or knowing violation of law, or unlawful payments of dividends. These provisions may discourage stockholders from bringing suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against a director. In addition, our certificate of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law.

Compliance with the rules established by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 is complex. Failure to comply in a timely manner could adversely affect investor confidence and our stock price.

Rules adopted by the SEC pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 require us to perform an annual assessment of our internal controls over financial reporting and certify the effectiveness of those controls. The standards that must be met for management to assess the internal controls over financial reporting now in effect are complex, costly and require significant documentation, testing and possible remediation to meet the detailed standards. We may encounter problems or delays in completing activities necessary to make an assessment of our internal controls over financial reporting. If we cannot perform the assessment or certify that our internal controls over financial reporting are effective investor confidence and share value may be negatively impacted.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES

In October 2021, we entered into a joint lease agreement with S Real Estate Holding, LLC (an affiliate of our Executive Vice President and Chief Scientific Officer) for the purpose of establishing a new corporate headquarters that combines the Company's research facility and corporate offices, including corporate, R&D, and manufacturing operations, in San Diego, California. In connection with entering into the joint lease agreement, we entered into a co-tenant agreement with S Real Estate Holdings, LLC, to share costs related to the leased premises. In addition to base rent, the Company and S Real Estate Holdings, LLC, are responsible for certain costs and expenses, including insurance, maintenance costs, taxes and operating expenses. The lease covers approximately 7,300 square feet, of which portions of the facility are designated for use by the Company, S Real Estate Holdings, LLC, or shared. The lease for this facility expires in December 2026. At commencement, base rent due under the lease was approximately $11 thousand and increases approximately 3.5% per annum over the lease term. Pursuant to the co-tenant agreement with S Real Estate Holdings, LLC, we are liable for 40% of total base rent and variable lease charges due under the joint lease agreement.

We also lease supplemental office space in a building adjacent to our new corporate headquarter from the same landlord. The supplemental office lease expires in December 2026 and is not subject to the co-tenant agreement with S Real Estate Holdings, LLC. The new corporate headquarters lease and supplemental office lease do not contain any options to renew to extend the lease terms.

In addition, we lease a 13,320 square foot facility in Frederick, Maryland, which is used for laboratory and administrative purposes. The current lease expires in November 2025. As of December 31, 2022, the base rent was approximately $18 thousand per month. The laboratory is used to develop and manufacture our research products and the administration facility is used for sales and marketing, and general administration purposes. The monthly base rent will increase by 3% on each anniversary date of the agreement.

We believe our existing facilities are adequate to meet our current operational needs, and that suitable alternatives will be available in the future as and when needed on commercially reasonably terms.

ITEM 3. LEGAL PROCEEDINGS.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

As of December 31, 2022, we had 8,004,389 shares of common stock outstanding, and approximately 636 holders of record of our common stock, and we had 5,254,353 shares of preferred stock outstanding, and four holders of record of our preferred stock, with the 5,254,353 shares of preferred stock being convertible into 6,076,522 shares of common stock.

On March 4, 2019, we were downgraded to trade from the OTC QB Venture Market to the OTC QX Best Market in the United States under the trading symbol "ISCO". The OTC QX is a regulated quotation service that displays real-time quotes, last-sale prices and volume information in over-the-counter equity securities. The OTC QX securities are traded by a community of market makers that enter quotes and trade reports. This market is limited in comparison to an exchange and any prices quoted may not be a reliable indication of the value of our common stock.

Dividends

Our Board of Directors determines any payment of dividends. We have never declared or paid cash dividends on our common stock. We do not expect to authorize the payment of cash dividends on our shares of common stock in the foreseeable future. Any future decision with respect to dividends will depend on our future earnings, operations, capital requirements and availability, restrictions in future financing agreements and other business and financial considerations.

ITEM 6. (RESERVED)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes and other financial information included elsewhere in this Annual Report on Form 10-K. The discussion contains forward-looking statements, such as our plans, expectations and intentions (including those related to clinical trials and business and expense trends), that are based upon current expectations and that involve risks and uncertainties. Our actual results may differ significantly from management's expectations. The factors that could affect these forward-looking statements are in Item 1A of Part I of this report. This discussion should not be construed to imply that the results discussed herein will necessarily continue into the future, or that any expectations expressed herein will necessarily be indicative of actual operating results in the future. Such discussion represents only the best present assessment by our management.

Business Overview

We have generated aggregate product revenues from our two commercial businesses of $8.2 million and $7.2 million for the years ended December 31, 2022 and 2021, respectively. We currently have no revenue generated from our principal operations in therapeutic and clinical product development.

Our products are based on multi-decade experience with human cell culture and a proprietary type of pluripotent stem cells, human parthenogenetic stem cells ("hpSCs"). Our hpSCs are comparable to human embryonic stem cells ("hESCs") in that they have the potential to be differentiated into many different cells in the human body. However, the derivation of hpSCs does not require the use of fertilized eggs or the destruction of viable human embryos and also offers the potential for the creation of immune-matched cells and tissues that are less likely to be rejected following transplantation. Our collection of hpSCs, known as UniStemCell™, currently consists of 15 stem cell lines. We have facilities and manufacturing protocols that comply with the requirements of Good Manufacturing Practice (GMP) standards as promulgated by the U.S. Code of Federal Regulations and enforced by the United States Food and Drug Administration ("FDA").

COVID-19 Pandemic

The impact of the COVID-19 pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Impacts to our business have included a reduction in sales volume primarily from media sales in our biomedical market segment and professional channel sales in our anti-aging market segment, temporary or reduced occupancy of portions of our manufacturing facilities, and disruptions or restrictions on our employee's ability to travel to such manufacturing facilities which caused minor delays in manufacturing. We have taken precautionary measures to better ensure the health and safety of our workers.

The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on our operations, are currently unknown. We are continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that we determine are in the best interests of public health and safety. We cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may continue to have on our business, strategy, collaborations, or financial and operating results.

Market Opportunity and Growth Strategy

Therapeutic Market – Clinical Applications of hpSCs for Disease Treatments

We believe that the most promising potential clinical applications of our technology are Parkinson's disease ("PD"), traumatic brain injury ("TBI"), and stroke. Using our proprietary technologies and know-how, we are creating neural stem cells from hpSCs as a potential treatment of PD, TBI, and stroke.

PD: Our most advanced project is the neural stem cell program for the treatment of Parkinson's disease. In 2013, we published in Nature Scientific Reports the basis for our patent on a new method of manufacturing neural stem cells, which is used to produce the clinical-grade cells necessary for future clinical studies and commercialization. In 2014, we completed the majority of the preclinical research, establishing the safety profile of NSC in various animal species, including non-human primates. In June 2016, we published the results of a 12-month pre-clinical non-human primate study, which demonstrated the safety, efficacy and mechanism of action of the ISC- hpNSC®. In 2017, we dosed four patients in our Phase I trial of ISC-hpNSC®, human parthenogenetic stem cell-derived neural stem cells for the treatment of Parkinson's disease. We reported 12-month results from the first cohort and 6-month interim results of the second cohort at the Society for Neuroscience annual meeting (Neuroscience 2018) in November 2018. In April 2019, we announced

the completion of subject enrollment, with the 12th subject receiving a transplantation of the highest dose of cells. There have been no safety signals or serious adverse effects seen to date as related to the transplanted ISC-hpNSC® cells.

We announced a successful completion of the dose escalating phase 1 clinical trial in June 2021. In terms of preliminary efficacy, where scores are compared against baseline before transplantation, we observed a potential dose-dependent response with an apparent peak effectiveness at our middle dose. The % OFF-Time, which is the time during the day when levodopa medication is not performing optimally and PD symptoms return, decreased an average 47% from the baseline at 12 months post transplantation in cohort 2. This trend continued through 24 months where the % OFF-Time in the second cohort dropped by 55% from the initial reading. The same was true for % ON-Time without dyskinesia, which is the time during the day when levodopa medication is performing optimally without dyskinesia. The % ON-Time increased an average of 42% above the initial evaluation at 12 months post-transplantation in the second cohort.

Stroke: In August 2014, we announced the launch of a stroke program, evaluating the use of ISC-hpNSC® transplantation for the treatment of ischemic stroke using a rodent model of the disease. The Company has a considerable amount of safety data on ISC-hpNSC® from the Parkinson's disease program and, as there is evidence that transplantation of ISC-hpNSC® may improve patient outcomes as an adjunctive therapeutic strategy in stroke, having a second program that can use this safety dataset is therefore a logical extension. In 2015, the Company together with Tulane University demonstrated that NSC can significantly reduce neurological dysfunction after a stroke in animal models.

TBI: In October 2016, we announced the results of the pre-clinical rodent study, evaluating the use of ISC-hpNSC® transplantation for the treatment of TBI. The study was conducted at the University of South Florida Morsani College of Medicine. We demonstrated that animals receiving injections of ISC-hpNSC® displayed the highest levels of improvements in cognitive performance and motor coordination compared to vehicle control treated animals. In February 2019, we published the results of the pre-clinical study in Theranostics, a prestigious peer-reviewed medical journal. The publication titled, "Human parthenogenetic neural stem cell grafts promote multiple regenerative processes in a traumatic brain injury model," demonstrated that the clinical-grade neural stem cells used in our Parkinson's disease clinical trial, ISC-hpNSC®, significantly improved TBI-associated motor, neurological, and cognitive deficits without any safety issues.

Anti-Aging Cosmetic Market – Skin Care Products

Our wholly owned subsidiary Lifeline Skin Care, Inc. ("LSC") develops, manufactures, and sells anti-aging skin care products based on two core technologies: encapsulated extract derived from hpSC and specially selected targeted small molecules. LSC's products include:

- ProPlus Advanced Defense Complex
- ProPlus Advanced Recovery Complex
- ProPlus Eye Firming Complex
- ProPlus Neck Firming Complex
- ProPlus Advanced Aqueous Treatment
- ProPlus Collagen Booster (Advanced Molecular Serum)
- ProPlus Elastin Booster
- ProPlus Brightening Toner

LSC's products are regulated as cosmetics. LSC's products are sold domestically through a branded website, Amazon, and ecommerce partners.

