Intellicell Biosciences, Inc.
Form 10-K
May 12, 2014

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

FORM 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2013

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 000-54729

INTELLICELL BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Nevada	91-1966948
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

460 Park Avenue, 17th Floor, New York, New York 10022

(Address of principal executive offices) (Zip Code)

(646) 576-8700
(Registrant's telephone number)

(Former Name, Former Address and Former Fiscal Year, if changed since last report)

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

Title of Each Class to be so Registered:	Name of each exchange on which registered
None	None

Securities registered under Section 12(g) of the Act: Common Stock, Par Value $0.0001 per share

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

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 o No ý

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 (the "Exchange Act") 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 o No ý

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes o No ý

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x
(Do not check if a smaller reporting company)	

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was 4,228,019, computed by reference to the closing price of the common stock on June 30, 2013. For purposes of the above statement only, all directors, executive officers and 10% shareholders are assumed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

The number of outstanding shares of the Registrant’s Common Stock, $0.0001 par value, at May 9, 2014 was 2,230,314,377.

Index

INTELLICELL BIOSCIENCES, INC.
FORM 10-K

INDEX

Index

FORWARD-LOOKING STATEMENTS

Statements in this annual report may be “forward-looking statements.” Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors, including those described above and those risks discussed from time to time in this prospectus, including the risks described under “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this annual report and in other documents which we file with the Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to our ability to raise any financing which we may require for our operations, competition, government regulations and requirements, pricing and development difficulties, our ability to make acquisitions and successfully integrate those acquisitions with our business, as well as general industry and market conditions and growth rates, and general economic conditions. Any forward-looking statements speak only as of the date on which they are made, and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the filing of this annual report, except as may be required under applicable securities laws.

Index

PART I

We urge you to read this entire Annual Report on Form 10-K, including the "Risk Factors" section and the financial statements and related notes included herein. As used in this Annual Report, unless context otherwise requires, the words "we," "us", "our," "the Company," "Intellicell" and "Registrant" refer to Intellicell Biosciences, Inc., including subsidi and predecessors, except where it is clear that the term refers to Intellicell Biosciences, Inc. Also, any reference to "common shares," or "common stock," refers to our common stock, par value $0.0001 per share.

ITEM 1. BUSINESS.

Overview

We are an emerging leader in the regenerative medicine market using adult autologous stromal vascular fraction cells (SVFs) derived from the blood vessels in adipose tissue. Among other cell types, stromal vascular fraction contains adult stem cells. We believe that our cell therapy processes and procedures are exempt under PHS Section 361, CFR 1271.10 or CFR 1271.15(b) same day surgical procedure. Therefore, we do not believe that we will be required to obtain Food and Drug Administration ("FDA") drug or biologic like approvals, although there can be no assurance that the FDA will require our products to obtain approval in the future.

We currently operate from Regen Medical PC office based surgery center facility in New York, NY, an entity controlled by Dr. Steven Victor, our chief executive officer, where we have our cGTP (current good tissue practices) cellular processing laboratory which is registered with the FDA. It is our intent to place our cGTP cellular processing labs in ambulatory surgery centers or hospitals and operate them under cGTP and SOPs in other major US metropolitan areas.

The Company anticipates that it will have multiple revenue streams in the next 12 months including, but not limited to: (i) cellular product sales revenues, (ii) continuing medical education courses, (iii) cell banking, (iv) international licenses and royalties.

Our Technology

We use a proprietary, patented technology developed by our founder, Dr. Steven Victor, which provides us with the ability to extract, separate and process the stromal vascular fraction cells from the blood vessels in adult adipose (fat) tissue in about one hour. We believe that our technology produces the most cells from the least amount of fat (60 cc) at the lowest cost and the least amount of manipulation when compared to other technology or processes currently available that employ manipulative processes or enzymes to achieve cell separation. Further, all cells manufactured using our technology and proprietary process are done so under strict United States Food and Drug Administration ("FDA") cGTP guidelines and SOPs that we have established.

We believe that stromular vascular fraction ("SVFs") derived from the application of our proprietary process yield a functionally diverse population of cells that are synergistic and able to communicate with each other and with other cells in their local environment. We also believe that since we do not have to wash out the blood and do not digest the extracellular matrix versus competitors' enzymatic protocols that our product is superior. The mixture of cells has multiple functions and is highly integrated and we believe more potent than adipose stem cells themselves.

