

**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, 2019

☐ **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  
(State of other jurisdiction of  
incorporation or organization)  
5950 Priestly Drive  
Carlsbad, CA  
(Address of principal executive offices)

20-4494098  
(I.R.S. Employer  
Identification Number)

92008  
(Zip Code)

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

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

Title of each class  
None

Name of each exchange on which registered  
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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately \$3,131,830 based upon the closing price of the common stock on June 28, 2019 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 May 22, 2020 there were 7,539,089 shares of the registrant's common stock outstanding

**DOCUMENTS INCORPORATED BY REFERENCE**

Information from the registrant's definitive Proxy Statement for its Annual Meeting of Stockholders to be held in 2020 is incorporated by reference into Part III of this Form 10-K.

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## EXPLANATORY NOTE

As previously disclosed on International Stem Cell Corporations (the "Company") Form 8-K filed with the SEC on March 30, 2020, the filing of this Annual Report on Form 10-K for the period ended December 31, 2019 (the "2019 Annual Report") was delayed due to circumstances related to the novel coronavirus ("COVID-19") and its impact on the Company's operations. The disruptions in transportation, staffing, and technology systems to the Company resulted in limited support from the Company's staff due to the COVID-19 outbreak. In particular, COVID-19 has caused disruptions in the Company's day-to-day activities and impaired the Company's ability to perform necessary work on the 2019 Annual Report and to file the 2019 Annual Report by its March 30, 2020 due date. The Company relied on the SEC's *Order Under Section 36 of the Securities Exchange Act of 1934 Modifying Exemptions From the Reporting and Proxy Delivery Requirements for Public Companies*, dated March 4, 2020 and amended March 25, 2020 (Release Nos. 34-88318 and 34-88465), to delay the filing of this 2019 Annual Report.

As of the date of filing of this Annual Report on Form 10-K (this "Report"), there are many uncertainties regarding the current COVID-19 pandemic, including the scope of health issues, the possible duration of the pandemic, and the extent of local and worldwide social, political, and economic disruption it may cause. To date, the COVID-19 pandemic has had far-reaching impacts on many aspects of the operations of International Stem Cell Corporation (the "Company," "we," "our" or "us"), including on consumer behavior, customer demand, timing of product availability, our employees' personal and business lives, and the market generally. The scope and nature of these impacts continue to evolve each day. The COVID-19 pandemic has resulted in, and may continue to result in, regional and local quarantines, labor stoppages and shortages, changes in consumer purchasing patterns, mandatory or elective shut-downs of retail locations, disruptions to supply chains, including the inability of our suppliers and service providers to deliver materials and services on a timely basis, or at all, severe market volatility, liquidity disruptions, and overall economic instability, which, in many cases, have had, and we expect will continue to have, adverse impacts on our business, financial condition and results of operations. This situation is changing rapidly, and additional impacts may arise that we are not aware of currently.

In light of the uncertain and rapidly evolving situation relating to the COVID-19 pandemic, we have taken certain precautionary measures intended to help minimize the risk to our Company, employees and customers, including the following:

- We are encouraging our staff to begin working from home. We expect that to be our operating model for an undetermined period of time, and to the extent permitted by federal, state and local instructions to reopen;
- We identified expense reductions that we intend to implement throughout the remainder of fiscal 2020, as necessary;
- Although our laboratory's in Frederick, Maryland and Oceanside, California currently continue to operate, we continue to evaluate its operations, and may elect, or be required, to shut down its operations temporarily at any time in the future;
- We have suspended all non-essential travel for our employees; and
- We are discouraging in-person work-related meetings.

Each of the remedial measures taken by the Company has had, and we expect will continue to have, adverse impacts on our current business, financial condition and results of operations, and may create additional risks for our Company. While we anticipate that the foregoing measures are temporary, we cannot predict the specific duration for which these precautionary measures will stay in effect, and we may elect or need to take additional measures as the information available to us continues to develop, including with respect to our employees, inventory receipts, and relationships with our lenders and licensors. We expect to continue to assess the evolving impact of the COVID-19 pandemic on our customers, consumers, employees, supply chain, and operations, and intend to make adjustments to our responses accordingly. However, the extent to which the COVID-19 pandemic and our precautionary measures in response thereto may impact our business, financial condition, and results of operations will depend on how the COVID-19 pandemic and its impact continues to develop in the United States and elsewhere in the world, which remains highly uncertain and cannot be predicted at this time.

In light of these uncertainties, for purposes of this report, except where otherwise indicated, the descriptions of our business, our strategies, our risk factors, and any other forward-looking statements, including regarding us, our business and the market generally, do not reflect the potential impact of the COVID-19 pandemic or our responses thereto. In addition, the disclosures contained in this report are made only as of the date hereof, and we undertake no obligation to publicly update or revise any forward-looking statement as a result of new information, future events or otherwise, except as otherwise required by law. For further information, see "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors."

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. For example, statements regarding our 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.

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## 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, cosmetic and research products, of a total of \$9.5 million and \$11.1 million for the years ended December 31, 2019 and 2018, 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 applications of our technology are:

- 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.
- Liver cells ("hepatocytes") that may be used to treat a variety of congenital and acquired liver diseases. Using the same precursor cell that leads to liver cells, it is also possible to create islet cells for potential treatment of diabetes.

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 anticipate providing full results of the phase I clinical study by the end of 2020.

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 12.

## ***Market Opportunity and Growth Strategy***

### ***Therapeutic Market – Clinical Applications of hpSCs for Disease Treatment***

With respect to therapeutic research and product candidates, we focus on applications where cell and tissue therapy is already proven but where there is an insufficient supply of safe and functional cells or tissue. We believe that the most promising potential clinical applications of our technology are: 1) Parkinson's disease ("PD"); 2) traumatic brain injury ("TBI"), and 3) metabolic/liver diseases. Using our proprietary technologies and know-how, we are creating neural stem cells from hpSCs as a potential treatment of PD, TBI, and stroke. Liver cells from our hpSCs may also be able to treat a variety of hepatic and metabolic liver diseases.

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 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. 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 anticipate providing full results of the Phase I clinical study by the end of 2020.

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 advancing stem cell therapies based on ISCO's core technology into clinical development and on to commercialization. Although the Phase I study is conducted in Australia, and therefore not subject to FDA oversight, we anticipate that a significant portion of future studies will be carried out in the United States where this approval is necessary.

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.

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 PD clinical trial, ISC-hpNSC®, significantly improved TBI-associated motor, neurological, and cognitive deficits without any safety issues.

### ***Anti-Aging Cosmetic Market – Skin Care Products***

Products that provide anti-aging benefits represent a significant portion of the global facial skincare market. In key regions, such as the United States and Asia, the growth of the facial skincare market is driven by an increase in consumer disposable income and growing popularity of skincare products based on biotechnology, such as human stem cells. Currently this market segment is in its early stages of development and we believe it has a significant growth potential. Our goal is to leverage our leadership in human stem cell and proprietary targeted small molecule technology in order to develop and commercialize advanced anti-aging skincare products for our retail and professional sales channels.

Our wholly-owned subsidiary, Lifeline Skin Care, Inc. ("LSC"), develops, manufactures and markets a line of luxury skincare products with anti-aging benefits that is based on our proprietary human non-embryonic stem cell extract and targeted small molecule technologies.

LSC's retail line of products are sold in the United States and internationally through a branded website and several authorized online retailers. LSC's professional line of products is distributed through a network of professional accounts, including dermatologists, plastic surgeons, medical, day and resort spas.

#### *Biomedical Market – Primary Human Cell Research Products*

The global market for human cell systems for use in basic research is extremely large, with continuing anticipated growth. We believe that the following are the main drivers in the research market:

- The need for experimental human cells which are more predictive of human biology than are non-human cells, 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.

Our wholly-owned subsidiary Lifeline Cell Technology, LLC ("LCT") develops, manufactures and commercializes over 200 human cell culture products, including frozen human "primary" cells and the reagents (called "media") needed to grow, maintain and differentiate the cells, in order to address this significant market opportunity. LCT's scientists have used a technology 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 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.

While we have continued to expand our sales and marketing efforts to increase revenue, our commercial operations do not generate sufficient funds to fully support our core therapeutic and research efforts. Underpinning our research into the therapeutic properties of hpSC, we plan to expand our collection of parthenogenetic stem cell lines by creating and banking new clinical-grade hpSC lines at our Oceanside, California facility. We intend to create these new lines according to good tissue practices ("GTP") and current good manufacturing practices ("cGMP") and use them as sources for our own internal development programs and to generate revenue through licensing opportunities. We are actively working with a number of *in vitro* fertility ("IVF") clinics in the southern California region enrolling individuals who are willing to donate oocytes for research purposes to create new hpSC lines.

#### *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"), LCT, 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 5950 Priestly Drive, Carlsbad, CA 92008, and our telephone number is (760) 940-6383. Our corporate website address is [www.internationalstemcell.com](http://www.internationalstemcell.com). Lifeline Cell Technology's website address is [www.lifelinecelltech.com](http://www.lifelinecelltech.com), and Lifeline Skin Care's website address is [www.lifelineskincare.com](http://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 manipulation. 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 use in preclinical and clinical trials and ultimately for therapeutic use through the completion of our cGMP manufacturing laboratories in Oceanside, California and Frederick, Maryland, which is currently cGMP

ready. The Oceanside laboratory is designed specifically for the derivation of clinical-grade parthenogenetic stem cell lines for our stem cell bank and their differentiated derivatives for future clinical trials.

## ***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:

- Neural stem cells (ISC-hpNSC®) for treatment of Parkinson's disease and potentially other neurological disorders, such as spinal cord injury, traumatic brain injury and stroke.
- Liver cells ("hepatocytes") that may be used to treat a variety of congenital and acquired liver diseases. Using the same precursor cell that leads to liver cells, it is also possible to create islet cells for potential treatment of diabetes.

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 we intend to use to produce the clinical-grade cells necessary for future clinical studies and commercialization. In 2016 we published all important pre-clinical data in two peer-reviewed journals, Cell Transplantation and Nature Scientific Reports. 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 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 anticipate providing full results of the phase I clinical study by the end of 2020.

In August 2014, we began evaluating the use of ISC-hpNSC® for the treatment of ischemic stroke using a rodent model of the disease. In October 2016 we evaluated the use of ISC-hpNSC® for the treatment of TBI using a rodent model of the disease. As we have already developed safety data on NSC from the Parkinson's disease program we believe can leverage such data in a program for the treatment of ischemic stroke.

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*

As of December 31, 2019 ISCO's LSC subsidiary had developed, launched and was actively selling a total of seven distinct skincare products based on its proprietary stem cell technology.

- Daily Defense Complex, which diminishes the appearance of fine lines and wrinkles, while improving skin texture and firmness.
- Recovery Night Moisture Serum, which helps improve skin tightness and provides hydration.
- Eye Firming Complex, that provides tightening benefits to the under-eye skin area.
- Neck Firming Serum which is specifically designed to nourish the skin in the decollate area.
- Aqueous Gel Serum (retail formula) combines LSC's core stem cell extract technology with a unique water base in order to deliver anti-aging and hydration benefits.
- ProPLUS Advanced Aqueous Treatment is a more potent, professional-only version of the retail Aqueous Gel Serum
- Intense Moisture Serum, which is especially designed to deliver long-lasting hydration and nourishment to the skin.

As of December 31, 2019, LSC marketed and sold five skincare products based on the Company's proprietary targeted small molecule technology.

- Collagen Booster (Molecular Renewal Serum)
- ProPLUS Collagen Booster (Advance Molecular Serum)
- Elastin Booster
- ProPLUS Elastin Booster
- Brightening Toner

LSC continues to offer three products designed to complement the core technology products:

- Brightening Cleanser uses ultra-fine conditioning powders to help cleanse and brighten the skin.
- Dual Action Exfoliator uses glycolic acid and microcrystals to exfoliate dead skin cells.
- Refresh Polishing Gelee combines calming ingredients and micro beads to gently exfoliate the skin.