Biomedical Market – Primary Human Cell Research Products

Our wholly-owned subsidiary LCT develops, manufactures and commercializes approximately 200 human cell culture products, including frozen human "primary" cells and the reagents (called "media") needed to grow, maintain and differentiate the cells. LCT's scientists have used a standardized, methodical, scientific approach to basal medium optimization to systematically produce optimized products designed to culture specific human cell types and to elicit specific cellular behaviors. These techniques can also be used to produce products that do not contain non-human animal proteins, a feature desirable to the research and therapeutic markets. Each LCT cell product is quality tested for the expression of specific markers (to assure the cells are the correct type), proliferation rate, viability, morphology and absence of pathogens. Each cell system also contains associated donor information and all informed consent

requirements are strictly followed. LCT's research products are marketed and sold by its internal sales force, OEM partners and LCT brand distributors in Europe and Asia.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021, together with the dollar and percent change in those items (in thousands):

	Years Ended December 31,			
	2022	**2021**	**$ Change**	**% Change**
Product sales	$ 8,180	$ 7,176	$ 1,004	14%
Cost of sales	3,269	2,935	334	11%
As a % of revenues	*40%*	*41%*		
General and administrative	3,357	4,084	(727)	-18%
Selling and marketing	1,245	1,383	(138)	-10%
Research and development	492	695	(203)	-29%
Other income (expense), net	(148)	1,022	(1,170)	-114%
Net loss	$ (331)	$ (899)	$ 568	-63%
As a % of revenues	*-4%*	*-13%*		

Product Sales

Product sales revenue for the year ended December 31, 2022 was $8,180 thousand, compared to $7,176 thousand for the year ended December 31, 2021. The increase was primarily attributable to a $1,195 thousand increase in sales in our biomedical market segment, largely offset by a $191 thousand decrease in sales in our anti-aging market during 2022 compared to 2021.

Our biomedical product sales continue to recover from the impacts of COVID-19 as purchasing activity from our original equipment manufacturer customers account for approximately 86% of the increase in this market segment.

Our professional line of anti-aging products was discontinued starting in 2022 resulting in only one product line and less demand. The products that were largely marketed to medical professionals and spas that offered walk-up retail, experienced a significant decline in customer demand due to COVID-19 and the related restrictions during the year ended December 31, 2021. The impact of shutting down to one line has been partially mitigated by our expanded offering of professional skin care products through our ecommerce channel. Anti-aging product sales through our ecommerce channel decreased slightly year-over-year.

Cost of Sales

Cost of sales for the year ended December 31, 2022 was $3,269 thousand, compared to $2,935 thousand for the year ended December 31, 2021. There was an increase in cost of sales as a result of the increase in product sales in our biomedical market segment of $589 thousand; however, this was offset by significant favorable manufacturing variances due to the increased sales volumes resulting in a net increase of $172 thousand year over year. There also was an increase in cost of goods sold in our anti-aging market of approximately $162 thousand, net primarily attributable to large amounts of expired product reserves booked as a result of the change in sales channel and lines of business from 2021 to 2022. In response to previous material scarcities primarily in plastics, we have increased our supply of raw materials on hand and have, where possible, sourced materials from alternative vendors.

Cost of sales consists primarily of salaries and benefits associated with employee efforts expended directly on the production of the Company's products, as well as related direct materials, general laboratory supplies and an allocation of overhead. We aim to continue refining our manufacturing processes and supply chain management to improve the cost of sales as a percentage of revenue for both LCT and LSC.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2022 was $3,357 thousand, compared to $4,084 thousand for the year ended December 31, 2021. The decrease was primarily attributable to a decrease in personnel-related costs including stock-based compensation, human resources, workers compensation and relocation expenses of $385 thousand, a $250 thousand decrease in patent impairment charges, $124 thousand decrease in building expenses, $49 thousand decrease in computer and amortization expenses,

and $60 thousand in legal and directors and officers insurance fees decreases, partially offset by $134 thousand increase primarily in consulting and servicing fees.

Our general and administrative expenses consist primarily of employee-related expenses including salaries, bonuses, benefits and share-based compensation. Other significant costs include facility costs not otherwise included in or allocated to other departments, legal fees not relating to patents and corporate matters, and fees for accounting and consulting services.

Selling and Marketing Expenses

Selling and marketing expenses for the year ended December 31, 2022 was $1,245 thousand, compared to $1,383 thousand for the year ended December 31, 2021. The decrease was primarily attributable to a $69 thousand decrease in personnel-related costs, sales commissions, stock-based compensation and consultant costs, primarily as a result of headcount reductions and changes in our anti-aging segment year over year. There was a decrease of approximately $16 thousand from dues and subscriptions, licensing and other merchant fees, and approximately $35 thousand decrease in building and other expenses. The decrease was partially offset by an increase of $61 thousand in marketing materials and website and search engine maximization advertising expense.

Our sales and marketing expenses consist primarily of employee-related expenses including salaries, bonuses, benefits, and share-based compensation for our Biomedical and Anti-aging cosmetic businesses. Other significant costs include facility costs not otherwise included in or allocated to other departments as well as marketing material costs, permits and licenses for ecommerce, and other advertising type expenses.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 was $492 thousand, compared to $695 thousand for the year ended December 31, 2021. The decrease was primarily attributable to $168 thousand decrease in building related expenses, $73 thousand decrease in consulting services, $54 thousand decrease in material, supplies and licensing related expenses partially offset by $50 thousand in personnel-related costs and stock-based compensation as a result of increased salaries in Research and Development after salary raise freezes during the pandemic and $42 thousand decrease in our Australian research and development tax credit related to qualifiable expenditures from our research and development activities of our Australian subsidiary, Cyto Therapeutics.

Our research and development efforts are primarily focused on the development of treatments for Parkinson's disease, traumatic brain injury, liver diseases, stroke, and the creation of new GMP grade human parthenogenetic stem cell lines. These projects are long-term investments that involve developing both new stem cell lines and new differentiation techniques that can provide higher purity populations of functional cells. Research and development expenses are expensed as incurred and are accounted for on a project-by-project basis. However, much of our research has potential applicability to each of our projects.

Other Income (Expense), Net

Other income, net, for the year ended December 31, 2022 was a loss of $148 thousand, compared to other income, net, of $1,022 thousand for the year ended December 31, 2021. The decrease was primarily attributable to the gain recognized on the forgiveness of debt related to our First and Second Draw Loan under the PPP, collectively totaling $1,137 thousand in 2021. The remainder of the difference relates to accrued interest on outstanding debt.

Liquidity and Capital Resources

The Company enters into contracts in the normal course of business with various third-party consultants and contract research organizations ("CRO") for preclinical research, clinical trials and manufacturing activities. These contracts generally provide for termination upon notice. Actual expenses associated with these arrangements may be higher or lower due to various reasons, including but not limited to, progress of our development products, enrollment in clinical trials, and product and personnel delays due to COVID. Other short-term and long terms commitments that would affect liquidity include lease obligations as well as related party debt repayments.

As of December 31, 2022, we had an accumulated deficit of approximately $110.3 million and have, on an annual basis, incurred net losses and negative operating cash flows since inception. Substantially all of our operating losses have resulted from the funding of our research and development programs and general and administrative expenses associated with our operations. We incurred net losses of $331 thousand and $899 thousand for years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had cash of $742 thousand, compared to $171 thousand as of December 31, 2021.

Licensed Patents

The Company had a minimum annual license fee of $75 thousand payable in two installments per year to Astellas Pharma pursuant to the amended UMass IP license agreement. The patents, along with the license agreement, expired at the end of July 2022. These patents were fully impaired in prior years and therefore the expiration did not result in any additional impairment for the year ended December 31, 2022. The Company does not anticipate any short-term liquidity effects from this obligation as we will no longer be liable for the annual licensing fee.

Cash Flows

Comparison of the Years Ended December 31, 2022 and 2021

The following table provides information regarding our cash flows for the years ended December 31, 2022 and 2021 (in thousands):

	Years Ended December 31,	
	2022	**2021**
Net cash provided by (used in) operating activities	$ 332	$ (1,297)
Net cash used in investing activities	(11)	(45)
Net cash provided by financing activities	250	824
Net increase (decrease) in cash	$ 571	$ (518)

Operating Cash Flows

For the year ended December 31, 2022, net cash provided by operating activities was $332 thousand, resulting primarily from our net loss of $331 thousand, and net changes in operating assets and liabilities of $226 thousand, consisting primarily of an increase in accrued liabilities of $104 thousand, inventory, net, of $114 thousand, and decrease in accounts payable of $186 thousand and operating lease liabilities of $179 thousand. The decrease in cash is offset by net recurring non-cash adjustments of $890 thousand, including depreciation and amortization, stock-based compensation, operating lease expense, and interest expense. For the year ended December 31, 2021, net cash used in operating activities was $1,297 thousand, resulting primarily from our net loss of $899 thousand and gain on forgiveness of debt of $1,137 thousand, offset by non-cash adjustments of stock-based compensation expense of $644 thousand, operating lease expense of $289 thousand, and depreciation and amortization of $262 thousand, coupled with net changes in operating assets and liabilities of $823 thousand.

Investing Cash Flows

Net cash used in investing activities for the year ended December 31, 2022 was $11 thousand, compared to $45 thousand for the year ended December 31, 2021. The decrease was attributable to a decrease in payments for patent licenses of $12 thousand and net decrease in the purchases of property and equipment of $22 thousand year-over-year.

Financing Cash Flows

Net cash provided by financing activities for year ended December 31, 2022 was $250 thousand, compared to $824 thousand for the year ended December 31, 2021. For the year ended December 31, 2022, net cash provided by financing activities consisted of $250 thousand in proceeds from a note payable from a related party. For the year ended December 31, 2021, net cash provided by financing activities consisted of $474 thousand in proceeds from our second draw loan under the Paycheck Protection Program, coupled with proceeds from a note payable from a related party of $350 thousand.

Liquidity and Going Concern

Management continues to evaluate various financing sources and options to raise working capital to help fund our current research and development programs and operations. We will need to obtain significant additional capital from sources including exercise of outstanding warrants, equity and/or debt financings, license arrangements, grants and/or collaborative research arrangements to sustain our operations and develop products. Unless we obtain additional financing, we do not have sufficient cash on hand to sustain our operations at least through one year after the issuance date. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying the estimates for capital needs in 2023 and beyond;

- the extent that revenues from sales of LSC and LCT products cover the related costs and provide capital;
- scientific progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with pre-clinical development and clinical trials;
- the extent to which third party interest in Company's research and commercial products can be realized through effective partnerships;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the number and type of product candidates that we pursue; and
- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the current and future impact of it and COVID-19 on our business operations and funding requirements.

Our failure to raise capital or enter into applicable arrangements when needed would have a negative impact on our financial condition. Additional debt financing may be expensive and require us to pledge all or a substantial portion of its assets. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of its technologies, product candidates or products that we would otherwise seek to develop and commercialize on its own. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of its product initiatives.

We currently have no revenue generated from our principal operations in therapeutic and clinical product development through research and development efforts. There can be no assurance that we will be successful in maintaining our normal operating cash flow and obtaining additional funds and that the timing of our capital raising or future financing will result in cash flow sufficient to sustain our operations at least through one year after the issuance date.