We further believe that IntelliCells™, when returned to a patient's own body by way of same-day same clinical procedure (autologous treatment) and delivered via Point of Care, have little or no risk of disease transfer, rejection or allergic reaction. We also believe that IntelliCells™ have the potential to treat a wide variety of clinical conditions

involving orthopedic, gastrointestinal, periodontal, aesthetic and other conditions or disorders.

Our Strategy

We plan to focus our initial efforts on regenerative medicine in the areas of orthopedics, sports medicine, pain, aesthetics and periodontal diseases. According to arthritistoday.org, at least 25 million people nationwide are affected in the world of orthopedics, sports medicine and pain, which, just nationally, makes that a penetrable market into the billions of dollars. Likewise, according to Research and Markets Aesthetics Report and Global Data's market report for the periodontal market, the aesthetics and periodontal markets make up at least a minimum of $750 million and over a billion dollar market, respectively. We will focus on orthopedics including osteoarthritis, aesthetics, pain, periodontal and other indications by making our Intellicells™ available to practicing physicians using Regen Medical's office based surgical center ("OBSC"). We plan to establish and install our cGTP cellular processing labs in ambulatory surgery centers and hospitals to make our cellular product available to a wide range of physician specialties to use under the practice of medicine. We believe that we may also be able to license our technology for wound care, cardiac, gastrointestinal (colitis/ileitis), multiple sclerosis and autism to other companies in the regenerative medicine field.

Index

In addition to our core focus noted above in which we provide cGTP cellular processing labs, we also intend to expand our areas of focus, as we are able to locate and partner with parties interested in utilizing or licensing our technology for other areas. In this regard, we intend to engage in a multi-pronged approach with respect to the utilization and commercialization of our proprietary process that will involve entering into technology licensing agreements and related service agreements with physicians and physician practice groups, that we will enable to practice our cell therapy procedures in our US facilities. We will also be seeking to enter into technology licensing agreements or other arrangements that cover particular international territories or countries as described in greater detail below.

Another focus of our business development will involve engaging in and our coordinating Institutional Review Board ("IRB") approved clinical studies at prominent medical centers, some of which studies may also be the subject of Investigational New Drug applications ("IND's") with the goal of obtaining medical or regulatory approval for significant clinical indications, where, if and as required, of the Intellicells™ produced with our proprietary process. We have recently formed a wholly-owned subsidiary, ICBS Research, Inc., through which we plan to engage in research and development activities by collaborating with university based research organizations. We have started our first FDA IND study that will be on osteoarthritis of the knee with Dr. James Andrews and inVentiv as our CRO. We believe these activities may lead to additional patents and intellectual. ICBS Research, Inc., our wholly owned subsidiary, will also coordinate scientific research with world class researchers to learn more about the Intellicell™ process and the use of the cells in medical procedures and as to how it may be used as a more efficacious delivery mechanism or as to how it may be co-administered in conjunction with other medical therapies. In the future Intellicell plans to conduct human clinical studies under an IND in osteoarthritis of the knee, diabetic ulcers of the lower extremities, multiple sclerosis, periodontal gum recession and dermal wrinkles to obtain FDA approval where such approval may be necessary.

We are also exploring and undertaking, either on our own or in collaboration with one or more third parties, providing a service for the collection, processing and storage of autologous cells. We intend to market this service to liposuction patients in addition to any patient who might want to store their SVFs for future use.

Our Competitive Advantage

We believe that our proprietary process offers significant advantages over other competing processes or technologies currently being employed that utilize enzymes or other manipulative methods to harvest or culture cells, including:

We believe that our process is in compliance with existing FDA regulations – under current FDA Guidelines for human cell and tissue based products (HCT/P) (based on FDA regulations found at 21 C.F.R. § 1271), patients are allowed to use their own HCT/P for just about any indication, so long as the use of those cells is autologous (a situation in which the donor and recipient are the same person), the cells are minimally manipulated, the clinical use is homologous, and the procedure takes place as a single procedure as defined by the physician.

Our procedure takes place during the same office visit. The point of care nature of the process is a required element of the protocol required by our licenses, and is emphasized in our technician and physician training.