#### *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 technology 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 (DermaLife<sup>®</sup>) for the study of skin disease, toxicology or wound healing.
- Human cells from the heart and blood vessels and associated reagents (VascuLife<sup>®</sup>), used by researchers to study cardiovascular disease and cancer.
- Human bronchial and tracheal cell lines for the study of toxicity, cystic fibrosis, asthma and pathogenesis.
- Human mammary epithelial cell lines 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<sup>™</sup>) to study prostate disease including cancer.
- Human renal and bladder cells and associated media (RenaLife<sup>™</sup>) 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.

*Liver disease.* Liver disease affects one in ten persons according to the American Liver Foundation, and is one of the top ten leading causes of death in the United States. There are more than 100 individual diseases of the liver; and for people with liver failure, the only effective treatment is full or partial organ transplantation. However, the demand for liver organs far exceeds the number of transplants available. According to the American Liver Foundation, over 16,000 individuals in the United States are waiting for a transplant. Using our proprietary technologies and know-how, we are creating liver cells from hpSCs that may be used to treat a variety of hepatic and metabolic liver diseases to address this significant market opportunity. Importantly, liver cell transplantation has already been used in early stage clinical trials to treat patients with liver failure and has proven especially useful as a "bridge" to keep patients alive until they can receive a whole liver transplant.

### *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 2019 ISCO was issued 8 patents for technology generated by our R&D team. The first patent issued in the European Union, covered various aspects of stem cell derivation. Three patents, issued in China, Japan, and the United States, covered small molecule technology utilized in the Company's skin care product lines. Four patents, issued in the United States and European Union, covered various aspects of our neurology platform. This technology can be used in many products that may or may not require regulatory approval. Based on the broad application of the patent, determining whether to capitalize or expense patent application costs involves judgement. When it is deemed probable there will be future economic benefit application costs will be capitalized and amortized over the expected life of the patent. Otherwise, costs are expensed as incurred.

We have pending patent applications covering homozygous parthenogenetic stem cells that can be immune matched to millions of persons and methods for deriving them. Other patents and pending patent applications include intellectual property concerning skin care formulations and methods of manufacturing stem-cell based skin care products and methods to differentiate stem cells.

In addition, we have obtained exclusive worldwide licenses to patents and patent applications from Astellas Pharma. 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. Our currently issued patents will expire at various times commencing in 2020.

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 \$75,000 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 days 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 37% of our total sales in 2019 were from one customer and another customer accounted for 15% of our total sales.

LSC launched its retail product line in November 2010 through the company's branded website—[www.lifelineskincare.com](http://www.lifelineskincare.com). Subsequent to the initial launch, LSC continues to expand its distribution network by developing partnerships with online retailers, as well as the launch of professional channels, which include destination and resort spas, dermatologists, and plastic surgeons. Domestically, we plan to increase distribution of our products by expanding and improving our retail and professional product lines, increasing brand awareness, strategic partnerships, sales promotions, and public relations.

### ***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.

#### *Employees*

In addition to our three executive officers, we utilize the services of 36 full-time and two part-time staff members.



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

The recent 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. While it is not possible at this time to estimate 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 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 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, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

***Our business 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 and our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern.***

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, our independent registered public accounting firm included an explanatory paragraph in its report on our consolidated financial statements as of and for the year ended December 31, 2019 regarding this uncertainty. The inclusion of the going concern statement by our auditors may adversely affect our stock price and our ability to raise needed capital or enter into advantageous contractual relationships with third parties. 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 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, 2019, 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 our estimates for capital needs in 2020 and beyond;
- 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 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.

Additionally, currently the United States government, through National Institute of Health appropriations restrictions, prevents federal funding to be used to create new embryonic and parthenogenetic stem cells, so access to grants from the NIH are limited.

***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, pharmaceutical and cosmetic 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, biotechnology and cosmetic 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 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.

***If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.***

Our business depends in part on licenses from third parties. These third party license agreements impose obligations on us, such as payment obligations and obligations to diligently pursue development of commercial products under the licensed patents. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products could be significantly and negatively affected. If our license rights were restricted or ultimately lost, our ability to continue our business based on the affected technology platform could be severely affected adversely.

***Significant delays or reductions in United States Government funding may negatively affect our results of operations.***

We estimate that governmental funding, either directly or indirectly (through sponsorship of academic research), comprises approximately 40% of the market for basic and applied research in biological sciences, which is the target market for our LCT research products. The United States Government is considering (and has implemented in the recent past) significant changes in government spending and other governmental programs, which in the recent past involved several automatic spending cuts being implemented. There are many variables in how these laws could be implemented in the future that make it difficult to determine specific impacts on our customers, and we are unable to predict the impact that future spending cuts or other budget initiatives would have on funding our customers receive and resulting sales of our LCT products. Additionally, United States Governmental programs are subject to annual congressional budget authorization and appropriation processes. However, whether through the automatic cuts or other decisions, long-term funding for certain programs in which our research product customers participate may be reduced, delayed or cancelled. In the event that governmental funding for any of our research product customers is reduced or delayed, our sales to those customers would likely suffer, which could have a material adverse effect on our results of operations. Further, currently the United States government, through National Institute of Health appropriations restrictions, prevents federal funding to be used to create new embryonic and parthenogenetic stem cells, so access to grants from the NIH are limited, which may adversely affect our partnering opportunities and internal therapeutic product development initiatives.

***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. These licenses are subject to termination under certain circumstances (including, for example, our failure to make minimum royalty payments). The

loss of any of such licenses, or the conversion of such licenses to non-exclusive licenses, could harm 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 be subject to litigation that will be costly to defend or pursue and uncertain in its outcome.***

Our business may bring us into conflict with our licensees, licensors or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. That litigation is likely to be expensive.

and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities, or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business.

***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, 2019, we derived approximately 37% of our revenues from one customer and 15% from another customer.***

During the year ended December 31, 2019, one customer accounted for 37% of our consolidated revenues and another customer accounted for 15% of revenues. To the extent that either of these significant customers reduce or delay 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.

## 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, 2019, 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 80% 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 and warrants that they hold and that are exercisable within 60 days of December 31, 2019. 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 five separate series of outstanding preferred stock, including Series B, Series D, Series G, Series I-1 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 involuntarily 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 \$1.08 to \$9.70 per share as of December 31, 2019). 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.

***Shares eligible for future sale may adversely affect the market.***

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended, subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who is not an affiliate of our company and who has satisfied a six month holding period may, as long as we are current in our required filings with the SEC, sell securities without further limitation. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a one year holding period. Affiliates of our company who have satisfied a six month holding period may sell securities subject to limitations. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities. Currently, a substantial majority of our securities are either free trading or subject to the release of trading restrictions under the six month or one year holding periods of Rule 144.

***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 five series of preferred stock that remain outstanding, including Series B, Series D, Series G, Series I-1 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 \$200,000 or \$300,000 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 our common stock to holders of Series I Preferred Stocks ("holders") may cause dilution and the sale of the shares of common stock acquired by those holders, or the perception that such sales may occur, could cause the price of our common stock to fall.***

On March 9, 2016, we entered into the Securities Purchase Agreement with two institutional investors and Dr. Andrey Semechkin, our Chief Executive Officer and Co-Chairman, pursuant to which those purchasers purchased 6,310 shares of Series I Convertible Preferred Stock initially convertible into approximately 3.6 million shares of our common stock, in addition to Series A, B, and C Warrants for approximately 10.8 million shares of our common stock, the Series A Warrants being exercisable for 5 years from the date of issuance, and the Series B Warrants being exercisable for six months from the date of issuance and the Series C Warrants being exercisable for one year from the date of issuance. As of December 31, 2019, we had 5,124 shares of Series I Convertible Preferred Stock outstanding and Series A Warrants for approximately 3.6 million shares of our common stock outstanding. The conversion price of the Preferred Stock and Warrants is subject to certain resets as set forth in the Certificates of Designation and Warrants, including the date of the amendment to the certificate of incorporation with respect to any reverse stock split. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

The holders may ultimately convert all, some or none of the Series I Convertible Preferred Stock into shares of our common stock, exercise all, some or none of the Series A warrants to acquire shares of our common stock. Such shares acquired by such holders may be sold, as such holders may sell all, some or none of those shares of common stock. Therefore, the conversion of the preferred stock and exercise of warrants by such holders will result in substantial dilution to the interests of other holders of our common stock. Additionally, the conversion into a substantial number of shares of our common stock such holders, or the anticipation of such conversion, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

***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.

***The exercise of outstanding options and warrants to acquire shares of our common stock would cause additional dilution which could cause the price of our common stock to decline.***

In the past, we have issued options and warrants to acquire shares of our common stock. At December 31, 2019, there were 3,951,052, shares issuable upon exercise of outstanding warrants, and 2,970,989 vested and 1,965,684 non-vested stock options outstanding, and we may issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses or other strategic transactions. To the extent these options and warrants are ultimately exercised, existing common stockholders would experience additional dilution which may cause the price of our common stock to decline.

***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.

***We do not expect to pay cash dividends in the foreseeable future on our common stock.***

We have not historically paid cash dividends on our common stock, and we do not plan to pay cash dividends on our common stock in the foreseeable future.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None

**ITEM 2. PROPERTIES**

We have established our primary research facility in 8,215 square feet of leased office and laboratory space in Oceanside, California. Our current lease for this facility expires in December 2021. The current base rent is approximately \$10,000 per month. The facility has leasehold improvements which include cGMP (current Good Manufacturing Practices) level clean rooms designed for the derivation of clinical-grade stem cells and their differentiated derivatives, research laboratories for our stem cell differentiation studies and segregated rooms for biohazard control and containment of human donor tissue. The monthly base rent will increase by 3% annually on the anniversary date of the agreement.

In addition to the primary research facility lease, we have entered into a lease agreement with S Real Estate Holding, LLC (an affiliate of our CEO and Executive Vice President and Chief Scientific Officer) to allow the Company to expand into new corporate offices located in Carlsbad, California. The current lease covers 9,028 square feet which is being used as the Company's headquarters. The current lease expires on February 28, 2023. As of December 31, 2019, the base rent was approximately \$13,000 per month. The monthly base rent will

increase by 2% annually on the anniversary date of the agreement. We are also obligated to pay a portion of the utilities for the building and increases in property tax and insurance.

In addition, we lease a 13,320 square foot facility in Frederick, Maryland, which is used for laboratory and administrative purposes. for a base rent of approximately \$17,000 effective as of December 1, 2018, with the lease term expiring in November 2025. 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.

**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, 2019, we had 7,539,089 shares of common stock outstanding, and approximately 632 holders of record of our common stock, and we had 5,255,167 shares of preferred stock outstanding, and seven holders of record of our preferred stock, with the 5,255,167 shares of preferred stock being convertible into 6,132,278 shares of common stock.

On March 4, 2019, we were upgraded 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. SELECTED FINANCIAL DATA**

Not required.

**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 \$9.5 million and \$11.1 million for the years ended December 31, 2019 and 2018, 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").

## ***Market Opportunity and Growth Strategy***

*Therapeutic Market – Clinical Applications of hpSCs for Disease Treatments.* With respect to therapeutic research and product candidates, we focus on applications where cell and tissue therapy is already proven but where there is an insufficient supply of safe and functional cells or tissue. We believe that the most promising potential clinical applications of our technology are: 1) Parkinson's disease ("PD"); 2) traumatic brain injury ("TBI"), and 3) metabolic/liver diseases. Using our proprietary technologies and know-how, we are creating neural stem cells from hpSCs as a potential treatment of PD and TBI and stroke liver cells from hpSCs that may be able to treat a variety of hepatic and metabolic liver diseases.