Based on the factors above, there is substantial doubt about our ability to continue as a going concern. The consolidated financial statements were prepared assuming that we will continue to operate as a going concern. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. Management's plans in regard to these matters are focused on managing our cash flow, the proper timing of our capital expenditures, and raising additional capital or financing in the future.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an on-going basis, we evaluate our estimates and assumptions and we base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our most critical accounting estimates include current and non-current inventory, intangible assets, and stock-based compensation. We review our estimates and assumptions periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that the following accounting policies are critical to the judgments and estimates used in preparation of our consolidated financial statements.

Allowance for Excess and Obsolete Inventory

Our inventory, particularly within our biomedical market, consists of certain products that have a long or, when frozen, indefinite shelf life. In addition, future demand for our products is uncertain. Accordingly, at each reporting period, we estimate a reserve for allowance for excess and obsolete inventory. This estimate is computed using historical sales data and inventory turnover rates, which are subjective in nature and fluctuate between periods. The establishment of a reserve for excess and obsolete inventory establishes a new cost basis in the inventory with a corresponding adjustment to cost of sales. If we are able to sell such inventory, any related reserves

are reduced in the period of sale. The Company's allowance for excess and obsolete inventory was $637 thousand and $526 thousand as of December 31, 2022 and December 31, 2021, respectively. A 10% change in our reserve estimate in total at December 31, 2022, would result in a change in reserve of approximately $64 thousand. Our reserves are estimates, which could vary significantly, either favorably or unfavorably, from actual results if future economic conditions, consumer demand and competitive environments differ from our expectations. At this time, we do not believe that there is a reasonable likelihood that there will be a material change in the future estimates or assumptions that we use to calculate our inventory reserves.

Stock-Based Compensation

We are required to measure and recognize compensation expense for all stock-based payment awards made to employees and consultants based on estimated fair value. We estimate the fair value of stock options granted using the Black-Scholes option-pricing model.

The determination of fair value of stock-based awards using the Black-Scholes option-pricing model requires the use of certain estimates and subjective assumptions that affect the amount of stock-based compensation expense recognized in our consolidated statements of operations. These include estimates of the expected volatility of our stock price, expected option life, expected dividends and the risk-free interest rate. Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the expected life of the award. The expected option life is calculated using the Simplified Method as prescribed by accounting guidance for stock-based compensation. We determined expected dividend yield to be 0% given that we have never declared or paid any cash dividends on our common stock, and we currently do not anticipate paying such cash dividends. The risk-free interest rate is based upon United States Treasury securities with remaining terms similar to the expected term of the share-based awards. If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation expense may differ materially from what we have recorded in the current period.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to our consolidated financial statements included in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The information required by this Item is set forth in our Consolidated Financial Statements and Notes thereto beginning at page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(e) and 15d-15(e) under the Exchange Act, the Company, with the participation of management, including our Chief Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in such rules) as of the end of the period covered by this report. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022, our Chief Executive Officer and Principal Financial Officer concluded that, as a result of material weaknesses in our internal control over financial reporting discussed below, our disclosure controls and procedures were not effective as of December 31, 2022.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Notwithstanding the material weakness, management has concluded the consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, the Company's financial position, results of operations and cash flows of the Company in accordance with generally accepted accounting principles in the United States ("GAAP").

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the guidelines established in the *Internal Control—Integrated Framework (2013 framework)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our internal control system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

(i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self-monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

During the year ended December 31, 2022, the Company did not design and maintain effective controls with respect to assessing that the Company's LCT inventory reserve was not inappropriately reversed on a per unit basis. The identified error related to the fourth quarter of 2022 and did not relate to a prior interim or annual periods. Accordingly, management has determined that this is a control deficiency that constitutes a material weakness.

Remediation Plan for the Material Weakness

To remediate the material weakness identified above, management will implement review procures to assess that inventory reserves are not inappropriately reversed.

We believe that these actions will remediate the material weakness. The weakness will not be considered remediated, however, until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control Over Financial Reporting

Except as described above, based on the evaluation of our management as required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, we believe that there were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item regarding our directors is incorporated by reference to the information in our definitive Proxy Statement (the "Proxy Statement") expected to be filed with the Securities and Exchange Commission within 120 days of December 31, 2022, in connection with our 2022 Annual Meeting of Stockholders under the heading "Election of Directors." The information required by this item regarding our Code of Conduct and Ethics in incorporated by reference to the information in the Proxy Statement, expected to be filed within 120 days of December 31, 2022, under the caption "Code of Conduct and Ethics." The information required by this item regarding our Governance Committee and Audit Committee is incorporated by reference to the information in the Proxy Statement, expected to be filed within 120 days of December 31, 2022, under the caption "Corporate Governance."

As of December 31, 2022, our executive officers were as follows:

Name	Position	Age
Andrey Semechkin	Co-Chairman and Chief Executive Officer	63
Russell Kern	Executive Vice President, Chief Scientific Officer, and Principal Financial Officer	37

Andrey Semechkin, Ph.D., Co-Chairman and CEO, has been a Director of the Company since December 2008. Dr. Semechkin has served as our Chief Executive Officer since November 2009, and from December 2008 to November 2009 he served in other senior management positions with the Company. Dr. Semechkin is a specialist in system analysis, strategic planning and corporate management. He is a member of the Russian Academy of Sciences and has been Deputy Director of Institute of System Analysis since 2004. Dr. Semechkin was awarded the Russian Government Award in Science and Technology in 2006 and has written several scientific books. He has over 30 years' experience creating and managing businesses across different industries and scientific sectors.

Russell Kern, Ph.D, Executive Vice President, Chief Scientific Officer, Principal Financial Officer, and CEO of Lifeline Skin Care Inc., became a Director in October 2008. Dr. Kern has served as our Chief Scientific officer since June 2013 and previously served since December 2008 in various scientific and management positions, including as Vice President Research and Development. Dr. Kern was trained in medical genetics, embryology and stem cell biology. He holds a Ph.D. degree in Human Physiology from the Russian Academy of Medical Sciences and has broad expertise in neuroscience, and was part of the team, along with scientists from the NYU Medical School that elucidated the physiological changes that occur in the brains of Parkinson's disease patients. Dr. Kern directs ISCO's R&D programs including stem cell derivation, differentiation and the pre-clinical and clinical evaluation of stem cell derived cells and tissue. He has developed a general method of deriving highly pure populations of neural stem cells and dopaminergic neurons from pluripotent stems cells that is novel, practical and suitable for use in a clinical setting. Dr. Kern is a well-known speaker on stem cell biology, including the use of stem cells for neurology and skin regeneration. He has more than 40 publications in the field of Parkinson's disease and stem cell biology and he is an active member of the American Academy of Neurology and the Society for Neuroscience. Dr. Russell Kern is the son of Dr. Andrey Semechkin, our Co-Chairman and Chief Executive Officer.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the information in the Proxy Statement, expected to be filed within 120 days of December 31, 2022, under the caption "Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to the information in the Proxy Statement, expected to be filed within 120 days of December 31, 2022, under the captions "Stock Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" and "Equity Compensation Plan Information."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to the information in the Proxy Statement, expected to be filed within 120 days of December 31, 2022, under the captions "Related Person Transactions" and "Corporate Governance – Director Independence."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to the information in the Proxy Statement, expected to be filed within 120 days of December 31, 2022, under the caption “Principal Accounting Fees and Services.”

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report.

1. **Financial Statements**

As part of this Annual report on Form 10-K, the consolidated financial statements are listed in the accompanying index to financial statements on page F-1.

2. **Financial Statement Schedules**

All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

3. **Exhibit Index**

The following is a list of exhibits filed as part of this Annual Report on Form 10-K (including those incorporated herein by reference):

Exhibit Number	Exhibit Description
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.4 of the Registrant's Form 10-SB filed on April 4, 2006).
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Preliminary Information Statement on Form 14C filed on December 29, 2006).
3.3	Certificate of Amendment of Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on June 4, 2012).
3.4	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on December 5, 2014).
3.5	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on July 28, 2015).
3.6	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on May 19, 2017).
3.7	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on May 6, 2011).
4.1	Form of Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Form 10-KSB filed on April 9, 2007).
4.2	Certification of Designation of Series B Preferred Stock (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed on May 12, 2008).
4.3	Certification of Designation of Series D Preferred Stock (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on January 5, 2009).
4.4	Certificate of Designation of Series G Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on March 14, 2012).
4.5	Certificate of Preferences, Rights and Limitations of Series I-2 Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 of the Registrant's Form 8-K filed on March 10, 2016).
4.6	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.7 of the Registrant's Form 10-K filed March 30, 2021).
10.1	2010 Equity Participation Plan (incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q filed on August 12, 2020).

Exhibit Number	Exhibit Description
10.2	Amended and Restated Investors Rights Agreement dated March 9, 2012 (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on March 15, 2012).
10.3	Management Rights Letter dated March 9, 2012 (incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed on March 15, 2012).
10.4	Dividend Waiver Agreement dated October 12, 2012 (incorporated by reference to Exhibit 10.29 of the Registrant's Form S-1 filed on October 18, 2012).
10.5	Amended and Restated License Agreement with Advanced Cell Technology, Inc. dated February 7, 2013 (ACT IP) (incorporated by reference to Exhibit 10.1 of the Registrant's Amendment to Form 8-K filed on February 14, 2013)
10.6	Amended and Restated License Agreement with Advanced Cell Technology, Inc. (UMass IP) (incorporated by reference to Exhibit 10.3 of the Registrant's Amendment to Form 8-K filed on February 14, 2013).
10.7	Amended and Restated License Agreement dated February 7, 2013 with Advanced Cell Technology, Inc. (Infigen IP) (incorporated by reference to Exhibit 10.2 of the Registrant's Amendment to Form 8-K filed on February 14, 2013).
10.8	Amendment dated November 13, 2014 to Amended and Restated Investor Rights Agreement dated as of March 9, 2012 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on November 18, 2014).
10.9	Waiver Agreement dated December 31, 2014 with holders of Series G Preferred Stock (incorporated by reference by Exhibit 10.32 of the Registrant's Form 10-K filed March 30, 2015).
10.10	Registration Rights Agreement, dated January 8, 2016, by and between International Stem Cell Corporation and Andrey Semechkin (incorporated by reference to Exhibit 10.3 of the Registrant's Form 8-K filed on January 12, 2016).
10.11	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on March 10, 2016).
10.12	Lease Agreement dated October 26, 2021 (incorporated by reference to Exhibit 10.12 of the Registrant's Form 10-K filed on March 29, 2022)
10.13	Lease Agreement dated November 30, 2021 (incorporated by reference to Exhibit 10.13 of the Registrant's Form 10-K filed on March 29, 2022)
10.14	Co-Tenant Agreement dated December 15, 2021 (incorporated by reference to Exhibit 10.14 of the Registrant's Form 10-K filed on March 29, 2022)
10.15	Form of Note issued on September 15, 2022 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on September 16, 2022).
10.16	Form of Note issued on March 15, 2023 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on March 16, 2023).
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Form 10-K filed on March 30, 2016).
23.1*	Consent of BDO USA, LLP
24.1*	Power of Attorney (included on signature page hereto)
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer
32.1*	Section 1350 Certification of Chief Executive Officer
32.2*	Section 1350 Certification of Chief Financial Officer
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase

Exhibit Number	Exhibit Description
101.DEF*	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
(c) Financial Statement Schedules. See Item 15(a) 2 above.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INTERNATIONAL STEM CELL CORPORATION

By: /s/ ANDREY SEMECHKIN
Name: **Andrey Semechkin**
Title: **Chief Executive Officer**

Dated: March 30, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Andrey Semechkin and Russell Kern, jointly and severally, his attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature:	Capacity:	Date:
/s/ ANDREY SEMECHKIN **Andrey Semechkin**	Co-Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 30, 2023
/s/ RUSSELL KERN **Russell Kern**	Executive Vice President, Chief Scientific Officer, and Director (Principal Financial and Accounting Officer)	March 30, 2023
/s/ DONALD A. WRIGHT **Donald A. Wright**	Co-Chairman of the Board	March 30, 2023
/s/ PAUL V. MAIER **Paul V. Maier**	Director	March 30, 2023

International Stem Cell Corporation and Subsidiaries
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Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
International Stem Cell Corporation
San Diego, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of International Stem Cell Corporation (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations that 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 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory Valuation – Excess and Obsolete Inventory

As described in Note 1 to the consolidated financial statements, the Company reviews the components of its inventory on a periodic basis for excess and obsolescence and adjusts inventory to the lower of cost or net realizable value as necessary. The Lifeline Cell Technology ("LCT") inventory has a long product life cycle, does not have a shelf life when frozen and future demand is uncertain. As such, management's estimate for excess and obsolete LCT inventory uses historical sales data and inventory turnover rates to estimate future demand.

We identified auditing the Company's estimate for excess and obsolete LCT inventory as a critical audit matter. Auditing historical sales data and inventory turnover rates involves especially challenging auditor judgment due to the extent of audit effort required to address these matters.

The primary procedures we performed to address this critical audit matter included:

- Testing the completeness and accuracy of the inventory reserve calculation by (i) re-performing calculations, including agreeing the underlying data to relevant source reports, and (ii) testing the source reports used in the calculation by sampling recent transactions and agreeing sales and use movements to relevant source documents.
- Assessing the inventory turnover assumptions to historical inventory turnover rates and evaluating the impact that would result from a range of alternative assumptions.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2019.

San Diego, California
March 30, 2023

International Stem Cell Corporation and Subsidiaries
Consolidated Balance Sheets
(In thousands, except share and par value data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash	$ 742	$ 171
Accounts receivable, net	747	844
Inventory, net	1,384	1,184
Prepaid expenses and other current assets	90	135
Total current assets	2,963	2,334
Non-current inventory, net	286	372
Property and equipment, net	248	384
Intangible assets, net	878	949
Right-of-use assets	727	868
Deposits and other assets	33	39
Total assets	$ 5,135	$ 4,946
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 322	$ 508
Accrued liabilities	508	404
Operating lease liabilities, current	230	179
Advances	250	250
Related party note payable	3,325	2,943
Total current liabilities	4,635	4,284
Operating lease liabilities, net of current portion	720	950
Total liabilities	5,355	5,234
Commitments and contingencies (Note 11)		
Series D redeemable convertible preferred stock, $0.001 par value; 50 shares authorized; 43 shares issued and outstanding; liquidation preference of $4,300 at December 31, 2022 and 2021	4,300	4,300
Stockholders' Deficit:		
Non-redeemable convertible preferred stock, $0.001 par value; 10,004,310 and 10,004,310 shares authorized, 5,254,310 and 5,254,310 shares issued and outstanding, liquidation preference of $9,781 and $9,766 at December 31, 2022 and December 31, 2021, respectively	5	5
Common stock, $0.001 par value; 120,000,000 shares authorized; 8,004,389 and 8,004,389 shares issued and outstanding at December 30, 2022 and 2021, respectively	8	8
Additional paid-in capital	105,812	105,413
Accumulated deficit	(110,345)	(110,014)
Total stockholders' deficit	(4,520)	(4,588)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 5,135	$ 4,946

See accompanying notes to consolidated financial statements.

International Stem Cell Corporation and Subsidiaries
Consolidated Statements of Operations
(In thousands, except per share data)

	Years Ended December 31,	
	2022	**2021**
Product sales	$ 8,180	$ 7,176
Operating expenses:		
Cost of sales	3,269	2,935
General and administrative	3,357	4,084
Selling and marketing	1,245	1,383
Research and development	492	695
Total operating expenses	8,363	9,097
Loss from operations	(183)	(1,921)
Other income (expense):		
Gain on forgiveness of debt	—	1,137
Interest expense	(135)	(128)
Other income, net	(13)	13
Total other income (expense), net	(148)	1,022
Net loss	$ (331)	$ (899)
Net loss per common share, basic and diluted	$ (0.04)	$ (0.11)
Weighted-average common shares used to compute net loss per share, basic and diluted	8,004	7,833

See accompanying notes to consolidated financial statements.

International Stem Cell Corporation and Subsidiaries
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficit
(In thousands)

	Series D Redeemable Convertible Preferred Stock		Non-redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	—	$ 4,300	5,255	$ 5	7,539	$ 8	$ 104,769	$ (109,115)	$ (4,333)
Conversion of Series I-1 preferred stock	—	—	(1)	—	465	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	644	—	644
Net loss	—	—	—	—	—	—	—	(899)	(899)
Balance at December 31, 2021	—	4,300	5,254	5	8,004	8	105,413	(110,014)	(4,588)
Stock-based compensation	—	—	—	—	—	—	399	—	399
Net loss	—	—	—	—	—	—	—	(331)	(331)
Balance at December 31, 2022	—	$ 4,300	5,254	$ 5	8,004	$ 8	$ 105,812	$ (110,345)	$ (4,520)

See accompanying notes to consolidated financial statements.

International Stem Cell Corporation and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (331)	$ (899)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	218	262
Non-cash operating lease expense	141	289
Impairment of intangible assets	—	250
Stock-based compensation	399	644
Gain on forgiveness of debt	—	(1,137)
Interest expense on related party note payable	132	118
Other non-cash operating activity	—	(1)
Changes in operating assets and liabilities:		
Accounts receivable	97	(441)
Inventory, net	(114)	(268)
Prepaid expenses and other current assets	45	39
Deposits and other assets	6	24
Accounts payable	(186)	148
Accrued liabilities	104	17
Operating lease liabilities	(179)	(342)
Net cash provided by (used in) operating activities	332	(1,297)
Cash flows from investing activities		
Purchases of property and equipment	(1)	(23)
Payments for patent licenses	(10)	(22)
Net cash used in investing activities	(11)	(45)
Cash flows from financing activities		
Proceeds from Paycheck Protection Program loans	—	474
Proceeds from note payable from a related party	250	350
Net cash provided by financing activities	250	824
Net increase (decrease) in cash	571	(518)
Cash, beginning of period	171	689
Cash, end of period	$ 742	$ 171
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3	$ 5
Supplemental disclosure of non-cash investing and financing activities:		
Gain on forgiveness of debt	$ —	$ 1,137
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 479
Right-of-use assets reduction related to operating lease termination	$ —	$ 196
Patent license costs included in accrued liabilities	$ 2	$ 6

See accompanying notes to consolidated financial statements.

1. Description of Business and Summary of Significant Accounting Policies

Description of Business

International Stem Cell Corporation (the "Company") was organized in Delaware in June 2005 and is publicly traded on the OTCQX under the symbol "ISCO". The Company is primarily a research and development company, for the therapeutic market, which has focused on advancing potential clinical applications of human parthenogenetic stem cells ("hpSCs") for the treatment of various diseases of the central nervous system and liver diseases. The Company has the following wholly-owned subsidiaries:

- Lifeline Cell Technology, LLC ("LCT") – for the biomedical market, develops, manufactures and commercializes primary human cell research products including over 200 human cell culture products, including frozen human "primary" cells and the reagents (called "media") needed to grow, maintain and differentiate the cells;
- Lifeline Skin Care, Inc. ("LSC") – for the anti-aging market, develops, manufactures and markets a category of anti-aging skin care products based on the Company's proprietary parthenogenetic stem cell technology and small molecule technology;
- Cyto Therapeutics Pty. Ltd. ("Cyto Therapeutics") – performs research and development ("R&D") for the therapeutic market and is currently conducting clinical trials in Australia for the use of ISC-hpNSC® in the treatment of Parkinson's disease.

COVID-19 Pandemic

The COVID-19 pandemic has caused business disruptions in the Company's business globally. The Company's consolidated financial statements reflect judgments and estimates that could change in the future as a result of the COVID-19 pandemic. As of the date of this report, the Company expects the COVID-19 pandemic will continue to impact its business, financial condition, liquidity, and future results of operations. The full extent to which the COVID-19 pandemic will impact the Company remains uncertain and ultimately will be dictated by the length and severity of the pandemic, as well as the economic recovery and federal, state and local government actions taken in response. The Company is continuing to monitor the impact of COVID-19 on the Company's operations, workforce, suppliers, customers and industry.

Liquidity and Going Concern

The Company had an accumulated deficit of approximately $110.3 million as of December 31, 2022 and has historically incurred net losses and negative operating cash flows. The Company has had no revenue from its principal operations in therapeutic and clinical product development through research and development efforts. Unless the Company obtains additional financing, the Company does not have sufficient cash on hand to sustain operations for at least through one year from the issuance date of these consolidated financial statements.

There can be no assurance that the Company will be successful in maintaining normal operating cash flow or obtaining additional funding. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. For the foreseeable future, the Company's ability to continue its operations is dependent upon its ability to obtain additional financing. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the outcome of the uncertainty concerning the Company's ability to continue as a going concern.

The Company continues to evaluate various financing sources and options to raise working capital to help fund current research and development programs and operations. The Company will need to obtain significant additional funding from sources, including debt and/or equity financing, license arrangements, grants and/or collaborative research arrangements to sustain its operations and develop products.

The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying the estimates for capital needs in 2022 and beyond;
- the extent that revenues from sales of LSC and LCT products cover the related costs and provide capital;
- scientific progress in research and development programs;

- the magnitude and scope of the Company's research and development programs and its ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- the progress with preclinical development and clinical trials;
- the extent to which third party interest in Company's research and commercial products can be realized through effective partnerships;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- the number and type of product candidates that the Company decides to pursue; and
- the development of major public health concerns, including COVID-19 or other pandemics arising globally, and the current and future impact that such concerns may have on the Company's operations and funding requirements.