We believe that the number of adult autologous stem cells and other progenitor cells that comprise the SVF's that are harvested from the tissue through the use of our proprietary process are significantly higher than the number of cells produced through the use of other technology or

processes currently available that employ manipulative processes or enzymes to achieve cell separation.

We had engaged Millipore, a division of Merck, to perform a CD (cluster of differentiation) antibody flow cytometry study which has confirmed the high-quality composition of the IntelliCells™.

We believe that our patented process provides significant time and cost efficiencies at the point of care- using our proprietary ultrasound cavitation technique, SVFs can be separated at low cost and in less time, as compared to competing technologies that utilize enzymes.

We also believe that IntelliCells™ have the potential to treat not only aesthetic conditions, orthopedic and sports injuries, and pain, but also a wide variety of clinical conditions involving cardiac, gastrointestinal, periodontal, and autistic disorders. In that regard, we will be seeking to undertake clinical studies in partnership with well-known universities and hospitals for the following indications and markets:

Application	Market
Osteoarthritis	Internal Medicine and Orthopedic
Gum Regeneration	Periodontal
Non-healing Diabetic Ulcers	Wound healing
Multiple Sclerosis	Internal Medicine
Cartilage Regeneration	Orthopedic and Sports Medicine
Tendon Repair	Orthopedic and Sports Medicine
Facial Lines and Wrinkles	Aesthetic Medicine
Chronic Migraine Headache	Neurological
Bone Regeneration	Periodontal and General Surgery
Hair Regeneration	Aesthetic Medicine

Index

The Regenerative Medicine Market

Overview of Stromal Vascular Fraction

Stromal Vascular Fraction ("Fraction") is the cells obtained from the blood vessels in the lipoaspirate from the small volume of fat harvested, minus the fat cells (adipocytes) and non-cellular material. The Fraction contains a wide number of cellular types including pre-adipocytes, endothelial cells, smooth muscle cells, pericytes, fibroblasts, and adult stem cells (ASCs). In addition, the Fraction also contains blood cells from the capillaries supplying the adipocytes and the extracellular matrix. We refer to this mixture of cells as SVF or SVF cells or SVFC.

SVF also includes erythrocytes or red blood cells, B and T cells, macrophages, monocytes, mast cells, natural killer (NK) cells, hematopoietic stem cells and endothelial progenitor cells and more. Also the Fraction includes adipocyte endocrine secretions, and importantly, contains growth factors such as transforming growth factor beta (TGF), platelet-derived growth factor (PDGF), and fibroblast growth factor (FGF), among others.

This is very much like the secretions of cells in the presence of an extracellular matrix. The SVF also contains the various proteins present in the tissue extracellular matrix.

How Do SVFs work?

Investigators have postulated a number of nonexclusive mechanisms through which SVFs can be used to repair and regenerate tissues. First, adult stem cells within the SVF delivered into an injured or diseased tissue may secrete cytokines and growth factors that stimulate recovery in a paracrine manner. These factors would modulate the "stem cell niche" of the host by stimulating the recruitment of endogenous stem cells to the site and promoting their differentiation along the required lineage pathway.

In a related manner, SVFs might provide antioxidants chemicals, free radical scavengers, and chaperone/heat shock proteins at an ischemic site. As a result, toxic substances released into the local environment would be removed, thereby promoting recovery of the surviving cells. Studies have suggested that transplanted bone marrow–derived mesenchymal stem cells or MSCs can deliver new mitochondria to damaged cells, thereby rescuing aerobic metabolism. It may develop that similar studies in SVFs will uncover a comparable ability to contribute mitochondria. A final mechanism is to differentiate components of SVFs along a desired cellular lineage.

Source: Adipose-Derived Stem Cells for Regenerative Medicine, Jeffrey M. Gimble, Adam J. Katz and Bruce A. Bunnell, Circ. Res. 2007;100;1249-1260

The Process of SVF Extraction

We intend to use our patented, proprietary laboratory system, which we have developed internally, that is composed primarily of an ultrasound unit and a centrifuge, and is performed in a closed sterile system which is readily available in the marketplace in conjunction with a proprietary closed process for the initial separating of SVF from vascular tissue found to be contained in adipose tissue. This process includes the use of a flow cytometer that will allow for immediate verification of the quantity and viability of processed cells prior to their reintroduction back to the same patient, a process overlooked by alternative systems and processes.