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 anticipate providing full results of the phase I clinical study by the end of 2020.

In November 2014 in an important ruling the FDA cleared our human parthenogenetic stem cells line for investigational clinical use. This was a necessary step in the process of advancing stem cell therapies based on our core technology into clinical development and on to commercialization. Although the Phase I study is conducted in Australia, and therefore not subject to FDA oversight, we anticipate that a significant portion of any future studies will likely be carried out in the United States where this approval is necessary.

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.

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 LSC develops, manufactures and offers for sale anti-aging skin care products based on two core technologies: encapsulated extract derived from hpSC and specially selected targeted small molecules. Products containing stem cell technology include: Defensive Day Serum, Recovery Night Serum, Firming Eye Complex, Neck Firming Complex, Aqueous Gel Serum, Intense Moisture Serum, and the ProPLUS Advanced Aqueous Treatment. Products based on the proprietary targeted small molecule technology include: retail and professional formulas of the Collagen Booster (Molecular Renewal Serum), retail and professional formulas of the Elastin Booster, and Brightening Toner. LSC's products are regulated as cosmetics. LSC's products are sold domestically through a branded website, Amazon, ecommerce partners and through the professional channel (including dermatologists, plastic surgeons, medical, day and resort spas).

**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 technology 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 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.

	Years Ended December 31,			
	2019 (in thousands)	2018 (in thousands)	\$ Change	% Change
Revenues	\$ 9,472	\$ 11,089	\$ (1,617)	-15%
Cost of sales	3,933	4,069	(136)	-3%
As a % of revenues	42%	37%		
Research and development	1,386	2,396	(1,010)	-42%
Selling and marketing	2,685	2,631	54	2%
General and administrative	7,196	5,467	1,729	32%
Other income, net	1,463	1,343	120	9%
Net loss	\$ (4,265)	\$ (2,131)	\$ (2,134)	100%
As a % of revenues	-45%	-19%		

## Results of Operations

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

### Revenues

Revenue for the year ended December 31, 2019, totaled \$9.5 million, compared to \$11.1 million in 2018. LCT contributed \$7.5 million or 79% of total revenue in 2019, compared to \$9.3 million or 84% of total revenue in 2018. The decrease of \$1.8 million or 19% in LCT's revenue for 2019 primarily consists of the reduction in OEM sales. LSC's revenue of \$2.0 million in 2019 accounted for 21% of total revenue, compared to \$1.8 million or 16% of total revenue in 2018. The increase of \$161,000 or 9% in LSC's revenue primarily consists of an increase in the professional channel sales.

### Cost of Sales

Cost of sales for the year ended December 31, 2019 was \$3.9 million or 42% of revenue, compared to \$4.1 million or 37% of revenue in 2018. Due to the decrease in revenue LCT saw a decrease in cost of item sold, however that decrease was mostly offset by the increased reserve recorded on the LCT inventory. LSC had a slight increase in cost of sales of \$51,000 compared to the prior year primarily due to higher sales in the current year.

Cost of sales reflects direct costs including salaries and benefits related to manufacturing, third party manufacturing costs, 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.

### *Research and Development ("R&D")*

Research and development expenses for the year ended December 31, 2019 amounted to \$1.4 million, reflecting a decrease of approximately \$1.0 million or 42% compared to \$2.4 million in 2018. The decrease is primarily due to lower expenses incurred for clinical trial study costs.

Our R&D efforts are primarily focused on the development of treatments for Parkinson's disease ("PD"), liver diseases, traumatic brain injury ("TBI"), stroke, and the creation of new cGMP 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 they are incurred, and are accounted for on a project by project basis. However, much of our research has potential applicability to each of our projects.

### *Selling and Marketing Expense*

Selling and marketing expenses for the year ended December 31, 2019 amounted to \$2.7 million, reflecting an increase of approximately \$54,000 or 2%, as compared to \$2.6 million in 2018. The increase is primarily due to stock-based compensation expense.

### *General and Administrative Expenses*

General and administrative expenses for the year ended December 31, 2019 were \$7.2 million, reflecting an increase of \$1.7 million or 32%, compared to \$5.5 million in 2018. The increase is primarily the result of higher audit and accounting fees of \$327,000, stock-based compensation expense of \$410,000 and impairment charges of \$1.5 million offset by a decrease in investor relation expenses of \$118,000.

### *Other Income/Expense*

Net other income was \$1.5 million for the year ended December 31, 2019, compared to \$1.3 million for the year ended December 31, 2018 for an increase of \$120,000 or 9%. The increase of \$120,000 is primarily due to a higher gain in the fair value of warrant liability compared to the prior year.

### *Liquidity and Capital Resources*

As of December 31, 2019 and 2018, our cash totaled \$484,000 and \$1.1 million, respectively. At December 31, 2019, we had a working capital of \$1.5 million compared to a working capital deficit of \$1.3 million at December 31, 2018. The \$2.8 million increase in working capital is primarily due to the reclass from current liabilities to long term liabilities of our related party note payable and the fair value of warrants related to our March 2016 financing transaction, a decrease in cash of \$591,000, an decrease in other current assets of \$336,000, an increase in accounts receivable of \$864,000, and an increase of \$196,000 in accounts payable.

### *Operating Cash Flows*

Net cash used in operating activities was \$1.4 million for the year ended December 31, 2019, compared to \$1.1 million in 2018. The primary factor contributing to the variability in the reported cash flow amounts relates to the net loss after non-cash adjustments totaling \$1.2 million, mostly attributable to the change in the fair value of warrants liability of \$1.5 million, recorded stock compensation expense of \$2.1 million, \$1.5 million of intangible asset impairment. There was also an increase in accounts receivable of \$864,000, decrease in prepaid and other current assets of \$336,000, and a decrease in operating lease liabilities of \$304,000 in 2019, compared to \$870,000 of net loss after non-cash adjustments, mostly attributable to the change in the fair value of warrants liability of \$1.4 million, recorded stock compensation expense of \$1.7 million, \$607,000 of intangible asset impairment, increase in accounts receivable of \$186,000, increase in inventory of \$287,000, decrease in prepaid and other current assets of \$245,000, a decrease in accounts payable of \$92,000, and an increase in accrued liabilities of \$112,000 in 2018.

### *Investing Cash Flows*

Net cash used in investing activities was \$494,000 for the year ended December 31, 2019, compared to net cash used of \$661,000 in 2018. The decrease was primarily the result of lower payments for patents licenses of \$146,000.

### *Financing Cash Flows*

Net cash provided by financing activities was \$1.3 million for the year ended December 31, 2019, compared to \$2.5 million in 2018. In 2019, \$1.3 million was received from a related party note payable compared to \$2.0 million for a similar loan in the prior year.

### *Liquidity and Going Concern*

The accompanying financial statements have been prepared under the assumption that the Company will continue as a going concern, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The accompanying 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 has an accumulated deficit of approximately \$106.4 million as of December 31, 2019 and has incurred net losses and has had negative operating cash flows since inception. The Company has had no revenue from its principal operations in therapeutic and clinical product development through research and development efforts. Based on cash on-hand at December 31, 2019 of \$484,000 and anticipated cash burn, the Company estimates it has existing resources to fund the Company's principal operations into the second quarter of 2020. 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 capital.

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 capital from sources including the exercise of outstanding warrants, equity and/or debt financings, 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 2020 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 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 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 financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to stockholders. Additional debt financing may be expensive and require the Company 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 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. 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.

### *Off-Balance Sheet Arrangements*

As of December 31, 2019, we did not have any off-balance sheet arrangements.

## **Critical Accounting Policies and 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 intangible assets which impacts operating expenses and accrued liabilities, stock-based compensation which impacts operating expenses and fair value of warrant liability. 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.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### ***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 lives of the underlying patents, generally 15 years. All amortization expense and impairment charges related to intangible assets are included in general and administrative expense.

### ***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 highly judgmental 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 mid-point 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.

### ***Fair Value of Warrant Liability***

We are required to recognize warrant agreements as a liability since they did not meet the specific conditions for equity classification and therefore we need to recognize the fair value. The fair value of the warrant liability is calculated using the Monte-Carlo simulation model, which requires the use of certain estimates. These estimates include the expected volatility of our stock price, expected warrant life, risk-free interest, and subsequent financing. 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 instrument. The expected warrant life represents the period of time remaining prior to the warrant expiring. The risk-free interest rate is based upon United States Treasury securities with remaining terms similar to the expected term of the warrant arrangements. Subsequent financing is the probability that financing will occur within a period of time. If any of the assumptions used in the Monte-Carlo simulation model change significantly, the fair value of the warrant liability may differ materially from what we have recorded in the current period.

### ***Recent Accounting Pronouncements***

See Note 1. Recent Accounting Pronouncements, in the Notes to consolidated Financial Statements of this Annual Report.

**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.**

On July 25, 2019, the Audit Committee of the Board of Directors of International Stem Cell Corporation (the "Company") elected to conclude the Company's 8-year engagement with its independent registered public accounting firm Mayer Hoffman McCann P.C. ("MHM"). MHM's audit reports on the Company's consolidated financial statements as of and for the fiscal years ended December 31, 2018 and 2017 did not contain an adverse opinion or a disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles, except for the inclusion of an explanatory paragraph regarding the Company's ability to continue as a going concern. During the fiscal years ended December 31, 2018 and 2017, and the subsequent interim period through July 25, 2019, there were (i) no disagreements between the Company and MHM on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, any of which, if not resolved to MHM's satisfaction, would have caused MHM to make reference thereto in its reports, and (ii) except as noted in the following paragraph, no reportable events within the meaning of Item 304(a)(1)(v) of Regulation S-K.

As previously disclosed in the Company's Annual Reports on Form 10-K for the fiscal year ended December 31, 2017 (the "2017 10-K") and for the fiscal year ended December 31, 2018 (the "2018 10-K"), the Company reported material weaknesses (the "Material Weaknesses") in its internal control over financial reporting. In particular, as of December 31, 2017, the Company concluded its disclosure controls and procedures were not effective due to a material weakness in internal control over financial reporting related to the accounting for and disclosure of equity transactions. As of December 31, 2018, the Company concluded that its disclosure controls and procedures were not effective due to a material weakness in internal control over financial reporting including the areas of financial reporting and technical accounting, disclosures of equity, complex, non-routine, and significant transactions, and adoption of new accounting standards, collectively resulting from lack of continuity and sufficient accounting and finance resources. MHM was not required to, and did not, audit the Company's internal control over financial reporting. The Audit Committee and management discussed the Material Weaknesses with MHM. The Company has authorized MHM to respond fully and without limitation to any inquiries of BDO USA, LLP ("BDO"), the Company's successor independent registered public accounting firm, concerning the Material Weaknesses.

Following a selection process that evaluated several potential successor independent registered public accounting firms, on July 25, 2019, the Audit Committee approved the appointment of BDO as the independent registered public accounting firm for the Company's fiscal year ending December 31, 2019. During the fiscal years ended December 31, 2018 and 2017, and the subsequent interim period through July 25, 2019, neither the Company nor anyone on its behalf consulted with BDO regarding (i) the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that BDO concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue, (ii) any matter that was the subject of a disagreement within the meaning of Item 304(a)(1)(iv) of Regulation S-K, or (iii) any reportable event within the meaning of Item 304(a)(1)(v) of Regulation S-K.

**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 this evaluation, Management concluded that, at December 31, 2019, our disclosure controls and procedures were not effective due to a material weakness in internal control over financial reporting including the areas of financial reporting and technical accounting, disclosures of equity, complex, non-routine, and significant transactions, and adoption of new accounting standards, collectively resulting from lack of continuity and sufficient accounting and finance resources.