Additional debt financing may be expensive and require the Company to pledge all or a substantial portion of its assets. If additional funds are obtained through arrangements with collaborative partners, these arrangements may require the Company to relinquish rights to some of its technologies, product candidates or products that the Company would otherwise seek to develop and commercialize on its own. Furthermore, if sufficient capital is not available, the Company may be required to delay, reduce the scope of or eliminate one or more of its product initiatives. The Company's failure to raise capital or enter into applicable arrangements when needed would have a negative impact on its financial condition.

Principles of Consolidation and Foreign Currency Transactions

The consolidated financial statements include the accounts of International Stem Cell Corporation and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The functional currency of the Company and its subsidiaries, including its wholly-owned Australian subsidiary, Cyto Therapeutics, is the U.S. dollar. Assets and liabilities that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the respective balance sheet dates. Revenue and expenses are translated at the average rate in effect on the date of the transaction. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in general and administrative expense in the accompanying consolidated statements of operations and were not material for the periods presented.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the accompanying consolidated financial statements. Significant estimates include patent life (remaining legal life versus remaining useful life), allowance for excess and obsolete inventories, and stock option awards using the Black-Scholes option valuation model. Actual results could differ from those estimates.

Segments

The Company's chief operating decision-maker reviews financial information presented on a consolidated basis, accompanied by disaggregated information by each reportable company's statement of operations. The Company operates the business on the basis of three reporting segments, the parent company and two business units: ISCO – therapeutic market; LCT – biomedical market, and; LSC – anti-aging market.

Inventory

Inventory is accounted for using the average cost and first-in, first-out ("FIFO") methods for LCT cell culture media and reagents, average cost and specific identification methods for LSC products, and specific identification method for other LCT products. Inventory balances are stated at the lower of cost or net realizable value. Laboratory supplies used in the research and development process are expensed as consumed. LCT's inventory has a long product life cycle, does not have a shelf life when frozen, and future demand is uncertain. As such, at each reporting period, the Company estimates its reserve for allowance for excess and obsolete inventory using historical sales data and inventory turnover rates. The establishment of a reserve for excess and obsolete inventory establishes a new cost basis in the inventory. If the Company is able to sell such inventory, any related reserves would be reduced in the period of sale. The value of the inventory that is not expected to be sold within one year of the current reporting period is classified as non-current inventory on the accompanying consolidated balance sheets.

Accounts Receivable

Trade accounts receivable are recorded at the net invoice value and are not interest bearing. Accounts receivable primarily consist of trade accounts receivable from the sales of LCT's products, timing of cash receipts by the Company related to LSC credit card sales to customers, as well as LSC trade receivable amounts related to spa and distributor sales. The Company considers receivables past due based on the contractual payment terms. The Company reviews its exposure to accounts receivable and reserves specific amounts if collectability is no longer reasonably assured. The Company recorded an allowance for doubtful accounts as of both December 31, 2022 and 2021 of $3 thousand.

Advances

In June 2008, the Company entered into an agreement with BioTime, Inc. ("BioTime"), whereby BioTime paid an advance of $250 thousand to LCT to produce, make, and distribute certain products. The $250 thousand advance will be paid down with the first $250 thousand of net revenues that otherwise would be allocated to LCT under the agreement. As of December 31, 2022, no revenues were realized and attributable to BioTime under this agreement.

Property and Equipment

Property and equipment are stated at cost. The provision for depreciation and amortization is computed using the straight-line method over the estimated useful lives of the assets, which are generally three to five years. Leasehold improvements are capitalized and amortized over the shorter of the remaining term of the lease or the estimated life of the assets.

Intangible Assets

Intangible assets consist of acquired patent licenses and capitalized legal fees related to the acquisition, filing, maintenance, and defense of patents and trademarks. Amortization begins once the patent is issued by the appropriate authoritative bodies. In the period in which a patent application is rejected or efforts to pursue the patent are abandoned, all the related accumulated costs are expensed. Patents and other intangible assets are amortized on a straight-line basis over the shorter of the useful life of the underlying patent, which is generally 15 years, or when the intangible asset is rejected or abandoned. All amortization expense and impairment charges related to intangible assets are included in general and administrative expense in the accompanying consolidated statements of operations.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use assets, operating lease obligations, current, and operating lease obligations, net of current portion, on the Company's consolidated balance sheets.

Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of future minimum lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses a discount rate based on its estimated incremental borrowing rate to determine the right-of-use asset and operating lease liabilities to be recognized. The Company determines its incremental borrowing rate based on the terms and lease payments of its operating leases and what it would normally pay to borrow, on a collateralized basis, over similar terms for an amount equal to the lease payments. Operating lease expense is recognized on a straight-line basis over the lease term. In addition, the Company does not separate lease components from non-lease components.

Long-Lived Asset Impairment

The Company reviews long-lived assets for impairment when events or changes in circumstances ("triggering event") indicate that the carrying value of an asset or group of assets may not be recovered. If a triggering event is determined to have occurred, the carrying value of an asset or group of assets is compared to the future undiscounted cash flows expected to be generated by the asset or group of assets. If the carrying value exceeds the undiscounted cash flows of the asset or group of assets, then impairment exists. Fair value is generally determined using the asset's expected future discounted cash flows or market value, if readily determinable.

Revenue Recognition

The Company's revenue consists primarily of sales of products from its two revenue-generating operating segments, the biomedical products market and anti-aging products market. The biomedical market segment markets and sells primary human cell research products with two product categories, cells and media, which are sold both domestically within the United States and internationally. The anti-aging market segment markets and sells a line of skincare products sold through two sales channels: ecommerce and professional. The ecommerce channel sells direct to customers through online orders, while professional sales are to spas, salons and other skincare providers.

The following table presents the Company’s revenue disaggregated by segment, product and geography (in thousands):

Biomedical market:

	Year Ended December 31, 2022			
	Domestic	International	Total Revenues	% of Total Revenues
Biomedical products				
Cells	$ 1,442	$ 499	$ 1,941	27%
Media	4,572	618	5,190	73%
Total	$ 6,014	$ 1,117	$ 7,131	100%

	Year Ended December 31, 2021			
	Domestic	International	Total Revenues	% of Total Revenues
Biomedical products				
Cells	$ 801	$ 546	$ 1,347	23%
Media	3,935	654	4,589	77%
Total	$ 4,736	$ 1,200	$ 5,936	100%

Anti-aging market:

	Year Ended December 31,			
	2022		2021	
	Total Revenues	% of Total Revenues	Total Revenues	% of Total Revenues
Skin care sales channels				
Ecommerce	$ 1,049	100%	$ 913	74%
Professional	—	0%	327	26%
Total	$ 1,049	100%	$ 1,240	100%

Contract terms for unit price, quantity, shipping and payment are governed by sales agreements, invoices or online order forms which the Company considers to be a customer's contract in all cases. The unit price is considered the observable stand-alone selling price for the arrangements. Any promotional or volume sales discounts are applied evenly to the units sold for purposes of calculating standalone selling price.

The Company recognizes revenue when its customer obtains control of the promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Product sales generally consist of a single performance obligation that the Company satisfies at a point in time (i.e., upon delivery of the product).

For LSC products, online sales and professional sales are pre-paid through credit card charges. The Company sometimes extends 15, 30, or 60-day credit terms to select professional accounts. For biomedical products, standard payment terms for its customers are generally 30 days after the Company satisfies the performance obligation(s). For LSC, the Company honors a 30-day return policy, but historical returns have been minimal and as such, no estimated allowance for sales returns was recorded as of December 31, 2022 and 2021.

The Company elects to account for shipping and handling costs, recognized as cost of sales, as activities to fulfill the promise to transfer the goods to a customer. As a result, no consideration is allocated to shipping and handling costs. Rather, the Company accrues the cost of shipping and handling upon shipment of the product, and all contract revenue (i.e., the transaction price) is recognized at the same time.

Variable Consideration

The Company records revenue from customers in an amount that reflects the transaction price it expects to be entitled to after transferring control of those goods or services. From time to time, the Company offers sales promotions on its skincare products such as discounts and free product offers. Variable consideration is estimated at contract inception only to the extent that it is probable that a significant reversal of revenue will not occur and updated at the end of each reporting period as additional information becomes available.

Contract Balances

The Company records a receivable when it has an unconditional right to receive consideration after a performance obligation is satisfied. As of December 31, 2022 and 2021, accounts receivable, net, totaled $747 thousand and $844 thousand, respectively. For the years ended December 31, 2022 and 2021, the Company did not incur material write-offs of its receivables.

Practical Expedients

The Company has elected the practical expedient to not determine whether contacts with customers contain significant financing components. The Company pays commissions on certain sales for its biomedical and anti-aging product markets once the customer payment has been received, which are accrued at the time of the sale. The Company generally expenses sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses. In addition, the Company has elected to exclude sales taxes consideration from the determined transaction price.

Allowance for Sales Returns

The Company's anti-aging products have a 30-day product return guarantee; however, the Company determined that there is a low probability that returns will occur based on its historical rate of returns. Historically, returns have not been significant and are recognized as a reduction to current period revenue. As of December 31, 2022 and 2021, the Company recorded no allowance for sales returns.

Cost of Sales

Cost of sales consists primarily of salaries and benefits associated with employee efforts expended directly on the production of the Company's products, as well as related direct materials, general laboratory supplies and an allocation of overhead. Certain of the Company's licensed technology agreements may require the Company to pay royalties based on the future sale of the Company's products. Such royalties will be recorded as a component of cost of sales when incurred. Additionally, milestone payments or the amortization of license fees related to developed technologies used in the Company's products will be included as a component of cost of sales to the extent that such payments become due in the future.

Advertising

Adverting costs are expensed as incurred and included as a component of selling and marketing costs on the accompanying consolidated statements of operations. For the years ended December 31, 2022 and 2021, advertising costs were approximately $220 thousand and $165 thousand, respectively.

Research and Development Costs

Research and development costs, which are expensed as incurred, primarily consist of salaries and benefits associated with research and development personnel, overhead and occupancy costs, contract services costs and amortization of license costs for technology used in research and development with alternative future uses. Research and development costs are net of research and development tax credits earned by Cyto Therapeutics, the Company's wholly-owned subsidiary based in Australia. The Australian Taxation Office provides for a refundable tax credit in the form of a cash refund equal to 43.5% of qualified research and development expenditures, not to exceed established thresholds. Since the refund does not depend on an entity's tax status or tax position, it is outside of the scope of accounting for income taxes and is treated as grant income. The Company recognized reductions to research and development costs of $80 thousand and $113 thousand for the years ended December 31, 2022 and 2021, respectively, attributable to the refundable tax credit.