The extraction process for the SVF cell therapies can be summarized as follows:

1. Harvest:

Using a simple procedure, a cannulae attached to a syringe is inserted into the abdomen or other location for fat extraction and 60 cc of adipose tissue is harvested from the patient. This is sufficient for most treatments and cell storage of excess SVFC.

2. Separate:

The harvested tissue is then broken down using an ultrasound mechanical separation process, leaving substantially all of the cells viable but allowing them to be separated from the non-cellular material.

The mix of SVF cells and unwanted materials are spun down in a centrifuge to isolate the desired cells that form a “pellet” like substance that can be drawn out of the now separated materials.

The cells are tested with a flow cytometer to determine cell count and cell viability.

Index

3. Return:

The cells are then administered back to the same patient by their physician under the practice of medicine through one or more of the following modes of administration:

Intravenous: The SVF's may be administered through a standard intravenous drip.

Intra-articular injection: The SVF's may be injected into and around an arthritic or injured joint such as the knee or shoulder.

Intra-oral injection: The SVF's may be injected into the oral cavity in the particular region around teeth where gum recession has been observed.

4. Cell Banking:

Banking of stem cells is useful for some procedures that require repeat therapeutic administration as well as for other therapeutic uses that may be required in the future. The Company currently does not have a cell banking license in New York State, but has applied for the license.

Market Data

Regenerative Medicine and Cell Therapy Overview

Source: Proteus Venture Partners

Regenerative Medicine (RM) is a rapidly expanding set of innovative medical technologies that restore function by enabling the body to repair, replace, and regenerate damaged, aging or diseased cells, tissues and organs.

According to a recent report, Worldwide Markets and Emerging Technologies for Tissue Engineering and Regenerative Medicine, by Life Science Intelligence (LSI), the largely untapped global market potential for tissue engineering and regenerative medicine products will exceed $118 billion by 2013. The actual current market, which represents only a fraction of the potential market, was estimated at $1.5 billion in 2008. The report forecasts rapid growth driven by various factors, including increased adoption in various clinical areas and trends in international markets.

Regenerative therapies have been demonstrated (in trials or the laboratory) to heal broken bones, treat severe burns, blindness, deafness, heart damage, nerve damage, Parkinson's Disease, diabetes and other conditions. Significant momentum has been achieved in recent years as evidenced by the surge in government and foundation research funding, with over 65 academic programs and more than $1.5 billion in worldwide funding for research, expected to grow to $14 billion in 10 years. There are greater than 175,000 peer-reviewed publications, over 10,000 issued and pending patents, and more than 900 FDA-approved clinical trials testing regenerative medicine technologies. More than 400 regenerative medicine products have reached the market today, with more than 600 in development. This, in turn, has led to a proliferation of patient advocacy groups rightfully demanding a shift in medical treatment paradigms from "band aid therapies" to prevention, cure, rejuvenation, restoration, and replacement. More than 1.2 million patients have been treated with regenerative products and therapies.

Index

Source: Proteus Venture Partners

Licensing

As described above, we intend to engage in a multi-pronged approach with respect to the utilization and commercialization of our proprietary process that will focus on:

Entering into licensing agreements and related service agreements with ambulatory surgery centers or hospitals that are located in the United States that provide for the sale of our cellular products, from our labs that will receive lipoaspirate harvested from their patients and employ our proprietary process to the obtain the IntelliCell™ product, and then return the IntelliCell™ product to the physician on the same day labeled "autologous and homologous." In these arrangements, the clinical use of these IntelliCells™ is not specified in labeling or promotion, but will be left solely to the physician in the exercise of their medical judgment and under the practice of medicine. Under these arrangements, we will be collecting processing fees and/or service fees from the physicians or hospitals.

Entering into technology licensing agreements that cover a particular international territory or country pursuant to which the licensee shall have the right to set up and/or sublicense the right to set up labs in the territory using equipment purchased from us and that are operated in accordance with protocols set by us. Under these arrangements, we will be collecting an up-front territorial licensing fee and then will receive additional fees based upon from sublicensing and/or processing fees received by the licensees during the term of the license.