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.

### ***Changes in Internal Control Over Financial Reporting***

Except for the remediation activities relating to revenue transactions under ASC 606 described below, there have been no changes in our internal control over financial reporting during the quarter ended December 31, 2019 that our certifying officers concluded materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

#### **Material Weakness Remediation Activities**

The Company, the Audit Committee and the Company's Board of Directors are committed to maintaining a strong internal control environment and are currently evaluating remediation efforts which are designed to enhance our internal control environment ultimately eliminating the material weakness.

We expect that the remediation efforts for the material weakness relating to the accounting for and disclosure of equity, complex, non-routine, and significant transactions will include design, implementation, and testing of process and review controls over accounting for equity and other significant transactions, and performing such review as promptly as possible after such transactions.

We consider it prudent to allow the newly implemented or updated internal controls to operate for a sufficient period of time to demonstrate consistent effectiveness. Once the remediation plan for each material weakness is fully implemented, the identified material weakness in internal control over financial reporting will be considered fully addressed when the relevant internal controls have been in operation for a sufficient period of time for our management to conclude that the material weakness has been fully remediated and our internal control over financial reporting is effective. The Company will work to design, implement, and rigorously test added controls to make these final determinations.

### ***Management Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. 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 generally accepted accounting principles in the United States ("GAAP") and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- 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
- 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.

Our management conducted an evaluation of the effectiveness of the system of internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway

Commission (the 2013 COSO Framework). Based on the above evaluation, the Company's Chief Executive Officer and Principal Financial Officer have concluded that as of December 31, 2019, the Company's internal control over financial reporting were not effective due to a material weakness in internal control over financial reporting including the areas of financial reporting and technical accounting, disclosures of equity, identification of the status of intangible assets as issued, pending, expired or abandoned, complex, non-routine, and significant transactions, and adoption of new accounting standards, collectively resulting from lack of continuity and sufficient accounting and finance resources.

**ITEM 9B. OTHER INFORMATION**

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") in connection with our 2020 Annual Meeting of Stockholders under the heading "Election of Directors." The information required by this item regarding compliance with Section 16a of the Securities and Exchange Act of 1934, as amended, is incorporated by reference to the information in the Proxy Statement, under the caption "Section 16a Beneficial Ownership Reporting Compliance." The information required by this item regarding our Code of Conduct and Ethics is incorporated by reference to the information in the Proxy Statement, 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, under the caption "Corporate Governance."

As a result of the outbreak of, and local, state and federal governmental responses to, the COVID-19 pandemic, the Company obtained an extension to file the Part III portion of its Annual Report on Form 10-K for the year ended December 31, 2019 (the "Part III Portion"), was originally due on April 29, 2020. Specifically, the Company is relying on an order issued by the SEC on March 25, 2020 (which extended and superseded a prior order issued on March 4, 2020), pursuant to Section 36 of the Securities Exchange Act of 1934, as amended (Release No. 34-88465) (the "Order"), regarding potential exemptions granted to public companies with respect to specified filing requirements, subject to the conditions contained in the Order. The Order allows a registrant up to an additional 45 days after the original due date of certain reports required to be filed with the SEC if the registrant's ability to file such report timely is affected by circumstances related to COVID-19.

As such, the Company will be relying on the Order and will be making use of the 45-day grace period provided by the Order to delay filing of the Part III Portion. The Company plans to file the Part III Portion (which may be accomplished by filing its definitive proxy materials for its 2020 Annual Meeting of Stockholders and incorporating the information comprising the Part III Portion by reference from the definitive Proxy Statement) by no later than June 13, 2020, 45 days after the original due date of the Part III Portion.

As of December 31, 2019, our executive officers were as follows:

Name	Position	Age
Andrey Semechkin	Co-Chairman and Chief Executive Officer	60
Russell Kern	Executive Vice President and Chief Scientific Officer	34
Sophia Garnette	Vice President, Legal Affairs & Operations and Principal Financial Officer	36

*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 20 years' experience creating and managing businesses across different industries and scientific sectors.

*Russell Kern*, Ph.D, Executive Vice President and Chief Scientific Officer, 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.

*Sophia Garnette*, J.D., Vice President, Legal Affairs & Operations and Principal Financial Officer, received her law degree from the University of Miami School of Law and has experience in various aspects of corporate and biotechnology law, regulatory affairs, project management, and business operations. After joining the Company in March 2011, she has held a variety of business and legal roles, including in-house counsel, advisor to the CEO, and Vice Chairman of the Board of Directors for Lifeline Skin Care. Ms. Garnette holds

a Bachelor's degree in Economics from San Francisco State University and worked in the banking and finance industries prior to beginning her legal career.

**Item 11. EXECUTIVE COMPENSATION**

The information required by this item is incorporated by reference to the information in the Proxy Statement, 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, under the caption "Stock Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

**Equity Compensation Plan Information**

<u>Plan Category</u>	(a) Number of securities to be issued upon exercise of outstanding options	Weighted- average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders:			
2006 Equity Participation Plan	4,951	\$ 9.30	—
2010 Equity Participation Plan	4,931,722	\$ 3.38	4,487,863
Total	<u>4,936,673</u>		<u>4,487,863</u>

**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, 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, 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:

[Reports of Independent Registered Public Accounting Firms](#)

[Consolidated Balance Sheets](#)

[Consolidated Statements of Operations](#)

[Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity \(Deficit\)](#)

[Consolidated Statements of Cash Flows](#)

[Notes to Consolidated Financial Statements](#)

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2. List of all Financial Statement schedules.

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

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits:

Exhibit Number	Description
3.2	<a href="#">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, File No. 000-51891).</a>
3.3	<a href="#">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, File No. 000-51891).</a>
3.4	<a href="#">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, File No. 000-51891).</a>
3.5	<a href="#">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, File No. 000-51891).</a>
3.6	<a href="#">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, File No. 000-51891).</a>
3.7	<a href="#">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, File No. 000-51891).</a>
4.1	<a href="#">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, File No. 000-51891).</a>
4.2	<a href="#">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, File No. 000-51891).</a>
4.3	<a href="#">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, File No. 000-51891).</a>
4.4	<a href="#">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, File No. 000-51891).</a>
4.5	<a href="#">Certificate of Preferences, Rights and Limitations of Series I-1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Registrant's Form 8-K filed on March 10, 2016, File No. 000-51891).</a>
4.6	<a href="#">Certificate of Preferences, Rights and Limitations of Series I-12 Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 of the Registrant's Form 8-K filed on March 10, 2016, File No. 000-51891).</a>

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
4.7	<a href="#"><u>Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Form 8-K filed on March 10, 2016, File No. 000-51891).</u></a>
4.8	<a href="#"><u>Form of Placement Agent Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.4 of the Registrant's Form 8-K filed on March 10, 2016, File No. 000-51891).</u></a>
10.1*	<a href="#"><u>International Stem Cell Corporation 2006 Equity Participation Plan (incorporated by reference to Exhibit 10.15 of the Registrant's Form 8-K filed on December 29, 2006, File No. 000-51891).</u></a>
10.2*	<a href="#"><u>Form of Stock Option Agreement for stock options granted outside of the 2006 Equity Participation Plan (incorporated by reference to Exhibit 10.19 of the Registrant's Form 10-K filed on March 30, 2010, File No. 000-51891).</u></a>
10.3	<a href="#"><u>Cell Culture Automation Agreement dated May 13, 2010 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on May 19, 2010, File No. 000-51891).</u></a>
10.4*	<a href="#"><u>2010 Equity Participation Plan (incorporated by reference to Appendix A of the Registrant's Schedule 14A filed April 18, 2016, File No. 000-51891).</u></a>
10.5	<a href="#"><u>Standard Multi-Tenant Office Lease – Gross Agreement, dated as of February 19, 2011, by and between the Company and S Real Estate Holdings, LLC (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed February 28, 2011, File No. 000-51891).</u></a>
10.6	<a href="#"><u>Amendment to Standard Multi-Tenant Office Lease – Gross Agreement, dated as of March 3, 2016, by and between the Company and S Real Estate Holdings, LLC (incorporated by reference to Exhibit 10.9 of the Registrant's Form 10-K filed March 30, 2016, File No. 000-51891).</u></a>
10.7	<a href="#"><u>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, File No. 000-51891).</u></a>
10.8	<a href="#"><u>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, File No. 000-51891).</u></a>
10.9	<a href="#"><u>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, File No. 000-51891).</u></a>
10.10	<a href="#"><u>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, File No. 000-51891).</u></a>
10.11	<a href="#"><u>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, File No. 000-51891).</u></a>
10.12	<a href="#"><u>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, File No. 000-51891).</u></a>
10.13	<a href="#"><u>Amendment, effective July 1, 2011, to Standard Multi-Tenant Office Lease with S Real Estate Holdings LLC (incorporated by reference to Exhibit 10.43 of the Registrant's Form 10-K filed on March 26, 2013, File No. 000-51891).</u></a>
10.14	<a href="#"><u>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, File No. 000-51891).</u></a>
10.15	<a href="#"><u>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, File No. 000-51891).</u></a>
10.16	<a href="#"><u>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).</u></a>
10.17	<a href="#"><u>Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on March 10, 2016).</u></a>
10.18	<a href="#"><u>Fourth Amendment to Standard Multi-Tenant Office Lease with S Real Estate Holdings LLC, effective March 1, 2017 (incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q filed on May 15, 2017).</u></a>

<b>Exhibit Number</b>	<b>Description</b>
10.25	<a href="#">Note Conversion Agreement dated January 21, 2019 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on January 23, 2019).</a>
21.1	<a href="#">Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Form 10-K filed on March 30, 2016).</a>
23.1	<a href="#">Consent of BDO USA, LLP</a>
23.2	<a href="#">Consent of Mayer Hoffman McCann P.C.</a>
31.1	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer</a>
31.2	<a href="#">Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer</a>
32.1	<a href="#">Section 1350 Certification of Chief Executive Officer</a>
32.2	<a href="#">Section 1350 Certification of Chief Financial Officer</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase
*	Indicates management contract or compensatory plan.
(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: May 29, 2020

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.

<b>Signature:</b>	<b>Capacity:</b>	<b>Date:</b>
<u>/ S/ ANDREY SEMECHKIN</u> Andrey Semechkin	Co-Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	May 29, 2020
<u>/ S/ SOPHIA GARNETTE</u> Sophia Garnette	Vice President Legal Affairs and Operations (Principal Financial Officer)	May 29, 2020
<u>/ S/ RUSSELL KERN</u> Russell Kern	Executive VP and Chief Scientific Officer and Director	May 29, 2020
<u>/ S/ DONALD A. WRIGHT</u> Donald A. Wright	Co-Chairman of the Board	May 29, 2020
<u>/ S/ PAUL V. MAIER</u> Paul V. Maier	Director	May 29, 2020

**Consolidated Financial Statements**  
**International Stem Cell Corporation and Subsidiaries**  
**Years Ended December 31, 2019 and 2018**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of International Stem Cell Corporation (the "Company") as of December 31, 2019, the related statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the year 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, 2019, and the results of its operations and its cash flows for the year 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 suffered 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.

### Change in Accounting Principle

As discussed in Notes 1 and 10 of the consolidated financial statements, effective January 1, 2019, the Company has changed its method of accounting for leases due to the adoption of Accounting Standards Codification Topic 842, *Leases*.

### 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

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

San Diego, California  
May 29, 2020



## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
International Stem Cell Corporation and Subsidiaries

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of International Stem Cell Corporation and Subsidiaries ("Company") as of December 31, 2018, the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the year ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### Adoption of New Accounting Standard

As discussed in Note 1 to the financial statements, the Company changed its method of accounting for revenue from contracts with customers as a result of the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, effective January 1, 2018, under the modified retrospective method.

### Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring operating losses and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 1 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

### Basis for Opinion

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

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

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

/s/ Mayer Hoffman McCann P.C.

We served as the Company's auditors from 2011 to 2019

San Diego, California  
April 12, 2019

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

	December 31, 2019	December 31, 2018
<b>Assets</b>		
Cash	\$ 484	\$ 1,075
Accounts receivable, net	1,515	651
Inventory, net	1,246	1,501
Prepaid expenses and other current assets	207	543
Total current assets	3,452	3,770
Non-current inventory	358	805
Property and equipment, net	668	469
Intangible assets, net	1,335	2,674
Right-of-use asset	717	—
Deposits and other assets	90	78
Total assets	<u>\$ 6,620</u>	<u>\$ 7,796</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Accounts payable	\$ 654	\$ 458
Accrued liabilities	642	579
Operating lease liability, current	367	—
Advances	250	250
Related party note payable	—	2,045
Fair value of warrant liability	—	1,745
Total current liabilities	1,913	5,077
Related party note payable	2,370	—
Fair value of warrant liability	207	—
Long-term deferred rent	—	182
Operating lease liability, net of current portion	718	—
Total liabilities	<u>5,208</u>	<u>5,259</u>
Commitments and contingencies		
Series D Redeemable Convertible Preferred stock, \$0.001 par value, 50 shares authorized, 43 issued and outstanding, with liquidation preference of \$4,300 at December 31, 2019	4,300	—
<b>Stockholders' Equity (Deficit)</b>		
Series B Convertible Preferred stock, \$0.001 par value, 5,000,000 shares authorized, 250,000 issued and outstanding, with liquidation preferences of \$426 and \$411 at December 31, 2019 and 2018, respectively	—	—
Series D Convertible Preferred stock, \$0.001 par value, 50 shares authorized, 43 shares issued and outstanding, with liquidation preference of \$4,320 at December 31, 2018	—	—
Series G Convertible Preferred stock, \$0.001 par value, 5,000,000 shares authorized, issued and outstanding, with liquidation preference of \$5,000 at December 31, 2019 and 2018, respectively	5	5
Series I-1 Convertible Preferred stock, \$0.001 par value, 2,000 shares authorized, 814 issued and outstanding with liquidation preferences of \$814 at December 31, 2019 and 2018, respectively	—	—
Series I-2 Convertible Preferred stock, \$0.001 par value, 4,310 shares authorized, issued and outstanding with liquidation preferences of \$4,310 at December 31, 2019 and 2018, respectively	—	—
Common stock, \$0.001 par value, 120,000,000 shares authorized, 7,539,089 and 6,933,861 shares issued and outstanding at December 31, 2019 and 2018, respectively	8	7
Additional paid-in capital	103,490	109,188
Accumulated deficit	(106,391)	(106,663)
Total stockholders' equity (deficit)	(2,888)	2,537
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 6,620</u>	<u>\$ 7,796</u>

*See accompanying notes to consolidated financial statements.*

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

	<b>Years Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Revenues		
Product sales	\$ 9,472	\$ 11,089
Total revenues	9,472	11,089
Expenses		
Cost of sales	3,933	4,069
Research and development	1,386	2,396
Selling and marketing	2,685	2,631
General and administrative	7,196	5,467
Total expenses	15,200	14,563
Loss from operations	(5,728)	(3,474)
Other income (expense)		
Change in fair value of warrant liability	1,538	1,368
Interest expense	(77)	(48)
Miscellaneous income	2	44
Miscellaneous expense	—	(21)
Total other income (expense), net	1,463	1,343
Net loss	\$ (4,265)	\$ (2,131)
Net loss applicable to common stockholders	\$ (4,265)	\$ (2,131)
Net loss per common share-basic and diluted	\$ (0.57)	\$ (0.33)
Weighted average shares outstanding-basic and diluted	7,513	6,388

*See accompanying notes to consolidated financial statements.*

**International Stem Cell Corporation and Subsidiaries**  
**Consolidated Statements of Changes in Redeemable**  
**Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**For the years ended December 31, 2019 and 2018 (in thousands)**

	Redeemable Convertible Preferred Stock		Convertible Preferred Stock					
	Series D		Series B		Series D		Series G	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
<b>Balance at December 31, 2017</b>	—	\$ —	250	\$ —	—	\$ —	5,000	\$ 5
Issuance of common stock								
for services	—	—	—	—	—	—	—	—
for cash	—	—	—	—	—	—	—	—
from exercise of options	—	—	—	—	—	—	—	—
for settlement of trade payables	—	—	—	—	—	—	—	—
Conversion of preferred stock	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
Balance at December 31, 2018	—	—	250	—	—	—	5,000	5
Out of period correction (Note 2)	—	4,300	—	—	—	—	—	—
Conversion of debt	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—
Issuance of common stock	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—
<b>Balance at December 31, 2019</b>	—	\$ 4,300	250	\$ —	—	\$ —	5,000	\$ 5

  

	Convertible Preferred Stock				Common Stock		Additional	Accumulated	Total
	Series I-1		Series I-2				Paid-In	Deficit	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital		Equity (Deficit)
<b>Balance at December 31, 2017</b>	1	\$ —	4	\$ —	6,057	\$ 6	\$ 106,585	\$ (104,532)	\$ 2,064
Issuance of common stock									
for services	—	—	—	—	10	—	15	—	15
for cash	—	—	—	—	286	1	499	—	500
from exercise of options	—	—	—	—	141	—	160	—	160
for settlement of trade payables	—	—	—	—	160	—	248	—	248
Conversion of preferred stock	—	—	—	—	280	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	1,681	—	1,681
Net loss	—	—	—	—	—	—	—	(2,131)	(2,131)
Balance at December 31, 2018	1	—	4	—	6,934	7	109,188	(106,663)	2,537
Out of period correction (Note 2)	—	—	—	—	—	—	(8,837)	4,537	(4,300)
Conversion of debt	—	—	—	—	599	1	1,048	—	1,049
Stock-based compensation	—	—	—	—	—	—	2,087	—	2,087
Issuance of common stock	—	—	—	—	6	—	4	—	4
Net loss	—	—	—	—	—	—	—	(4,265)	(4,265)
<b>Balance at December 31, 2019</b>	1	\$ —	4	\$ —	7,539	\$ 8	\$ 103,490	\$ (106,391)	\$ (2,888)

*See accompanying notes to consolidated financial statements.*

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

	Years Ended December 31,	
	2019	2018
<b>Cash flows from operating activities</b>		
Net loss	\$ (4,265)	\$ (2,131)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	285	308
Stock-based compensation expense	2,087	1,681
Common stock issued for services	4	15
Change in fair value of warrant liability	(1,538)	(1,368)
Allowance for inventory obsolescence	579	(20)
Interest expense on related party note payable	73	45
Gain on settlement of trade payables	—	(32)
Loss on disposal of property and equipment	—	25
Impairment of intangible assets	1,540	607
Changes in operating assets and liabilities		
Accounts receivable	(864)	(186)
Inventory	123	(287)
Prepaid expenses and other current assets	336	245
Deposits and other assets	(12)	(4)
Right-of-use assets under lease obligations	289	—
Accounts payable	196	(92)
Accrued liabilities	74	112
Operating lease liabilities	(304)	—
<b>Net cash used in operating activities</b>	<b>(1,397)</b>	<b>(1,082)</b>
<b>Investing activities</b>		
Purchases of property and equipment	(164)	(185)
Payments for patent licenses	(330)	(476)
<b>Net cash used in investing activities</b>	<b>(494)</b>	<b>(661)</b>
<b>Financing activities</b>		
Proceeds from related party note payable	1,300	2,000
Proceeds from sale of common stock	—	500
Proceeds from exercise of stock options	—	160
Payments on financed insurance premiums	—	(146)
<b>Net cash provided by financing activities</b>	<b>1,300</b>	<b>2,514</b>
Net (decrease) increase in cash	(591)	771
Cash, beginning of year	1,075	304
Cash, end of year	<b>\$ 484</b>	<b>\$ 1,075</b>
<b>Supplemental disclosure of cash flow information</b>		
Cash paid for interest	<b>\$ 5</b>	<b>\$ 3</b>
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Issuance of common stock for settlement of trade payables	<b>\$ —</b>	<b>\$ 248</b>
Conversion of a related party note payable to common stock	<b>\$ 1,049</b>	<b>\$ —</b>
Financed insurance premiums	<b>\$ —</b>	<b>\$ 9</b>
Lease incentives received for leasehold improvements and construction in progress	<b>\$ —</b>	<b>\$ 179</b>

*See accompanying notes to consolidated financial statements.*

**International Stem Cell Corporation and Subsidiaries**  
**Notes to Consolidated Financial Statements**

**1. Organization and Significant Accounting Policies**

***Organization and Business***

International Stem Cell Corporation (the "Company") was organized in Delaware in June 2005 and is publicly traded in OTC QX. The Company is 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 208 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 cosmetic market, develops, manufactures and markets a category of anti-aging cosmetic 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 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.

The Company is a biotechnology company focused on therapeutic and clinical product development with multiple long-term therapeutic opportunities and two revenue-generating subsidiaries with potential for increased future revenues. The Company has generated product revenues from the two commercial businesses of \$9,472,000 and \$11,089,000 for the years ended December 31, 2019 and 2018, respectively. The Company currently has no revenue generated from its principal operations in therapeutic and clinical product development through research and development efforts.

***Liquidity and Going Concern***

The accompanying financial statements have been prepared under the assumption that the Company will continue as a going concern, which assumes that the Company will realize its assets and satisfy its liabilities in the normal course of business. The accompanying 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 has an accumulated deficit of approximately \$106.4 million as of December 31, 2019 and has incurred net losses and has had negative operating cash flows since inception. The Company has had no revenue from its principal operations in therapeutic and clinical product development through research and development efforts. Based on cash on-hand at December 31, 2019 of \$484,000 and anticipated cash burn, the Company estimates it has existing resources to fund the Company's principal operations into the second quarter of 2020. 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 capital.

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 capital from sources including the exercise of outstanding warrants, equity and/or debt financings, 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 2020 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 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 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 (see Note 12 for further discussion).

Additional financing through strategic collaborations, public or private equity financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to stockholders. Additional debt financing may be expensive and require the Company 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 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. 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.

### ***Principles of Consolidation***

The Company's consolidated financial statements include the accounts of International Stem Cell Corporation and its subsidiaries after intercompany balances and transactions have been eliminated.

### ***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 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. Inventory is reviewed periodically for product expiration and obsolescence and is adjusted accordingly. The value of the inventory that is not expected to be sold within twelve months of the year end is classified as non-current inventory on the 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. As of December 31, 2019 and 2018, the Company had an allowance for doubtful accounts totaling \$12,000.

### ***Advances***

On June 18, 2008, the Company entered into an agreement with BioTime, Inc. ("BioTime"), where BioTime paid an advance of \$250,000 to LCT to produce, make, and distribute Joint Products. The \$250,000 advance will be reduced with the first \$250,000 of net revenues that otherwise would be allocated to LCT under the agreement. As of December 31, 2019, no revenues were realized from 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, generally over three to five years. The costs of major remodeling and leasehold improvements are capitalized and amortized over the shorter of the remaining term of the lease or the estimated life of the asset.

### ***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 lives of the underlying patents, generally 15 years. All amortization expense and impairment charges related to intangible assets are included in general and administrative expense.

### ***Long-Lived Asset Impairment***

The Company reviews long-lived assets for impairment when events or changes in business conditions indicate that their carrying value may not be recoverable. The Company considers assets to be impaired and writes them down to estimated fair value if expected associated undiscounted cash flows are less than the carrying amounts. Fair value is the present value of the associated cash flows.