Stock-Based Compensation

The cost of a stock-based award is measured at the grant date based on the estimated fair value of the award, and is recognized as expense on a straight-line basis, net of forfeitures which are recognized as incurred, over the requisite service period of the award. The fair value of stock options is estimated using the Black-Scholes option valuation model, which requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option. The Company uses the Simplified Method to estimate the term of options granted. The fair value of restricted stock awards is based on the market value of the Company's common stock on the date of grant.

Fair Value of Financial Instruments

The Company believes that the carrying value of its cash, accounts receivables, accounts payable, accrued liabilities, Paycheck Protection Program loan and related party note payable as of December 31, 2022 and 2021 approximate their fair values because of the short-term nature of those instruments.

Fair Value Measurements

Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

As of December 31, 2022 and 2021, the Company had no financial assets or liabilities measured at fair value on a recurring basis.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. When the Company prepares its consolidated financial statements, it estimates income taxes based on the various jurisdictions and countries where it conducts business. This requires the Company to estimate current tax exposure and to assess temporary differences that result from differing treatments of certain items for tax and accounting purposes. Deferred income taxes are recognized based on the differences between the financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The Company then assesses the likelihood that deferred tax assets will be realized. Valuation allowances are established, when it is more likely than not the deferred tax assets will not be realized. When the Company establishes a valuation allowance or increases this allowance in an accounting period, it records a corresponding tax expense in the consolidated statements of operations. The Company includes interest and penalties related to income taxes within its provision for income taxes.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Potentially dilutive common stock equivalents are comprised of stock options, common stock warrants and convertible preferred stock. For the years ended December 31, 2022 and 2021, there was no difference in the number of shares used to calculate basic and diluted shares outstanding as the Company was in a net loss position.

For the years ended December 31, 2022 and 2021, the following common stock options and convertible preferred stock were not included in the diluted net loss per share calculation because the effect would be anti-dilutive.

	Years Ended December 31,	
	2022	2021
Options outstanding	6,460,654	4,885,531
Redeemable convertible preferred stock	2,457,143	2,457,143
Non-redeemable convertible preferred stock	3,619,379	3,385,075
Total	12,537,176	10,727,749

Comprehensive Loss

Comprehensive loss includes all changes in stockholders' deficit except those resulting from investments by owners and distributions to owners. The Company did not have any items of comprehensive loss other than net loss from operations for the years ended December 31, 2022 and 2021.

Customer Concentrations

For the years ended December 31, 2022 and 2021, one major customer accounted for approximately 45% and 39%, respectively, of product sales. As of December 31, 2022 and 2021, the customer accounted for 73% and 62%, respectively, of accounts receivable, net. No other single customer accounted for more than 10% of product sales or accounts receivable, net, for the years ended.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments— Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The ASU introduced a new credit loss methodology, the Current Expected Credit Losses ("CECL") methodology, which requires earlier recognition of credit losses, while also providing additional transparency about credit risk. The CECL methodology utilizes a lifetime "expected credit loss" measurement objective for the recognition of credit losses for loans, held-to maturity debt securities, trade receivables and other receivables measured at amortized cost at the time the financial asset is originated or acquired. Subsequent to the issuance of ASU 2016-13, the FASB issued several additional ASUs to clarify implementation guidance, provide narrow-scope improvements and provide additional disclosure guidance. In November 2019, the FASB issued an amendment making this ASU effective for fiscal years beginning after December 15, 2022 for smaller reporting companies. The new standard will be effective for the Company on January 1, 2023 or at such earlier time where it is no longer a smaller reporting company. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible debt instruments by reducing the number of accounting models and the number of embedded features that could be recognized separately from the host contract. Consequently, more convertible debt instruments will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. ASU 2020-06 also requires use of the if-converted method in the diluted earnings per share calculation for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years for smaller reporting companies, with early adoption permitted. The new standard will be effective for the Company on January 1, 2024 or at such earlier time where it is no longer a smaller reporting company. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In May 2021, the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force) ("ASU 2021-04"), which clarifies and reduces the diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. ASU 2021-04 is effective for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years, with early adoption permitted. The Company adopted ASU 2021-04 on January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In November 2021, the FASB issued ASU No. 2021-10, Government Assistance (Topic 832): Disclosure by Business Entities about Government Assistance ("ASU 2021-10"), which improves the transparency of government assistance received by certain business entities by requiring the disclosure of (1) the types of government assistance received; (2) the accounting for such assistance, and (3) the effect of the assistance on the business entity's financial statements. ASU 2021-10 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted. The Company adopted ASU 2021-10 on January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

2. Inventory

The components of inventories are as follows (in thousands):

	As of December 31,	
	2022	**2021**
Raw materials	$ 615	$ 592
Work in process	498	507
Finished goods	1,194	983
	2,307	2,082
Less: allowance for inventory excess and obsolescence	(637)	(526)
Total current and non-current inventory, net	$ 1,670	$ 1,556
Inventory, net	$ 1,384	$ 1,184
Non-current inventory	286	372
Total current and non-current inventory, net	$ 1,670	$ 1,556

As of December 31, 2022 and 2021, the allowance for inventory excess and obsolescence consists of the following activity:

	As of December 31,	
	2022	**2021**
Balance, beginning of year	$ 526	$ 611
Provision for inventory reserve	218	89
Write-offs	(107)	(174)
Balance, end of year	$ 637	$ 526

The write-offs include scrapped inventory and reserved inventory sold.

3. Property and Equipment

Property and equipment consist of the following (in thousands):

	As of December 31,	
	2022	**2021**
Machinery and equipment	$ 1,603	$ 1,610
Computer equipment and software	217	243
Office equipment	89	104
Leasehold improvements	558	549
Construction in progress	—	1
	2,467	2,507
Less: accumulated depreciation and amortization	(2,219)	(2,123)
Property and equipment, net	$ 248	$ 384

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was $137 thousand and $171 thousand. During the year ended December 31, 2022 and 2021, the Company disposed of approximately $41 thousand and $1.0 million, respectively, in property and equipment that had been depreciated and amortized in full and had no impact on the accompanying consolidated statements of operations.

4. Intangible Assets

Intangible Assets consists of the following (in thousands):

	As of December 31,	
	2022	2021
Patents	$ 1,286	$ 1,277
Less: accumulated amortization	(483)	(403)
	803	874
Indefinite life logos and trademarks	75	75
Intangible assets, net	$ 878	$ 949

Amortization expense for the years ended December 31, 2022 and 2021 was $81 thousand and $91 thousand, respectively. During the years ended December 31, 2022 and 2021, the Company fully impaired and abandoned certain patents that the Company concluded it would no longer defend or incur additional costs to maintain. Impairment charges for the years ended December 31, 2022 and 2021 was zero and $250 thousand, respectively. The impairment charges, measured on a cost basis, related to abandonment of certain internally generated and licensed intellectual property in the Company's therapeutic market segment that was determined by management to have no future economic benefit.

The timing of approval of pending patent applications is uncertain and, therefore, are included in the thereafter period below until issued. Pending patents as of December 31, 2022 and 2021 was $57 thousand and $108 thousand. As of December 31, 2022, future amortization expense related to intangible assets subject to amortization is expected to be as follows (in thousands):

Years ending December 31,	
2023	$ 82
2024	82
2025	80
2026	76
2027	73
Thereafter	410
Total	$ 803

5. Paycheck Protection Program Loan

In May 2020, the Company received a loan of $654 thousand from its lender under the Paycheck Protection Program ("First Draw Loan"). The Paycheck Protection Program ("PPP"), as amended, was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration ("SBA"). The First Draw Loan has a two-year term and bears interest at a rate of 1% per annum. Principal and interest payments are deferred for ten months following the loan forgiveness period, which is defined as the 24-week period following the loan origination date, at which time the loan balance is payable in monthly installments unless the Company applies for, and receives, forgiveness in accordance with the CARES Act and the terms of the loan executed by the Company and its lender. As required by the CARES Act, the Company used the proceeds from the PPP Loan for payroll, healthcare benefits, rent and other qualifying expenses.

On March 2021, the Company received a loan of approximately $474 thousand from its lender under the PPP ("Second Draw Loan"). The Second Draw Loan has a five-year term and bears interest at a rate of 1% per annum. Principal and interest payments are deferred until August 2022, at which time the loan balance is payable in monthly installments unless the Company applies for, and receives, forgiveness in accordance with the CARES Act and the terms of the loan executed by the Company and its lender. The Second Draw Loan was used to help fund payroll, healthcare benefits, rent, worker protection costs related to COVID-19, certain supplier costs and other qualifying expenses.

In June 2021, the Company applied for and received forgiveness of its First Draw Loan in whole from the SBA and its lender. The amount of forgiveness totaled $661 thousand which consisted of unpaid principal and accrued interest.

In August 2021, the Company applied for and received forgiveness of its Second Draw Loan in whole from the SBA and its lender. The amount of forgiveness totaled $476 thousand, which consisted of unpaid principal and accrued interest. The Company recorded the forgiveness of the First Draw Loan and Second Draw Loan as a gain in other income (expense), net, on the accompanying consolidated statements of operations.

6. Convertible Preferred Stock

As of December 31, 2022 and 2021, the Company was authorized to issue 20,000,000 shares of preferred stock, $0.001 par value per share. The Company has designated 50 shares of Series D redeemable convertible preferred stock and as of both December 31, 2022 and 2021, a total of 10,004,310 of Series B, Series G and Series I-2 non-redeemable convertible preferred stock. The Company's Series B, Series G and Series I-2 non-redeemable convertible preferred stock has been classified as equity on the accompanying consolidated balance sheets.

During the year ended December 31, 2021, holders of all remaining shares of the Company's Series I-1 preferred stock converted 814 shares of issued and outstanding Series I-1 preferred stock into 465,300 shares of common stock of the Company. In June 2021, the Company filed a Certificate of Elimination for the Series I-1 convertible preferred stock with the Secretary of State of the State of Delaware. The Certificate of Elimination amended the provisions of the Certificate of Incorporation of the Company to eliminate the powers, designations, preferences, privileges and other rights of the Series I-1 preferred stock.

The authorized, issued and outstanding shares of non-redeemable convertible preferred stock as of December 31, 2022 consist of the following:

	Shares Authorized	Shares Issued and Outstanding	Liquidation Preference	Carrying Value
			(in thousands)	
Series B	5,000,000	250,000	$ 471	$ —
Series G	5,000,000	5,000,000	5,000	5
Series I-2	4,310	4,310	4,310	—
Total	10,004,310	5,254,310	$ 9,781	$ 5

The authorized, issued and outstanding shares of non-redeemable convertible preferred stock as of December 31, 2021 consist of the following:

	Shares Authorized	Shares Issued and Outstanding	Liquidation Preference	Carrying Value
			(in thousands)	
Series B	5,000,000	250,000	$ 456	$ —
Series G	5,000,000	5,000,000	5,000	5
Series I-2	4,310	4,310	4,310	—
Total	10,004,310	5,254,310	$ 9,766	$ 5

The significant rights and preferences of the Company's convertible preferred stock are as follows:

Dividends

Holders of the Company's convertible preferred stock are entitled to participating dividends with common stock when and if declared by the Company's board of directors. No dividends have been declared as of December 31, 2022.