Licensing Agreement with The Andrews Research and Education Foundation, Inc. and related Consulting Agreement with Dr. James Andrews

On March 11, 2014 (the "Effective Date"), the Company executed a Laboratory Services and License Agreement (the "License Agreement"), effective March 7, 2014, with The Andrews Research and Education Foundation, Inc. ("AREF") pursuant to which the Company agreed to grant certain technology and trademark licenses to AREF.

The term of the License Agreement shall be for a period of three (3) years commencing on March 7, 2014 and shall automatically renew for subsequent periods of three (3) years unless either party to the License Agreement provides notice of its intention not to renew at least ninety (90) days prior to the expiration of any three (3) year term.

Subject to the terms and conditions of the License Agreement, the Company agreed to grant AREF a non-exclusive (except for the Pensacola, Florida area and a surrounding radius of 150 miles), non-assignable, non-transferrable, non-sublicensable license to market the use of and practice the Technology (as such term is defined in the License Agreement) at AREF's premises for restricted purposes as provided in the License Agreement. The Company also agreed to grant AREF a non-exclusive, non-assignable, non-sublicensable, license to the Trademarks (as such term is defined in the Agreement). Furthermore, the Company reserved the perpetual worldwide right to license and use the Patent (as defined in the License Agreement), Trademarks and the Technology licensed under the License Agreement for any purpose.

Except for when performed for research purposes, AREF shall pay to the Company a fee equal to Two Thousand Five Hundred Dollars ($2,500.00) per Tissue Processing (as such term is defined in the License Agreement) case processed. The parties to the License Agreement have mutually agreed not to disclose any Confidential Information (as such term is defined in the License Agreement), whether verbal or written, conveyed to them prior to, during or

subsequent to the term of the License Agreement.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to such document and incorporated herein as Exhibit 10.1 to the Current Report on Form 8-K filed with the SEC on March 12, 2014.

Additionally, on March 11, 2014, the Company executed a Consulting Agreement (the "Consulting Agreement") with Dr. James Andrews, effective March 7, 2014, pursuant to which Dr. Andrews shall serve as Chairman of the Intellicell Orthopedic Cellular Therapy Advisory Board. The initial term of the Agreement shall be for a period of ten (10) years unless extended as provided in the Agreement or unless terminated by either party with thirty (30) days advance written notice to the other party. In consideration for Consultant's services, the Consultant shall be paid a monthly fee and make a monthly charitable contribution to the Andrews Foundation after the Company closes a Capital Raise (as defined in the Consulting Agreement), and the amount of such monthly fee and monthly charitable contribution shall be determined based on the amount raised in the Capital Raise. For example, if the value of the Capital Raise is equal to or greater than $2,000,000 but less than $15,000,000, the monthly fee payable to the Consultant thereafter shall be equal to $30,000 (with $6,000 of such amount payable to Dr. Michael Immel) with a charitable contribution of $10,000 payable to the Andrews Foundation thereafter for the term of the Consulting Agreement.

Index

Furthermore, commencing on March 1, 2014 and ending on May 1, 2017, on each of March 1, June 1, October 1 and January 1 during such period, the Company shall issue and the Consultant shall be entitled to receive non-qualified stock options to purchase a number of shares of the Company's common stock equal to 750,000 divided by the average of the closing bid price per share of such common stock for the ten (10) trading days immediately prior to the date of issuance, subject to certain adjustments as set forth in the Consulting Agreement. The options have a strike price of $0.0058 per share and are exercisable for ten (10) years. A portion (13.33%) of such options will be issued to the Andrews Foundation (and Dr. Immel shall receive 20% of such options). In addition, The Company shall issue to the Consultant 6,666,666 shares of its common stock based on the market price at the date of the execution of the License Agreement (see description above), as well as 2,000,000 shares to Dr. Immel and 1,333,333 shares to the Andrews Foundation. Additionally, 1,000,000 shares shall be issued to the Consultant, 200,000 shares shall be issued to Dr. Immel and 133,333 shares shall be issued to the Andrews Foundation upon FDA approval of the Company's Stromal Vascular Fraction Cell injection for treatment of osteoarthritis.

The Consulting Agreement contains customary representations and warranties, as well as a mutual indemnification provision, an assignment of inventions and patents provision and a confidentiality and trade secrets provision. The foregoing description of the Consulting Agreement does not purport to be complete and is qualified in its entirety by reference to such document and incorporated herein as Exhibit 10.2 to the Current Report on Form 8-K filed with the SEC on March 12, 2014.