### ***Revenue Recognition***

Revenue is recognized at an amount that reflects the consideration to which the Company expects to be entitled in exchange for transferring goods or services to a customer. This principle is applied using the following five-step process:

1. Identify the contract with the customer
2. Identify the performance obligations in the contract
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations in the contract
5. Recognize revenue when (or as) each performance obligation is satisfied

Under ASC 606, the Company recognizes revenue when it satisfies a performance obligation by transferring control of the promised goods or services to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services.

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

#### **Biomedical Market:**

	<b>Year Ended December 31, 2019</b>			
	<b>U.S.</b>	<b>OUS*</b>	<b>Total Revenues</b>	<b>% of Total Revenues</b>
Biomedical products				
Media	\$ 5,750	\$ 483	\$ 6,233	83%
Cells	851	395	1,246	17%
Other	20	—	20	0%
Total	<u>\$ 6,621</u>	<u>\$ 878</u>	<u>\$ 7,499</u>	<u>100%</u>

#### **\*Outside the United States**

	<b>Year Ended December 31, 2018</b>			
	<b>U.S.</b>	<b>OUS*</b>	<b>Total Revenues</b>	<b>% of Total Revenues</b>
Biomedical products				
Media	\$ 7,336	\$ 516	\$ 7,852	85%
Cells	1,002	405	1,407	15%
Other	18	—	18	0%
Total	<u>\$ 8,356</u>	<u>\$ 921</u>	<u>\$ 9,277</u>	<u>100%</u>

#### **\*Outside the United States**

#### **Cosmetic Market:**

	<b>Year Ended December 31, 2019</b>		<b>Year Ended December 31, 2018</b>	
	<b>Total Revenues</b>	<b>% of Total Revenues</b>	<b>Total Revenues</b>	<b>% of Total Revenues</b>
Cosmetic sales channels				
e-commerce	\$ 1,043	53%	\$ 976	54%
Professional	930	47%	836	46%
Total	<u>\$ 1,973</u>	<u>100%</u>	<u>\$ 1,812</u>	<u>100%</u>



The Company's revenue consists primarily of sales of products from its two revenue-generating operating segments, the biomedical products and anti-aging cosmetics products business segments. The biomedical market segment markets and sells primary human cell research products with two product categories, cells and media, both sold within and outside the United States. The cosmetic market segment markets and sells a line of luxury skincare products sold through two sales channels: ecommerce and professional.

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 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.

For LSC products, ecommerce sales are primarily paid through credit card charges, while professional and international sales are invoiced. The professional sales and biomedical products' standard payment terms for its customers are generally 30 days after the Company satisfies the performance obligations. For cosmetic products, 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, 2019 and 2018.

The Company elects to account for shipping and handling as activities to fulfill the promise to transfer the goods. As a result, no consideration is allocated to shipping and handling. Rather, the Company accrues the cost of shipping and handling upon shipment of the product, and all contract revenue 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 the performance obligations are satisfied. As of December 31, 2019 and 2018, accounts receivable, net, totaled \$1,515,000 and \$651,000, respectively. For the year ended December 31, 2019, the Company did not incur material impairment losses with respect to its receivables.

#### *Practical Expedients*

The Company has elected the practical expedient not to determine whether contracts with customers contain significant financing components. The Company pays commissions on certain sales for its biomedical and cosmetic market(s) 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 in consideration of the transaction price.

#### *Allowance for Sales Returns*

The Company's cosmetic products have a 30-day product return guarantee. Historical returns have been immaterial, so as of December 31, 2019 and 2018, the Company had 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 and include related direct materials, general laboratory supplies and allocation of overhead. Certain of the agreements under which the Company has licensed technology will require the payment of royalties based on the sale of its future products. Such royalties will be recorded as a component of cost of sales. Additionally, the amortization of license fees or milestone payments related to developed technologies used in the Company's products will be classified as a component of cost of sales to the extent such payments become due in the future.

### ***Research and Development Costs***

Research and development costs, which are expensed as incurred, are primarily comprised of costs and expenses for salaries and benefits associated with research and development personnel, overhead, occupancy and contract services.

### ***Australian Tax Incentive***

The Company is eligible to obtain a cash refund from the Australian Taxation Office under the Australian R&D Tax Incentive Program. The tax incentive reduces company R&D costs by offering tax offsets for eligible R&D expenditure. Eligible companies with a turnover of less than \$20 million receive a refundable tax offset, allowing the benefit to be paid as a cash refund if they are in a tax loss position. 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. Due to uncertainty regarding allowable costs, the Company records the grants when the funds are received. The Company recognized reductions to R&D expense of \$615,000 and \$346,000 for the years ended December 31, 2019 and 2018, respectively.

### ***Stock-Based Compensation***

The Company recognizes stock-based compensation expense associated with stock options and other stock-based awards in accordance with the authoritative guidance for 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 estimated forfeitures 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 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 Measurements***

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. Assets and liabilities that are measured at fair value are reported using a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1	Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
Level 2	Quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability; and
Level 3	Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The table below sets forth a summary of the Company's liabilities which are measured at fair value on a recurring basis as of December 31, 2019 and 2018 (in thousands).

	Total	Level 1	Level 2	Level 3
Warrant Liabilities				
Balance as of December 31, 2019	\$ 207	\$ —	\$ —	\$ 207
Balance as of December 31, 2018	1,745	—	—	1,745

The following table displays the rollforward activity of liabilities with inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity) (in thousands):

	<b>Warrant Liability</b>
Ending balance at December 31, 2017	\$ 3,113
Adjustments to estimated fair value	(1,368)
Ending balance at December 31, 2018	\$ 1,745
Adjustments to estimated fair value	(1,538)
Ending balance at December 31, 2019	\$ 207

#### *Warrant Liability*

The Company is required to recognize warrant agreements as a liability since the warrants do not meet the specific conditions for equity classification and therefore need to be recognized at its fair value. The fair value of the warrant liability is calculated using the Monte-Carlo simulation model, which requires the use of certain estimates. The fair value of these warrants is re-measured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying consolidated statements of operations.

The following assumptions were used as inputs to the model:

	<b>Years Ended December 31,</b>	
	<b>2019</b>	<b>2018</b>
Significant assumptions:		
Risk-free interest rate	1.55% - 1.59%	2.48% - 2.59%
Volatility	85.0%	94.2%
Term to expiration	0.29 - 1.21 years	1.29 - 2.21 years
Subsequent financing	0%	90%

#### *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. Penalties and interest are recorded with general and administrative expenses.

#### *Use of Estimates*

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements. Significant estimates include patent life (remaining legal life versus remaining useful life), inventory carrying values, allowance for excess and obsolete inventories, allowance for sales returns and doubtful accounts, and transactions using the Black-Scholes option pricing model, e.g., warrants and stock options, as well as the Monte-Carlo valuation method for certain warrants. Actual results could differ from those estimates.

#### *Fair Value of Financial Instruments*

The Company believes that the carrying value of its cash and cash equivalents, receivables, accounts payable, accrued liabilities, and related party payable as of December 31, 2019 and 2018 approximate their fair values because of the short-term nature of those instruments. The fair value of certain warrants was determined at each issuance and reporting date and other applicable re-measurement dates in 2019 and 2018 using the Monte-Carlo valuation methodology.

### ***Income (Loss) Per Common 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 options, convertible preferred stock and warrants. For the years ended December 31, 2019 and 2018, there is no difference in the number of shares used to calculate basic and diluted shares outstanding as the inclusion of the potentially dilutive securities would be antidilutive.

For the periods below, these stock options, warrants, and convertible preferred stock were not included in the diluted loss per share calculation because the effect would have been anti-dilutive.

	Years Ended December 31,	
	2019	2018
Options outstanding	4,936,673	4,367,342
Convertible preferred stock	6,132,278	6,120,725
Warrants outstanding	3,951,052	3,951,052

### ***Comprehensive Income***

Comprehensive income or loss includes all changes in stockholders' equity except those resulting from investments by owners and distributions to owners. The Company did not have any items of comprehensive income or loss other than net loss from operations for the years ended December 31, 2019 and 2018.

### ***Recent Accounting Pronouncements***

In June 2018, the FASB issued ASU 2018-07, *"Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting."* ASU 2018-07 makes nonemployee share-based payments to be consistent with the accounting for employee share-based payment awards, which measures the fair value of the payment based on grant date and considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. The updated standard is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The adoption of ASU 2018-07 on January 1, 2019 did not result in a material impact on the Company's balance sheet or statement of operations.

In July 2017, the FASB issued ASU No. 2017-11, *"Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), and Derivatives and Hedging (Topic 815)"* ("ASU 2017-11") effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. ASU 2017-11 changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments require entities that present earnings per share ("EPS") in accordance with Topic 260 to recognize the effect of the down round feature when triggered with the effect treated as a dividend and as a reduction of income available to common shareholders in basic EPS. The adoption of ASU 2017-11 on January 1, 2019 did not result in a material impact on the Company's balance sheet or statement of operations.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize "right-of-use" assets and a lease liability for all leases with lease terms of more than 12 months. The Company elected the exception from applying the new guidance for any short-term leases with initial terms less than or equal to 12 months. Topic 842 requires additional quantitative and qualitative financial statement footnote disclosures about the leases, significant judgments made in accounting for those leases and amounts recognized in the financial statements about those leases. In 2018 and 2019, the FASB has issued and incorporated several additional ASUs to provide clarifying guidance associated with the application of certain principles within Topic 842. The effective date will be the first quarter of fiscal year 2019. The Company elected the "package of practical expedients," which allowed the Company to not reassess under the new guidance, the Company's prior conclusions about lease identification, classification, and treatment of initial direct costs as well as electing the modified retrospective approach effective January 1, 2019. At adoption, total right-of-use assets and operating lease liabilities were approximately \$1,180,000 and \$1,389,000 respectively. All operating lease expense is recognized on a straight-line basis over the lease term.

### ***Accounting Pronouncements Being Evaluated***

In June 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. 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. The Company is currently evaluating the impact of the adoption of this ASU, which will be effective for the Company as of January 1, 2023.

In August 2018, the FASB issued Accounting Standards Update ("ASU") 2018-13, *"Fair Value Measurement (Topic 820), 'Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement'"* ("ASU 2018-13), which removes the valuation processes for Level 3 fair value measurements and adds the disclosure for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The updated standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company is currently evaluating the impact of the adoption of this accounting standard update.

In December 2019, the FASB issued ASU No 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* (ASU 2019-12). ASU 2019-12 removes certain exceptions to the general principles in Topic 740. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

## 2. Correction of Immaterial Misstatements in the Financial Statements for the Year Ended December 31, 2018

During the quarter ended June 30, 2019, the Company determined that the Series D Preferred Stock has a contingent redemption feature. As this feature may trigger the redemption of the convertible preferred stock that is not solely within the Company's control, the convertible preferred stock should be classified in temporary equity (outside of permanent equity) on the Company's consolidated balance sheet as of December 31, 2018. The March 31, 2019 consolidated balance sheet has been corrected by classifying the Series D redeemable convertible preferred stock within temporary equity from additional paid-in capital in the amount of \$4,300,000. The Company also determined that the beneficial conversion feature was previously incorrectly recorded in accumulated deficit instead of additional paid-in capital in the amount of \$4,537,000. Based on a quantitative and qualitative analysis of the errors as required by authoritative guidance, management concluded the errors were not material to any of the previously issued financial statements from 2009 through 2018 and corrected the error prospectively.