Liquidation

Liquidation preference among classes of preferred shares is first with Series D with priority, followed by Series G, Series B and Series I-2 on the proceeds from any sale or liquidation of the Company in an amount equal to the purchase price of shares plus (in the case of the Series B) an amount equal to 1% of the Series B original issue price for every two calendar months from February 1, 2008. Following the satisfaction of the liquidation preferences, all shares of common stock participate in any remaining distribution.

Conversion

The conversion rates of the Series B, Series D, and Series I-2 are subject to anti-dilution adjustments whereby, subject to specified exceptions, if the Company issues equity securities or securities convertible into equity at a price below the applicable conversion price of the Series B, Series D, and Series I-2, the conversion price of each such series shall be adjusted downward to equal the price of the new securities. The conversion rate of the Series G is subject to a weighted-average adjustment in the event of the issuance of additional shares of common stock below the conversion price, subject to specified exceptions. Upon the occurrence of an event that triggers a down round protection, the Company will recognize the value of the down round as a beneficial conversion discount. The conversion price of the Series I-2 are also subject to certain resets as set forth in the Certificates of Designation, including a reverse stock split.

The following table summarizes the number of shares of common stock into which each share of convertible preferred stock can be converted as of December 31, 2022:

	Initial Conversion Price	Current Conversion Price	Conversion Ratio to Common Stock
Series B	$ 75.00	$ 0.39	2.56
Series D	$ 37.50	$ 1.75	57,142.86
Series G	$ 60.00	$ 9.69	0.10
Series I-2	$ 1.75	$ 1.75	571.43

Voting

The holders of Series B, Series D, and Series G are entitled to one vote for each share of common stock into which it would convert. As long as there are at least 10 shares of Series D outstanding, the holders of Series D have (i) the right to nominate and elect two members of the Board of Directors, and (ii) the right to approve specified significant transactions affecting the Company. As long as there are at least 1,000,000 shares of Series G outstanding, the holders of Series G have the initial right to propose the nomination of two members of the Board, at least one of which such nominees shall be subject to the approval of the Company's independent directors, for election by the stockholders at the Company's next annual meeting of stockholders, or, elected by the full board of directors to fill a vacancy, as the case may be. At least one of the two directors nominated by holders of the Series G shall be independent. The holder of Series I-2 has no voting rights, except as required by law.

Series D Preferred Stock Redemption

The Company's Series D redeemable convertible preferred stock contains a contingent redemption feature that is not solely within the Company's control. Accordingly, the Series D redeemable convertible preferred stock is classified in temporary equity (outside of permanent equity) on the accompanying consolidated balance sheets.

7. Stockholders' Deficit

Common Stock

As of December 31, 2022, the Company was authorized to issue 120,000,000 shares of common stock, $0.001 par value per share.

Common Stock Warrants

In March 2016, the Company issued warrants exercisable for 11,159,995 shares of common stock at an exercise price of $1.75 per share to certain placement agents and existing investors in connection with financing arrangements. The common stock warrants issued in March 2016 expired unexercised on March 15, 2021.

Common Stock Reserved for Future Issuance

As of December 31, 2022, the Company had shares of common stock reserved for future issuance as follows:

Options outstanding	6,858,492
Common stock available for issuance under the 2010 Plan	2,674,566
Redeemable convertible preferred stock	2,457,143
Non-redeemable convertible preferred stock	3,619,379
Total	15,609,580

8. Equity Incentive Plans

The Company adopted the 2006 Equity Participation Plan (as amended the "2006 Plan"), which provides for the grant of stock options, restricted stock and other equity-based awards. Awards for up to 100,000 shares may be granted to employees, directors and consultants under this Plan. The options granted under the 2006 Plan may be either qualified or non-qualified options. Options may be granted with different vesting terms and expire no later than 10 years from the date of grant. The 2006 Plan expired on November 16, 2016. Options and other equity-based awards granted prior to the expiration of the 2006 Plan will continue in effect until the option or award is exercised or terminates pursuant to its terms. No new awards may be granted under the 2006 Plan following its expiration.

In April 2010, the Company adopted the 2010 Equity Participation Plan, as amended (the "2010 Plan"), which provides for the grant of stock options, restricted stock and other equity-based awards. Awards for up to 9,700,000 shares may be granted to employees, directors and consultants under the 2010 Plan. The options granted under the 2010 Plan may be either qualified or non-qualified options. Options may be granted with different vesting terms and expire no later than 10 years from the date of grant. In June 2020, the Company amended the 2010 Plan to extend the term of the 2010 Plan until March 2030. No other material provisions were amended.

Stock Options

Transactions involving stock options issued to employees, directors and consultants under the 2006 Plan and the 2010 Plan are summarized below. Options issued have a maximum life of 10 years and no options were exercised in the years ended December 31, 2022 and 2021. The following tables summarize the changes in options outstanding and the related exercise prices for the Company's common stock options issued:

	Number of Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	5,373,203	$ 1.42		
Granted	2,338,528	$ 0.45		
Forfeited or cancelled	(846,468)	$ 1.58		
Expired	(6,771)	$ 51.98		
Outstanding at December 31, 2022	6,858,492	$ 1.02	7.37	$ —
Vested and expected to vest at December 31, 2022	6,557,597	$ 1.05	7.29	$ —
Exercisable at December 31, 2022	4,561,172	$ 1.31	6.49	$ —

Stock-Based Compensation

The weighted-average assumptions used in the Black-Scholes option valuation model to determine the fair value of stock options grants for the years ended December 31, 2022 and 2021 were as follows:

	Years Ended December 31,	
	2022	**2021**
Risk-free interest rate	2.86%	0.89%
Expected stock price volatility	90.29%	83.90%
Expected dividend yield	0%	0%
Expected life of options (in years)	5.71	5.67
Weighted-average fair value of awards granted	$0.33	$0.27

Total stock-based compensation expense for the years ended December 31, 2022 and 2021 was comprised of the following (in thousands):

	Years Ended December 31,	
	2022	**2021**
Cost of sales	$ 5	$ 21
Research and development	42	46
Selling and marketing	7	32
General and administrative	345	545
Total	$ 399	$ 644

Unrecognized compensation expense related to stock options as of December 31, 2022 was $609 thousand, which is expected to be recognized over a weighted-average period of approximately 1.99 years.

9. Related Party Transactions

Related party lease agreements

In 2011, the Company executed an operating lease for its corporate offices with S Real Estate Holdings LLC. S Real Estate Holdings LLC is owned by Dr. Russell Kern, the Company's Executive Vice President and Chief Scientific Officer. The lease agreement was approved by the Board of Directors and was reviewed by the Company's outside legal counsel. The terms of the lease were reviewed by a committee of independent directors, and the Company believes that, in total, those terms are at least as favorable to the Company as could be obtained for comparable facilities from an unaffiliated party. In March 2017, the Company signed an amendment to the lease agreement to extend the term of the lease until 2020 and include annual adjustments to the monthly lease payments. In March 2020, the Company entered into an amendment to the lease agreement. The amendment extended the term of the lease for three years (until February 28, 2023) and provided for a 2% increase in monthly rent. For the years ended December 31, 2022 and 2021, the Company recorded zero and $157 thousand, respectively, in operating lease cost that was related to the facility lease arrangement with related parties.

On October 26, 2021, the Company and S Real Estate Holdings, LLC jointly entered into a lease agreement with Rehco Holdings, LLC (the "Lease"), for the purpose of establishing a new corporate headquarters, including corporate, R&D, and manufacturing operations. The Lease was personally guaranteed by the Dr. Russell Kern, the Company's Executive Vice President and Chief Scientific Officer.

On December 15, 2021, the Company and S Real Estate Holdings LLC entered into a co-tenant agreement, whereby the Company and S Real Estate Holdings LLC agreed to allocate portions of the base rent and variable charges, including insurance, maintenance costs, taxes and operating expenses, between the parties. During the term of the Lease, the Company will be liable for 40% of all costs incurred in connection with the Lease, while S Real Estate Holdings LLC will be liable for the remaining 60%.

On December 27, 2021, the Company and S Real Estate Holdings LLC mutually agreed to terminate the operating lease for its corporate offices for the purpose of consolidating its operations to its new corporate headquarters (refer to Note 11 – Commitments and Contingencies, for further information). Pursuant to the termination agreement, the Company surrendered the leased premises effective

December 31, 2021, and no termination penalties were incurred by the Company. In addition, S Real Estate Holdings LLC released the Company of its obligation to pay base rent for the month of December 2021.

Related party note payable

Between March 6, 2018 and December 17, 2019, to obtain funding for working capital purposes, the Company borrowed a total of $2.3 million from Dr. Semechkin and issued an unsecured, non-convertible promissory note in the principal amount of $2.3 million (the "Note") to Dr. Semechkin. The outstanding principal amount under the Note accrued interest at a rate of 4.5% per annum. The outstanding principal and accrued interest on the Note was due and payable on January 15, 2021 and could be pre-paid without penalty at any time.

On January 15, 2021, the Company and Dr. Semechkin agreed to extend the maturity date of the New Note to January 15, 2022. No other terms of the Note were modified as a result of the extension.

On March 5, 2021, to obtain additional funding for working capital purposes, the Company further modified the Note and issued an unsecured, non-convertible promissory note (the "New Note") in the amount of $2.7 million to Dr. Semechkin. In exchange, Dr. Semechkin surrendered the Note and provided additional funding in the amount of $350 thousand to the Company. The outstanding principal amount under the New Note accrues interest at a rate of 4.5% per annum. The outstanding principal and accrued interest on the New Note is due and payable on January 15, 2022 and may be pre-paid by the Company without penalty at any time.

On January 13, 2022, to obtain additional funding for working capital purposes, the Company further modified the Note and issued an unsecured, non-convertible promissory note (the "January 2022 Note") in the amount of $2.9 million to Dr. Semechkin. In exchange, Dr. Semechkin surrendered the Note and provided additional funding in the amount of $250 thousand to the Company. The outstanding principal amount under the January 2022 Note accrues interest at a rate of 4.5% per annum. The outstanding principal and accrued interest on the January 2022 Note was due and payable on March 15, 2022 and may be pre-paid by the Company without penalty at any time.