Agreement with Regen Medical P.C.

On April 16, 2012, we entered into a technology license and administrative services agreement with Regen Medical P.C., the medical practice which is owned by, and through which, our Chief Executive Officer, Dr. Steven Victor, engages in the practice of Cosmetic Dermatology. Pursuant to the agreement, we, among other things, (i) granted Regen Medical the non-exclusive and non-assignable license to utilize our proprietary process and technology for its patients, (ii) granted Regen Medical a license to use a laboratory which can be used by Regen Medical for use of the Company's proprietary process, (iii) were appointed as the exclusive manager and administrator of Regen Medical's operations which relate to the implementation of our proprietary process as well as Regen Medical's cosmetic dermatology practice, and (iv) were appointed the sole provider of non-medical managerial, administrative and business functions for Regen Medical's cosmetic dermatology practice. The agreement was effective as of April 16, 2012 and was to continue until April 16, 2017.

On August 26, 2013, the Company and Regen entered into a termination and general release agreement (the "Termination Agreement"), effective December 31, 2012 (the "Effective Date"), pursuant to which the Company and Regen agreed, among other things, that as of the Effective Date, (i) the Company shall forgive the $514,000 owed to the Company by Regen under the Regen Agreement in exchange for the exclusive right to certain open label data and other data which the Company would like to have the rights to use as empirical data or evidence of the efficacy of the Company's proprietary process (the "Clinical Data"), (ii) the parties will take all necessary steps to enter into an agreement for the grant of a license to Regen for the Company's proprietary process as well as a license of the Clinical Data, (iii) the Regen Agreement is terminated in its entirety and shall be deemed null and void and of no further force or effect and (iii) neither Company nor Regen shall have any further rights or obligations under the Regen Agreement. Each party also provided a general release to the other party with respect to the Regen Agreement and all transactions contemplated by the Regen Agreement.

International Licensing Agreements

As of the date hereof, we have entered into the licensing agreements covering the territories of Canada, Australia, New Zealand, and Thailand.

Canadian License Agreement

On December 15, 2011, we entered into an exclusive lab services agreement with Regenastem, Inc., a Canadian corporation, pursuant to which we granted the licensee the exclusive right and license to utilize our proprietary process as well as our trademarks for the purpose of providing tissue processing services for humans and animals in Canada. The agreement had an initial term ending on August 26, 2031, and shall continue on successive five-year terms thereafter unless terminated by either party. Either party may terminate the agreement, for among other things, the failure to cure a material breach of the agreement within 10 business days or if either party makes an assignment for the benefit of creditors, is adjudicated bankrupt or insolvent, commences proceedings under bankruptcy law or licensee is unable to generate at least $500,000 in fees payable to us with any eighteen (18) month period during the Term. We may terminate the agreement, if among other things, the licensee fails to follow our protocol for tissue processing or if the licensee fails to report any tissue processing case to us. If the agreement is terminated for non-performance as described above, we shall repurchase the license from the licensee for an amount equal to two times the license fee earned by the licensee through the date of such termination.

In addition, licensee agreed to invest $500,000 in our Series D Preferred Stock financing, $250,000 of which was invested in December 2011 after the signing of the license and the remaining $250,000 of which was invested in January 2012. The parties agreed that, within one hundred and twenty (120) days before the expiration of the term, the licensee will pay a renewal fee of $500,000 for the next 10 years and/or two 5 year renewal terms in total. For each tissue processing case performed by licensee, the licensee is required to pay us, on a monthly basis, a fee of thirty percent (30%) of the fess designated by us for tissue processing. In addition, for each laboratory facility set up by the licensee, the licensee shall pay us 30% of the net profit realized from the establishment of such laboratory facility.

Index

Australia and New Zealand

On December 16, 2011, the Company entered into an exclusive lab services agreement (the "Australian Agreement") with Cell-Innovations Pty Ltd. ("Australian Licensee") pursuant to which the Company granted Australian Licensee the exclusive right and license to the Company's technology and trademarks so that the Australian Licensee can utilize the Company's technology and trademarks to provide tissue processing services for humans in Australia and New Zealand. As of the date hereof, the Company and Australian Licensee are in a dispute over some of the terms of the Australian Agreement, inc