## 3. Inventory

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

	December 31, 2019	December 31, 2018
Raw materials	\$ 688	\$ 656
Work in process	492	590
Finished goods	1,219	1,276
Total	2,399	2,522
Less: allowance for inventory excess and obsolescence	(795)	(216)
Total current and non-current inventory, net	\$ 1,604	\$ 2,306
Inventory, net	\$ 1,246	\$ 1,501
Non-current inventory	358	805
Total current and non-current inventory, net	\$ 1,604	\$ 2,306

#### 4. Property and Equipment

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

	December 31, 2019	December 31, 2018
Machinery and equipment	\$ 1,642	\$ 1,614
Computer equipment and software	236	251
Office equipment	230	215
Leasehold improvements	1,290	996
Construction in progress	12	45
	3,410	3,121
Less: accumulated depreciation and amortization	(2,742)	(2,652)
Property and equipment, net	\$ 668	\$ 469

Depreciation and amortization expense for the years ended December 31, 2019 and 2018 were \$156,000 and \$191,000, respectively.

#### 5. Intangible Assets

Intangible Assets consists of the following (in thousands):

	Years Ended December 31,	
	2019	2018
Patents	\$ 2,268	\$ 3,549
Less: accumulated amortization	(1,008)	(958)
Total	1,260	2,591
Indefinite life logos and trademarks	75	83
Intangible assets, net	\$ 1,335	\$ 2,674

Amortization expense for the years ended December 31, 2019 and 2018 was \$129,000 and \$117,000, respectively. During the years ended December 31, 2019 and 2018, the Company abandoned and fully impaired certain patents that the Company concluded it would no longer defend or incur additional costs to maintain. Impairment charges for the year ended December 31, 2019 and 2018 was \$1,540,000 and \$607,000 respectively.

The timing of approval of pending patent applications is uncertain, so they are included in the thereafter period below until issued. Pending patents at December 31, 2019 was \$260,000. At December 31, 2019, future amortization expense related to the intangible assets subject to amortization is expected to be as follows (in thousands):

	Amount
2020	\$ 84
2021	84
2022	84
2023	84
2024	84
Thereafter	840
Total	\$ 1,260

#### 6. Capital Stock

##### Common Stock

As of December 31, 2019, the Company is authorized to issue 120,000,000 shares of common stock, \$0.001 par value per share, and 20,000,000 shares of preferred stock, \$0.001 par value per share.

##### Description of Preferred Stock

###### Dividends

Holders of 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, 2019.

#### *Liquidation*

Liquidation preference among classes of preferred shares is first with Series D Redeemable Preferred stock ("Series D") with priority, followed by Series G Preferred stock ("Series G"), Series B Preferred stock ("Series B"), Series I-1 Preferred stock ("Series I-1") and Series I-2 Preferred stock ("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, Series I-1 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, Series I-1 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. The conversion price of the Series I-1 and 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 preferred stock can be converted at December 31, 2019 and 2018:

Series	Initial Conversion Price	As of December 31, 2019		As of December 31, 2018	
		Conversion Price	Conversion Ratio to Common Stock	Conversion Price	Conversion Ratio to Common Stock
Series B	\$ 75.00	\$ 1.08	0.925924	\$ 1.08	0.925924
Series D	\$ 37.50	\$ 1.75	57,142.860500	\$ 1.75	57,142.860500
Series G	\$ 60.00	\$ 9.70	0.103099	\$ 9.92	0.100790
Series I-1	\$ 1.75	\$ 1.75	571.428571	\$ 1.75	571.428571
Series I-2	\$ 1.75	\$ 1.75	571.428571	\$ 1.75	571.428571

#### *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 stockholder's 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 based on the NASDAQ listing requirements. The holders of Series I-1 and Series I-2 have no voting rights, except as required by law.

#### *Series D Preferred Stock Redemption*

During the quarter ended June 30, 2019, the Company determined that Series D has a contingent redemption feature. As this feature may trigger the redemption of Series D that is not solely within the Company's control, Series D is classified in temporary equity (outside of permanent equity) on the Company's consolidated balance sheet as of December 31, 2019. See Note 2 for further discussion of the error as of December 31, 2018 and the conclusion that the error was immaterial.

#### *Capital Transactions*

On January 21, 2019, the Company issued 599,222 shares of common stock upon conversion of a portion of the Company's outstanding indebtedness with a principal amount of \$1 million and accrued and unpaid interest on the principal of \$49,000 (See Note 7 for details of the conversion). In accordance with the Series G Certificate of Designation, the issuance of Common Shares at the conversion price of \$1.75 per share triggered further adjustment in the conversion price and conversion ratio of the Series G Preferred Stock from \$9.92 per share and 0.1008 shares to \$9.70 per share and 0.1031 shares, respectively. The deemed dividend as a result of the down-round adjustment was trivial.

#### *Reserved Shares*

At December 31, 2019, the Company had shares of common stock reserved for future issuance as follows:

Options outstanding	4,936,673
Options available for future grant under the 2010 Equity Participation Plan	4,487,863
Convertible preferred stock	6,132,278
Warrants	3,951,052
<b>Total</b>	<b>19,507,866</b>

## **7. Related Party Transactions**

During the first quarter of 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 and a director and was previously owned by Dr. Andrey Semechkin, the Company's Chief Executive Officer and Co-Chairman of the Board of Directors. The lease agreement was negotiated at arm's length 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 2019 and include annual adjustments to the monthly lease payments. For the years ended December 31, 2019 and 2018, the Company recorded \$160,000, in rent expense that was related to the facility lease arrangement with related parties.

Between March 6, 2018 and August 8, 2018, to obtain funding for working capital purposes, the Company borrowed a total of \$2.0 million from Dr. Andrey Semechkin and issued an unsecured non-convertible promissory note in the principal amount of \$2.0 million (the "Note") to Dr. Semechkin (the "Noteholder"). The outstanding principal amount under the Note accrued interest at a rate of four percent (4%) per annum. The Note was due and payable November 1, 2018 and on November 12, 2018, to satisfy the indebtedness incurred on the Note, an amendment to the Note was entered into extending the due date to January 15, 2019.

On January 21, 2019, the Company entered into a Note Conversion Agreement with Dr. Andrey Semechkin, the Company's Co-Chairman and Chief Executive Officer (the "Conversion Agreement"). The Conversion Agreement provides for the conversion of a total of about \$1.0 million (representing \$1.0 million of principal and \$49,000 of accrued interest, representing all accrued interest on the amount owed to Dr. Semechkin through January 21, 2019) under the promissory note issued to Dr. Semechkin on August 8, 2018 into a total of 599,222 shares of the Company's common stock, representing a conversion price of \$1.75 per share, which was greater than the fair value of common stock on the date of conversion at a price of \$1.60 per share. Dr. Semechkin took less than fair value to avoid further dilution by triggering down-round adjustments to outstanding warrants and convertible preferred stock. Due to Dr. Semechkin's role in the Company and controlling interest in the Company, no gain was recorded by the Company upon conversion and the excess was recorded within additional paid-in capital due to the absence of retained earnings. Under the Conversion Agreement, the remaining \$1.0 million owed to Dr. Semechkin under the Note has been reflected in a new unsecured, non-convertible promissory note in the principal amount of \$1.0 million (the "Note"). The outstanding principal amount under the Note accrues interest at a rate of 4.5% per annum. The Note is due and payable on January 15, 2021, but may be pre-paid by the Company without penalty at any time.

On April 17, 2019 to obtain additional funding for working capital purposes, the Company issued an unsecured, non-convertible promissory note (the "New Promissory Note") in the amount of \$1.8 million to Dr. Andrey Semechkin, the Company's Chief Executive Officer and Co-Chairman of the Board of Directors. Dr. Andrey Semechkin surrendered an existing promissory note from the Company for \$1.0 million and provided an additional \$800,000 of funds to the Company. The outstanding principal amount accrues interest at a rate of 4.5% per annum and is due and payable, on January 15, 2021 but may be pre-paid by the Company without penalty at any time.

On December 17, 2019 to obtain additional funding for working capital purposes the Company issued an unsecured, non-convertible promissory note in the principal amount of \$2.3 million (the "New Note") to Dr. Andrey Semechkin. On December 17, 2019 the Noteholder provided additional \$500,000 of funds to the Company and surrendered the New Promissory Note, in return for the New



Note. Dr. Semechkin is the Company's Co-Chairman and Chief Executive Officer. The outstanding principal amount under the New Note accrues interest at a rate of 4.5% per annum. The New Note is due and payable January 15, 2021 but may be pre-paid by the Company without penalty at any time

## 8. 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 had available at December 31, 2019, net operating loss carryforwards of approximately \$70.0 million, which may be applied against future taxable income and will expire in various years through 2039. However, any net operating loss carryforwards generated in 2018 and future years will not expire and are carried forward indefinitely. At December 31, 2018, the Company had net operating loss carryforwards of approximately \$67.2 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, research and development 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 years ended December 31, 2019 and 2018 follows:

	December 31, 2019	December 31, 2018
Statutory federal income tax rate	21%	21%
Permanent items	3%	6%
State income taxes, net of federal taxes	0%	4%
Foreign	5%	(2)%
Change in valuation allowance*	(13)%	(27)%
Lease accounting	2%	0%
Stock options true-up*	(19)%	0%
Tax credits claimed	0%	(1)%
Other	1%	(1)%
Effective income tax rate	0%	0%

*\*includes a prior year correction (see below for more details)*

During the year ended December 31, 2019, the Company determined that it had incorrectly recorded deferred tax assets related to stock-based compensation in the amount of \$392,000. These assets had a full valuation allowance. As a result, the Company wrote-off the prior year stock options expense used in calculating deferred tax assets were incorrectly reported and as a result, the valuation allowance was also impacted. The effective income tax rate, however, remained the same. As a result, the December 31, 2019 table above includes this correction that included an increase of 13% to the change in valuation allowance and a 13% decrease to stock options true-up. Based on a quantitative and qualitative analysis, management concluded the errors were not material to historical financial statements and corrected the error prospectively.

The Company files income tax returns in the U.S. federal jurisdiction and various states. The Company is no longer subject to U.S. federal, state and local income tax examinations by tax authorities for years before 2015. The Company does not have any material uncertain tax positions as of December 31, 2019 and 2018. The Company does not believe it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2019 will materially change in the next 12 months.

The Company may be subject to IRC Code Sections 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 Code 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 a 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 will 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 the 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, 2019	December 31, 2018
Net operating loss carryforwards	\$ 18,452	\$ 17,569
Stock based compensation	1,980	2,437
Research and development tax credit	2,871	2,729
Other	547	260
Non-current deferred tax assets	23,850	22,995
Valuation allowances	(23,850)	(22,995)
Net deferred tax assets	\$ —	\$ —

During the preparation of the 2019 and 2018 income tax provision, the Company completed its analysis to determine the effect of the Tax Act and recorded no additional adjustments.

## 9. Stock Options and Warrants

### *Stock Options*

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 November and December of 2009, the Company issued non-qualified stock options to purchase 68,384 shares of common stock outside the 2006 and 2010 option plans to certain employees and consultants. These options vest over 50 months and expire no later than 10 years from the date of grant. As of December 31, 2019 and 2018, zero and 12,634 options were outstanding, respectively.

Total stock-based compensation expense for the years ended December 31, 2019 and 2018 was comprised of the following (in thousands):

	Years Ended December 31,	
	2019	2018
Cost of sales	\$ 112	\$ 57
Research and development	519	641
Selling and marketing	118	54
General and administrative	1,338	929
	\$ 2,087	\$ 1,681

Unrecognized compensation expense related to stock options as of December 31, 2019 was \$1,919,000, which is expected to be recognized over a weighted average period of approximately 1.51 years.

In accordance with applicable authoritative guidance, the Company is required to establish assumptions and estimates of the fair value of stock options granted, as well as use a valuation model to calculate the fair value of stock-based awards. The Company uses the Black-Scholes option-pricing model to determine the fair-value of stock-based awards. All options are amortized over the requisite service periods.