On March 1, 2022, the Noteholder surrendered the January 2022 Note, and the Company issued a new promissory note ("March 2022 Note"), which featured all the same terms as the previously outstanding note, with the exception of an extension of the maturity date from March 15, 2022 to September 15, 2022. The March 2022 Note has a principal balance of $2.9 million, an interest rate of 4.5%, and features optional prepayment terms. There were no debt issuance fees associated with this issuance.

On September 15, 2022, the Noteholder surrendered the March 2022 Note, and the Company issued a new promissory note ("September 2022 Note"), which featured all the same terms as the previously outstanding note, with the exception of an extension of the maturity date from September 15, 2022 to March 15, 2023. The September 2022 Note has a principal balance of $2.9 million, an interest rate of 4.5%, and features optional prepayment terms. There were no debt issuance fees associated with this issuance. The amendments qualify as a troubled debt restructuring which did not result in a gain as the carrying amount of the debt was less than the total future cash payments of the restructured debt.

On March 14, 2023, the Noteholder surrendered the September 2022 Note, and the Company issued a new promissory note ("March 2023 Note"), which featured all the same terms as the previously outstanding note, with the exception of an extension of the maturity date from March 15, 2023 to September 15, 2023. The March 2023 Note has a principal balance of $2.9 million, an interest rate of 4.5%, and features optional prepayment terms. There were no debt issuance fees associated with this issuance.

10. Income Taxes

The Company accounts for income taxes in accordance with applicable authoritative guidance, which requires the Company to provide a net deferred tax asset/liability equal to the expected future tax benefit/expense of temporary reporting differences between book and tax accounting methods and any available operating loss or tax credit carryforwards. The Company has available at December 31, 2022, operating loss carryforwards of approximately $73.5 million, which may be applied against future taxable income and will expire in various years through 2038. However, any net operating loss carryforwards generated in 2018 and future tax years will not expire and are carried forward indefinitely. At December 31, 2021, the Company had operating loss carryforwards of approximately $74.9 million. The decrease in federal operating loss carryforwards for the year ended December 31, 2022 is approximately $1.4 million.

The amount of and ultimate realization of the benefits from the operating loss carryforwards for income tax purposes is dependent, in part, upon the tax laws in effect, the future earnings of the Company, and other future events, the effects of which cannot be determined at this time. Because of the uncertainty surrounding the realization of the loss carryforwards, the Company has established a valuation allowance equal to the tax effect of the loss carryforwards, R&D credits, and accruals; therefore, no net deferred tax asset has been

recognized. A reconciliation of the statutory federal income tax rate and the effective income tax rate for the year ended December 31, 2022 and 2021:

	Years Ended December 31,	
	2022	2021
Statutory federal income tax rate	21.0%	21.0%
Permanent items	%	%
State income taxes, net of federal taxes	(5.1)	(7.0)
Foreign	%	%
Change in valuation allowance	(8.5)	(0.2)
Forgiveness of PPP loans	%	%
Stock-based compensation	0.8%	(0.8)
Adjustment to NOL for ERC	190.7%	46.6%
Change in uncertain tax positions	0.0%	26.7%
Other	%	%
Effective income tax rate	8.0%	(83.8)
	%	
	(40.6)	0.0%
	%	
	(170.0)	0.0%
	%	%
	3.7%	(2.5)
	0.0%	0.0%

The Company files income tax returns in the U.S. federal jurisdiction, and various states. With few exceptions, the Company is no longer subject to U.S. federal, state and local income tax examinations by tax authorities for years before 2017. The Company follows the provisions of FASB Accounting Standards Codification 740-10 (ASC 740-10), Accounting for Uncertainty in Income Taxes. ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in consolidated financial statements of uncertain tax positions that have been taken or expected to be taken on a tax return.

At December 31, 2022 and 2021, the Company's reserve for unrecognized tax benefits is approximately $953 thousand and zero, respectively. Due to the full valuation allowance at December 31, 2022, current adjustments to the unrecognized tax benefits will have no impact on the Company's effective tax rate. The Company does not anticipate any significant change in its unrecognized tax benefits within 12 months of this reporting date. The Company includes penalties and interest expense related to income taxes as a component of other expense and interest expense, respectively, as necessary. A reconciliation of the reserve for unrecognized tax benefits is as follows (in thousands):

Balance at December 31, 2021	$ —
Increase (decrease) of unrecognized tax benefits taken in prior years	953
Balance at December 31, 2022	$ 953

The Company may be subject to IRC Code Section 382 and 383, which could limit the amount of the net operating loss and tax credit carryovers that can be used in future years. The Company has not completed a study to assess whether an ownership change has occurred, as defined by IRC Sections 382 and 383, or whether there have been ownership changes since the Company's formation due to the complexity and cost associated with such study, and the fact that there may be additional such ownership changes in the future. The Company estimates that if such a change did occur, the federal and state net operating loss carryforwards and research and development credit carryforwards that can be utilized in the future would be significantly limited. There can be no assurance that the Company will ever be able to realize the benefit of some or all of the federal and state loss carryforwards or credit carryforwards, either due to ongoing operating losses or due to ownership change limitations.

Significant components of deferred tax assets and liabilities are as follows (in thousands):

	December 31, 2022	December 31, 2021
Net operating loss carryforwards	$ 19,266	$ 19,603
Research and development tax credit	1,993	2,899
Stock-based compensation	1,252	1,153
Other	425	235
Non-current deferred tax assets	22,936	23,890
Valuation allowance	(22,936)	(23,890)
Net deferred tax assets	$ —	$ —

11. Commitments and Contingencies

Leases

As of December 31, 2022, the Company has three operating leases for real estate in California and Maryland:

- San Diego, California – corporate headquarters, including corporate, R&D, and manufacturing operations, with a term date of December 2026, jointly leased with a related party (refer to Note 9 – Related Party Transactions, for further information);
- San Diego, California – supplemental office space adjacent to the Company’s corporate headquarters with a term date of December 2026; and
- Frederick, Maryland – mixed laboratory and administrative space with a term date of November 2025.

In October 2021, the Company entered into an operating lease for its new corporate headquarters. The lease commenced on November 1, 2021 and expires on December 31, 2026. At commencement, base rent due under the lease was approximately $11 thousand and increases approximately 3.5% per annum over the lease term. The lease is subject to additional variable charges, including insurance, maintenance costs, taxes and operating expenses. Base rent and additional variable charges are shared between the Company and S Real Estate Holdings LLC, a related party, pursuant to a co-tenant agreement between the parties (refer to Note 9 – Related Party Transactions, for further information). In addition, base rent for months two through five of the lease term were abated by 50%. At lease commencement, the Company recognized a right-of-use asset and lease liabilities of approximately $232 thousand.

In November 2021, the Company entered into an operating lease for supplemental office space adjacent to its new corporate headquarters with the same landlord. The lease commenced on December 1, 2021 and expires on December 31, 2026 and is not subject to the co-tenant agreement with S Real Estate Holdings, LLC. At commencement, base rent due under the supplemental office lease was approximately $4 thousand per month and increases at a fixed amount per annum over the lease term. At lease commencement, the Company recognized a right-of-use asset and lease liabilities of approximately $247 thousand.

The Company’s operating leases for real estate are subject to additional variable charges for common area maintenance and other variable costs, and do not include an option to extend the lease term. As of December 31, 2022, total right-of-use assets and operating lease liabilities were approximately $727 thousand and $950 thousand, respectively. As of December 31, 2022, the Company had no finance leases.

Information related to the Company's right-of-use assets and related lease liabilities were as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Operating lease costs	$ 278	$ 456
Short-term lease costs	7	1
Variable lease costs	167	225
Total lease costs	$ 452	$ 682
Operating cash used for operating leases	317	508
Right-of-use asset obtained in exchange for operating lease liability	—	479
Weighted-average remaining lease term (years)	3.43	4.42
Weighted-average discount rate	13.38%	13.48%

Maturities of lease liabilities as of December 31, 2022 were as follows (in thousands):

Years ending December 31,	
2023	$ 338
2024	349
2025	360
2026	118
Total minimum lease payments	1,165
Less: imputed interest	(215)
Total future minimum lease payments	950
Less: operating lease liabilities, current	(230)
Operating lease liabilities, net of current portion	$ 720

Licensed Patents

The Company had a minimum annual license fee of $75 thousand payable in two installments per year to Astellas Pharma pursuant to the amended UMass IP license agreement. The patents, along with the license agreement, expired at the end of July 2022. These patents were fully impaired in prior years and therefore the expiration did not result in any impairment for the year ended December 31, 2022. The Company does not anticipate any short-term liquidity effects from this obligation as they will no longer be liable for the annual licensing fee.

12. Segments and Geographic Information

The Company operates the business on the basis of three reporting segments, the parent company and two business units: ISCO – therapeutic market; LCT – biomedical market, and; LSC – anti-aging market.

The Company does not measure the performance of its segments on any asset-based metrics. Therefore, segment information is presented only for net loss. Results of operations by market segment were as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Revenues:		
Biomedical market	$ 7,131	$ 5,936
Anti-aging market	1,049	1,240
Total revenues	8,180	7,176
Operating expenses:		
Therapeutic market	2,369	3,267
Biomedical market	4,384	4,346
Anti-aging market	1,610	1,484
Total operating expenses	8,363	9,097
Operating income (loss):		
Therapeutic market	(2,369)	(3,267)
Biomedical market	2,747	1,590
Anti-aging market	(561)	(244)
Total operating loss	(183)	(1,921)
Other income (expense), net:		
Therapeutic market	(135)	1,012
Biomedical market	(8)	(2)
Anti-aging market	(5)	12
Total other income (expense), net	(148)	1,022
Net loss:		
Therapeutic market	(2,504)	(2,255)
Biomedical market	2,739	1,588
Anti-aging market	(566)	(232)
Total net loss	$ (331)	$ (899)

Geographic Information

The Company’s wholly-owned subsidiaries are located in Maryland, California and Melbourne, Australia, and have customer and vendor relationships worldwide. The Company's long-lived assets including property, plant, and equipment, net, right-of-use assets, and intangible assets, net are domiciled in the United States. Significant revenues in the following regions are those that are attributable to the individual country within the region to which the product was shipped (in thousands):

	Years Ended December 31,	
	2022	2021
United States	$ 7,016	$ 5,917
Asia	690	806
Europe	393	345
All other regions	81	108
Total	$ 8,180	$ 7,176

13. Subsequent Events

On March 14, 2023, the Noteholder surrendered the September 2022 Note, and the Company issued a new Promissory Note (“March 2023 Note”), which featured all the same terms as the previously outstanding note, with the exception of an extension of the maturity date from March 15, 2023 to September 15, 2023. The March 2023 Note has a principal balance of $2.9 million, an interest rate of 4.5%, and features optional prepayment terms. There were no debt issuance fees associated with this issuance.