The fair value of options granted is estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions for the years ended December 31, 2019 and 2018:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Significant assumptions (weighted average):		
Risk-free interest rate at grant date	2.44%	2.72%
Expected stock price volatility	84.95%	92.68%
Expected dividend payout	0%	0%
Expected option life based on management's estimate	5.71 years	5.70 years

Transactions involving stock options issued to employees, directors and consultants under the 2006 Plan, the 2010 Plan and outside the plans are summarized below. Options issued have a maximum life of 10 years. The following table summarizes the changes in options outstanding and the related exercise prices for the Company's common stock options issued:

	Number of Options Issued Under 2006 Plan and 2010 Plan	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	2,245,349	\$ 8.25		
Granted	2,568,842	\$ 1.56		
Exercised	(140,968)	\$ 1.13		
Canceled or expired	(318,515)	\$ 16.21		
Outstanding at December 31, 2018	4,354,708	\$ 3.95		
Granted	1,345,964	\$ 1.44		
Canceled or expired	(763,999)	\$ 3.18		
Outstanding at December 31, 2019	4,936,673	\$ 3.38	8.09 years	\$ —
Vested and expected to vest at December 31, 2019	4,759,057	\$ 3.45	8.06 years	\$ —
Exercisable at December 31, 2019	2,970,989	\$ 4.61	7.67 years	\$ —
	Number of Options Issued Outside the Plan	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Outstanding, vested and exercisable at December 31, 2017	50,730	\$ 92.31		
Canceled or expired	(38,096)	\$ 93.00		
Outstanding, vested and exercisable at December 31, 2018	12,634	\$ 90.23		
Canceled or expired	(12,634)	\$ 90.23		
Outstanding, vested and exercisable at December 31, 2019	—	\$ —	0.0 years	\$ —

During the fiscal year ended December 31, 2018, four optionees exercised 140,968 options at a weighted average exercise price of \$1.13 for a total exercise price of \$160,000. On the various dates of exercise, the aggregate intrinsic value of the options was \$60,000 or a weighted average of \$0.42 per share.

### ***Restricted Stock Awards***

Restricted stock awards are grants that entitle the holder to acquire shares of common stock at zero or a fixed price, which is typically nominal. The Company accounts for the restricted stock awards as issued and outstanding common stock, even though the shares covered by a restricted stock award cannot be sold, pledged, or otherwise disposed of until the award vests and any unvested shares may be reacquired by the Company for the original purchase price following the awardee's termination of service.

For the year ended December 31, 2019, there were 6,006 shares of restricted stock were awarded and fully vested at a weighted average grant date fair value of \$0.62. For the year ended December 31, 2018, there were 9,855 shares of restricted stock awarded and fully vested at a weighted average grant date fair value of \$1.55 per share.

The fair value of the restricted stock awards is based on the market value of the common stock on the date of grant. The total grant-date fair value of restricted stock awards vested during the years ended December 31, 2019 and 2018 was approximately \$3,700 and \$15,000, respectively. The Company recognized approximately \$3,700 and \$15,000 of stock-based compensation expense related to the restricted stock awards for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019 and 2018, there was no unrecognized compensation costs related to unvested awards.

#### ***Warrants Issued with Common Stock***

Share data related to warrant transactions as of the years ended December 31, 2019 and 2018 were as follows:

	Common Stock October 2014 Financing	Common Stock March 2016 Financing	Total Warrants	Exercise Price
Outstanding, December 31, 2019, 2018 and 2017	2,483	3,948,569	3,951,052	\$ 1.75
Expiration Date	April 14, 2020	March 15, 2021		

## **10. Commitments and Contingencies**

### ***Leases***

The Company has three operating leases for real estate in California and Maryland:

- Carlsbad, California – corporate offices with a term date of February 2020 and leased from a related party (see also Note 7),
- Oceanside, California – primary research facility and laboratory space with a term date of December 2021 with the Company's option to terminate the lease on January 1, 2020 upon a six-month advanced notice,
- Frederick, Maryland – mixed laboratory and administrative space with a term date of November 2025.

These operating leases are included in "right-of-use assets" on the Company's December 31, 2019 balance sheet and represent the Company's right to use the underlying asset for the lease term. The Company's obligation to make lease payments is included in "operating lease liabilities, current" and "operating lease liabilities, net of current portion" on the Company's December 31, 2019 balance sheet. Operating lease right-of-use assets and liabilities commencing after January 1, 2019 are recognized at commencement date based on the present value of lease payments over the lease term. As of December 31, 2019, total right-of-use assets and operating lease liabilities were approximately \$717,000 and \$1,085,000, respectively. All operating lease expense is recognized on a straight-line basis over the lease term.

As most of the Company's operating leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would expect to pay to borrow on a collateralized and fully amortizing basis over a similar term an amount equal to the lease payments in a similar economic environment.

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

	Year Ended December 31, 2019
Operating lease costs	\$ 490
Operating cash flows from operating leases	486
Right-of-use assets obtained in exchange for new operating lease obligations at adoption	1,180
Weighted-average remaining lease term (years)	5.02
Weighted average discount rate	17.65%

Maturities of lease liabilities as of December 31, 2019 were as follows (in thousands):

2020	\$	367
2021		347
2022		220
2023		226
2024		233
Thereafter		240
		<u>1,633</u>
Less: present value adjustments		(548)
Total lease liabilities	\$	<u>1,085</u>
Current operating lease liabilities	\$	367
Non-current operating lease liabilities		718
Total operating lease liabilities	\$	<u>1,085</u>

Total annual commitments under non-cancelable lease agreements as of December 31, 2018 under the previous lease accounting guidance are as follows (in thousands):

	Amount
2019	\$ 491
2020	368
2021	347
2022	220
2023	227
Thereafter	454
Total	<u>\$ 2,107</u>

The Company incurred rent expense of \$322,000 for the year ended December 31, 2018.

#### *Licensed Patents*

The Company has a minimum annual license fee of \$75,000 payable in two installments per year to Astellas Pharma pursuant to the amended UMass IP license agreement and is noncancelable.

#### *Customer Concentration*

During the year ended December 31, 2019 for the Biomedical market segment, one major customer accounted for approximately 37% and another customer accounted for 15% of consolidated revenues. During the year ended December 31, 2018 for the Biomedical market segment, one major customer accounted for 33% of consolidated revenues and another customer accounted for 24% of consolidated revenues. No other single customer accounted for more than 10% of revenues for any period presented.

#### *Vendor Concentration*

During the year ended December 31, 2019, no single vendor accounted for more than 10% of consolidated purchases, while during the year ended December 31, 2018, one vendor accounted for approximately 21% of consolidated purchases.

### **11. Segments and Geographic Information**

The Company's chief operating decision-maker reviews financial information presented on a consolidated basis, accompanied by disaggregated information by each reporting segment's statement of operations. The Company operates the business on the basis of three reporting segments, the therapeutics market and two business units:

### ***Revenues, Expenses and Operating Income (loss)***

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

	Years Ended December 31,	
	2019	2018
Revenues:		
Cosmetic market	\$ 1,973	\$ 1,812
Biomedical market	7,499	9,277
Total revenues	9,472	11,089
Expenses:		
Therapeutics market	6,345	5,904
Cosmetic market	2,699	2,637
Biomedical market	6,156	6,022
Total operating expenses	15,200	14,563
Operating income (loss):		
Therapeutics market	(6,345)	(5,904)
Cosmetic market	(726)	(825)
Biomedical market	1,343	3,255
Total loss from operations	\$ (5,728)	\$ (3,474)

### ***Geographic Information***

The Company's wholly-owned subsidiaries are located in Maryland, California and Melbourne, Australia, and have customer and vendor relationships worldwide. 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,	
	2019	2018
North America	\$ 8,583	\$ 10,160
Asia	540	612
Europe	325	293
All other regions	24	24
Total	\$ 9,472	\$ 11,089

## **12. Subsequent Events**

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company's financial condition, liquidity, and future results of operations. Management is actively monitoring the situation on its financial condition, liquidity, operations, customers, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the response to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak to its results of operations, financial condition, or liquidity for fiscal year 2020.

On March 1, 2020, the Company entered into an amendment to its existing facilities lease with S Real Estate Holding LLC (owned by Dr. Russell Kem, the Company's Executive Vice President and Chief Scientific Officer and a director, and was previously owned by Dr. Andrey Semechkin, the Company's Chief Executive Officer and Co-Chairman of the Board of Directors). The amendment extended the term of the lease for three years (until February 28, 2023) and provided for a 2% increase in monthly rent.

On March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief and Economic Security (CARES) Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction

limitations, increased limitations on qualified charitable contributions and technical corrections to tax depreciation methods for qualified improvement property. We continue to examine the impact that the CARES Act may have on our business. Currently, we are unable to determine the impact that the CARES Act will have on our financial condition, results of operations, or liquidity.

It also appropriated funds for the SBA Paycheck Protection Program ("PPP") loans that are forgivable in certain situations to promote continued employment, as well as Economic Injury Disaster Loans to provide liquidity to small businesses harmed by COVID-19. The Company applied for and received \$654,000 from the PPP as government aid for payroll, rent and utilities. The application for these funds required the Company to, in good faith, certify that the current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to take into account our current business activity and our ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The certification made by the Company did not contain any objective criteria and is subject to interpretation. If, despite the good-faith belief that given the Company's circumstances all eligibility requirements for the PPP Loan were satisfied, it is later determined that the Company had violated any applicable laws or regulations or it is otherwise determined the Company was ineligible to receive the PPP Loan, it may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties.

**Consent of Independent Registered Public Accounting Firm**

International Stem Cell Corporation  
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-210840, 333-201589, and 333-199799) and Form S-8 (Nos. 333-226844, 333-211411, 333-206930, 333-169549, 333-166883, 333-166421, 333-166420, 333-164539, 333-159424, 333-159421, and 333-150920) of International Stem Cell Corporation (the "Company") of our report dated May 29, 2020, relating to the consolidated financial statements, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP  
San Diego, California

May 29, 2020



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Prospectus constituting a part of the Registration Statements on Form S-8 (Nos. 333-226844, 333-211411, 333-206930, 333-169549, 333-166883, 333-166421, 333-166420, 333-164539, 333-159424, 333-159421, and 333-150920) and on Form S-1 (Nos. 333-210840, 333-201589, and 333-199799) of our report dated April 12, 2019 (which includes explanatory paragraphs related to the change in the method of accounting for revenue and the uncertainty of the Company's ability to continue as a going concern) relating to the consolidated financial statements of International Stem Cell Corporation and Subsidiaries (the Company), as of and for the year ended December 31, 2018, which report is included in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Mayer Hoffman McCann P.C.

San Diego, California  
May 29, 2020

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Andrey Semechkin, certify that:

1. I have reviewed this annual report on Form 10-K of International Stem Cell Corporation;

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

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

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

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

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

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

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

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

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

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

Date: May 29, 2020

/s/ ANDREY SEMECHKIN

\_\_\_\_\_  
Andrey Semechkin  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

I, Sophia Gamette, certify that:

1. I have reviewed this annual report on Form 10-K of International Stem Cell Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the periods covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the period presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 29, 2020

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/s/ Sophia Gamette  
 Sophia Gamette  
*Vice President, Legal Affairs and Operations*  
*(Principal Financial Officer)*

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of International Stem Cell Corporation (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on May 29, 2020 (the "Report"), I, Andrey Semechkin, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 29, 2020

/S/ ANDREY SEMECHKIN

\_\_\_\_\_  
Andrey Semechkin  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of International Stem Cell Corporation (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on May 29, 2020 (the "Report"), I, Sophia Gamette, Vice President, Legal Affairs & Operations of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 29, 2020

/s/ Sophia Gamette  
\_\_\_\_\_  
Sophia Gamette  
*Vice President, Legal Affairs & Operations*  
*(Principal Financial Officer)*